SLOVENSKI STANDARD
oSIST prEN IEC 61847:2024

01-oktober-2024

Ultrazvok - Kirurški sistemi - Merjenje in navajanje osnovnih izhodnih karakteristik

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

Ultraschall - Chirurgische Systeme - Messung und Deklaration der grundlegenden Ausgangsrößen

Ultrasons - Systèmes chirurgicaux - Mesurage et déclaration des caractéristiques d'émission de base

Ta slovenski standard je istoveten z: **prEN IEC 61847:2024**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
17.140.50	Elektroakustika	Electroacoustics

oSIST prEN IEC 61847:2024 **en**

87/870/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 61847 ED2	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2024-07-19	**2024-10-11**
SUPERSEDES DOCUMENTS:	
87/835/CD, 87/866/CC	

IEC TC 87 : ULTRASONICS	
SECRETARIAT: United Kingdom	SECRETARY: Mr Petar Luzajic
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: ☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY	
☒ SUBMITTED FOR CENELEC PARALLEL VOTING **Attention IEC-CENELEC parallel voting** The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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TITLE:

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

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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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/XXX/FDIS	87/XXX/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 is expected to be issued at a later date.

INTRODUCTION

Ultrasonic surgical systems, operating in the 20 kHz to 120 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. The use of these devices has expanded to areas such as liposuction and wound treatments.

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 area of use 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. While available data indicate that inertial cavitation is an important component of efficacy for certain applications, other effects such as acoustic streaming can be more important in other applications. Overall, it is recommended that manufacturers provide users with quantified acoustic and vibrational output metrics, so that systems can be properly compared, and so that users can improve their surgical technique by minimizing output while maintaining surgical efficacy.

It is recognised that manufacturers can develop systems with complicated vibrational patterns and applicator tip geometries. In order to properly compare acoustic output dynamics of such system, it is the recommendation that acoustic pressure measurements be taken, which, when combined with excursion and frequency information, allow for the derivation of the effective acoustic output area. This area is fundamental to the operation of ultrasound surgical devices and is a key metric for device and applicator tip comparison.

It is recognized that there are difficulties performing acoustic measurements when cavitation, either inertial or non-inertial, occurs. Therefore, this standard only requires measurements to be performed at low vibration excursion levels when no cavitation is present. The acoustic output at higher excursions shall be linearly extrapolated from low level measurements. In addition, the excursion level at which cavitation is first detected should be reported, as information for the user. Cavitation measurement techniques are discussed in other standards currently under development.

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 primarily addresses the low-frequency (under 120 kHz) component of the total delivered energy. The high-frequency component, which relates to cavitation developed at the tip, is discussed but not required as a reported parameter (see A.4). However, the vibration amplitude at which cavitation occurs shall be measured, noted and reported

– 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 a straight tubular shape is used in the basic description of the parameters and measurements to be made. Guidance is provided to the user of this standard to adapt the basic methodology described to more complex designs as required. It is recognized that complex designs and vibration patterns are design features of many surgical devices, and therefore it is important that output characteristics be declared for those conditions. The manufacturer is required to declare which vibrational modes and excursion directions are under user control, and provide information on all such modes.

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 120 kHz; and

b) ultrasonic surgical systems, whose use is the fragmentation, emulsification, debridement, 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, phacoemulsifiers, intracorporeal lithotripters, end-cutting devices, ultrasonic liposuction devices, etc. Devices which do not make direct contact with the surgical or wound site are covered by this Standard, although the acoustic power calculation must be modified to account for the acoustic characteristics of air rather than tissue.

NOTE 4 – The upper frequency limit has been set to accommodate more recently developed devices operating at higher frequencies than the original standard. The requirements and techniques of this standard are also applicable to devices operating at higher frequencies that use the same mechanisms of action.

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 mechanism of action is through frictional heat generated by tissue in contact with the wave guide, e.g. clamp coagulator/cutters

- surgical devices whose mechanism of action is through focused ultrasound for either thermal degradation (High Intensity Focused Ultrasound – HIFU/HITU) or cavitation erosion (Histotripsy) of tissue remote from the ultrasound transducer.

- surgical devices whose mechanism of action is through erosion of hard tissues in contact with the applicator tip, e.g. bone cutting/drilling, although declaration of vibrational frequency(ies) and amplitude(s) shall be required for these systems.

