SLOVENSKI STANDARD
SIST EN 61846:2002

01-september-2002

Ultrasonics - Pressure pulse lithotripters -Characteristics of field (IEC 61846:1998)

Ultrasonics - Pressure pulse lithotripters - Characteristics of fields

Ultraschall - Druckpuls-Lithotripter - Feldcharakterisierung

Ultrasons - Lithotripteurs à ondes de pression - Caractérisation des champs

Ta slovenski standard je istoveten z: **EN 61846:1998**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
17.140.50	Elektroakustika	Electroacoustics

SIST EN 61846:2002 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 61846

April 1998

ICS 11.040.50

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)

This European Standard was approved by CENELEC on 1998-04-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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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 annexes A, B, C and 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.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
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	EN 61102	1993

INTERNATIONAL STANDARD

IEC 61846

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Ultrasonics –

Pressure pulse lithotripters – Characteristics of fields

Ultrasons –

Lithotripteurs à ondes de pression – Caractérisation des champs

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http: //www.iec.ch

Commission Electrotechnique Internationale
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.

3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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}