

TECHNICAL SPECIFICATION



Ultrasonics – Field characterization – Specification and measurement of field parameters for high intensity therapeutic ultrasound (HITU) transducers and systems

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

PRICE CODE **XD**

ICS 17.140.50

ISBN 978-2-8322-1505-0

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD.....	6
INTRODUCTION.....	8
1 Scope.....	9
2 Normative references	9
3 Terms and definitions	10
4 List of symbols	31
5 Independent measurement of total acoustic output power.....	33
6 Acoustic field measurement: equipment.....	33
6.1 Hydrophone	33
6.1.1 General	33
6.1.2 Sensitivity of a hydrophone.....	34
6.1.3 Directional response of a hydrophone.....	34
6.1.4 Effective hydrophone radius	34
6.1.5 Choice of the size of a hydrophone active element	34
6.1.6 Hydrophone pressure limits	35
6.1.7 Hydrophone intensity limits.....	35
6.1.8 Hydrophone cable length and amplifiers	36
6.2 Requirements for positioning and water baths.....	36
6.2.1 General	36
6.2.2 Positioning systems.....	36
6.2.3 Water bath.....	37
6.3 Requirements for data acquisition and analysis systems.....	38
6.4 Requirements and recommendations for ultrasonic equipment being characterized.....	39
7 Measurement procedure	39
7.1 General.....	39
7.2 Preparation and alignment	39
7.2.1 Initial adjustment to driving voltage.....	39
7.2.2 Preparation of source transducer.....	40
7.2.3 Aligning an ultrasonic transducer and hydrophone	41
7.2.4 Beam-axis scan	41
7.2.5 Measurements to be made at $z = z_p$	41
7.2.6 Further evaluation for sidelobes and pre-focal maxima	43
7.3 Considerations for scanning transducers and transducers with multiple sources.....	44
7.3.1 Automatic scanning transducers	44
7.4 Linear extrapolation of field values.....	44
7.4.1 General	44
7.4.2 Calculation of I_{sa}	45
7.4.3 Scaling for sidelobes and pre-focal maxima.....	45
7.5 Reporting.....	45
Annex A (informative) Rationale.....	53
A.1 General.....	53
A.2 Detailed discussion of difficulties in HITU field measurements	53
A.2.1 Very high pressures.....	53
A.2.2 Very high intensities	54

A.2.3	Strong focusing	54
A.2.4	Nonlinear harmonics	54
A.2.5	Acoustic saturation and nonlinear loss	55
A.2.6	Damage to hydrophones may only be apparent at high pressures	55
A.3	Approach of this technical specification	55
Annex B (informative)	Assessment of uncertainty in the acoustic quantities obtained by hydrophone measurements	57
B.1	General	57
B.2	Overall (expanded) uncertainty	57
B.3	Common sources of uncertainty	57
Annex C (informative)	Transducer and hydrophone positioning systems	59
Annex D (informative)	Rationale for I_{sa}	60
D.1	General rationale	60
D.2	Determination of $P_{\text{C},6}$ using hydrophone measurements and extrapolation from linear measurements	60
D.3	Alternative determination of $P_{\text{C},6}$ using an aperture in combination with a measurement of total acoustic output power	60
D.4	Special case of uniformly vibrating spherically shaped transducers	61
Annex E (normative)	Propagation and back-propagation methods for field reconstruction: basic formulae and requirements	62
E.1	Motivation and background	62
E.2	Theory	62
E.2.1	General	62
E.2.2	Fourier projection approach	64
E.2.3	Rayleigh integral approach	67
E.3	Implementation	68
E.3.1	General	68
E.3.2	Recommendations for hydrophone	68
E.3.3	Recommendation for planar scan parameters	69
E.4	Assessment of uncertainties	71
Annex F (informative)	Propagation and back-propagation methods for field reconstruction: examples and uses	73
F.1	Examples	73
F.1.1	Fourier projection example	73
F.1.2	Rayleigh integral projection example	77
F.2	Other propagation method applications	81
Annex G (normative)	Planar scanning of a hydrophone to determine acoustic output power	82
G.1	Introduction	82
G.2	General principle	82
G.3	Hydrophone scanning methodology	83
G.3.1	General methodology	83
G.3.2	Particular considerations for implementation for HITU fields	84
G.4	Corrections and sources of measurement uncertainty	84
G.4.1	Uncertainty in the hydrophone calibration	84
G.4.2	Planar scanning	84
G.4.3	Attenuation factor of water: unfocusing transducers	85
G.4.4	Attenuation factor of water: focusing transducers	85
G.4.5	Received hydrophone signal	85

