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TECHNICAL REPORT

Requirements for measurement standards for high intensity therapeutic ultrasound (HITU) devices

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Requirements for measurement standards for high intensity therapeutic ultrasound (HITU) devices

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COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

REQUIREMENTS FOR MEASUREMENT STANDARDS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) DEVICES

FOREWORD

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IEC 62649, which is a technical report, has been prepared by committee TC 87: Ultrasonics.

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

Enquiry draft	Report on voting
87/420/DTR	87/428/RVC

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

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

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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

INTRODUCTION

This Technical Report is concerned with standards for high intensity therapeutic ultrasound (HITU) and concentrates on applications that destroy tissue by heating which may or may not be accompanied by acoustic cavitation and other mechanisms. The purpose of the report is to identify topics where there is a consensus that the development of international standards would benefit the industries and/or patients involved with these forms of therapeutic ultrasound. The shortcomings of existing standards as they may be related to the applications of interest are reviewed. It is not its purpose to propose or evaluate specific alternative measurement methods which may be more reliably applied to HITU or other therapeutic equipment. Physiotherapy and lithotripsy are excluded as there are existing standards for these established uses. Lower intensity applications such as enhanced bone healing or ultrasound-induced gene therapy are not explicitly considered.

The use of HITU has advanced to the point where systems have achieved clinical approval for general use in several countries. Medical applications and product development are continuing rapidly. The corresponding products of many companies have been approved for marketing and clinical applications. Fast development in preclinical medicine, clinic 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, international standards are required.

REQUIREMENTS FOR MEASUREMENT STANDARDS FOR HIGH INTENSITY THERAPEUTIC ULTRASOUND (HITU) DEVICES

1 Scope

This technical report is relevant to the measurement and specification of ultrasound fields intended for medical therapeutic purposes. Lithotripsy and physiotherapy are excluded, since there are existing International Standards for these applications.

It establishes:

- topics where there is a consensus that the development of International Standards would benefit the industries and/or patients;
- topics where the writing of standards should start immediately;
- topics where the writing of technical specifications should start immediately in order to gain practical experience and establish consensus prior to standardisation;
- topics which require future standardisation but where further research is required before initiating the writing of standards or technical specifications.

This report addresses primarily the requirements for measurement standards related to high intensity therapeutic ultrasound (HITU) [also known as high intensity focused ultrasound (HIFU)] fields which are both high intensity and focused and where the main mechanism for action is thermal. However, aspects of the discussion, conclusions and any resulting standards or technical specifications may also be relevant to therapeutic applications which are either focused or high intensity or where the main mechanism is not thermal.

Scientific literature has been reviewed and responses to a questionnaire which was sent to experts around the world are reported.

2 Background

Recent years have seen a dramatic rise in interest in using ultrasound as a surgical and therapeutic tool in its own right. Much of this growth has been due to the use of High Intensity Therapeutic Ultrasound (HITU) for tissue ablation in the treatment of cancers and conditions such as benign prostate hyperplasia (BPH). Here, ultrasound is brought to a focus within tissue with the intention of generating intensity levels sufficient to raise the local tissue temperature above 55 °C. Like so much in ultrasound, this technique was first tested many years ago (Lynn *et al*, 1942; Wall *et al*, 1951, Fry *et al*, 1954), but recent materials, computing and other technological advances have allowed it to come close to the medical mainstream. The ability to generate such high temperatures within tissue brings with it the absolute requirement to ensure that the treatment is delivered to the correct level and at the correct site. This in turn means that accurate methods of predicting the dose and monitoring performance are required. Consequently, reliable measurement and characterisation methods are needed for this application above all others.

However, HITU is not the only therapeutic application. Ultrasound physiotherapy, of course, has been widely used since the 1950s (Imig *et al*, 1954; Gersten, 1955) and lithotripsy since 1980 (Chaussy *et al*) for the destruction of kidney stones. More experimental applications include treatment of tendon injuries using lithotripter-like devices, stimulation of bone repair by low intensity ultrasound, ultrasound-induced haemostasis, and the targeted delivery of drugs through the localised destruction of carrier particles by ultrasound. Typical characteristics of ultrasound used for these different applications are described in general terms in Table 1.

