INTERNATIONAL STANDARD

IEC 61846

First edition
1998-04

Ultrasonics –

Pressure pulse lithotripters – Characteristics of fields

Ultrasons –

Lithotripteurs à ondes de pression – Caractérisation des champs

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CONTENTS

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.

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

6 Test equipment

6.1 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 the **focus** to be several centimetres away from any reflective boundary, in particular the water surface. The distance between the **focus** and reflective boundaries shall be chosen such that no spurious or multiple reflections of the **pressure pulse** interfere with the measurements.

There shall be a suitable mechanical holder for the **hydrophone** which shall be mounted on a coordinate positioning system to allow adjustment and measurement of the position of the **hydrophone** in three orthogonal directions relative to the **focus**. One axis (z axis) of the co-ordinate 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 the coupling membranes do not influence the measurements. The coupling media shall be as specified by the manufacturer.

6.2 Hydrophone

The **hydrophone** shall have characteristics complying with IEC 60866.

For the purposes of this standard, two classes of **hydrophones** are specified:

– a **focus hydrophone**;
– a field **hydrophone**.

6.2.1 Focus hydrophone

The **focus hydrophone** shall be equivalent to a single-film piezopolymer spot-poled membrane type not thicker than 25 µm (see annex C and IEC 61102).

Calibration shall be performed in the frequency range 0,5 MHz to 15 MHz in accordance with the requirements of IEC 60866.

The frequency response shall not vary by more than ±3 dB over the calibrated frequency range.

The effective diameter of the hydrophone shall be not greater than 1,0 mm, it should be as small as possible and its value shall be stated.

NOTE – The lower frequency limit of current **hydrophone** calibration according to IEC 60866 and IEC 61102 is 0,5 MHz. It would be desirable, however, for the purpose of the measurements described here to extend the **hydrophone** calibration to lower frequencies, at least to 0,2 MHz.

6.2.2 Field hydrophone

The field **hydrophone** shall have a robust construction and shall have a response which does not vary by more than ±3 dB per octave over the frequency range from 0,5 MHz to 15 MHz.

The effective diameter of the hydrophone shall be not greater than 1,0 mm, it should be as small as possible and its value shall be stated.

The sensitivity of the **hydrophone** shall not vary by more than ±10 % over the course of the measurements.

NOTE – Two different **hydrophones** are permitted because many of those suitable for measurements at the **focus** are very fragile. A more robust, less highly specified device is therefore permitted for general field measurements. Care is to be taken, when selecting a field **hydrophone** to select a type which will provide the needed linearity and negative acoustic pressure readings of the high pressures encountered.

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 61102, 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;
- **peak-negative acoustic pressure**, p_-;
- **peak-positive acoustic pressure**, p_+;
- **rise time**, t_r;
- **compressional pulse duration**, t_{FWHMp+};
- **instantaneous intensity**, I.

7 Measurement procedure

The measurements shall be made at least at one clinical setting as specified by the manufacturer. If only one setting is used, this setting shall be the maximum available for clinical application. The settings used shall be documented.

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 which contains the **focus**. The distance between the **focus** and the **target location** shall be documented. If the **peak-positive acoustic pressure** p_+ in the **target location** does not differ by more than 10 % of p_+ in the **focus**, it is feasible to do the measurements in the x-y plane at the z position indicated by the **target location**.

7.1 Spatial measurements

The spatial distribution of acoustic pressure shall be measured in the test chamber. The maximum sampling interval shall be the lesser of 1 mm or 1/5 th of the minimum width of the –6 dB isobar in the x-y plane. It shall be the lesser of 2 mm or 1/5 th of the maximum dimension of the –6 dB isobar in the x-z plane. If the values of p_+ from sampling point to sampling point do not differ by more than 10 %, the sampling intervals can be extended, e.g. to 5 or 10 mm. The sampling intervals actually used shall be documented. The field **hydrophone** may be used.

NOTE 1 – It may be worthwhile to perform measurements in the vicinity of the **target location** to locate the **focus** 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 7.1.1 has been completed.

