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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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Technical specifications are subject to review within three years of publication to decide whether they can be transformed into International Standards.

IEC 61949, which is a technical specification, has been prepared by IEC technical committee 87: Ultrasonics.

The text of this technical specification is based on the following documents:

Enquiry draft	Report on voting
87/349/DTS	87/364A/RVC

Full information on the voting for the approval of this technical specification 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.

This publication is being issued as a technical specification (according to 3.1.1.1 of the IEC/ISO directives, Part 1) as a “prospective standard for provisional application” in the field of finite-amplitude ultrasonic beams, because there is an urgent need for guidance on how standards in this field should be used to meet an identified need.

This document is not to be regarded as an “International Standard”. It is proposed for provisional application so that information and experience of its use in practice may be gathered. Comments on the content of this document should be sent to the IEC Central Office.

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

- transformed into an International standard,
- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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*