IEC TS 62556

Edition 1.0 2014-04

TECHNICAL SPECIFICATION

colour inside

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

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)*