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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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.

6.1.3 Feedback voltage method

For devices which have a feedback system which is directly coupled to the mechanical tip excursion, the feedback voltage is proportional to the **primary tip vibration excursion**. The optical microscope method of 6.1.1 shall be used to calibrate the feedback voltage in terms of tip vibration excursion for a particular combination of ultrasonic handpiece and applicator.

The feedback voltage shall be displayed on an oscilloscope with a time base accurate to ±2 % and vertical deflection amplifiers accurate to ±2 % while optical measurements are taken in accordance with 6.1.1. Once calibrated in this fashion only the feedback voltage need be observed to record the magnitude of tip vibration excursions.

6.2 Secondary tip vibration excursion

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

6.2.1 Optical microscope

The method shall be as described in 6.1.1 but the **applicator tip** shall be first rotated about its primary vibration axis while monitoring the length of the minor axis of the ellipse. The maximum observed length of the minor axis of the ellipse shall be measured as the **secondary tip vibration excursion** (see figure 1).

6.3 Drive frequency

One of the following methods shall be used. The accuracy of the **drive frequency** measurement shall be better than ±2 %.

6.3.1 Frequency counter method

An electronic frequency counter shall be used to determine the frequency of the driving voltage or current applied to the ultrasonic handpiece. The signal can be obtained either by connecting a suitably shielded cable to the circuit locations specified by the manufacturer or by winding a coil around the body of the ultrasonic handpiece and feeding the induced signal to a frequency counter.

6.3.2 Spectrum analyzer method

A spectrum analyzer with a frequency range of 10 000 Hz to 100 000 Hz shall be used to determine the frequency of the driving voltage or current. This shall be connected to the circuit locations specified by the manufacturer.

6.4 Tip vibration frequency

One of the following methods shall be used to measure the primary **tip vibration frequency**. The accuracy of the **tip vibration frequency** measurement shall be better than ±2 %.

6.4.1 Vibrometer method

A non-contacting vibrometer shall be used to indicate the frequency of oscillation of the **applicator tip**. This shall be measured from the output of the vibrometer using an electronic frequency counter, a spectrum analyzer or an oscilloscope with a calibrated time base (see IEC 60782).

6.4.2 Hydrophone method

A hydrophone which satisfies IEC 60500 shall be used to measure the frequency of the radiated acoustic pressure from the **applicator tip**. The hydrophone shall be placed in the range from 30 mm to 100 mm of the **applicator tip** to reduce the effects of nonlinear propagation. The frequency of the hydrophone output shall be measured using an electronic frequency counter, a spectrum analyzer or an oscilloscope with a calibrated time base.

6.5 Derived output acoustic power and output acoustic power

Derived output acoustic power or **output acoustic power** shall be determined using the method specified in 6.5.1 or 6.5.2, respectively.

6.5.1 Derived output acoustic power – Hydrophone method

This method is based on the use of a calibrated hydrophone. The uncertainty of the determination of **derived output acoustic power** shall be ±20 %. As a method based on a single point sensor and a measurement at a single distance from the **applicator tip**, it is chosen to eliminate the ideal requirement of integrating the pressure field and to avoid the possibility of cavitational shielding (see clause A.4). A hydrophone which satisfies IEC 60500 shall be used to measure pressure at a known distance from the **applicator tip**. Then, using the model of a monopole or a dipole source (see below), the **derived output acoustic power** can be calculated for any tip vibration excursion desired. The applicator shall be positioned so that the axis of symmetry of the **primary tip vibration excursion** coincides with the plane of the geometric axis of the hydrophone track.

An **applicator tip** which reciprocates in the direction of its **primary tip vibration excursion** (see figure 2) and which acts as a source which is small compared to the wavelength in the acoustic medium can be considered as a monopole (see [4] and [5]). The general case for an ultrasonic surgical device deeply immersed in the water tank is that the **derived output acoustic power** is given by the formula:

$$P_{\mathrm{ad}} = \frac{2\pi r^2 |p(r)|^2}{\rho c}$$

where

r is the separation of the **applicator tip** and the hydrophone;

$p(r)$ is the pressure amplitude measured at r;

ρ is the density of the measuring medium;

c is the speed of sound in the medium.

NOTE – If the acoustic pressure is determined in terms of r.m.s. acoustic pressure, p_{rms}, then $|p(r)|^2$ is replaced by 2 p_{rms}^2 in the above equation.

Many devices, however, have **applicator tips** which are designed to be in contact with the tissue while the rest of the applicator is outside the body. For these devices the **applicator tip** shall be positioned so that it is approximately 1/4 wavelength beneath the surface of the water in the measuring chamber. For this special case, whether for measurement convenience or so as not to add the energy radiated from the handle which is never put into tissue contact, the monopole source is reflected from the water/air boundary. This produces an effective second monopole source, 180° out of phase with the monopole tip source. Therefore this combination will effectively act as a dipole source.

For this case, where the **applicator tip** is approximately 1/4 wavelength beneath the surface of the water, the **derived output acoustic power** is given by (see A.8):

$$P_{\mathrm{ad}} = \frac{\pi r^2 |p(r)|^2}{2\rho c}$$

where

r is the distance from the hydrophone to the surface of the water.

A hydrophone which satisfies IEC 60500 shall be used to measure pressure at a known distance from the intersection of the axis of the tip and the surface of the water (see figure A.2). Then, using the model of a dipole source, above, the **derived output acoustic power** can be calculated for any tip vibration excursion desired.

6.5.2 Output acoustic power – Calorimeter method

This is an alternative but much less repeatable method than the hydrophone-based method specified in 6.5.1. However, it can be used as a first order approximation.

The end of the **applicator tip** shall be inserted into a calorimeter containing an absorbing fluid. The rate of temperature rise of the absorbing fluid shall be determined and used to calculate the power delivered by the probe. It should be noted that depth of immersion of the **applicator tip** will affect the results obtained with this method (see [1] and [3]).

6.6 Directivity pattern

The **directivity pattern** (field distribution) shall be determined by measuring the angular distribution, about a centre of rotation, of the magnitude of the acoustic pressure field at a specified range. The hydrophone shall satisfy IEC 60500. The hydrophone shall be mounted on a circular track. It shall be moved in a water bath over a 180° sector. The applicator shall be positioned so that the axis of symmetry of the **primary tip vibration excursion** coincides with the plane of the geometric axis of the hydrophone track.