NOTE 3 – Care is to be used in selecting **hydrophones** of sufficient linearity in negative and positive regions so that the 6 dB measurements can be made without distortion.

7.1.1 Beam plots of peak-positive acoustic pressure

The values of **peak-positive acoustic pressure** in the *x*-*y* plane which contains the **focus** shall be measured. The –6 dB beam widths shall be determined from the –6 dB contour plot.

NOTE – At each value of *y* that **peak-positive acoustic pressure** is measured, **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 7.3.1.)

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 –6 dB contour in each plane.

7.1.2 Beam plots of peak-negative acoustic pressure

The values of **peak-negative acoustic pressure** in *x*-*z* and *y*-*z* planes shall be measured. 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_- does not exceed 10 % from point to point, the sampling intervals may be chosen accordingly. The intervals used shall be declared.

7.1.3 Focus

The separation of the **focus** and the **target location** shall be determined to a precision of ±2 mm in the *x* and *y* directions and ±3 mm in the *z* direction.

7.1.4 Focal width

The width of the –6 dB contour in the *x* direction, **focal width, maximum**, f_x, and in the *y* direction, **focal width, orthogonal**, f_y, shall be measured from the results derived from 7.1.1.

7.1.5 Focal extent

The length of the –6 dB contour along the *z* direction, f_z, shall be measured from the –6 dB contour in the *x*-*z* plane derived from 7.1.1.

7.1.6 Focal area

The **focal cross-sectional area** along the *x* and *y* axes shall be established from the spatial distributions.

NOTE – It is reasonable to approximate the **focal cross-sectional area** to an ellipse with axes of lengths f_x and f_y.

7.1.7 Focal volume

The **focal volume** along the *x*, *y* and *z* axes shall be established from the spatial distributions.

NOTE – It is reasonable to approximate the **focal volume** to an ellipsoid with axes of lengths f_x, f_y and f_z.

7.2 Temporal measurements

A **focus hydrophone** shall be positioned at the **focus** in such a way as to register the **peak-positive acoustic pressure** to a precision of ±20 %.

The **pressure pulse waveform** shall be measured at the **focus**. The following parameters shall be derived:

– **peak-positive acoustic pressure** and the **peak-negative acoustic pressure**;

– **compressional pulse duration**;

– **rise time**.

7.3 Acoustic energy measurements

7.3.1 Pulse-pressure-squared integral

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

$$p_{\mathrm{i}}(r,\theta) = \int_T p^2(r,\theta,t)\, dt \tag{1}$$

NOTE – The temporal limits over which integration is performed, T, should be stated and can be either T_{p} or T_{T}.

7.3.2 Derived pulse-intensity integral

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

$$PII(r,\theta) = \frac{1}{Z}\int_T p^2(r,\theta,t)\, dt \tag{2}$$

NOTE – The temporal limits over which integration is performed, T, should be stated and can be either T_{p} or T_{T}.

This measurement shall be made with a **focus** type **hydrophone**.

7.3.3 Derived focal acoustic pulse energy

The **derived focal acoustic pulse energy** shall be calculated from measurements of the **derived pulse-intensity integral** taken within the region of the **focal cross-sectional area**.

The **derived focal acoustic pulse energy** may be calculated from:

$$E_f = \frac{1}{Z}\int_S\int_T p^2(r,\theta,t)\, dS\, dt = \int_S PII(r,\theta)\, dS \tag{3}$$

NOTE – The temporal limits over which integration is performed, T, should be stated and can be either T_{p} or T_{T}.

where

p (r, θ, t) is the **instantaneous acoustic pressure** at position (r, θ) and time t;

S is the surface lying in the plane passing through the **focus** and perpendicular to the **beam axis**, with spatial polar coordinates r and θ; bounded by the –6 dB contour.

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

7.3.4 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*.

$$E_R = \frac{1}{Z}\int_S \int_T p^2(r,\theta,t)\, dS\, dt = \int_S PII(r,\theta)\, dS \quad (4)$$

The value of *R* shall be specified and should be chosen to mimic a stone.

