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Edition 2.1 2017-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Ultrasons – Caractérisation du champ – Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical

IEC 62359:2010-10+AMD1:2017-09 CSV(en-fr)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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ULTRASONICS – FIELD CHARACTERIZATION – TEST METHODS FOR THE DETERMINATION OF THERMAL AND MECHANICAL INDICES RELATED TO MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

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IEC 62359 edition 2.1 contains the second edition (2010-10) [documents 87/445/FDIS and 87/453/RVD] and its corrigendum 1 (2011-03), and its amendment 1 (2017-09) [documents 87/661/FDIS and 87/665/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 62359 has been prepared by IEC technical committee 87: Ultrasonics.

This second edition It constitutes a technical revision.

Major changes with respect to the previous edition include the following:

- The methods of determination set out in the first edition of this standard were based on those contained in the American standard for Real–Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (ODS) and were intended to yield identical results. While this second edition also follows the ODS in principal and uses the same basic formulae and assumptions (see Annex A), it contains a few significant modifications which deviate from the ODS.

- One of the primary issues dealt with in preparing this second edition of IEC 62359 was "missing" *TI* equations. In Edition 1 there were not enough equations to make complete "at-surface" and "below-surface" summations for *TIS* and *TIB* in combined-operating modes. Thus major changes with respect to the previous edition are related to the introduction of new calculations of thermal indices to take into account both "at-surface" and "below-surface" thermal effects.

For the specific technical changes involved please see Annex E.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This standard may be used to support the requirements of IEC 60601-2-37.

In this particular standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: in roman type
– notes, explanations, advice, introductions, general statements, exceptions, and references: in smaller type
– *test specifications: in italic type*
– words in **bold** are defined terms in Clause 3

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

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INTRODUCTION

Medical diagnostic ultrasonic equipment is widely used in clinical practice for imaging and monitoring purposes. Equipment normally operates at frequencies in the low megahertz frequency range and comprises an ultrasonic transducer acoustically coupled to the patient and associated electronics. There is an extremely wide range of different types of systems in current clinical practice.

The ultrasound entering the patient interacts with the patient's tissue, and this interaction can be considered in terms of both thermal and non-thermal effects. The purpose of this International standard is to specify methods of determining thermal and non-thermal exposure indices that can be used to help in assessing the hazard caused by exposure to a particular ultrasonic field used for medical diagnosis or monitoring. It is recognised that these indices have limitations, and knowledge of the indices at the time of an examination is not sufficient in itself to make an informed clinical risk assessment. It is intended that these limitations will be addressed in future revisions of this standard and as scientific understanding increases. While such increases remain pending, several organizations have published **prudent-use statements.**

Under certain conditions specified in IEC 60601-2-37, these indices are displayed on medical ultrasonic equipment intended for these purposes.

INTRODUCTION to Amendment

The second edition of IEC 62359 was published in 2010. Since then, IEC 60601-2-37:2007/AMD1:2015 has been published and calls for provision of **attenuated spatial peak temporal average intensity**, $I_{\text{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\text{sppa},\alpha}$, at specific spatial maximum points in the ultrasonic field on the **beam axis**. No IEC standard describes the determination of these quantities at these specific positions. IEC 62359 for determining the thermal indices currently uses similar values at other positions, therefore, the determination of **attenuated spatial peak temporal average intensity**, $I_{\text{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\text{sppa},\alpha}$, has been added as an annex in this amendment.

Additionally, references to newly published collateral standards have been updated.

ULTRASONICS – FIELD CHARACTERIZATION – TEST METHODS FOR THE DETERMINATION OF THERMAL AND MECHANICAL INDICES RELATED TO MEDICAL DIAGNOSTIC ULTRASONIC FIELDS

1 Scope

This International standard is applicable to medical diagnostic ultrasound fields.

This standard establishes

– parameters related to thermal and non-thermal exposure aspects of diagnostic ultrasonic fields;
– methods for the determination of an exposure parameter relating to temperature rise in theoretical tissue-equivalent models, resulting from absorption of ultrasound;
– methods for the determination of an exposure parameter appropriate to certain non-thermal effects.

NOTE 1 In Clause 3 of this standard, SI units are used (per ISO/IEC Directives, Part 2, ed. 5, Annex I b) in the Notes below definitions of certain parameters, such as beam areas and intensities; it may be convenient to use decimal multiples or submultiples in practice. Users must take care of decimal prefixes used in combination with the units when using and calculating numerical data. For example, beam area may be specified in cm^2 and intensities in W/cm^2 or mW/cm^2.

NOTE 2 Underlying calculations have been done from 0,25 MHz to 15 MHz for MI and 0,5 MHz to 15 MHz for *TI*.

NOTE 3 The thermal indices are steady state estimates based on the acoustic **output power** required to produce a 1°C temperature rise in tissue conforming to the "homogeneous tissue 0,3 $dBcm^{-1}MHz^{-1}$ attenuation model" [1][1)] and may not be appropriate for radiation force imaging, or similar techniques that employ pulses or pulse bursts of sufficient duration to create a significant transient temperature rise.[2]

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 60601-2-37:2007, *Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment*
IEC 60601-2-37:2007/AMD1:2015

IEC 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*
IEC 61157:2007/AMD1:2013

IEC 61161:~~2006~~ 2013, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

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

1) Figures in square brackets refer to Bibliography.

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 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to 40 MHz*

IEC 62127-3:2007, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-2-37, IEC 62127-1~~:2007~~, IEC 62127-2~~:2007~~, IEC 62127-3~~:2007~~, IEC 61157~~:2007~~ and IEC 61161~~:2006 (several of which are repeated below for convenience)~~ apply. Several of these are repeated below for convenience and others are listed because they have been modified for application to this standard.

