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Edition 2.1 2017-09

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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REDLINE VERSION

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

CONTENTS

FOREWORD 4
INTRODUCTION 6
INTRODUCTION to Amendment 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 List of symbols 27
5 Test methods for determining the mechanical index and the thermal index 29
5.1 General 29
5.2 Determination of mechanical index 30
5.2.1 Determination of attenuated peak-rarefactional acoustic pressure 30
5.2.2 Calculation of mechanical index 30
5.3 Determination of thermal index – general 30
5.4 Determination of thermal index in non-scanning mode 30
5.4.1 Determination of soft tissue thermal index for non-scanning modes 30
5.4.2 Determination of bone thermal index, TIB, for non-scanning modes 32
5.5 Determination of thermal index in scanning modes 33
5.5.1 Determination of soft tissue thermal index for scanning modes 33
5.5.2 Determination of bone thermal index for scanning modes 33
5.6 Calculations for combined-operating mode 34
5.6.1 Acoustic working frequency 34
5.6.2 Thermal index 34
5.6.3 Mechanical index 35
5.7 Summary of measured quantities for index determination 35
Annex A (informative) Rationale and derivation of index models 37
Annex B (informative) Guidance notes for measurement of output power in combined modes, scanning modes and in 1 cm × 1 cm windows 59
Annex C (informative) The contribution of transducer self-heating to the temperature rise occurring during ultrasound exposure 66
Annex D (informative) Guidance on the interpretation of TI and MI 67
Annex E (informative) Differences from IEC 62359 Edition 1 69
Annex F (informative) Rationale and determination of maximum non-attenuated and attenuated spatial-peak temporal-average intensity and spatial-peak pulse-average intensity values 72
Bibliography 83

Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field (modified from IEC 61828 and IEC 62127-1) 12
Figure A.1 – Focusing transducer with a f-number of about 7 44
Figure A.2 – Strongly focusing transducer with a low f-number of about 1 45
Figure A.3 – Focusing transducer (f-number ≈ 10) with severe undulations close to the transducer 45
Figure A.4 – Focusing transducer 52
Figure A.5 – Focusing transducer with smaller aperture than that of Figure A.4 52
Figure A.6 – Focusing transducer with a weak focus near z_{bp} 53

Figure A.7 – Weakly focusing transducer 53
Figure B.1 – Example of curved linear array in scanning mode 61
Figure B.2 – Suggested 1 cm × 1 cm square-aperture mask 64
Figure B.3 – Suggested orientation of transducer, mask aperture and RFB target 64
Figure B.4 – Suggested orientation of transducer and 1 cm-square RFB target 65

Table 1 – Summary of combination formulae for each of the THERMAL INDEX categories 35
Table 2 – Summary of the acoustic quantities required for the determination of the indices 36
Table A.1 – Thermal index categories and models 43
Table A.2 – Consolidated thermal index formulae 49
Table E.1 – Summary of differences 71

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

FOREWORD

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This Consolidated version of IEC 62359 bears the edition number 2.1. It consists of 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]. The technical content is identical to the base edition and its amendment.

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

The committee has decided that the contents of the base publication and its amendment 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.

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

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**, $I_{\mathrm{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\mathrm{sppa},\alpha}$, 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**, $I_{\mathrm{spta},\alpha}$, and **attenuated spatial peak pulse average intensity**, $I_{\mathrm{sppa},\alpha}$, 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*

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FINAL VERSION

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CONTENTS

FOREWORD 4
INTRODUCTION 6
INTRODUCTION to Amendment 6
1 Scope 7
2 Normative references 7
3 Terms and definitions 8
4 List of symbols 27
5 Test methods for determining the mechanical index and the thermal index 29
5.1 General 29
5.2 Determination of mechanical index 30
5.2.1 Determination of attenuated peak-rarefactional acoustic pressure 30
5.2.2 Calculation of mechanical index 30
5.3 Determination of thermal index – general 30
5.4 Determination of thermal index in non-scanning mode 30
5.4.1 Determination of soft tissue thermal index for non-scanning modes 30
5.4.2 Determination of bone thermal index, TIB, for non-scanning modes 31
5.5 Determination of thermal index in scanning modes 33
5.5.1 Determination of soft tissue thermal index for scanning modes 33
5.5.2 Determination of bone thermal index for scanning modes 33
5.6 Calculations for combined-operating mode 34
5.6.1 Acoustic working frequency 34
5.6.2 Thermal index 34
5.6.3 Mechanical index 35
5.7 Summary of measured quantities for index determination 35
Annex A (informative) Rationale and derivation of index models 37
Annex B (informative) Guidance notes for measurement of output power in combined modes, scanning modes and in 1 cm × 1 cm windows 58
Annex C (informative) The contribution of transducer self-heating to the temperature rise occurring during ultrasound exposure 65
Annex D (informative) Guidance on the interpretation of TI and MI 66
Annex E (informative) Differences from IEC 62359 Edition 1 68
Annex F (informative) Rationale and determination of maximum non-attenuated and attenuated spatial-peak temporal-average intensity and spatial-peak pulse-average intensity values 71
Bibliography 82

Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field (modified from IEC 61828 and IEC 62127-1) 12
Figure A.1 – Focusing transducer with a f-number of about 7 43
Figure A.2 – Strongly focusing transducer with a low f-number of about 1 44
Figure A.3 – Focusing transducer (f-number ≈ 10) with severe undulations close to the transducer 44
Figure A.4 – Focusing transducer 51
Figure A.5 – Focusing transducer with smaller aperture than that of Figure A.4 51
Figure A.6 – Focusing transducer with a weak focus near z_{bp} 52

Figure A.7 – Weakly focusing transducer 52
Figure B.1 – Example of curved linear array in scanning mode 60
Figure B.2 – Suggested 1 cm × 1 cm square-aperture mask 63
Figure B.3 – Suggested orientation of transducer, mask aperture and RFB target 63
Figure B.4 – Suggested orientation of transducer and 1 cm-square RFB target 64

Table 1 – Summary of combination formulae for each of the THERMAL INDEX categories 35
Table 2 – Summary of the acoustic quantities required for the determination of the indices 36
Table A.1 – Thermal index categories and models 42
Table A.2 – Consolidated thermal index formulae 48
Table E.1 – Summary of differences 70

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