NOTE – For straight symmetrical **applicator tips** the direction of maximum amplitude coincides with the axis of symmetry of the applicator. However, for curved or bent tips the motion at the distal end of the **applicator tip** will be at an angle to the axis of the ultrasonic handpiece (applicator).

For devices where the **applicator tip** is designed to be in contact with the tissue while the rest of the applicator is outside the body, the **applicator tip** shall be positioned so that it is approximately 1/4 wavelength in water beneath the surface of the water in the measuring chamber. For this condition, the centre of rotation shall be at the intersection of the surface of the water and the axis of rotation of the **applicator tip** (see figure 3).

For percutaneous devices where the majority of the long slender **applicator tip** is within the body, the **applicator tip** may be deeply immersed in the water chamber. For this condition, the distal end of the **applicator tip** shall be used as the centre of rotation.

For the above conditions, the hydrophone shall be mounted so as to maintain a constant sensitivity in the direction of the **applicator tip**. The separation between hydrophone and **applicator tip** as well as the depth of immersion of the **applicator tip** shall be noted. The separation of the **applicator tip** and the hydrophone shall be constant to within 2 mm during the measurement.

6.7 Primary tip vibration excursion modulation

The following method shall be used for the determination of **primary tip vibration excursion modulation**. The accuracy of the measurement shall be at least ±15 %.

6.7.1 Laser vibrometer method

Use the method described in 6.1.2 to determine the change in vibration excursion during the modulation cycle. The **primary tip vibration excursion modulation**, M_{sp}, expressed as a percentage, is given by:

$$M_{sp} = \{(s_{p\ on} - s_{p\ off})/s_{p\ on}\} \times 100$$

where

$s_{p\ on}$ is the **primary tip vibration excursion** during the on-time;

$s_{p\ off}$ is the **primary tip vibration excursion** during the off-time.

6.8 Duty cycle

For systems which modulate electrical drive power, the duty cycle is determined as follows.

The drive voltage or current shall be displayed on an oscilloscope with a time base accurate to ±2 % and vertical deflection amplifiers accurate to ±2 %. Determine the minimum and maximum peak-to-peak drive levels.

NOTE – It is assumed here that the peak-to-peak voltage or current is being measured and that the minimum peak-to-peak level may or may not be zero.

Determine a reference level from the sum of the minimum drive voltage or current and 10 % of the difference between the maximum and minimum drive voltage or current levels. The **pulse duration,** t_p, is determined from the oscilloscope trace by measuring the time interval between the first time, t_1, that the electrical drive signal exceeds the reference level and ending at the last time, t_2, that the electrical drive signal returns to the reference level (see figure 4). Thus, the pulse duration, t_p, is given by:

$$t_p = t_2 - t_1$$

If t_3 is the time at which the electrical drive signal exceeds the reference level at the start of the next pulse cycle, the **duty cycle**, D_{cy} is given by:

$$D_{cy} = \frac{t_p}{t_3 - t_1}$$

6.9 Quiescent electrical power

Set the **primary tip vibration excursion** to the desired level. Then, by using a phase-corrected wattmeter designed for ultrasonic applications, measure the electrical power directly into the ultrasonic handpiece to an accuracy of ±10 %.

6.10 Maximum electrical power

Set the **primary tip vibration excursion** to its maximum level. Then, by using a phase-corrected wattmeter designed for ultrasonic applications, measure the electrical power directly into the ultrasonic handpiece to an accuracy of ±10 %. In a water bath as shown in figure 5, load the surgical tip in the direction of the **primary tip vibration excursion**. Loading shall be effected against a material which will not damage the **applicator tip**. An open cell plastic foam or other water-containing medium may be used. The density of the loading material shall be sufficient to drive the input electrical power to the ultrasonic handpiece to the maximum value and to reduce the **reference primary tip excursion**. Measure the electrical drive power as the load is increased and note the maximum value reached just before the **primary tip vibration excursion** is reduced from its maximum excursion.

NOTE – The **primary tip vibration excursion** may be monitored using such methods as those described in 6.1.3.

6.11 Primary acoustic output area

For the specific example of a hollow cylinder **applicator tip**, the **primary acoustic output area** can be computed. Measure the inside and outside diameters of a hollow tubular **applicator tip**. The **primary acoustic output area** is given by the area of the projected annular ring formed by the two diameters and determined from (see figure 2):

$$A_{ap} = \frac{\pi}{4}(d_o^2 - d_i^2)$$

where

d_o is the outside diameter of the projected annular ring;

d_i is the inside diameter of the projected annular ring.

6.12 Secondary acoustic output area

For the specific example of a hollow cylinder **applicator tip**, the **secondary acoustic output area** can be computed. In the direction of the **secondary tip vibration excursion**, the **secondary acoustic output area** is calculated from the projected rectangle by (see figure 6):

$$A_{as} = d_o\ l$$

where

d_o is the diameter of the exposed tip;

l is the length of the exposed tip.

6.13 Power reserve index

The **power reserve index** is an indication of the relationship between the maximum available input electrical power, P_{max}, and the electrical power necessary to keep the surgical handpiece running without any external (tissue) load applied, P_q. The **power reserve index** is given by:

$$P_i = \frac{P_{max}}{P_q}$$

See cautionary note in clause 7.

7 Declaration of output characteristics

The following characteristics shall be declared in the accompanying documents of an ultrasonic surgical system:

NOTE 1 – For the rationale on the use and specification of these parameters, see clause B.4.

– **reference primary tip vibration excursion** for each type of **applicator tip** (i.e. the maximum **primary tip vibration excursion**);

– **primary acoustic output area** for each type of **applicator tip**;

– **drive frequency** for each ultrasonic handpiece;

– **derived output acoustic power or output acoustic power** for each type of **applicator tip** operating at the **reference primary tip vibration excursion**;

NOTE 2 – When declaring this characteristic care must be taken to ensure that the terminology appropriate to the method of measurement is noted. See 6.5.

– the type of frequency control of the system, i.e. whether initial tuning is required with later changes during the operation or if there is continuous automatic tuning of **drive frequency**, independent of load, during the operation;

NOTE 3 – This parameter gives the user an indication of how consistently a system can maintain a particular setting without the need for frequent operator intervention.

– **power reserve index** corresponding to the **reference primary tip vibration excursion** for each ultrasonic handpiece/**applicator tip** combination.

