Ultrasonics - Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

Ultrasonics - Hydrophones -- Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 62127-1:2007 sisaldab Euroopa standardi EN 62127-1:2007 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.2007 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 62127-1:2007 consists of the English text of the European standard EN 62127-1:2007. This document is endorsed on 23.11.2007 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of IEC 62127 specifies methods of use of calibrated hydrophones for the measurement in liquids of acoustic fields generated by ultrasonic medical equipment operating in the frequency range up to 40 MHz. The objectives of this standard are: – to define a group of acoustic parameters that can be measured on a physically sound basis; – to define a second group of parameters that can be derived under certain assumptions from these measurements, and called derived intensity parameters; – to define a measurement procedure that may be used for the determination of acoustic pressure parameters; – to define the conditions under which the measurements of acoustic parameters can be made in the frequency range up to 40 MHz using calibrated hydrophones; – to define procedures for correcting, for limitations caused by the use of hydrophones with finite bandwidth and finite active element size. NOTE 1 Throughout this standard, SI units are used. In the specification of certain parameters, such as beam areas and intensities, it may be convenient to use decimal multiples or submultiples. For example beam area may be specified in cm2 and intensities in W/cm2 or mW/cm2. NOTE 2 The hydrophone as defined may be of a piezoelectric or an optic type. The introduction however implies that optical hydrophones are not covered.	**Scope:** This part of IEC 62127 specifies methods of use of calibrated hydrophones for the measurement in liquids of acoustic fields generated by ultrasonic medical equipment operating in the frequency range up to 40 MHz. The objectives of this standard are: – to define a group of acoustic parameters that can be measured on a physically sound basis; – to define a second group of parameters that can be derived under certain assumptions from these measurements, and called derived intensity parameters; – to define a measurement procedure that may be used for the determination of acoustic pressure parameters; – to define the conditions under which the measurements of acoustic parameters can be made in the frequency range up to 40 MHz using calibrated hydrophones; – to define procedures for correcting, for limitations caused by the use of hydrophones with finite bandwidth and finite active element size. NOTE 1 Throughout this standard, SI units are used. In the specification of certain parameters, such as beam areas and intensities, it may be convenient to use decimal multiples or submultiples. For example beam area may be specified in cm2 and intensities in W/cm2 or mW/cm2. NOTE 2 The hydrophone as defined may be of a piezoelectric or an optic type. The introduction however implies that optical hydrophones are not covered.

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 62127-1

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Partially supersedes EN 61101:1993, EN 61102:1993 + A1:1994, EN 61220:1995 and EN 62092:2001

English version

Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

(IEC 62127-1:2007)

Ultrasons - Hydrophones - Partie 1: Mesures et caractérisation des champs ultrasonores médicaux jusqu'à 40 Mhz (CEI 62127-1:2007)

Ultraschall - Hydrophone - Teil 1: Messung und Charakterisierung von medizinischen Ultraschallfeldern bis zu 40 MHz (IEC 62127-1:2007)

This European Standard was approved by CENELEC on 2007-09-01. 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, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the 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

Ref. No. EN 62127-1:2007 E

Foreword

The text of document 87/352/CDV, future edition 1 of IEC 62127-1, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC parallel Unique Acceptance Procedure and was approved by CENELEC as EN 62127-1 on 2007-09-01.

EN 62127-1, EN 62127-2 and EN 62127-3 are being published simultaneously. Together these European Standards cancel and replace EN 61101:1993, EN 61102:1993 + A1:1994, EN 61220:1995 and EN 62092:2001.

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)	2008-06-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2010-09-01

Annex ZA has been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 62127-1:2007 was approved by CENELEC as a European Standard without any modification.

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

IEC 60601-2-37	NOTE	Harmonized as EN 60601-2-37:2001 (not modified).
IEC 61157	NOTE	Harmonized as EN 61157:1994 (not modified).
IEC 61161	NOTE	Harmonized as EN 61161:2007 (not modified).
IEC 62359	NOTE	Harmonized as EN 62359:2005 (not modified).

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050-801	1994	International Electrotechnical Vocabulary (IEV) - Chapter 801: Acoustics and electroacoustics	-	-
IEC 60565	-[1)]	Underwater acoustics - Hydrophones - Calibration in the frequency range 0,01 Hz to 1 MHz	EN 60565	2007[2)]
IEC/TR 60854	1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	-	-
IEC 61689	-[1)]	Ultrasonics - Physiotherapy systems - Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	EN 61689	2007
IEC 61828	-[1)]	Ultrasonics - Focusing transducers - Definitions and measurement methods for the transmitted fields	EN 61828	2001[2)]
IEC 61846	-[1)]	Ultrasonics - Pressure pulse lithotripters - Characteristics of fields	EN 61846	1998[2)]
IEC 61847	-[1)]	Ultrasonics - Surgical systems - Measurement and declaration of the basic output characteristics	EN 61847	1998[2)]
IEC 62127-2	-[1)]	Ultrasonics - Hydrophones - Part 2: Calibration for ultrasonic fields up to 40 MHz	EN 62127-2	2007[2)]
IEC 62127-3	-[1)]	Ultrasonics - Hydrophones - Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	EN 62127-3	2007[2)]
ISO 16269-6	2005	Statistical interpretation of data - Part 6: Determination of statistical tolerance intervals	-	-
ISO/IEC Guide 98	1995	Guide to the expression of uncertainty in measurement	-	-

[1)] Undated reference.

