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Interested committees:

Title: BS EN IEC 61847 Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



87/835/CD

COMMITTEE DRAFT (CD)

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CLOSING DATE FOR COMMENTS:

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SUPERSEDES DOCUMENTS:

87/787/RR

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 CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☐ SAFETY

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Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

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CONTENTS

	Page
FOREWORD.....	3
INTRODUCTION.....	4
1 Scope	5
2 Normative references	5
3 Definitions	7
4 List of symbols.....	11
5 General measurement requirements	11
5.1 Operating conditions	11
5.2 Load conditions	11
5.3 Preparation for measurements	12
6 Measurement procedures	12
6.1 Primary tip vibration excursion	12
6.2 Secondary tip vibration excursion	13
6.3 Drive frequency	13
6.4 Tip vibration frequency	14
6.5 Derived output acoustic power and output acoustic power	14
6.6 Directivity pattern	15
6.7 Primary tip vibration excursion modulation	16
6.8 Duty cycle	17
6.9 Primary acoustic output area	18
6.10 Secondary acoustic output area	18
7 Declaration of output characteristics	18
Figures	16
Annexes	
A Measurement methods and conditions.....	21
B Theory of operation of ultrasonic surgical devices	26
C Bibliography	29

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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/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 may 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 may be more important in other applications. Overall, it is recommended that manufacturers provide users with quantified acoustic and vibrational output metrics, so that systems may be properly compared, and so that users can improve their surgical technique by minimizing output while maintaining surgical efficacy.

It is recognised that manufacturers may 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 is reported, as information for the user.

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.

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 erosion of hard tissues in contact with the applicator tip, e.g. bone cutting/drilling, although declaration of vibrational frequency(ies) and amplitude(s) may be required for these systems.

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

161 of applying the most recent editions of the normative documents indicated below. Members of
162 IEC and ISO maintain registers of currently valid International Standards.

163 NOTE: this section must be updated to include all revisions of the standards below as well as
164 any new applicable standards.

165 IEC 60500:1974, *IEC standard hydrophone*

166

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.

NOTE – 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.

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. For some systems, the tip vibration frequency f_{ip} may happen at a higher or sub-harmonic of this frequency.

NOTE – For some system, there may 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} .

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

3.6

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.

215 Symbol: P_{ad}

216 Unit: milliwatts, mW

217 NOTE – For some system, there may be more than one operating condition, with different drive frequencies,
218 excursions, and effective radiating areas. In this case, each shall be described with additional subscripts, e.g.,
219 P_{ad1} , P_{ad2} .

220

221 3.8

222 primary vibration mode

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

225 Secondary vibration mode

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

231 3.9

232 primary acoustic output area

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

235 NOTE – **Primary acoustic output area** is used in determining the energy radiated from the end of an **applicator**
236 **tip** for different tips operating at the same vibration excursion and frequency. For hollow or blunt cylinder
237 **applicator tips** operated in an excursion direction perpendicular to their face, the **primary acoustic output area**
238 can be computed from geometric considerations (see 6.9). For more complex shapes, or for movement that is not
239 perpendicular to a flat surface, the acoustic output area may be derived from measurements of the tip vibration
240 frequency, tip excursion, and the pressure measured at a known distance from the tip, using the equations and
241 methods within this standard.

242 Symbol: A_{ap}

243 Unit: square millimetres, mm²

244 3.10

245 primary tip vibration excursion

246 peak-to-peak displacement of the **applicator tip** in the direction of maximum amplitude, at a
247 point on the **applicator tip** not more than 1 mm from its free end in the direction of maximum
248 amplitude

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

250 NOTE – For some systems, the primary tip vibration direction may not be colinear with the direction of motion
251 generated by the vibrational source.

252 Symbol: s_p

253 Unit: micrometre, μm

254 3.11

255 primary tip vibration excursion modulation

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

258 Symbol: M_{sp}

259 Unit: dimensionless

260 3.12

261 pulse duration

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