Annex A
(informative)

Acoustic wave lithotripsy

A.1 Background

Renal and ureteric stones are very common in many countries and in Western Europe the incidence is estimated at 3 % to 4 % of the population. To this figure must also be added the frequent problem of gallstones.

Conventional removal of renal, most ureteric and gall bladder stones involves a traumatic surgical incision, which is associated with a hospital stay of one to three weeks and a prolonged convalescent period.

Since about 1978 two new methods, percutaneous ultrasonic lithotripsy and extracorporeal lithotripsy, have grown in importance and a large number of operations now involve one or the other of these methods. Both reduce or eliminate invasive surgery and greatly reduce hospitalization and post-operational convalescence. Both procedures employ high intensity acoustic waves to produce disintegration of the stones.

Early ultrasonic equipment for this application was based on continuous wave sources and direct contact applicators. Extracorporeally induced stone destruction is usually carried out using the application of sequential pressure waves. The use of laser techniques for percutaneous lithotripsy has become important as another example of minimally invasive surgery.

In the 1990s increasing interest has been shown in the literature in evaluating the potential of high intensity acoustic waves for the treatment of orthopaedic pain, delayed bone fracture healing and calcifications of tendons.

A.2 Percutaneous continuous wave systems

The concept of the use of ultrasonic energy for stone disintegration was reported as early as 1953 and practical work was carried out in the early 1970s. The slowness of the action has prevented wide adoption of the method, although equipment is still produced.

A.3 Exclusions

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

A.4 Extracorporeally induced lithotripsy

This method of treatment is rapidly growing in importance despite the high capital cost of equipment. Pioneered in Germany 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 determination of the stone location and the orientation of the transducer to position the **focal volume** at the stone. This is carried out using X-ray or diagnostic acoustic scanning in three dimensions. With an ultrasonic scanning system an examination of progress can be undertaken in real-time.

The treatment time is very variable and depends critically on the lithotripter system, as well as on the form, location and size of the stone. With kidney stones the disintegrated fragments are passed through the ureter, bladder and urethra by normal excretory processes during the next few days. Gall stones are somewhat more difficult to deal with because of their anatomical location and in some cases their relative softness.

Annex B
(informative)

Types of pressure wave transducers

B.1 Introduction

Four techniques are at present employed for the generation of the required **pressure pulse**, the operating principles being: spark discharge; piezoelectric excitation; electromagnetic induction; chemical explosion. Future equipment may use magnetostrictive elements, based on the new massive magnetostriction materials. In the three electrical systems, the short duration high peak energy is supplied by the electrical discharge of a bank of capacitors into an electromechanical transducer. The chemical system employs small explosive charges detonated within a focusing reflector.

B.1.1 Spark discharge

An ellipsoidal reflector is used with a spark gap mounted at one of the two foci. The spark gap may be a self-contained unit that is easily demountable for servicing or replacement. In most cases the life of the discharge tips is relatively short and ease of replacement forms an important part of the design. The gap can be in the form of a cartridge or fitted as two separate electrodes. The reflector may be closed by a flexible diaphragm and filled with degassed water or other acoustically efficient transmissive liquid. Application to the patient may be from above or below 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.1.2 Piezoelectric

The transducer can be of two types. The more common form is composed of multiple piezoelectric ceramic elements mounted in a mosaic pattern on a spherical dish. Each element is synchronized to ensure simultaneous operation and the large aperture energy source provides accurate focusing of the pressure wave. Unlike a spark gap, each individual element has a relatively low emission energy, high intensity occurs only at the **focus**. The low stress lengthens the maintenance-free period and ensures high reliability. The breakdown of a few isolated elements will not materially affect the overall performance and the construction enables these to be replaced.

A second form uses a ring or tubular piezoceramic transducer mounted within a focusing parabolic reflector.

Plane wave sources can also be used and focusing is produced using acoustic lenses manufactured from plastics or metals.

B.1.3 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 is focused with an acoustic lens to provide a convenient focal point within the patient. The front of the cylinder in contact with the patient is closed by a flexible diaphragm.