[2)] Valid edition at date of issue.

IEC 62127-1

Edition 1.0 2007-08

INTERNATIONAL STANDARD

Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

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INTERNATIONAL STANDARD

Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – HYDROPHONES –

Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. 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 62127-1 has been prepared by IEC technical committee 87: Ultrasonics.

IEC 62127-1, IEC 62127-2 and IEC 62127-3 are being published simultaneously. Together these cancel and replace IEC 60866:1987, IEC 61101:1991, IEC 61102:1991, IEC 61220:1993 and IEC 62092:2001.

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

Enquiry draft	Report on voting
87/352/CDV	87/371/RVC

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of IEC 62127 series, published under the general title *Ultrasonics – Hydrophones,* can be found on the IEC website**.**

NOTE Words in **bold** in the text are defined in Clause 3.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition; or
- amended.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

The main purpose of this part of IEC 62127 is to define various acoustic parameters that can be used to specify and characterize ultrasonic fields propagating in liquids, and, in particular, water, using hydrophones. Measurement procedures are outlined that may be used to determine these parameters. Specific device related measurement standards, for example IEC 61689, IEC 61157, IEC 61847 or IEC 62359, can refer to this standard for appropriate acoustic parameters.

The philosophy behind this standard is the specification of the acoustic field in terms of acoustic pressure parameters, acoustic pressure being the primary measurement quantity when piezoelectric hydrophones are used to characterize the field. Of course, if other measurement devices come into use in the future, a new standard with additional definitions and procedures will be necessary. Examples of such devices would be thermistors, thermocouples or optical hydrophones.

Intensity parameters are specified in this standard, but these are regarded as derived quantities that are meaningful only under certain assumptions related to the ultrasonic field being measured.

ULTRASONICS – HYDROPHONES –

Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz

1 Scope and object

This part of IEC 62127 specifies methods of use of calibrated hydrophones for the measurement in liquids of acoustic fields generated by ultrasonic medical equipment operating in the frequency range up to 40 MHz.

The objectives of this standard are:

– to define a group of acoustic parameters that can be measured on a physically sound basis;

– to define a second group of parameters that can be derived under certain assumptions from these measurements, and called derived intensity parameters;

– to define a measurement procedure that may be used for the determination of acoustic pressure parameters;

– to define the conditions under which the measurements of acoustic parameters can be made in the frequency range up to 40 MHz using calibrated hydrophones;

– to define procedures for correcting, for limitations caused by the use of hydrophones with finite bandwidth and finite active element size.

NOTE 1 Throughout this standard, SI units are used. In the specification of certain parameters, such as beam areas and intensities, it may be convenient to use decimal multiples or submultiples. For example beam area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2.

NOTE 2 The hydrophone as defined may be of a piezoelectric or an optic type. The introduction however implies that optical hydrophones are not covered.

2 Normative references

The following referenced documents are indispensable for the application 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 60050-801:1994, *International Electrotechnical Vocabulary – Chapter 801: Acoustics and electroacoustics*

IEC 60565, *Underwater acoustics – Hydrophones – Calibration in the frequency range 0,01 Hz to 1 MHz*

IEC/TR 60854:1986, *Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment*

IEC 61689, *Ultrasonics – Physiotherapy systems – Performance requirements and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC 61828, *Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields*

IEC 61846, *Ultrasonics – Pressure pulse lithotripters – Characteristics of fields*

IEC 61847, *Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics*

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

IEC 62127-3, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

ISO 16269-6:2005, *Statistical interpretation of data – Part 6: Determination of statistical tolerance intervals*

ISO, *Guide to the expression of uncertainty in measurement*. Geneva, Switzerland: International Organization for Standardization (ISO), 1995

NOTE The following standards rely on the proper use of this document.

IEC 61157, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 62359, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

IEC 61847, *Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics*.

3 Terms, definitions and symbols

For the purposes of this document, the terms and definitions given in IEC 62127-2, IEC 62127-3 and the following apply. It also includes definitions related to subjects in this document to be used in particular medical ultrasound device standards.

3.1
acoustic pulse waveform
temporal waveform of the instantaneous acoustic pressure at a specified position in an acoustic field and displayed over a period sufficiently long to include all significant acoustic information in a single pulse or tone-burst, or one or more cycles in a continuous wave

NOTE 1 Temporal waveform is a representation (e.g oscilloscope presentation or equation) of the **instantaneous acoustic pressure**.

NOTE 2 Definition adopted from IEC 60469-1.

3.2
acoustic repetition period
arp
pulse repetition period for non-automatic scanning systems and the **scan repetition period** for automatic scanning systems, equal to the time interval between corresponding points of consecutive cycles for continuous wave systems

NOTE The **acoustic repetition period** is expressed in seconds (s).

3.3
acoustic frequency
acoustic-working frequency
frequency of an acoustic signal based on the observation of the output of a **hydrophone** placed in an acoustic field at the position corresponding to the **spatial-peak temporal-peak acoustic pressure**

NOTE 1 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Acoustic-working frequencies are defined in 3.3.1 and 3.3.2.