

**Ultrasonics -
Field characterization -
In situ exposure estimation in finite-amplitude ultrasonic beams
(IEC/TS 61949:2007)**

Ultrasons -
Caractérisation des champs -
Estimation de l'exposition in situ
dans les faisceaux ultrasonores
d'amplitude finie
(CEI/TS 61949:2007)

Ultraschall -
Charakterisierung von Feldern -
Schätzung der In-situ-Expositionswerte in
Ultraschallbündeln mit finiten Amplituden
(IEC/TS 61949:2007)

This Technical Specification was approved by CENELEC on 2008-05-01.

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CENELEC

European Committee for Electrotechnical Standardization
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Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 87/349/CDV, future edition 1 of IEC/TS 61949, prepared by IEC TC 87, Ultrasonics, was submitted to the IEC-CENELEC Parallel Unique Acceptance Procedure and was approved by CENELEC as CLC/TS 61949 on 2008-05-01.

The following date was fixed:

- latest date by which the existence of the CLC/TS
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Annex ZA has been added by CENELEC.

Endorsement notice

The text of the Technical Specification IEC/TS 61949:2007 was approved by CENELEC as a Technical Specification 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 60601-2-37:2008 (not modified).
IEC 61828	NOTE Harmonized as EN 61828:2001 (not modified).
IEC 62359	NOTE Harmonized as EN 62359:2005 (not modified).

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.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 61161	- ¹⁾	Ultrasonics - Power measurement - Radiation force balances and performance requirements	EN 61161	2007 ²⁾
IEC 62127-1	2007	Ultrasonics - Hydrophones - Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	EN 62127-1	2007

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

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INTRODUCTION

Acoustic waves of finite amplitude generate acoustic components at higher frequencies than the fundamental frequency. This provides a mechanism for acoustic attenuation which is not significant at lower acoustic pressure, and for which there is substantial experimental and theoretical evidence (Tables A.1 and A.2). The generation of harmonic frequency components, and their associated higher attenuation coefficient, can occur very strongly when high amplitude pulses, associated with the use of ultrasound in medical diagnostic applications, propagate through water. This fact is of importance when measurements of **acoustic pressure**, made in water, are used to estimate **acoustic pressure** in another medium, or when intensity derived from hydrophone measurements in water is used to estimate intensity within another medium. In particular, errors occur in the estimation of the **acoustic pressure** and intensity *in situ*, if it is assumed that the propagation of ultrasound through water, and through tissue, is linear.

Standards for measurement of frequency-rich pulse waveforms in water are well established (IEC 62127-1). Whilst means to quantify nonlinear behaviour of medical ultrasonic beams are specified, no procedures are given for their use. Since that time IEC 60601-2-37 and IEC 62359 have introduced “attenuated” acoustic quantities, which are derived from measurements in water and intended to enable the estimation of *in situ* exposure for safety purposes.

This Technical Specification describes means to allow “attenuated” acoustic quantities to be calculated under conditions where the associated acoustic measurements, made in water using standard procedures, may be accompanied by significant finite-amplitude effects. A number of alternative methods have been proposed (Table B.1). The approach used in this Technical Specification is aligned with the proposal of the World Federation for Ultrasound in Medicine and Biology [1]¹⁾, that “Estimates of tissue field parameters at the point of interest should be based on derated values calculated according to an appropriate specified model and be extrapolated linearly from small signal characterization of source-field relationships.”

¹⁾ Figures in square brackets refer to the Bibliography.

ULTRASONICS – FIELD CHARACTERIZATION – IN SITU EXPOSURE ESTIMATION IN FINITE-AMPLITUDE ULTRASONIC BEAMS

1 Scope

This Technical Specification establishes:

- the general concept of the limits of applicability of acoustic measurements in water resulting from finite-amplitude acoustic effects;
- a method to ensure that measurements are made under quasi-linear conditions in order to minimise finite-amplitude effects, which may be applied under the following conditions:
 - to acoustic fields in the frequency range 0,5 MHz to 15 MHz;
 - to acoustic fields generated by plane sources and focusing sources of amplitude gain up to 12;
 - at all depths for which the maximum acoustic pressure in the plane perpendicular to the acoustic axis lies on the axis;
 - to both circular and rectangular source geometries;
 - to both continuous-wave and pulsed fields;
- the definition of an acoustic quantity appropriate for establishing quasi-linear conditions;
- a threshold value for the acoustic quantity as an upper limit for quasi-linear conditions;
- a method for the estimation of attenuated acoustic quantities under conditions of nonlinear propagation in water.

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 61161, *Ultrasonics – Power – Radiation force balances and performance requirements*

IEC 62127-1:2007 *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document, the following definitions apply.

3.1

acoustic attenuation coefficient

coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point

Symbol: α

Unit: decibels per centimetre per megahertz, $\text{dB cm}^{-1} \text{MHz}^{-1}$

[IEC 62359, definition 3.1]