SLOVENSKI STANDARD
SIST EN 61847:2002

01-september-2002

Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics (IEC 61847:1998)

Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics

Ultraschall - Chirurgische Systeme - Messung und Deklaration der grundlegenden Ausgangsrößen

Ultrasons - Systèmes de chirurgie - Mesure et déclaration des caractéristiques de sortie

Ta slovenski standard je istoveten z: **EN 61847:1998**

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11.040.01	Medicinska oprema na splošno	Medical equipment in general
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SIST EN 61847:2002 **en**

EUROPEAN STANDARD

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English version

Ultrasonics - Surgical systems
Measurement and declaration of the basic output characteristics
(IEC 61847:1998)

Ultrasons - Systèmes de chirurgie
Mesure et déclaration des caractéristiques de sortie
(CEI 61847:1998)

Ultraschall - Chirurgische Systeme
Messung und Deklaration der Ausgangsgrößen
(IEC 61847:1998)

This European Standard was approved by CENELEC on 1998-01-01. 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.

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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.

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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 87/114/FDIS, future edition 1 of IEC 61847, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61847 on 1998-01-01.

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) 1998-10-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-10-01

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 and C are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61847:1998 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 60500	1974	IEC standard hydrophone	-	-
IEC 61205	1993	Ultrasonics - Dental descaler systems Measurement and declaration of the output characteristics	EN 61205	1994

INTERNATIONAL STANDARD

IEC 61847

First edition
1998-01

Ultrasonics – Surgical systems –

Measurement and declaration of the basic output characteristics

Ultrasons – Systèmes de chirurgie –

Mesure et déclaration des caractéristiques de sortie

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

ULTRASONICS – SURGICAL SYSTEMS –
Measurement and declaration of the basic output characteristics

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 61847 has been prepared by IEC technical committee 87: Ultrasonics.

The text of this standard is based on the following documents:

FDIS	Report on voting
87/114/FDIS	87/117/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 and C are for information only.

In this standard the following print types are used:

– Requirements: in roman type
– *Test specifications: in italic type*
– Notes: in small roman type
– Words in **bold** in the text are defined in clause 3.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

Ultrasonic surgical systems, operating in the 20 kHz to 60 kHz range, are used widely in ophthalmology and neurosurgery to fragment or disintegrate and aspirate unwanted tissue. Their commercial use in ophthalmology started in 1970. Their application in neurosurgery followed about 10 years later. Ultrasonic surgical systems are also widely used in oncology surgery.

This International Standard defines the parameters which characterize the output and performance of open and closed site ultrasonic surgical systems, and indicates which parameters should be declared. In addition, measurement procedures are described so that technically qualified people will be able to report on the parameters in a uniform and understandable fashion. An open surgical site is one in which the incision is large relative to the size of the applicator tip being inserted thus precluding any increase in pressure of the organ due to an imbalance of irrigant flow and suction flow. An example of a closed surgical site is an eye where the incision is closely controlled.

This International Standard does not provide any guidance on what is the resultant safety or efficacy of devices described by these parameters since very little scientifically controlled data are available by which such judgements can be made.

ULTRASONICS – SURGICAL SYSTEMS – Measurement and declaration of the basic output characteristics

1 Scope

This International Standard specifies:

– the essential non-thermal output characteristics of ultrasonic surgical units;

NOTE 1 – One of the parameters of interest is output acoustic power. This standard addresses only the low-frequency (under 100 kHz) component of the total delivered energy. The high-frequency component, which probably relates to cavitation developed at the tip, is not addressed (see A.4).

– methods of measurement of these output characteristics;

– those characteristics which should be declared by the manufacturers of such equipment.

NOTE 2 – In the interest of clarity, this standard does not address all of the complex surfaces and shapes possible for **applicator tips**. A straight tubular shape is used in the description of the parameters and measurements to be made. It is left to the user of this standard to adapt the basic methodology described to more complex designs if required.

This International Standard is applicable to equipment which meets the requirements of a, b and c below:

a) ultrasonic surgical systems operating in the frequency range 20 kHz to 60 kHz; and

b) ultrasonic surgical systems, whose use is the fragmentation or cutting of human tissue, whether or not those effects are delivered in conjunction with tissue removal or coagulation; and

c) ultrasonic surgical systems, in which an acoustic wave is conducted by means of a specifically designed wave guide to deliver energy to the surgical site.

NOTE 3 – Examples of these types of systems are surgical aspirators, intracorporeal lithotripters, end-cutting devices etc.

This International Standard is not applicable to:

– lithotripsy equipment which uses extracorporeally induced pressure pulses, focussed through liquid conducting media and the soft tissues of the body;

– surgical devices used as part of the therapeutic process (hyperthermia systems);

– surgical devices whose acoustic application areas are not at the end of a longitudinally vibrating applicator tip and therefore would not fit the monopole model used in this standard.

This International Standard does not deal with the effectiveness or safety of ultrasonic surgical systems.

NOTE 4 – Throughout this standard, the term accuracy means the overall uncertainty expressed at the 95 % confidence level.

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 60500:1974, *IEC standard hydrophone*

IEC 61205:1993, *Ultrasonics – Dental descaler systems – Measurement and declaration of the output characteristics*

3 Definitions

For the purpose of this International Standard, the following definitions apply.

3.1
applicator tip; applied part
that part of the surgical tool which comes into direct contact with body tissues

3.2
directivity pattern
normalized variation in acoustic pressure as a function of angle at constant range from the **applicator tip**

NOTE – This parameter is important when operating adjacent to body structures which are sensitive to pressure and motion such as the endothelial cells on the inside of the cornea or acoustic nerves.

Symbol: p_{fd}

Unit: dimensionless plot

3.3
drive frequency
mean frequency of the driving voltage or current

NOTE – This parameter, coupled with tip vibration excursion, allows the user to compare the velocities of applicator tips.

Symbol: f_d

Unit: kilohertz, kHz

3.4
duty cycle
for those systems which modulate the electrical drive power, the ratio of the voltage or current pulse duration (on time) to the duration of one complete modulation cycle while the equipment is active

Symbol: D_{cy}

Unit: dimensionless

3.5
maximum electrical power
the peak input electrical power to the ultrasonic handpiece when the load on the **applicator tip** is gradually increased from its quiescent condition

NOTE – The peak electrical power occurs at the point at which a reduction in the **primary tip vibration excursion** from its value corresponding to the **quiescent electrical power** occurs (see 6.9 and 6.10).

Symbol: P_{max}

Unit: watts, W

3.6
output acoustic power
the acoustic power delivered by the **applicator tip** into water, and measured using a calorimetric method (see 6.5)

NOTE – Measurement of acoustic power delivered by **applicator tips** having different output areas and/or excursion amplitudes will facilitate application of the ALARA principle, the use of exposure levels that are as low as reasonably achievable.

Symbol: P_a

Unit: milliwatts, mW