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TECHNICAL SPECIFICATION

colour inside

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

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

FOREWORD

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– withdrawn,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)*

3 Terms and definitions

For the purposes of this document the following terms and definitions apply.

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

[SOURCE: IEC 62127-1:2007, 3.1]

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 1 to entry: The a**coustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2007, 3.2]

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 to entry: 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.

Note 2 to entry: In a number of cases the present definition is not very helpful or convenient, especially for **broadband transducers**. In that case a full description of the frequency spectrum should be given in order to enable any frequency-dependent correction to the signal.

Note 3 to entry: **Acoustic frequency** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.3]

3.3.1
zero-crossing acoustic-working frequency
$f_{\mathbf{awf}}$
number, n, of consecutive half-cycles (irrespective of polarity) divided by twice the time between the commencement of the first half-cycle and the end of the n-th half-cycle

Note 1 to entry: None of the n consecutive half-cycles should show evidence of phase change.

Note 2 to entry: This frequency is intended for continuous-wave systems only.

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.3.1, modified – The second and third notes in the original definition have been deleted.]

3.3.2
arithmetic-mean acoustic-working frequency
$f_{\mathbf{awf}}$
arithmetic mean of the most widely separated frequencies f_1 and f_2, within the range of three times f_1, at which the magnitude of the acoustic pressure spectrum is 3 dB below the peak magnitude

Note 1 to entry: This frequency is intended for pulse-wave systems only.

Note 2 to entry: It is assumed that $f_1 < f_2$.

Note 3 to entry: If f_2 is not found within the range < 3 f_1, f_2 is to be understood as the lowest frequency above this range at which the spectrum magnitude is 3 dB below the peak magnitude.

Note 4 to entry: See IEC 62127-1 for methods of determining the arithmetic-mean acoustic working frequency.

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.3.2, modified – A fourth note to entry has been added to the definition.]

3.4
azimuth axis
axis formed by the junction of the **azimuth plane** and the **source aperture plane** (measurement) or **transducer aperture plane** (design)

SEE: Figures 1 to 4.

Note 1 to entry: The selection of this axis is arbitrary for a circularly-symmetric HITU transducer without a hole in its centre but is perpendicular to the elevation axis.

Note 2 to entry: If a HITU transducer has a hole in its centre, within which is a diagnostic imaging transducer, then this axis is aligned with the azimuth axis of the imaging transducer.

[SOURCE: IEC 61828:2001, 4.2.7, modified – Two notes to entry have been added.]

3.5
azimuth plane
for a scanning **ultrasonic transducer**: this is the **scan plane**; for a non-scanning **ultrasonic transducer:** this is the **principal longitudinal plane**

SEE: Figure 1.

[SOURCE: IEC 61828:2001, 4.2.8, modified – A note in the original has been deleted.]

3.6
bandwidth
BW
difference in the most widely separated frequencies f_1 and f_2 at which the magnitude of the acoustic pressure spectrum becomes 3 dB below the peak magnitude, at a specified point in the acoustic field

Note 1 to entry: **Bandwidth** is expressed in hertz (Hz).

[SOURCE: IEC 62127-1:2007, 3.6]

3.7
beam area
$A_{b,6}$, $A_{b,12}$, $A_{b,20}$
area in a specified plane perpendicular to the **beam axis** consisting of all points at which the **pulse-pressure-squared integral** is greater than a specified fraction of the maximum value of the **pulse-pressure-squared integral** in that plane

Note 1 to entry: If the position of the plane is not specified, it is the plane passing through the point corresponding to the maximum value of the **pulse-pressure-squared integral** in the whole acoustic field.

Note 2 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced everywhere in the above definition by any linearly related quantity, e.g.:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,

b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

Note 3 to entry: Some specified fractions are 0,25 and 0,01 for the -6 dB and -20 dB beam areas, respectively.

Note 4 to entry: **Beam area** is expressed in square metres (m^2).

[SOURCE: IEC 62127-1:2007/AMD 1:2013, 3.7, modified – the symbol has been modified to include $A_{b,12}$.]

3.8
beam axis
straight line that passes through the **beam centrepoints** of two planes perpendicular to the line which connects the point of maximal **pulse-pressure-squared integral** with the centre of the **external transducer surface plane**

SEE: Figure 1.

Note 1 to entry: The location of the first plane is the location of the plane containing the maximum **pulse-pressure-squared integral** or, alternatively, is one containing a single main lobe which is in the focal Fraunhofer zone. The location of the second plane is as far as is practicable from the first plane and parallel to the first with the same two orthogonal scan lines (x and y axes) used for the first plane.

Note 2 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.:

a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,

b) in cases where signal synchronisation with the scanframe is not available the term **pulse-pressure-squared integral** may be replaced by **temporal average intensity**.

[SOURCE: IEC 62127-1:2007, 3.7]

3.9
beam centrepoint
position determined by the intersection of two lines passing through the **beamwidth midpoints** of two orthogonal planes, *xz* and *yz*

[SOURCE: IEC 61828:2001, 4.2.13.]

3.10
beam maximum
bm
maximum measured **pulse-pressure-squared integral** on the **beam axis**

3.11
beam maximum depth
L_{bm}
smallest distance between two points on the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the **beam axis** by 6 dB

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared** integral is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689.

Note 2 to entry: **Beam maximum depth** is expressed in metres (m).

3.12
beam maximum point

position on the **beam axis** where the maximum **pulse-pressure-squared integral** is measured

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave by the mean square acoustic pressure as defined in IEC 61689.

3.13
beam maximum volume
V_{bm}
volume in a specified space consisting of all points at which the **pulse-pressure-squared integral** is greater than –6 dB of the **pulse-pressure-squared integral** value at the **beam maximum point**

Note 1 to entry: In a number of cases, the term **pulse-pressure-squared integral** is replaced in the above definition by any linearly related quantity, e.g.: in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689.

Note 2 to entry: **Beam maximum volume** is expressed in cubic metres (m^3).

3.14
beamwidth midpoint
linear average of the location of the centres of **beamwidth**s in a plane

Note 1 to entry: The average is taken over as many beamwidth levels given in Table B.2 of IEC 61828:2001, as signal level permits.

[SOURCE: IEC 61828:2001, 4.2.17, modified – The second sentence of the original definition has been transformed into a note to entry here.]

3.15
beamwidth
w_6, w_{12}, w_{20}
greatest distance between two points on a specified axis perpendicular to the **beam axis** where the **pulse-pressure-squared integral** falls below its maximum on the specified axis by a specified amount