SVENSK STANDARD SS-EN 62127-1

Fastställd	Utgåva	Sida	Ansvarig kommitté
2008-05-19	1	1 (1+79)	SEK TK 62

Ultraljud – Hydrofoner – Del 1: Mätning och karaktärisering av medicinska ultraljudsfält upp till 40 MHz

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

Som svensk standard gäller europastandarden EN 62127-1:2007. Den svenska standarden innehåller den officiella engelska språkversionen av EN 62127-1:2007.

Nationellt förord

Europastandarden EN 62127-1:2007

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

– **IEC 62127-1, First edition, 2007 - Ultrasonics - Hydrophones - Part 1: Measurement and characteristization of medical ultrasonic fields up to 40 MHz using hydrophones**

utarbetad inom International Electrotechnical Commission, IEC.

SS-EN 62127-1, SS-EN 62127-2 och SS-EN 62127-3 ersätter tillsammans SS-EN 61101, utgåva 1, 1995, SS-EN 61102, utgåva 1, 1995, SS-EN 61102/A1, utgåva 1, 1995, SS-EN 61220, utgåva 1, 1995 och SS-EN 62092, utgåva 1, 2002, som inte gäller fr o m 2010-09-01.

ICS 17.040.50

Denna standard är fastställd av SEK Svensk Elstandard,
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

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Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62127-1

October 2007

ICS 17.140.50

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

SEK Svensk Elstandard

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.

CONTENTS

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*