Table 1 – General characteristics of ultrasound used for different therapeutic applications

Physiotherapy	1 MHz; 1 W cm^{-2}; <0,5 MPa
Lithotripsy	0,5 MHz; very low, >20 MPa
Soft tissue lithotripsy[a]	0,25 MHz; very low, 5 to 30 MPa
HITU[a]	0,5 MHz to 5 MHz; 1 000 W cm^{-2} to 10 000 W cm^{-2}; 10 MPa
Haemostasis[a]	1 MHz to 10 MHz; 100 W cm^{-2} to 5 000 W cm^{-2}
Bone growth stimulation	1,5 MHz; 30 mW cm^{-2}; 50 kPa
Drug delivery[a]	Up to 2 MHz; various; 0,2 MPa to 8 MPa
[a] Experimental techniques: limited information or wide range of characteristics under investigation. Acoustic parameters shown are a strong function of treatment duration or dose time and other factors.	

Medical ultrasound fields in the MHz frequency range are typically characterised in water by measuring the spatial and temporal distribution of pressure using a piezoelectric hydrophone, and by measuring the radiation force on a target which intercepts the entire field. International standards directly relevant to the measurement of medical ultrasound fields generally are given in Table 2; national standards are generally identical to international standards or specify parameters which are very similar. A range of terms defined in selected IEC standards (which are identical to the equivalently numbered British Standards) are given in Appendix B. Measurement aspects are also included in many textbooks on medical ultrasound and are the specific subject of Preston (1991), Ziskin and Lewin (1992), and Harris (2005), amongst others.

Table 2 – International standards and related documents for the measurement of medical ultrasound fields

Number	Title	Relevance
IEC 60500:1974	IEC standard hydrophone	L
IEC 60565:2006	Underwater acoustics – Hydrophones – Calibration in the frequency range 0,01 Hz to 1 MHz	L
IEC/TR 60854:1986	Methods of measuring the performance of ultrasonic pulse-echo diagnostic equipment	H
IEC 60866:1987 (withdrawn)	Characteristics and calibration of hydrophones for operation in the frequency range 0,5 MHz to 15 MHz	L
IEC 61101:1991 (withdrawn)	The absolute calibration of hydrophones using the planar scanning technique in the frequency range 0,5 MHz to 15 MHz	L
IEC 61102:1991 (withdrawn):	Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	H
IEC 61102-am1:1993 (withdrawn)	Amendment 1 – Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz	H
IEC 61157:2007	Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment	M
IEC 61161:2006	Ultrasonics – Power measurement – Radiation force balances and performance requirements	H
IEC 61205:1993	Ultrasonics – Dental descaler systems – Measurement and declaration of the output characteristics	L
IEC/TR 61206:1993	Ultrasonics – Continuous-wave Doppler systems – Test procedures	L
IEC/TS 61220:1993 (withdrawn)	Ultrasonics – Fields – Guidance for the measurement and characterization of ultrasonic fields generated by medical ultrasonic equipment using hydrophones in the frequency range 0,5 to 15 MHz	H
IEC 61266:1994	Ultrasonics – Hand-held probe Doppler foetal heartbeat detectors – Performance requirements and methods of measurement and reporting	L
IEC/TS 61390:1996	Ultrasonics – Real-time pulse-echo systems – Test procedures to determine performance specifications	L
IEC 61685:2001	Ultrasonics – Flow measurement systems – Flow test object	L
IEC 61689:2007	Ultrasonics – Physiotherapy systems Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz	M
IEC 61828:2001	Ultrasonics – Focusing transducers – Definitions and measurement methods for the transmitted fields	H
IEC 61846:1998	Ultrasonics – Pressure pulse lithotripters – Characteristics of fields	M
IEC 61847:1998	Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics	L
IEC/TS 61895:1999	Ultrasonics – Pulsed Doppler diagnostic systems – Test procedures to determine performance	L
IEC 61949:2007	Ultrasonics – Field characterization – In-situ exposure estimation in finite-amplitude ultrasonic beams	H
IEC 62092:2001 (withdrawn)	Ultrasonics – Hydrophones – Characteristics and calibration in the frequency range from 15 MHz to 40 MHz	H
IEC 62126 Ed. 1.0 (in preparation)	Ultrasonics – Fields: Methods for computing temperature rise in homogeneous soft tissue for diagnostic ultrasonic fields	H
IEC 62127-1:2007	Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz	H
IEC 62127-2:2007	Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz	H