Another type uses a paraboloid reflector with a cylindrical electromagnetic transducer mounted on the axis of the reflector.

B.1.4 Magnetostrictive

The development of high-efficiency magnetostrictive materials has stimulated development of single-pulse transducers operating with low-voltage drives. Commercial exploitation has not yet commenced.

B.1.5 Chemical

Small explosive charges mounted on an "ammunition belt" are located one at a time at the internal **focus** of an ellipsoidal bowl. The discharge produces a rapidly expanding gas bubble which causes the acoustic **pressure pulse**.

B.2 Positioning systems

The accurate external positioning of the **pressure pulse** transmitter is of great importance if damage to the surrounding tissue is to be avoided. As the position is defined within three-dimensional space, the detection method should be capable of defining all axes. In some equipment a high resolution ultrasonic scanner is used with the probe positioned within the treatment head or mounted on a location arm. The position of the **focus** relative to the probe is fixed and a continuous image of the stone can be displayed during the operating procedure. Microprocessor control of the movement of the transmitter relative to the patient can be used to ensure accurate setting irrespective of patient movement.

The alternative system is X-ray fluoroscopy, often with image intensifying for increased contrast. The disadvantage is discontinuous viewing due to dosage limitations, and in the case of gallstones the relative X-ray transparency of the stone material.

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 at the **focus** 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 [18] [19].)

The measuring **hydrophone** should ideally have a flat frequency response extending over the range from well below the acoustic working frequency of the lithotripter, usually approximately 0,25 MHz, to a frequency as high as possible (see [19] and [20]). Thus ideally, the **hydrophone** should have an overall frequency response flat to within ±3 dB over the range of 0,05 MHz to 100 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 6.2.1 and 6.2.2 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 lithotripter pulses.

Detectors are required to perform two functions: measurement of the amplitude of the shock wave at the **focus**; trace of the shape of the pressure envelope.

Piezoelectric polymer membrane **hydrophones** are widely employed. (See tables C.1 and C.2.)

Some **hydrophones** with a rigid backing to the polymer element do not reproduce the rarefactional portion of shock waves demonstrated with membrane type **hydrophones.**

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.

Acousto-optic fibre **hydrophones** have been developed (see [9]-[12]). Quartz-glass fibres seem capable of reproducing the rarefactional acoustic pressure more faithfully than membrane hydrophones. They are reported to be more sensitive to the presence of cavitation bubbles and the fibre tip has a limited lifetime. However, their repair and recalibration is described as uncomplicated.

An electromagnetic probe has been developed [14] 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.

* Figures in square brackets refer to the bibliography given in annex D.

Pressure sensitive paper is also available for use at the pressures found in the **focus** of a lithotripter although its value for quantitative measurements is not clear (see [2]).

Model stones may be used as a test of overall system efficacy. Stones are available with sufficiently well controlled construction that this method is valuable for routine checking.

The spatial and temporal measurements in the focal region are carried out only for the pattern evaluation and basic evaluation in specialized laboratories with **focus hydrophones** and precision instruments. The continuous day-to-day monitoring of lithotripter performance may be carried out by scanning in a few non-focal planes perpendicular to the **beam axis** at specified axial distances from the focal point. In this case the user will not need a **focus hydrophone**. The requirements for the measuring equipment are less strict.

For monitoring shock waves in real-time it is useful to use an integrated hydrophone, for example on the inner surface of the ellipsoid. To improve the reliability of this day-to-day monitoring it is necessary to carry out similar measurements for pattern evaluation and to determine the correlation of measurements in the focal and non-focal planes.

Table C.1 gives guidance on the choice of different **hydrophones** for **focus** and field measurements. Table C.2 gives guidance on other techniques and probes which may be used for quality assurance purposes.