NOTE 4 – The absolute number is dependent on the type of transducer used. Therefore caution should be exercised not to use the **power reserve index** to compare the performance of dissimilar transducers.

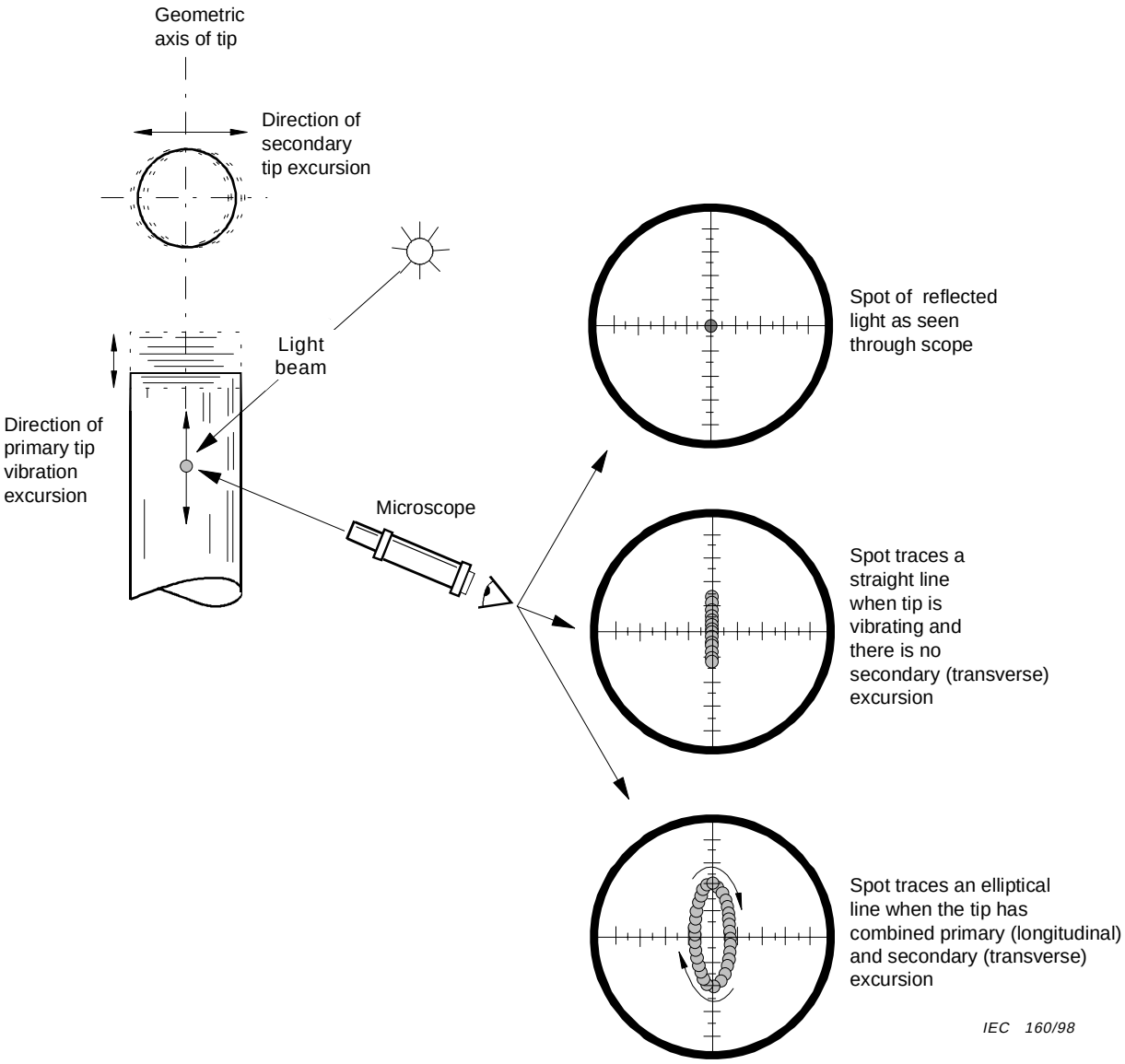

Figure 1 – Measuring the primary and secondary tip vibration excursion

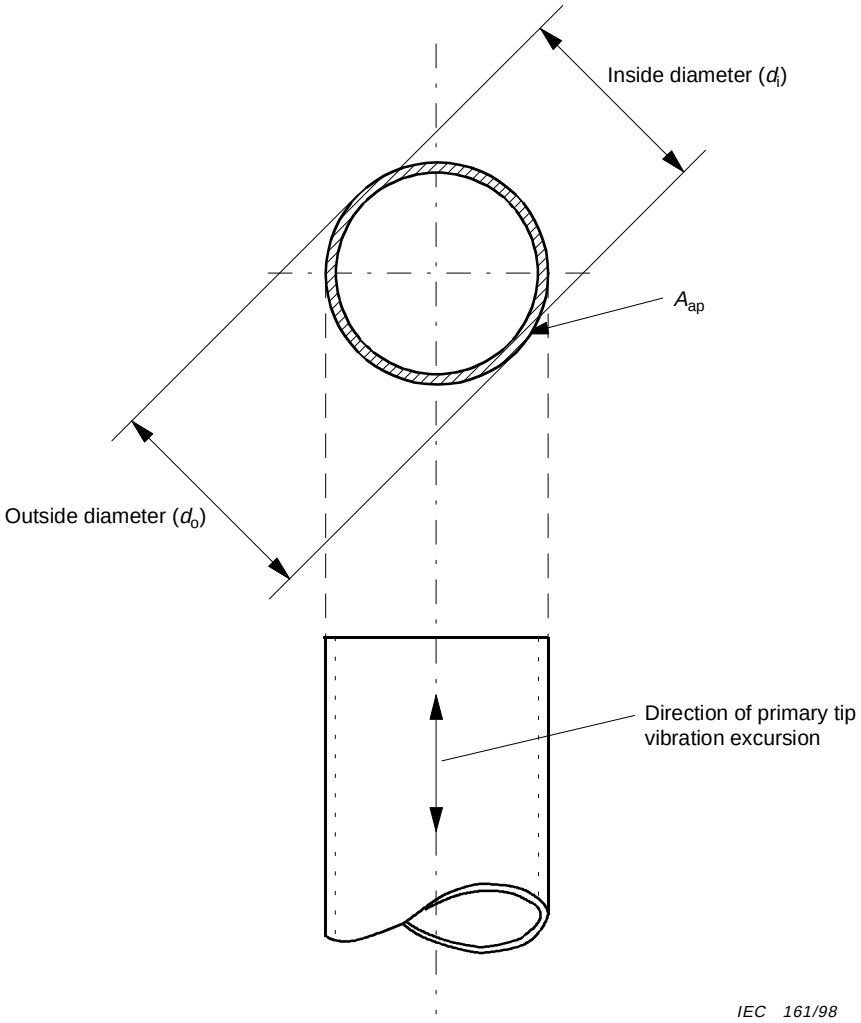

Figure 2 – Example of a primary acoustic output area