Number	Title	Relevance
IEC 62127-3:2007	Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz	H
IEC 62359:2005	Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	L
IEC/TS 62462:2007	Ultrasonics – Output test – Guide for the maintenance of ultrasound physiotherapy systems	L
IEC 60601-2-5:2009	Medical electrical equipment – Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	H
IEC 60601-2-36:1997	Medical electrical equipment – Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	M
IEC 60601-2-37:2007	Medical electrical equipment: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	H

In normal practice, no attempt is made to measure intensity (or the distribution of intensity) directly but it is derived from the measurement of pressure by assuming that the local pressure and particle velocity are in phase and therefore that the intensity is proportional to pressure squared (a 'plane-wave' assumption). Ultrasound power is not directly measured either but is derived either by integrating the derived intensity over a plane which intersects the field, or by measuring the radiation force experienced by a target and assuming that power is proportional to the radiation force and that the constant of proportionality can be determined from the acoustic and geometric properties of the target (another 'plane-wave' assumption). Geometric properties of the field (for example, focal distance and beamwidth) can be defined in terms of either pressure or derived intensity: most commonly, derived intensity (or, equivalently, pressure-squared integral) is used.

Although these measurement standards are well established and the measurement procedures laid down in them are widely practised, there are known limitations with both the measurement devices and the procedures. These limitations introduce uncertainties in attempting to characterise the true acoustic field. In addition, the existing defined terms may not be the most appropriate for characterising HITU fields, especially when attempting to compare their probable therapeutic effectiveness.

There is, however, a National Standard from China which relates specifically to characterisation of HITU transducers. An English translation of this standard is included in Appendix C. In brief, the approach is to characterise the field with a hydrophone at a low output setting using the techniques of the IEC standards for diagnostic fields. In addition, power is measured with a radiation force balance over a wider range of output settings. Some electrical characteristics of the transducer are also determined.

The standards listed in Table 2 have been reviewed for their relevance (L = Low, M = Medium, and H = High) as annotated above. It is possible that parts of relevant standards may be adapted for therapeutic applications; however, most standards are not directly applicable to HIFU and related applications. These shortcomings and limitations are the subject of the next section.

3 Limitations of existing standard methods

3.1 General

It can be difficult or inaccurate to apply many of the standard measurement methods to HITU fields, either due to fundamental measurement issues or to practical problems.

For radiation force balances, the major problems relate to:

- shielding by bubbles:
- thermal damage of target;
- force dependence on field geometry, not just on power;
- measurements away from the focal plane;
- extreme nonlinear effects including shock loss.

For hydrophone measurements, the major problems relate to:

- shielding by bubbles;
- thermal or cavitation damage;
- non-ideal frequency response;
- non-ideal directional response/spatial-averaging;
- high pressure levels;
- high harmonic content;
- off-axis measurements.

Some of the causes of these difficulties and inaccuracies are introduced in the following subsections.

3.2 Very high pressures

Pressures above the cavitation threshold for the measurement medium (usually water) can produce bubbles as dissolved gas is drawn out of solution. Three main problems may then arise: first, the bubbles formed may partly shield the sensor from the ultrasound field; secondly, violent bubble activity can damage or destroy the sensor. The occurrence of both of these effects can be minimised by removing dissolved gas and particulate matter from the measurement medium, but it may be difficult to maintain sufficient purity for a prolonged period. Thirdly, because of the high pressure levels involved, a proportionately larger fraction of the pressure spectrum is distributed into higher harmonics compared to a bubble-less medium.

