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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.

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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.

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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

3.7
derived output acoustic power
the acoustic power delivered by the **applicator tip** into water, and derived from measurements made using a hydrophone (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_{ad}

Unit: milliwatts, mW

3.8
power reserve index
the ratio of **maximum electrical power** to **quiescent electrical power**

NOTE 1 – The **power reserve index** gives the user a measure of how much "extra" power is available to maintain a constant tip excursion amplitude under various load conditions.

Symbol: P_i

Unit: dimensionless

NOTE 2 – The **power reserve index** will only allow direct comparison of different devices if those devices share the same operating modality. Piezoelectric and magnetostrictive devices cannot be validly compared using the **power reserve index**.

3.9
primary acoustic output area
the area of the projection of the solid part of the **applicator tip** in the direction of **primary tip vibration excursion**

NOTE – **Primary acoustic output area** is used in determining the energy radiated from the end of an **applicator tip** for different tips operating at the same vibration excursion and frequency.

Symbol: A_{ap}

Unit: square millimetres, mm^2

3.10
primary tip vibration excursion
peak-to-peak displacement of the **applicator tip** in the direction of maximum amplitude, at a point on the **applicator tip** not more than 1 mm from its free (distal) end (see 3.2 of IEC 61205)

NOTE – The ability to fragment tissue can be correlated to **primary tip vibration excursion**.

Symbol: s_p

Unit: micrometre, µm

3.11
primary tip vibration excursion modulation
for those systems which modulate the electrical drive power, the percentage change in the **primary tip vibration excursion** from its maximum value to its minimum value

Symbol: M_{sp}

Unit: dimensionless

3.12
pulse duration
for those devices which modulate the electrical drive power, the time interval beginning at the first time the drive voltage or current exceeds a reference level and ending at the last time the drive voltage or current returns to that level. The reference level is equal to the sum of the minimum drive voltage or current and 10 % of the difference between the maximum and the minimum drive voltage or current.

Symbol: t_p

Unit: milliseconds, ms

3.13
quiescent electrical power
The input electrical power to the ultrasonic handpiece with the **applicator tip** unloaded, for a given **primary tip vibration excursion**.

Symbol: P_q

Unit: watts, W

3.14
reference primary tip vibration excursion
The maximum **primary tip vibration excursion** for the combination of **applicator tip** and handpiece chosen for measurement.

NOTE – The **reference primary tip vibration excursion** is used to obtain the values of **quiescent** and **maximum electrical power** needed to calculate the **power reserve index** of a device configuration.

Symbol: s_{pr}

Unit: micrometre, µm

3.15
secondary acoustic output area
the area of the projection of the exposed part of the **applicator tip** in the direction perpendicular to the direction of the **primary tip vibration excursion** and corresponding to the second largest component of motion

Symbol: A_{as}

Unit: square millimetres, mm^2

NOTE – Definitions 3.9 and 3.15 are intended to give the basic areas of interest when considering acoustic output of simple tubular **applicator tips**. They do not cover the infinite variety of complex end shapes which may be available from individual devices.

3.16
secondary tip vibration excursion
peak-to-peak displacement of the **applicator tip** in a direction perpendicular to the direction of the **primary tip vibration excursion** and corresponding to the direction of the second largest component of motion, of a point on the **applicator tip** not more than 1 mm from its free (distal) end

Symbol: s_s

Unit: micrometre, µm

3.17
tip vibration frequency
fundamental frequency at which the **applicator tip** oscillates (see 3.3 of IEC 61205)

Symbol: f_r

Unit: kilohertz, kHz

4 List of symbols

A_{as} **secondary acoustic output area**

A_{ap} **primary acoustic output area**

c speed of sound in the medium

D_{cy} **duty cycle**

f_d **drive frequency**

f_r **tip vibration frequency**

M_{sp} **primary tip vibration excursion modulation**

p_{fd} **directivity pattern**

$p(r)$ pressure amplitude at position r

P_a **output acoustic power**

P_{ad} **derived output acoustic power**

P_i **power reserve index**

P_q **quiescent electrical power**

P_{max} **maximum electrical power**

s_p **primary tip vibration excursion**

s_{pr} **reference primary tip vibration excursion**

s_s **secondary tip vibration excursion**

t_p **pulse duration**

ρ density of the measuring medium

5 General measurement requirements

5.1 Operating conditions

Measurements shall be performed with parameters set to values recommended by the manufacturer. The parameters to be considered are:

– ambient temperature;

– tip irrigant flow rate;

– tip vibration excursion;

– tip aspiration flow rate.

The parameters listed above are not set independently during actual surgical use. Therefore, when a particular surgical environment is to be studied, the parameters listed above shall be specified so that meaningful comparisons of performance can be made (see clause B.5).

5.2 Load conditions

5.2.1 For measurement of derived output acoustic power

Measurements of **derived output acoustic power or output acoustic power** shall be made using degassed water (see clause A.6 for rationale and references to degassing techniques) in a tank, lined with sound absorbing material and having a suitable size to render it essentially anechoic for the **tip vibration frequency** of concern i.e. free field condition. In addition, for devices which have suction available, sufficient flow through tip can be used to minimize the accumulation of bubbles on the front surface of the tip.

5.2.2 For measurements of quiescent electrical power

Measurements of **quiescent electrical power** to the ultrasonic handpiece shall be made with all system fluid flow operational and with the distal end of the **applicator tip** in air.

5.2.3 For measurements of maximum electrical power

Measurements of **maximum electrical power** (the power just prior to stall) to the ultrasonic handpiece shall be made as indicated by 5.2.2 but with the distal end of the **applicator tip** loaded with a suitable acoustically absorbing material capable of loading the applicator without damaging it.

5.3 Preparation for measurements

5.3.1 Preparation of the applicator

Prior to any measurements all surfaces and parts of the applicator shall be free from contamination. The **applicator tip**, the ultrasonic handpiece and the measurement devices which come into contact with the water and irrigant shall be cleaned with detergent and rinsed with warm water (see also [1]* and [2]).

5.3.2 Preparation of the water

Degassed water shall be used (see annex A for reference to suitable degassing techniques, see also [2] and [3] of annex C).

5.3.3 Preparation of the system

The apparatus shall be allowed a warm-up period as specified by the manufacturer. If a warm-up period is not specified by the manufacturer, a warm-up period shall be allowed which is long enough to allow stable operation to be achieved, up to a maximum of 15 min.

6 Measurement procedures

6.1 Primary tip vibration excursion

One of the following methods shall be used for measuring the **primary tip vibration excursion**. The accuracy of the vibration excursion measurement shall be better than ±10 %.

6.1.1 Optical microscope method

A microscope shall be focused on a point not more than 1,0 mm from the free end of the **applicator tip** which shall be illuminated by a light beam. When the equipment is energized, the point traces a line. The relative orientation of the **applicator tip** and the microscope shall be altered until the maximum line length is observed. The line length, equal to the **primary tip vibration excursion**, shall be measured to an accuracy of ±10 % by means of a calibrated eyepiece reticule or micrometer movement. If transverse vibrations occur simultaneously then the point on the applicator describes an elliptical path and the length of the major axis of the ellipse shall be measured (see figure 1).

6.1.2 Laser vibrometer method

A laser vibrometer shall have an output beam spot size small enough to focus on the end of the **applicator tip**. The beam shall be directed parallel to the longitudinal axis of the tip vibration i.e. in line with the direction of tip vibration excursion to be measured. The output of the vibrometer control module can be displayed and recorded on instruments as specified by the laser vibrometer manufacturer.

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* Figures in square brackets refer to the bibliography given in annex C.