Table C.1 – Hydrophones possible for focus and field measurements

Description	Use	Remarks	Literature (examples)
PVDF single-sheet spot-poled membrane, less than 25 μm thick	**Focus hydrophone**	Life may be restricted to few shocks	see [3] to [5]
PVDF needle type	Field **hydrophone**	Widely used for lithotripter measurements	see [7], [8] and [22]
Laser optic fibre	**Focus** and field type	Easy repair and recalibration following stress failure	see [9] to [12]
PVDF single-sheet spot-poled membrane, less than 50 μm thick	**Focus** and field type	Designed for extended life with disposable hydrophone elements	see [16] and [17]

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 [13]
Capacitively coupled PVDF spot poled membrane	Large sensitive area, very robust	Pressure waveform	see [6]
Steel ball electromechanical	Very robust	Energy per pulse Pressure waveform	see [14]
Model stones	Mimics clinical application	Destructive force per pulse	see [15]
Pressure sensitive paper	Robust, qualitative field parameters	Spatial pressure distribution, semi-quantitative peak pressure measurement	see [2]
Piezoelectric **hydrophones** with metal-coated elements	Robust	Pressure waveform	Used for quality control of stability of shock-wave generation

C.2 Test chamber

The measurement of the pressure wave and the mapping of the focal zone 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-wave 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 lithotripters the pressure-wave unit 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-compressional acoustic pressure**, it is essential that the **hydrophone** is accurately positioned at the **focus**. The location detector and visualizing unit integral with the lithotripter is used for an approximate siting. With membrane **hydrophones** a small metal disc is placed on the membrane at the position of maximum sensitivity and the visualizing unit can detect the dense mass. It is removed after positioning and the **hydrophone** finally adjusted for the maximum signal.

C.3 Degassing procedures

Measurements involving water baths should use distilled and degassed water. This requirement may be slackened if the interval between pulses is sufficiently long so that bubbles created have time to be reabsorbed.

A number of methods are available for degassing water and the following are representative. The efficacy of the above procedure may be checked by determination of the dissolved oxygen content in samples of degassed water using dissolved oxygen test kits. It is important that bubbles do not collect at the surface of the hydrophone.

C.3.1 Boiling

a) Water maintained at boiling temperature for 15 min.

b) Cooled to 54 °C.

c) Bottle filled to brim with the boiled water and closed with rubber stopper having a glass tube and rubber hose attached. The hose should be completely filled with water and then clamped.

d) Cooled and stored until needed with a partial vacuum maintained in the hose.

C.3.2 Boiling at reduced pressure

Water boiled under reduced pressure (less than 10^4 Pa) in 20 l glass jars using electric immersion heaters, then allowed to cool to 39 °C overnight. The same temperature and reduced pressure are maintained until the water is used (1 day to 1 week later).

C.3.3 Reduced pressure spray

Water passed into a partially evacuated flask (pressure less than 10^4 Pa) in the form of a fine spray. Degassing is effected by the agitation of the inflowing water combined with the large surface area of the droplets.

C.4 Acoustic pulse energy

The energy per pulse can be calculated by integrating the field over the –6 dB surface around the **focus**. Refer to figures C.1 and C.2 for explanation of some of the parameters used to describe a typical **pressure pulse waveform** and spatial distribution at the **focus**.

The energy in a lithotripsy pulse at the **focus** can be approximated by:

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

where

p is the acoustic pressure function;

S is the focal surface, in the *x*-*y* plane containing the **focus**, with spatial polar co-ordinates *r* and θ;

t is time;

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

For a beam with circular symmetry:

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

where

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

$$PII(r) = \frac{1}{Z} \int p^2(r, t)\, dt \qquad \text{(C.3)}$$

and

R is the –6 dB beam radius based on the plot of **peak-positive acoustic pressure**.

In evaluating *E*, the results from measurements along four radii along two orthogonal diameters should be averaged.

One numerical solution of equation (2) is [21]:

$$E = 0{,}5\pi \sum_{i=1}^{N} (PII_i + PII_{i-1})(R_i^2 - R_{i-1}^2) \qquad \text{(C.4)}$$

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 $R_N = R$.