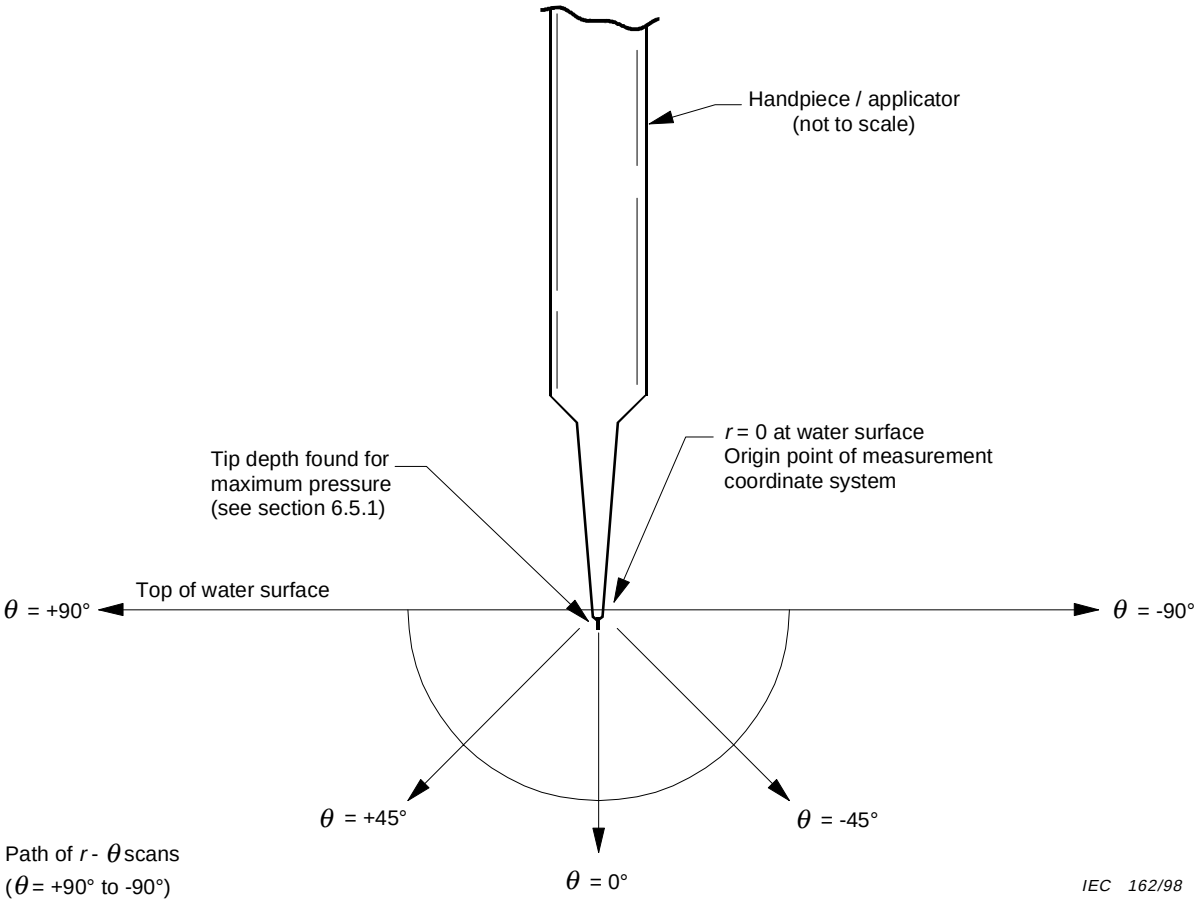

Figure 3 – Measuring the pressure field

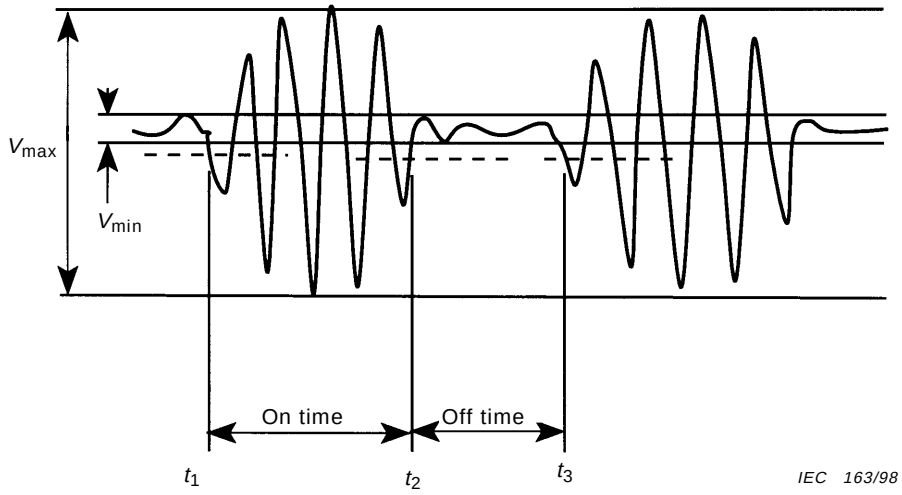

Figure 4 – Illustration of the method of determining duty cycle from an oscilloscope trace. The dotted line is at a level equal to the minimum peak-to-peak level plus 10 % of the difference between the maximum and the minimum peak-to-peak levels

