

INTERNATIONAL STANDARD

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

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

IEC 61847:2025

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ULTRASONICS – SURGICAL SYSTEMS –
MEASUREMENT AND DECLARATION OF
THE BASIC OUTPUT CHARACTERISTICS**

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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,
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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.