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

NOTE 5 – 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 60500:2017, *Underwater acoustics - Hydrophones - Properties of hydrophones in the frequency range 1 Hz to 500 kHz*

IEC 60565-1:2020 *Underwater acoustics - Hydrophones - Calibration of hydrophones - Part 1: Procedures for free-field calibration of hydrophones*

IEC TR 62781:2012 *Ultrasonics - Conditioning of water for ultrasonic measurements*

IEC 62127-1:2022 *Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields*

IEC 62127-2:2007 - *Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC TS 63001:2024 - *Measurement of cavitation noise in ultrasonic baths and ultrasonic reactors*

IEC 60601-2-58 Ed. 1:2014 - *Medical electrical equipment—particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

3 Definitions

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

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

3.2 3.2
cavitation
formation, oscillation, vibration, and potential collapse of a bubble or bubbles (gas or vapor) within a liquid medium

Note 1 to entry – The definitions of cavitation are taken from IEC TS63001 ed. 2, 3.2, 3.4, and 3.5, with modifications

3.3 3.2.1
acoustic cavitation
cavitation driven by the presence of an acoustic field

3.4 3.2.2
inertial cavitation
cavitation in which the collapse of bubbles is driven by the inertia of the medium, including repetitively, in response to an externally applied acoustic field

3.5 3.1.3
non-inertial cavitation
oscillation in the size or shape of bubbles in a medium, in response to an externally applied acoustic field and generally sustained over multiple cycles of the **drive frequency**, but not involving the collapses ascribed to **inertial cavitation**

3.6 3.3
directivity pattern

$p_{fd}(\Theta)$
normalized variation in acoustic pressure as a function of angle at constant range from the **applicator tip**

Note 1 to entry – This parameter is used to confirm that the applicator tip produces the directivity pattern that conforms to the acoustic model used, i.e., monopole or dipole.

Note 2 to entry – The **directivity pattern** is dimensionless.

3.7 3.4
drive frequency
f_d
mean frequency of the driving voltage or current

Note 1 to entry – This parameter, coupled with tip vibration excursion, allows the user to compare the velocities of applicator tips. For some systems, the tip vibration frequency f_{rp} can happen at a higher or sub-harmonic of this frequency.

Note 2 to entry – For some system, there can be more than one drive frequency, depending on the intended modes of operation. In this case, each shall be described with additional subscripts, e.g., f_{d1}, f_{d2}.

Note 3 to entry – The **drive frequency** is expressed in Units of Hertz (Hz).

3.8 3.5
duty cycle
D_{cy}
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

Note 1 to entry – The **duty cycle** is dimensionless and is typically expressed as a percentage.

3.9 3.6
output acoustic power
P_a

the acoustic power delivered by the **applicator tip** into water

Note 1 to entry – 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.

Note 2 to entry – For some system, there can be more than one operating condition, with different drive frequencies, excursions, and effective radiating areas. In this case, each shall be described with additional subscripts, e.g., P_{a1}, P_{a2}.

Note 3 to entry – The hydrophone method is the recommended (Section 6.5). The calorimetric method had been previously proposed (Informative Annex), but difficulties in the measurement of ultrasonic surgical devices, especially those systems that involve fluid irrigation and aspiration, result in large uncertainties. For limited cases, the calorimetric method can be used if the technique can be demonstrated to meet the uncertainty requirements.

Note 4 to entry - The **output acoustic power** is expressed in Units of Watts (W).

3.10 3.7
primary vibration mode

the direction of tip vibration that is considered by the manufacturer to be the default or primary one that is under user control.

3.11 3.8
Secondary vibration mode

Additional vibration modes other than the primary vibration mode. If the vibration mode is not under user control, i.e., it is a vibration mode associated with the primary vibration mode as a parasitic, then it shall be measured but it is not required to be reported. If the vibration mode is under user control, i.e., it represents a specific alternate mode of operation from the primary vibration mode, then it shall be measured and reported.

3.12 3.9
primary acoustic output area

A_{ap}

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

Note 1 to entry – **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. For hollow or blunt cylinder **applicator tips** operated in an excursion direction perpendicular to their face, the **primary acoustic output area** can be computed from geometric considerations (see 6.9). For more complex shapes, or for movement that is not perpendicular to a flat surface, the acoustic output area can be derived from measurements of the tip vibration frequency, tip excursion, and the pressure measured at a known distance from the tip, using the equations and methods within this standard.

Note 2 to entry - The **primary acoustic output area** is expressed in Units of meters-squared (m^2).

3.13 3.10
primary tip vibration excursion

s_p

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 end in the direction of maximum amplitude

Note 1 to entry – The ability to fragment tissue can be correlated to **primary tip vibration excursion**.

Note 2 to entry – For some systems, the primary tip vibration direction is not colinear with the direction of motion generated by the vibrational source.

Note 3 to entry - The **primary tip vibration excursion** is expressed in Units of meters (m).

3.14 3.11
primary tip vibration excursion modulation

M_{sp}

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

Note 1 to entry - The **primary tip vibration excursion modulation** is dimensionless and is expressed as a percentage.