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STN	**Ultrazvuk Chirurgické systémy Meranie a zaznamenávanie základných výstupných charakteristík**	**STN EN IEC 61847 36 4888**

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 10/25

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61847

July 2025

ICS 11.040.01; 17.140.50 Supersedes EN 61847:1998

English Version

Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics (IEC 61847:2025)

Ultrasons - Systèmes chirurgicaux - Mesurage et déclaration des caractéristiques d'émission de base (IEC 61847:2025)

Ultraschall - Chirurgische Systeme - Messung und Deklaration der grundlegenden Ausgangsrößen (IEC 61847:2025)

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Ref. No. EN IEC 61847:2025 E

European foreword

The text of document 87/894/FDIS, future edition 2 of IEC 61847, prepared by TC 87 "Ultrasonics" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61847:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-07-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-07-31

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In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1	NOTE	Approved as EN 60601-1
IEC 80601-2-58	NOTE	Approved as EN IEC 80601-2-58

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Publication	Year	Title	EN/HD	Year
IEC 60500	-	Underwater acoustics - Hydrophones - Properties of hydrophones in the frequency range 1 Hz to 500 kHz	EN 60500	-

IEC 61847

Edition 2.0 2025-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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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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IEC 61847 has been prepared by IEC technical committee 87: Ultrasonics. It is an International Standard.

This second edition cancels and replaces the first edition published in 1998. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) The upper frequency covered by this document has been raised from 60 kHz to 120 kHz.
b) The hydrophone method of measuring ultrasound power is now normative. Because of difficulties in using the calorimetry method of measuring ultrasound power, it is no longer the primary approach.

c) It is recognised that some systems can have more than one mode of vibration under user control, and the measurement techniques and declarations have been updated to address this.

d) The high-frequency component, which relates to **cavitation** developed at the **applicator tip** and the vibration amplitude at which **cavitation** occurs is addressed.

e) Specific requirements for measurement at excursion levels where no **cavitation** is present, and extrapolation to maximum excursion level(s) are described.

f) Guidance is provided to adapt the methodology described to more complex designs and vibration patterns, excursion directions, and their output characteristics.

g) Guidance is provided with respect to measurement tank arrangements for different types of systems.

h) The list of ultrasound methods and systems not covered by this document was extended to incorporate recent developments.

i) Definitions for **cavitation** related terms were added.

j) Requirements for the measurement of directivity characteristics of the **applicator tip** were changed.

k) Annex A was modified and Figure A.1 was added.

l) New literature was added, and the references to other standards were updated.

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

Draft	Report on voting
87/894/FDIS	87/900/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this document is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document 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.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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 systems has expanded to areas such as liposuction and wound treatments.

This document 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 document does not provide any guidance on what is the resultant safety or efficacy of systems 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 important 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 recognized that manufacturers can develop systems with complicated vibrational patterns and **applicator tip** geometries. In order to properly compare acoustic output dynamics of such system, this document describes acoustic pressure measurements to 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 systems and is a key metric for system and **applicator tip** comparison.

It is recognized that there are difficulties performing acoustic measurements when **cavitation**, either inertial or non-inertial, occurs. Therefore, this document describes measurements performed at low vibration excursion levels when no **cavitation** is present, with the acoustic output at higher excursions linearly extrapolated from the low-level measurements. The excursion level at which **cavitation** is first detected is also important 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 document specifies:

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

NOTE 1 One of the parameters of interest is **output acoustic power**. This document 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 in Clause A.4.

– methods of measurement of these output characteristics;

– those characteristics to 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 document 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 systems, and therefore it is important that output characteristics be declared for those conditions.

This document is applicable to equipment which meets the criteria 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 systems, ultrasonic liposuction systems, etc.

NOTE 4 The upper frequency limit has been set to accommodate more recently developed systems operating at higher frequencies than IEC 61847:1998. The techniques of this document are also useful for systems operating at higher frequencies that use the same mechanisms of action.

This document is not applicable to:

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

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

– surgical systems whose mechanism of action is through frictional heat generated by tissue in contact with the wave guide, e.g. clamp coagulators or clamping vibrational cutters;

– surgical systems whose mechanism of action is through focused ultrasound for either thermal degradation (high intensity focused ultrasound – HIFU or HITU) or **cavitation** erosion (Histotripsy) of tissue remote from the ultrasound transducer;

– surgical systems whose mechanism of action is through erosion of hard tissues in contact with the **applicator tip**, e.g. bone cutting or drilling.

NOTE 5 Limited declaration requirements for surgical systems whose mechanism of action is through erosion of hard tissues in contact with the **applicator tip** are listed in Clause 7.

This document does not deal with the effectiveness or safety of ultrasonic surgical systems. This document does not deal with airborne noise from the systems, which can affect operators and patients.

NOTE 6 Airborne noise levels are addressed in IEC 60601-1 [1][1].

NOTE 7 The safety of ultrasonic surgical systems for ophthalmic applications are addressed in IEC 80601-2-58 [2].

NOTE 8 Throughout this document, the term accuracy means the overall uncertainty expressed at the 95 % confidence level.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60500, *Underwater acoustics – Hydrophones – Properties of hydrophones in the frequency range 1 Hz to 500 kHz*

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