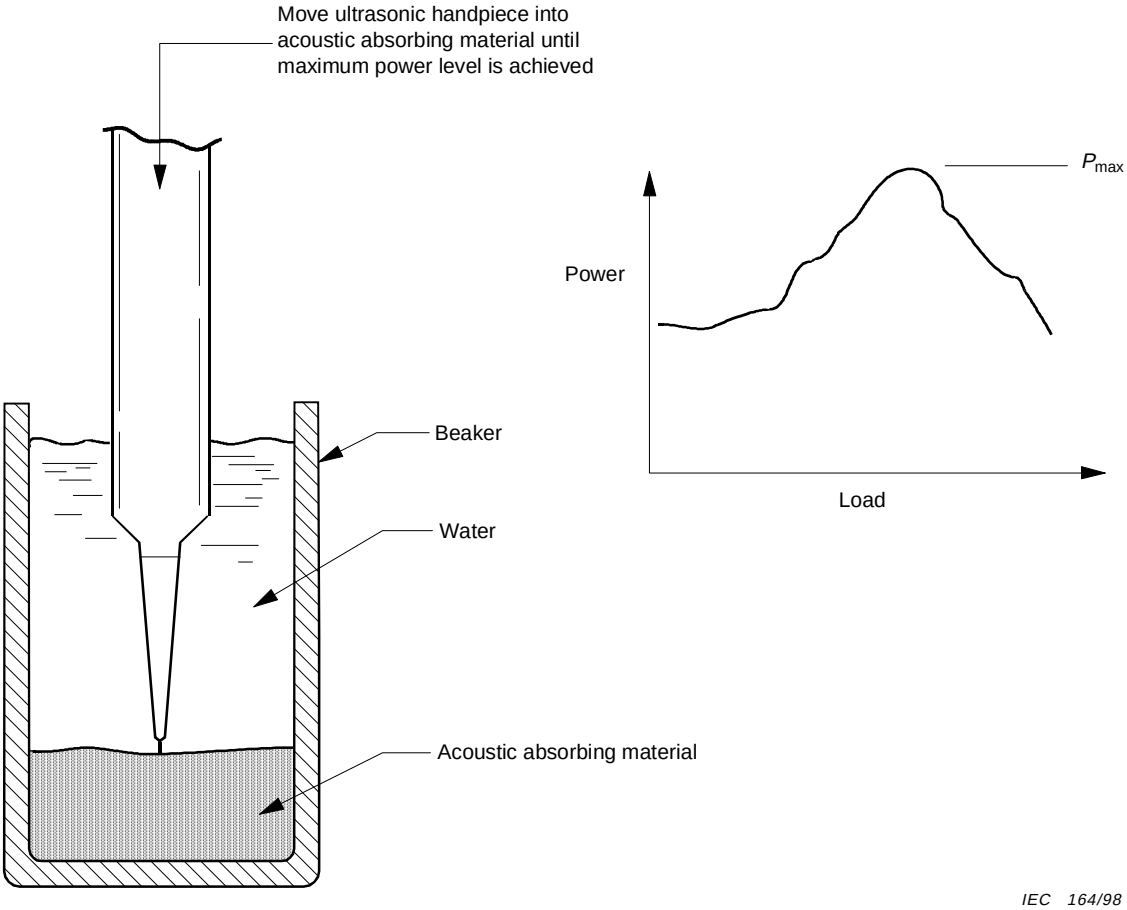

Figure 5 – Measuring the maximum electrical power (P_{max}) at a given primary tip vibration excursion (s_p)

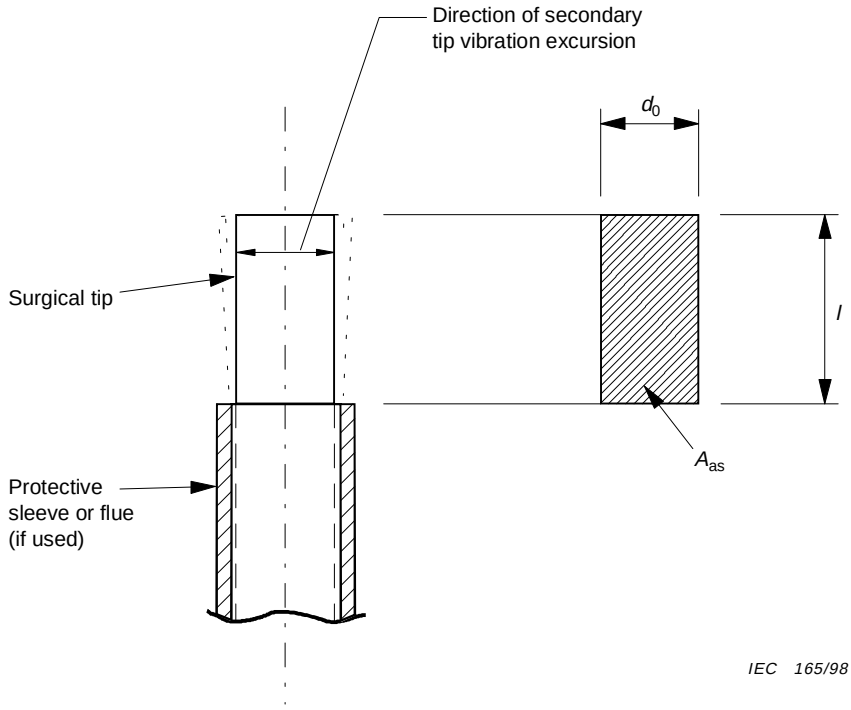

Figure 6 – Example of a secondary acoustic output area

Annex A
(informative)

Measurement methods and conditions

A.1 Optical microscope method

This method is based on direct observation of the tip oscillation with a microscope to view a spot of light reflected from the probe surface. To produce the spot, a miniature fibre optic is used or a pinhole located at the back focal plane of a condenser lens; the magnified image of the pinhole should be no greater than 5 % of the amplitude of tip oscillation. Assuming a circular spot, the peak-to-peak excursion is determined by measuring the peak-to-peak response and subtracting the width of the optical trace.

The magnification of the microscope is in the range of 60× to 200×. The scale is calibrated in micrometres with at least 400 μm full-scale.

A.2 Vibrometer method

As stated in IEC 60782 [1], methods, using vibrometers of different types for the measurement of transducer vibrational displacement amplitude, are secondary methods, used for transducers of both A and P categories in unloaded condition (category P transducers without liquid). They are also applicable for measurements of the displacement amplitude at the rear side of transducers in the loaded condition.

