

Ultrasonics — Pressure pulse lithotripters — Characteristics of fields

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British Standard

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National foreword

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 19 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Amendments issued since publication

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Electrotechnical Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 January 1999

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English version

Ultrasonics — Pressure pulse lithotripters — Characteristics of fields

(IEC 61846:1998)

Ultrasons — Lithotripteurs à ondes de
pression — Caractérisation des champs
(CEI 61846:1998)

Ultraschall — Druckpuls-Lithotripter
Feldcharakterisierung
(IEC 61846:1998)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 87/115/FDIS, future edition 1 of IEC 61846, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61846 on 1998-04-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex A, Annex B, Annex C and Annex D are informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61846:1998 was approved by CENELEC as a European Standard without any modification.

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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.

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).