There is also the risk of direct mechanical effects on the sensor itself due to large compressional and tensional forces. This is most likely to be a problem when there are weak points between different components of the sensor (for instance, if there is delamination of the glue layer in a bilaminar hydrophone).

3.3 Very high intensities

Energy absorbed from the ultrasound beam heats the sensor and this may affect its performance or even destroy it. For instance, the sensitivity of a membrane hydrophone can change if it is heated close to its Curie temperature. For polyvinylidenefluoride (pvdf), the most widely used hydrophone material, depolarisation occurs progressively with time at temperatures above about 70 °C and almost immediately at 110 °C. The thinness of membrane hydrophones will offer some protection against thermal damage because heat is very quickly lost to the surrounding medium. However, the sensitivity of pvdf hydrophones is temperature dependent and this change will be an additional source of uncertainty. Probe hydrophones may face greater risk and absorbing radiation force balance targets will certainly be damaged unless great care is taken to dissipate the absorbed energy. Heating can be reduced by generating low duty cycle toneburst ultrasound rather than continuous-wave. However, HITU transducers are generally only weakly damped and, consequently, may take many acoustic cycles for the pressure ‘ring-up’ at the start of the toneburst; there is an equivalent ‘ring-down’ at the end of the toneburst. This must be accounted for by scaling results from toneburst to the c.w. situation. In addition, since typically 30-50 % of the electrical energy is dissipated within the transducer, its temperature and properties will change with time during operation. Using toneburst mode will reduce this self-heating and may lead to significant differences in acoustic output compared to the c.w. case.

3.4 Strong focusing

In a focused field, two important plane-wave assumptions are not valid. Firstly, the particle velocity is not strictly in phase with the pressure, meaning that the local intensity is not truly proportional to the square of the pressure; hence, there is an increased uncertainty when deriving the intensity from a pressure measurement with a hydrophone. Secondly, the radiation force on a target placed in the field is no longer determined solely by the properties of the target and the total ultrasound power. The geometry of the field also plays a role, especially for the widely-used conical reflecting targets; absorbing targets are preferable provided that they are not damaged by excessive heating.

There is also a third effect which relates to the directional response of a hydrophone. In a plane wave, the hydrophone can be aligned so that the wave is incident in the preferred direction for the hydrophone (usually perpendicular to the plane of the sensing element). In a focused field, the pressure at the hydrophone can be considered as the superposition of wavelets with a relative phase and an angular distribution which are determined by the transducer geometry and its distance from the hydrophone. An ideal hydrophone would respond equally to wavelets from any direction and the output signal would be proportional to the sum of the wavelets. A real hydrophone, on the other hand, has a sensitivity which depends on the angle of incidence of the wavefront and the output voltage therefore depends on a **weighted** summation of the wavelets. This means that the output voltage waveform is different in magnitude and shape from the pressure waveform. This distortion increases with the large physical apertures and short focal lengths frequently used for therapeutic applications. Furthermore, the non-ideal nature of real transducers which have amplitude and phase variations across their apertures introduce additional complexities into the measurement process. There is no information available on the measurement uncertainties in cases where the field is generated by two or more widely separated transducers, or where the point of measurement lies within or close to the volume defined by the surface of the transducer or transducers.

In other therapeutic applications, the transducer is nonfocusing, or it operates over short distances or it has an unusual geometry. In these cases, existing measurement standards cannot be applied.