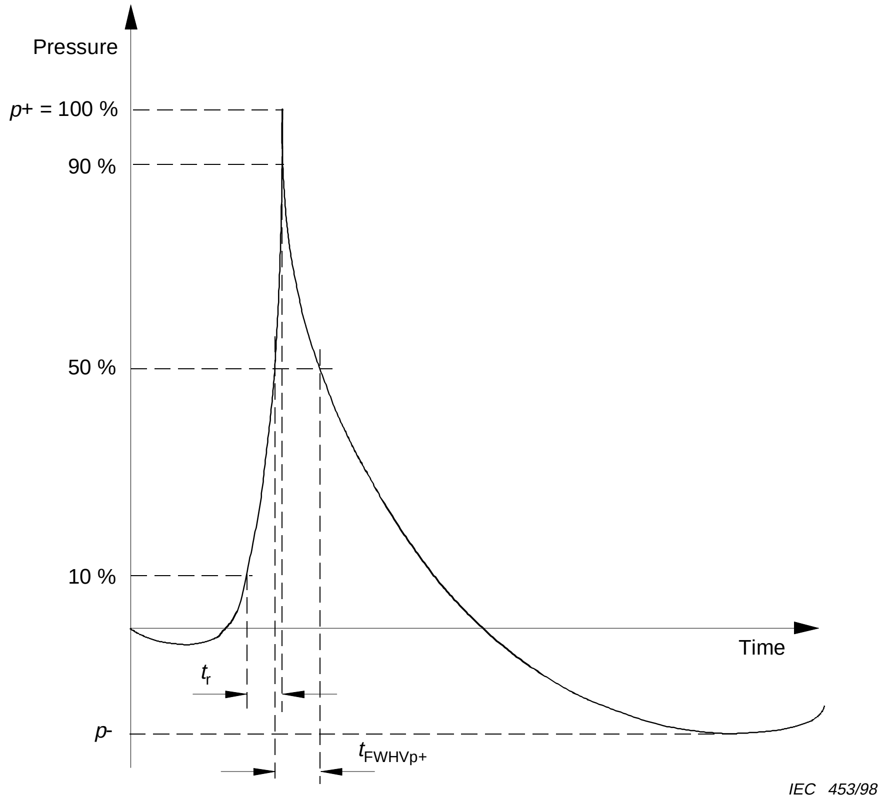

Figure C.1 – Typical pressure pulse waveform at the focus

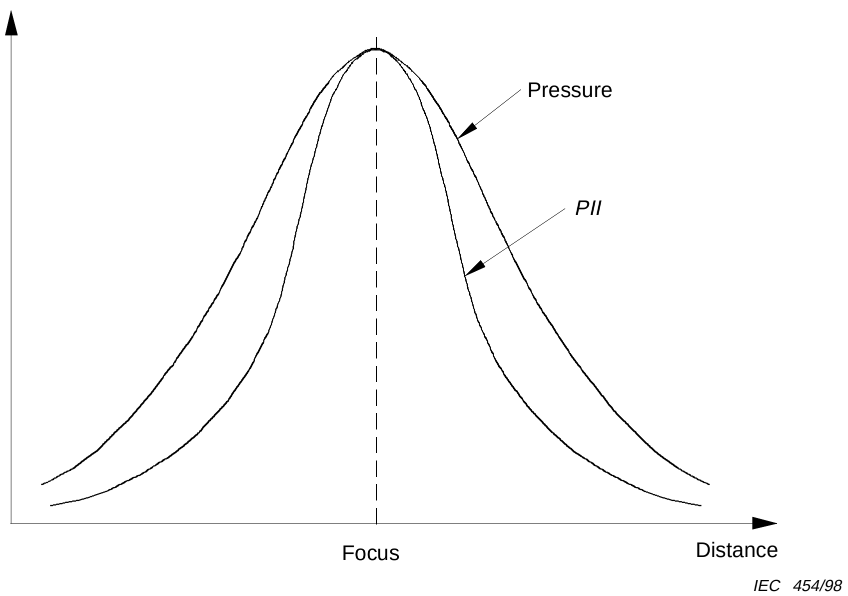

Figure C.2 – Typical spatial pressure distribution at the focus (upper plot) and the derived pulse-intensity integral (lower plot)

Both plots are normalized to have the same peak amplitude.

Annex D
(informative)

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