Non-contacting high-frequency vibrometers of different types should be used in this method (see [1] of appendix D). The scale of the instrument should be graduated directly in micrometres, its frequency range being 8 kHz to 100 kHz and the dynamical range 0,5 μm to 100 μm. The measurement error should be not more than ±10 %. Vibrometers used with magnetostrictive transducers should not be disturbed by strong variable magnetic fields.

A.3 Output acoustic power using the calorimeter method

The basis of the calorimetric method of measuring the acoustical power and its limitations are discussed in references [1] and [3]. The following is based on reference [1].

The calorimetric method of measuring acoustical power is based on the effect of sound absorption in liquids and their heating due to absorbed energy. It is well suited for measuring the acoustical power in the non-linear range, i.e. at high power levels.

It may also be used at low power levels, provided that the temperatures rise due to ultrasound absorption in the liquid is not too small. At high energy levels the liquid may partly vaporize or atomize. The energy used for this does not contribute to the heating of the liquid. Therefore the energy level should not be too high.

Some factors may considerably reduce the accuracy of the method, notably the direct heat conduction from the transducer to the liquid load, heat exchange between the liquid and the surroundings and the occurrence of standing waves.

In order to eliminate or to diminish the influence of the first factor (direct heat conduction), operating time of the transducer should not exceed 30 s. The slowness of the instrument for the temperature measurement should, however, be taken into consideration. When thermometers with small-scale divisions are used, the temperature indication probably reaches its maximum value some time after the energy supply has been switched off, and therefore this indication should be awaited. Because of this, the duration of the complete measurement will be longer than 30 s. Therefore, thermometers with small time constants should be used and the operating time of the transducer should be short.

The influence of the second factor (the heat exchange between the liquid and the surroundings) is reduced by making the initial temperature in the measuring tank nearly equal to the temperature of the surrounding media. Heat exchange with the surroundings may also be nearly completely excluded by using a standard calorimeter as a liquid tank.

Some modifications of the calorimetric method are used in order to eliminate the possibility that the heat absorption by the tank walls may affect the measurement results. These are compensation methods, using an equivalent heater in the form of an electrical wire heater with known consumed electrical power or in the form of a lump of metal with known mass, specific heat and high initial temperature. By comparing the heating of water in the measuring tanks induced by the equivalent heater and by the ultrasound produced by the transducer, the acoustical power produced by the transducer can be easily calculated.

The use of calorimeters may introduce standing waves in the liquid bath, as a result of which the acoustic load of the transducer may change greatly. This can be verified by measuring the electrical impedance of the transducer and by changing its position in the bath.

A.4 Derived output acoustic power using the pressure method

Acoustic pressure generated by a vibrating tip in water is a method which has been long used where there is a need to undertake measurements of the acoustic energy delivered to a medium. As pointed out by Muir and Carstensen [6], developments in this field have often relied on the convenient assumptions of infinitesimal acoustics. Unfortunately, many of these become invalid at biomedical frequencies and intensities. Some examples of questionable assumptions are that the acoustic frequencies generated by a source are the only frequencies produced in the medium, and that there is a linear relationship between source amplitude and acoustic pressure in the medium at points away from the source.

The underlying reasons for the invalidity of these assumptions involves harmonic distortion, localized extreme pressure gradients and the formation of shock waves which may enhance other effects involving cavitation, streaming and accelerated thermal deposition in an absorbing medium.

If one assumes a simplified mono-frequency source, in the kilohertz frequency region of interest, which produces a spherically radiating pressure wave, then a linear relationship between tip vibration amplitude and acoustic pressure is expected. However, as described by Schafer and Broadwin [7], the relationship is as shown in figure A.1.

Results shown in figure A.1 are obtained using a hydrophone which complies with IEC 60500 and calculating derived output acoustic power using the formulas in 6.5. Schafer and Broadwin [7] report that by measuring the high frequency components of the acoustic output, those created by cavitational implosions, and adding them to the low frequency component of the radiated energy one approaches the theoretical linear model. The high frequency portion of the acoustic energy should be measured with a hydrophone complying with IEC 60866 [8]. Because the method of obtaining the **derived output acoustic power**, although well known, is not in common practice at this time, the resultant values may not provide an absolute measure of power but rather a relative value. Understanding of these uncertainties is important.

To obtain the high-frequency component of the acoustic energy, the measurement method used [7] accounts for the acoustic radiation caused by cavitation bubble collapse at the tip by considering the energy in a single shock wave event, the number of events per unit time, and the spherical divergence of the wave. This measurement method uses some innovative computer routines and is not yet in widespread use. Therefore, until the method is more widely used and validated, measurement and reporting of this high-frequency component of acoustic energy should be deferred to a later edition of this International Standard. Consequently, the exclusion of the high-frequency component will lead to an underestimation of the total acoustic power delivered. The advantage of measuring only the low-frequency component in a recognized, repeatable and transferable manner outweighs the lack of knowledge of the true "total" power at this stage.

A.5 Feedback voltage method

Some systems use feedback signals to control the power levels driving their handpieces. These operate as closed loop resonant systems with the handpiece acting as a loss resonant transformer whose resonant frequency is determined by the mechanical resonance of the applicator and the handpiece. This arrangement results in the ultrasonic generator oscillating at the resonant frequency of the applicator.

The **primary tip vibration excursion** in these systems is determined by the level of the drive voltage or current delivered to the handpiece. A feedback control varies the drive signal so that the desired feedback signal is achieved. Since the feedback signal is proportional to the **primary tip vibration excursion** a reliable indication of applicator tip motion can be obtained from measurement of the feedback signal.

NOTE – The feedback signal should be initially calibrated with an external measuring instrument.

A.6 Influence of air bubbles and contaminations

When measuring transducers radiating into water, the water should be degassed, even though for most operating conditions the liquids used are saturated with air or other gasses. However, the measurements with saturated liquid loads are generally unstable, owing to the adhesion of bubbles and the possible occurrence of cavitation at relatively low power levels (see [1] for details). As stated in 5.2.1, depending on the type of tip being used, a variety of methods to keep the radiating surface "clear" of bubbles should be used. If a bubble cloud forms on the output surface of the tip it will result in masking of the true acoustic pressure field. Suction can be used if available or intermittent wiping of the output of the tip may be used.

