

AS/NZS 4511:1999  
IEC 61846:1998

AS/NZS 4511

Australian/New Zealand Standard™

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**Ultrasonics—Pressure pulse  
lithotripters—Characteristics  
of fields**

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## PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE/3, Medical Electrical Equipment as a Joint Standard.

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## CONTENTS

|                                            | <i>Page</i> |
|--------------------------------------------|-------------|
| 1 Scope .....                              | 1           |
| 2 Normative references .....               | 1           |
| 3 Definition .....                         | 2           |
| 4 List of symbols .....                    | 6           |
| 5 Conditions of measurement .....          | 6           |
| 6 Test equipment .....                     | 7           |
| 6.1 Test chamber .....                     | 7           |
| 6.2 Hydrophone .....                       | 7           |
| 6.3 Voltage measurement .....              | 8           |
| 7 Measurement procedure .....              | 8           |
| 7.1 Spatial measurements .....             | 8           |
| 7.2 Temporal measurements .....            | 9           |
| 7.3 Acoustic energy measurements .....     | 9           |
| <br>Annexes                                |             |
| A Acoustic wave lithotripsy .....          | 12          |
| B Types of pressure wave transducers ..... | 14          |
| C Field measurement .....                  | 16          |
| D Bibliography .....                       | 21          |

## AUSTRALIAN/NEW ZEALAND STANDARD

**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<sup>2</sup>

**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**