NOTE Units below definitions are given is SI units as per ISO/IEC Directives, Part 2, ed. 5, Annex I b). Users must be alert to possible need to convert units when using this standard in situations where data are received in units that are different from those used in the SI system.

3.1
acoustic attenuation coefficient
α
coefficient intended to account for ultrasonic attenuation of tissue between the **external transducer aperture** and a specified point

NOTE 1 A linear dependence on frequency is assumed.

NOTE 2 **Acoustic attenuation coefficient** is expressed in decibels per metre per hertz (dB m^{-1} Hz^{-1}).

3.2
acoustic absorption coefficient
μ_0
coefficient intended to account for ultrasonic absorption of tissue in the region of interest

NOTE 1 A linear dependence on frequency is assumed.

NOTE 2 **Acoustic absorption coefficient** is expressed in neper per metre per hertz (Np m^{-1} Hz^{-1}).

3.3
acoustic repetition period
arp
time interval between corresponding points of consecutive cycles~~ for continuous wave systems~~, pulses or scans, depending on the current operating mode

NOTE 1 The **acoustic repetition period** is equal to the **pulse repetition period** for non-automatic scanning systems and to the **scan repetition period** for automatic scanning systems**.**

NOTE 2 For continuous wave modes, the **acoustic repetition period** is the time interval between corresponding points of consecutive cycles

NOTE 3 For **combined operating modes** where transmit pulsing of the constituent modes may be interrupted, the ***arp*** determination should take into account non-pulsing time to calculate an average period.

NOTE ~~2~~ 4 The **acoustic repetition period** is expressed in seconds (s).

[IEC 62127-1:2007, definition 3.2, modified]

3.4
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**~~ on the **beam axis**, beyond the **break-point depth**, corresponding to **depth of maximum pulse-intensity integral** z_{pii}.

NOTE 1 The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or a spectrum analysis method. Specific acoustic-working frequencies are defined in 3.4.1 and 3.4.2.

NOTE 2 For pulsed waveforms the **acoustic-working frequency** shall be measured at the ~~position of maximum pulse-pressure-squared integral~~ **depth for peak pulse-intensity integral**.

NOTE 3 **Acoustic frequency** is expressed in hertz (Hz).

[IEC 62127-1:2007, definition 3.3, modified]

3.4.1
zero-crossing acoustic-working frequency
f_{awf}
number 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 Any half-cycle in which the waveform shows evidence of phase change shall not be counted.

NOTE 2 The measurement should be performed at terminals in the receiver, that are as close as possible to the receiving transducer (hydrophone) and, in all cases, before rectification.

NOTE 3 This frequency is determined according to the procedure specified in IEC/TR 60854 [3].

NOTE 4 This frequency is intended for continuous-wave systems only.

3.4.2
arithmetic-mean acoustic-working frequency
f_{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 This frequency is intended for pulse-wave systems only.

NOTE 2 It is assumed that $f_1 < f_2$.

NOTE 3 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 from the peak magnitude.

3.5
attenuated bounded-square output power
$P_{1x1,\alpha}(z)$
The maximum value of the **attenuated output power** passing through any one square centimeter of the plane perpendicular to the **beam axis** at depth z

NOTE 1 At z = 0 (the transducer surface) $P_{1x1,\alpha}(z)$ becomes the **bounded-square output power**, that is, at z = 0, $P_{1x1,\alpha} = P_{1x1}$.

NOTE 2 **Attenuated bounded-square output power** is expressed in watts (W).

3.6
attenuated output power
$P_\alpha(z)$
value of the acoustic **output power** after attenuation, at a specified distance from the **external transducer aperture**, and given by

$$P_\alpha(z) = P\,10^{(-\alpha z\, f_{awf}/10\,\mathrm{dB})} \quad (1)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** to the point of interest;

f_{awf} is the **acoustic working frequency**;

P is the **output power** measured in water.

NOTE 1 **Attenuated output power** is expressed in watts (W).

NOTE 2 In the case of stand-offs the P should represent the **output power** emanating from the stand-off.

3.7
attenuated peak-rarefactional acoustic pressure
$p_{r,\alpha}(z)$
value of the **peak-rarefactional acoustic pressure** after attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**, and given by

$$p_{r,\alpha}(z) = p_r(z) 10^{(-\alpha z \, f_{awf}/20 \, dB)} \qquad (2)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest;

f_{awf} is the **acoustic working frequency**;

$p_r(z)$ is the **peak-rarefactional acoustic pressure** measured in water.

NOTE Attenuated peak-rarefactional acoustic pressure is expressed in pascals (Pa).

3.8
attenuated pulse-intensity integral
$pii_\alpha(z)$
value of the **pulse-intensity integral** after attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**, and given by

$$pii_\alpha(z) = pii \, 10^{(-\alpha z \, f_{awf}/10 \, dB)} \qquad (3)$$

where

α is the **acoustic attenuation coefficient**;

z is the distance from the **external transducer aperture** along the **beam axis** to the plane containing the point of interest;

f_{awf} is the **acoustic working frequency**;

pii is the **pulse-intensity integral** measured in water.

NOTE 1 **Attenuated pulse-intensity integral** is expressed in joules per metre squared, (J m^{-2}).

NOTE 2 For measurement purposes of this standard, pii_α is equivalent to $1/(\rho c)$ times the **attenuated pulse-pressure-squared integral** at depth z, with ρc denoting the characteristic acoustic impedance of pure water.

3.9
attenuated spatial-average temporal-average intensity
$I_{sata,\alpha}(z)$
value of the **spatial-average temporal-average intensity** after attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**, and given by

$$I_{sata,\alpha}(z) = I_{sata} \, 10^{(-\alpha z \, f_{awf}/10 \, dB)} \qquad (4)$$