A.7 Test tank

To undertake the acoustic pressure measurements in accordance with 5.2.1, a water tank is required in which acoustic reflections from its walls do not significantly interfere with the measurements. This may involve the use of small tank (say 0,6 m × 0,6 m × 1,3 m) lined with acoustically absorbing material. Alternatively, a large tank (say 5 m × 10 m × 3 m) may be used. Whichever is used, the signal detected at the hydrophone as a result of echoes from the walls should be more than 20 dB below the direct signal from the tip.

In addition, a rectilinear positioning system is needed to hold the hydrophone and to enable it to be rotated about the tip. For more details of a typical measurement system, see [7] and [9].

A.8 Derivation of formula for derived output acoustic power for the case of a dipole

Because the tip is small relative to the size of the wavelength in water, it radiates energy as a monopole source [5]. When it is immersed in the water tank to an immersion depth on the order of less than two wavelengths, then a secondary, image source is created by the interaction of the monopole sound field and the water surface (see figure A.2). Source 1 is the true, monopole source at the tip; source 2 is the image source caused by reflection from the water surface. The field at any point in the water tank can be found by summing the pressure from the true and image sources. Note that the image source is 180° out of phase with the true source.

The total pressure amplitude p_{total} at the observation point in the water tank may be expressed as (see p. 355, equation 55 of [5]):

$$p_{total} = p_{S1} + p_{S2} = \left(\frac{j\rho ck}{4\pi}\right)(Q_S)\left(\frac{e^{-jkr_1}}{r_1} - \frac{e^{-jkr_2}}{r_2}\right) \quad (A.1)$$

where

ρ is the density;

c is the sound speed;

k is the wave number ($2\pi/\lambda$);

r_1 and r_2 are the distances to source 1 and source 2 respectively;

Q_S is the source strength (radiating area times normal surface velocity) of the tip.

If this expression is integrated over a spherical surface, the total power radiated from a dipole-like source can be expressed as:

$$P = \frac{\rho c\, k^2 Q_S^2}{8\pi}\left(1 - \frac{\sin kd}{kd}\right) \quad (A.2)$$

For purposes of repetitive measurements, a series of assumptions and simplifications can be made so that the total power can be estimated from a single pressure measurement. First, it is assumed that the distance to the hydrophone is much greater than the depth of immersion, so that r_1 and r_2 can be approximated by r. Further, the equation is solved for the specific case of a measurement location which is co-axial with the tip direction, that is, it is directly in line with the tip. Under those conditions, equation (A.1) can be simplified to give the on-axis pressure:

$$|p_{on\text{-}axis}(r, d)| = \left(\frac{\rho ck}{2\pi r}\right)(Q_S)\left|\left[\sin\left(\frac{kd}{2}\right)\right]\right| \quad (A.3)$$

By solving equation A.3 for Q_S and substituting into equation A.2, an expression for the radiated power using an on-axis pressure measurement can be found. For the case in which the immersion depth is one-quarter of a wavelength, such that d is $\lambda/2$, and (kd) equals π, then the expression for radiated power from an on-axis, far-field pressure measurement is:

$$P = \frac{\pi r^2 |p(r)|^2}{2\rho c} \quad (A.4)$$

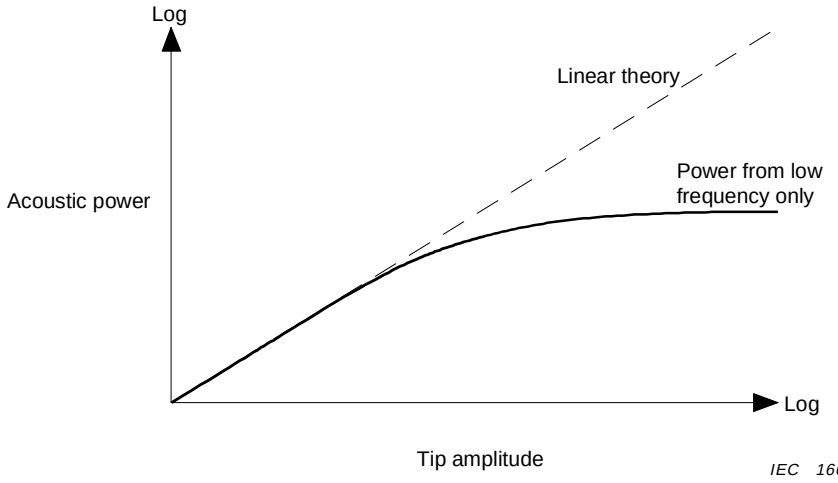

Figure A.1 – A typical relationship between tip vibration amplitude and acoustic pressure

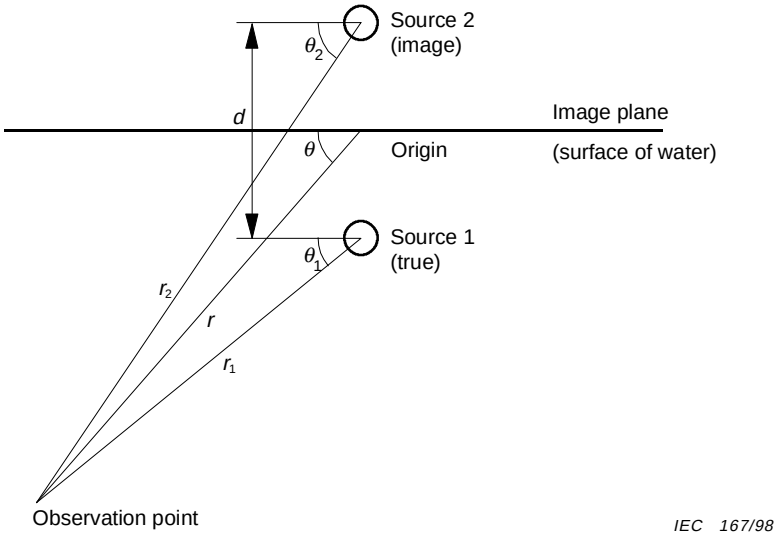

Figure A.2 – Schematic diagram of the theoretical model geometry for the tip immersed below the surface of the water

Annex B
(informative)

Theory of operation of ultrasonic surgical devices

B.1 Introduction

Successful ultrasonic systems for many industrial and military applications have been commercially available since the 1940s. In the early 1960s the use in dentistry became increasingly popular. 1970 saw the expansion into the field of ophthalmology. By the mid 1970s the application to neurosurgical cases firmly established the ultrasonic modality as an important surgical tool.

