

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 61847:2002 sisaldab Euroopa standardi EN 61847:1998 ingliskeelset teksti.

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This standard is ratified with the order of Estonian Centre for Standardisation dated 15.10.2002 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

The standard is available from Estonian standardisation organisation.

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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)

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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

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with the EN have to be withdrawn (dow) 1998-10-01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.

This document is a preview

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60500	1974	IEC standard hydrophone	-	-
IEC 61205	1993	Ultrasonics - Dental descaler systems Measurement and declaration of the output characteristics	EN 61205	1994

This document is a preview

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*



Reference number
CEI/IEC 61847:1998(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

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- **IEC Bulletin**
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Published yearly with regular updates
(On-line access)*

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

IEC publications prepared by the same technical committee

The attention of readers is drawn to the end pages of this publication which list the IEC publications issued by the technical committee which has prepared the present publication.

* See web site address on title page.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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.
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- 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.

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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*