

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

The European Standard EN 61847:1998 has the status of a
British Standard

ICS 11.040.50

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

National foreword

This British Standard is the English language version of EN 61847:1998. It is identical with IEC 61847:1998.

The UK participation in its preparation was entrusted to Technical Committee EPL/87, Ultrasonics, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

From 1 January 1997, all IEC publications have the number 60 000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-references

Attention is drawn to the fact that CEN and CENELEC Standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 26 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Amendments issued since publication

Amd. No.	Date	Comments

This British Standard, having been prepared under the direction of the Electrotechnical Sector Board, was published under the authority of the Standards Board and comes into effect on 15 May 1998

© BSI 04-1999

ISBN 0 580 29318 1

Contents

	Page
National foreword	Inside front cover
Foreword	2
Text of EN 61847	5

English version

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

(IEC 61847:1998)

Ultrasons — Systèmes de chirurgie
Mesure et déclaration des caractéristiques de
sortie (CEI 61847:1998)

Ultraschall — Chirurgische Systeme Messung
und Deklaration der Ausgangsgrößen
(IEC 61847:1998)

This European Standard was approved by CENELEC on 1998-01-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

Foreword

The text of document 87/114/FDIS, future edition 1 of IEC 61847, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61847 on 1998-01-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1998-10-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-10-01

Annexes designated “normative” are part of the body of the standard. Annexes designated “informative” are given for information only. In this standard, Annex ZA is normative and Annex A, Annex B and Annex C are informative. Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61847:1998 was approved by CENELEC as a European Standard without any modification.

Contents

		Page
Foreword	2	
Introduction	5	
1 Scope	5	
2 Normative references	5	
3 Definitions	5	
4 List of symbols	7	
5 General measurement requirements	7	
5.1 Operating conditions	7	
5.2 Load conditions	8	
5.3 Preparation for measurements	8	
6 Measurement procedures	8	
6.1 Primary tip vibration excursion	8	
6.2 Secondary tip vibration excursion	9	
6.3 Drive frequency	9	
6.4 Tip vibration frequency	9	
6.5 Derived output acoustic power and output acoustic power	9	
6.6 Directivity pattern	10	
6.7 Primary tip vibration excursion modulation	10	
6.8 Duty cycle	11	
6.9 Quiescent electrical power	11	
6.10 Maximum electrical power	11	
6.11 Primary acoustic output area	11	
6.12 Secondary acoustic output area	12	
6.13 Power reserve index	12	
7 Declaration of output characteristics	12	
Annex A (informative) Measurement methods and conditions	18	
Annex B (informative) Theory of operation of ultrasonic surgical devices	22	
Annex C (informative) Bibliography	24	
Annex ZA (normative) Normative reference to international publications with their corresponding European publications	26	
Figure 1 — Measuring the primary and secondary tip vibration excursion	13	
Figure 2 — Example of a primary acoustic output area	14	
Figure 3 — Measuring the pressure field	15	
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		15
Figure 5 — Measuring the maximum electrical power ($P_{\max}$) at a given primary tip vibration excursion (s_p)		16
Figure 6 — Example of a secondary acoustic output area		17
Figure A.1 — A typical relationship between tip vibration amplitude and acoustic pressure		21
Figure A.2 — Schematic diagram of the theoretical model geometry for the tip immersed below the surface of the water		21

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.

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 scaler 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, mm²

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