In the period from 1980 to 1992 the number of surgical specialities to which this energy source is applied has increased dramatically. With the rapid growth of applications has come a proliferation of surgical device manufacturers and delivery devices. In addition, with the increasing number of surgical requirements has come an expanding number of applicators and surgical tips depending on the surgical requirement or the manufacturer's preference.

These devices have traditionally been measured using non-acoustic parameters, i.e. displacement, frequency and input electrical power. This approach to device characterization grew out of the industrial power ultrasonics field. The industry which makes plastic welders, for example, is basically interested in displacement per unit time and application force.

The parameters reported up to now do not provide a characterization of ultrasonic surgical devices which can be used as a basis for eventual correlation to biological effects. Nor can they be used for comparisons of performance of alternate devices or alternate **applicator tip** when applied to the same acoustic vibrator.

B.2 System description

Ultrasonic surgical instruments consist of a generator and a handpiece with a surgical tip. Many of the tips are hollow, however there is an increasing variety of solid tips also. Often there are ancillary features to allow simultaneous irrigation and suction at the tip to ensure good ultrasonic contact, to allow easy removal of fragmented tissue, to provide cooling and protection for the tissue at the surgical site and to provide cooling for the handpiece transducer.

Additionally, units for ophthalmic use incorporate a control to maintain a constant intraocular pressure during surgery via a closed hydraulic system which includes the eye under operation.

The handpieces may have either magnetostrictive transducers or piezoceramic transducers. In either case care should be taken in the design to ensure adequate cooling of the transducer and the **applicator tip** so as to protect the patient and ensure that the devices will operate reliably and will not exhibit unwanted frequency drift while in operation. Handpieces are designed as resonant devices to maximize the efficiency of energy conversion. Thus every handpiece consists of a transducer, a connecting member and an **applicator tip**.

The combination of these three elements is usually called an acoustic vibrator.

B.3 Possible mechanisms of tissue interaction

Although in use for over twenty years, little is known about what mechanism causes tissue fragmentation and the selective removal of tissue. It is believed that at least one of the mechanisms is the force created by cavitational bubbles imploding in cellular fluid and in the microscopic convolutions of hard or brittle tissue. Ultrasonic surgical device **applicator tips** having sharp features also apparently cause tissue cutting or tearing by the simple mechanism of rapid, sharp cutting.

Since ultrasonically vibrating members have very high surface velocities, another effect seen is the frictional heat generated by the side of the tip when its unprotected portion rubs against tissue. This effect can have two outcomes. One, it can damage sensitive tissue which is not intended for removal. Second, it may account for some of the secondary cauterizing effects which are observed in surgery and are in fact desired in some applications.

NOTE – The velocity of the distal end of a surgical tip vibrating at 23 kHz and 350 μm is given by:

$$2\pi f_r \frac{s_p}{2} \approx 24 \text{ m/s } (85 \text{ km/h})$$

Reports from the surgical community over the last 20 years have indicated that with normal and professional application of these instruments, little or no distant mechanical damage is evident. In addition, the tissue removed during tumour surgery by the action of the annular end of a hollow tip appears well enough preserved to allow accurate histo-pathology of the samples.

B.4 Typical values of output and discussion of parameters

Primary tip vibration excursions can vary from 0 μm to 600 μm. At a given **drive frequency** the excursion is controlled by the design of the acoustic vibrator and the drive power.

Secondary tip vibration excursions may be present due to a lack of symmetry of the resonant structure. This can be by design or due to manufacturing variations. These non-axial motions are typically less than a fifth of the **primary tip vibration excursion**.

NOTE – In the case where the direction of **primary tip vibration excursion** is intended to be along the longitudinal axis of the surgical tip, the ratio of primary to **secondary tip vibration excursion** may provide an indication of the quality of the device.

Drive frequencies of commercially available ultrasonic fragmentation units are in the range of 20 kHz to 60 kHz. In some units the operator has manual control of the **drive frequency** of the acoustic vibrator. For maximum efficiency of energy conversion the **drive frequency** should match the resonant frequency of the acoustic vibrator. Therefore most current devices have automatic frequency control circuits.

Tip vibration frequencies or acoustic vibrator vibration frequencies are nominally equal to the **drive frequency**. However, other harmonic frequencies will always be present. These may affect the performance of the device.

Derived output acoustic power is of consequence for considerations involving the possible hazards of the use of these devices in close proximity to sensitive body structures. Although these devices are designed for tissue destruction, there may be situations where radiated energy could have undesirable effects.

Directivity pattern (field distribution) is also of consequence so that the direction of acoustic emission can be controlled when designing or applying a particular **applicator tip**.

Primary tip vibration excursion modulation changes the performance of devices for particular surgical situations. It appears to improve the ability of devices with this feature to discriminate between tissue structures. This feature is controlled by the absolute values of the on and off times of the drive voltage as well as the magnitude of the excursion. The reason devices with a modulation feature have an improved tissue discrimination is as follows. In many surgical situations, the physician is working in very sensitive areas (neurosurgery or spinal column surgery). Under these conditions the natural tendancy is for the physician to proceed cautiously. He therefore would request that the tip vibration excursion be reduced so that he can control the rate of tissue removal. When this is done however, the ability to fragment and remove tissue is diminished. By modulating the tip vibration excursion the physician can use a higher excursion while reducing the rate of tissue removal. This yields an effective ability to discriminate between tissues.

B.5 Operating conditions

As with any measurement, the environment affects the absolute value and the consistency of measurements.

Ambient temperature will affect the level of entrapped air in the water bath and the temperature of the tip and transducer. Entrapped air affects the generation of cavitation bubbles.

Irrigant flow rate will affect the temperature and the loading of the transducer and therefore the ability of the whole transducer to maintain the frequency setting desired. If a tip heats up too much it can drive a handpiece off resonance and therefore affect its performance.

Tip vibration excursion affects the acoustic energy delivered to the water or tissue as the case may be. The higher the tip vibration, the greater the tissue fragmentation rate will be, all other parameters being equal.

Tip aspiration flow rate affects the ability of the system to "clear" cavitation bubbles from the front of the tip. It also affects the loading of the transducer and the equilibrium temperature which the transducer operates at.

Annex C
(informative)

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17.

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.....

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.....

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.....

.....

18.

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company: .....

address:.....

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