3.5 Nonlinear harmonics

Hydrophones have a frequency dependent amplitude and phase response. Consequently, in any ultrasound field where the acoustic spectrum at the point of measurement contains a significant spread of frequencies, the output voltage waveform (which is the acoustic spectrum convolved with the complex frequency response of the measurement system) will differ in shape from the true pressure waveform. In general, membrane hydrophones have a smoother frequency response (particularly in the low MHz region) and will give a closer representation of the pressure waveform. However, when the acoustic spectrum contains many high harmonics (as are generated by nonlinear propagation of high pressure fields), the output signal from the hydrophone can still be very different from the acoustic pressure waveform because the thickness resonance of the membrane typically results in a sensitivity which is 6 dB to 8 dB higher at the resonance frequency than at 1 MHz. Pulses of sufficiently high amplitude can achieve ‘full-shock’ conditions in which several hundred harmonics can be present with a relative amplitude proportional to 1/N, where N is the harmonic number. This problem is well recognised in the measurement of diagnostic ultrasound pulses and research is being carried out on the determination of the complex frequency response of hydrophones and the best method for deconvolving this response. So far, it seems that deconvolution to determine temporal-average intensity is relatively straightforward because it requires knowledge only of the amplitude response. The problem of determining peak negative and, particularly, peak positive pressures has not yet been solved with accuracy since it requires phase response data up to high frequencies.

3.6 Acoustic saturation and nonlinear loss

High amplitude acoustic pulses propagate nonlinearly in water, which results in a distortion of the wave and the generation of harmonics. Since the acoustic attenuation coefficient of water

is proportional to frequency squared, these harmonics are absorbed more quickly than the fundamental, leading to 'nonlinear loss' and eventually to 'acoustic saturation', where any change in the acoustic pressure generated at the transducer is not seen at the measurement point in the field. For radiation force balance measurements, nonlinear loss can mean that the incident power is strongly dependent on the distance at which the measurement is made. It can also mean that there is significant streaming in the water path and this also results in a force on the target. Determining the output power of the transducer is therefore subject to greater uncertainties.

For hydrophone measurements, acoustic saturation and nonlinear loss can be problematic when making measurements in water. Unlike diagnostic pressure levels measured in water, which fall within a prescribed range, the high pressures and extended pulse lengths for therapeutics can contain a significantly more extended and higher harmonic spectrum and this places a more stringent requirements on the frequency response of the measurement system.

NOTE The amplitude of a narrowband spectrum at the fundamental from a tone burst is proportional to the number of cycles; therefore, the harmonics also increase under high drive pressures. Acoustic saturation will be more pronounced at these levels. In addition, a problem arises when extrapolating from measurements in water to anticipated values in tissue, where the nonlinear properties and attenuation coefficients are significantly different. This is being addressed for diagnostic ultrasound by an IEC project which specifies a parameter and associated threshold that guarantees 'quasi-linear' conditions. To ensure quasi-linear conditions, the transducer output is reduced until nonlinear propagation processes transfer less than 10 % of the energy flux through any point in the field to the higher harmonics; it is believed that extrapolation from water values to tissue values can be better made by making measurements under these quasi-linear conditions.

3.7 Relevant parameters

Parameters for ultrasonic fields in existing standards have been defined primarily to compare fields propagating in water near the acoustic axis. A selection of these parameters taken from IEC standards current in 2005 is given in Annex B. Whilst these are still relevant to the description of HITU and other therapeutic fields, it may be possible to define a different set of parameters which can be related more closely either to therapeutic effect or to safety. For instance, it may be helpful to integrate intensity over a fixed area, to average pressure or intensity over a fixed area, or to determine a thermal dose or cavitation volume according to a specified protocol. While most previous measurements were near an acoustic axis, for therapeutic applications, a more complete regional measurement may be necessary to determine localized contributions to heating.

In addition, most existing defined parameters rely on either hydrophone or radiation force measurements. It may be possible to use alternative sensors to measure different quantities directly: for instance, intensity, temperature distribution, or cavitation activity.

4 Survey of experts

To establish the views of experts around the world as to where standards would be of benefit, a questionnaire was prepared and sent initially to attendees of the 2003 International Society of Therapeutic Ultrasound (ISTU) meeting which was held on Lyon, France. Further to this circulation, the questionnaire was handed out at the 2004 ISTU meeting in Kyoto, Japan, and at the 2004 meeting of Technical Committee 87 (Ultrasonics) of the International Electrotechnical Commission (IEC) held in Hangzhou, China.

The questions related to three different topics and are given with summarised responses in Table 3. A total of 26 replies were received and are given in full in Annex A.