G.4.6	Integration	86
G.4.7	Finite size of the hydrophone	86
G.4.8	partial extent of integration	86
G.4.9	Non-linear propagation	86
G.4.10	Directional response	87
G.4.11	Noise	87
G.4.12	Intensity approximated by derived intensity.....	87
Annex H (informative)	Properties of water	88
H.1	General.....	88
H.2	Attenuation coefficient for propagation in water.....	89
Annex I (informative)	Propagation medium and degassing	90
Bibliography.....		91
Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field for a rectangular HITU transducer		47
Figure 2 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer		48
Figure 3 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer with a circular hole in its center.....		49
Figure 4 – Schematic diagram of the different planes and lines in an ultrasonic field for a circularly symmetric HITU transducer with a rectangular hole in its center for a diagnostic transducer (HITU transducer azimuth axis aligned with azimuth scan axis of diagnostic transducer)		50
Figure 5 – Parameters for describing a focusing transducer of an unknown geometry (IEC 61828)		51
Figure 6 – Overall measurement scheme		52
Figure C.1 – Schematic diagram of the ultrasonic transducer and hydrophone degrees of freedom. X, Y and Z denote the axis directions relative to the mounted hydrophone and ultrasonic transducer.....		59
Figure E.1 – Geometry of problem for forward and backward projection techniques.....		63
Figure E.2 – Transducer focused at -15mm , $y = 48,16\text{ mm}$, $z = 56,85\text{ mm}$		66
Figure E.3 – Selection of acquisition window		70
Figure E.4 – Scanned field compared to its reconstruction from a finite window.....		71
Figure F.1 – Transducer inside 2-axis scanner setup		73
Figure F.2 – Pressure amplitude as scanned		74
Figure F.3 – Reconstructed pressure amplitude distribution in 3 orthogonal planes that contain the focal point.....		75
Figure F.4 – 3D representation of the focal beam for nominal focus at $x = -0,85\text{ mm}$, $y = -0,25\text{ mm}$, $z = 58,95\text{ mm}$		76
Figure F.5 – Reconstruction of pressure amplitudes on the transducer surface (transducer aperture plane).....		77
Figure F.6 – Experimental arrangement.....		78
Figure F.7 – Amplitude and phase distribution of acoustic pressure measured at the scanning region		79
Figure F.8 – Amplitude and phase distribution of acoustic pressure reconstructed at the transducer aperture plane		79
Figure F.9 – Comparison of the axial distribution of pressure amplitudes as projected from the aperture plane (red) and as measured (blue)		80

Figure F.10 –Comparison of the schlieren image (A) and the corresponding *YZ* distribution of acoustic pressure amplitudes projected from the transducer aperture plane (B)..... 81

Table H.1 – Speed of sound *c* [,] and characteristic acoustic impedance, ρc , as a function of temperature, for propagation in water 88

INTERNATIONAL ELECTROTECHNICAL COMMISSION

ULTRASONICS – FIELD CHARACTERIZATION – SPECIFICATION AND MEASUREMENT OF FIELD PARAMETERS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. In exceptional circumstances, a technical committee may propose the publication of a technical specification when

- the required support cannot be obtained for the publication of an International Standard, despite repeated efforts, or
- the subject is still under technical development or where, for any other reason, there is the future but no immediate possibility of an agreement on an International Standard.

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

IEC/TS 62556, 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
87/521/DTS	87/545/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.

NOTE 1 The following point types are used:

- Requirements: in roman type
- Notes: small roman type
- Words in **bold** in the text are defined in Clause 3
- Symbols and formulae: in *Times New Roman + Italic*.

NOTE 2 There are some inconsistencies in font type for symbols and formulae between some of the normative references and this technical specification. They will be resolved in a future revision of the normative references.

The committee has decided that the contents of this publication will remain unchanged until the stability 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.

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The use of **high intensity therapeutic ultrasound (HITU)** has advanced to the point where systems have achieved clinical approval for general use in numerous countries. Medical applications and product development are continuing rapidly. Fast development in preclinical medicine, clinical medicine, and product manufacture has created an urgent need to standardize measurements of the basic acoustic parameters and the field characteristics of HITU. In order to promote the further development of HITU and to ensure its safe and effective use, common technical Specifications are required.

This technical specification is relevant to the measurement and specification of ultrasound fields intended for medical therapeutic purposes. It addresses the requirements for **high intensity therapeutic ultrasound (HITU)** fields, including those generally referred to as **high intensity focused ultrasound (HIFU)**. Lithotripsy and physiotherapy are excluded, since there are existing International Standards for these applications.

As described in Annex A, because measurement at full output power from HITU systems still presents technical challenges, this standard specifies measurement methods at relatively low output levels and methodology for extrapolating these to higher therapeutic level fields.

ULTRASONICS – FIELD CHARACTERIZATION – SPECIFICATION AND MEASUREMENT OF FIELD PARAMETERS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) TRANSDUCERS AND SYSTEMS

1 Scope

This technical specification is applicable to **high intensity therapeutic ultrasound (HITU)** devices, specifying:

- relevant parameters for quantifying the field;
- measurement methods at relatively low output levels and methodology for extrapolating these to higher therapeutic level fields;
- consideration of sidelobes and pre-focal maxima;
- parameters relevant to HITU transducers of different construction and geometry, including non-focusing, focusing with or without lenses, collimated, diverging and convergent transducers, multi-element transducers, scanning transducers and multiple sources.

This technical specification is intended to support the ultrasonic measurement requirements given in IEC 60601-2-62.

These specifications would have use in quality assurance, safety testing, and the standardization of communications regarding the clinical performance of HITU systems. Where possible, this technical specification incorporates specifications from other related standards.

This technical specification does *not* apply to the following types of devices, which are covered by other standards:

- lithotripters (see IEC 61846);
- surgical equipment (see IEC 61847);
- physiotherapy devices (see IEC 61689).

Throughout this technical specification 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 sub-multiples. For example, beam-area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2 .

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050 (all parts), *International Electrotechnical Vocabulary* (available at <http://www.electropedia.org>)

IEC 60601-2-62, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment*

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

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

IEC 61828:2001, *Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields*

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

IEC 62127-1:2007/AMD1:2013

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*

IEC 62555, *Ultrasonics – Power measurement – High intensity therapeutic ultrasound (HITU) transducers and systems*

ISO/IEC Guide 98-3:2008: *Guide to the expression of uncertainty in measurement (GUM:1995)*