

INTERNATIONAL STANDARD

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Ultrasonics – Pressure pulse lithotripters – Characteristics of fields

*Ultrasons –
Lithotripteurs à ondes de pression –
Caractérisation des champs*

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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*