



DPC: 23 / 30434159 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 16 May 2023

Origin: International

Latest date for receipt of comments: 7 June 2023

Project No. 2021/00443

Responsible committee: EPL/87 Ultrasonics

Interested committees:

Title: BS EN IEC 62359 Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices and acoustic intensities related to medical diagnostic ultrasonic fields

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 7 June 2023**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



87/834/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:

IEC 62359 ED3

DATE OF CIRCULATION:

2023-05-12

CLOSING DATE FOR COMMENTS:

2023-07-07

SUPERSEDES DOCUMENTS:

87/802/CD, 87/819A/CC

IEC TC 87 : ULTRASONICS

SECRETARIAT:

United Kingdom

SECRETARY:

Mr Petar Luzajic

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:

☐

Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☐ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any local regulations or technical reasons that may exist and should be considered should this proposal proceed, recognizing that failure to address such requirements could result in the need for new or existing "In Some Countries" clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

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

NOTE FROM TC/SC OFFICERS:

Copyright © 2023 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

Documents
AVA Document Sharing Hub

CONTENTS

1	FOREWORD.....	5
2	INTRODUCTION to Editions 1 and 2.....	8
3	INTRODUCTION to Amendment – Edition 2.1.....	8
4	INTRODUCTION to Edition 3.....	8
5	1 Scope.....	10
6	2 Normative references	10
7	3 Terms and definitions	11
8	4 List of symbols	40
9	5 Test methods for determining the mechanical index and the thermal index	44
10	5.1 General.....	44
11	5.2 Determination of mechanical index	45
12	5.2.1 Determination of attenuated peak-rarefactional acoustic pressure	45
13	5.2.2 Calculation of mechanical index.....	45
14	5.3 Determination of the quasi-linear application-specific mechanical index.....	45
15	5.3.1 Symbol to Display.....	45
16	5.3.2 Determine the values of application-specific acoustic attenuation coefficient.....	45
17	5.3.3 Determination of $p_{r,\alpha_{APP},ql}(z_{MI_{APP}}, p_{Source,target})$, the application-specific attenuated quasi-linear peak-rarefactional acoustic pressure at the depth for application-specific mechanical index for a target source acoustic pressure	46
18	5.3.4 Calculation of the application-specific quasi-linear mechanical index.....	50
19	5.4 Determination of thermal index – general.....	50
20	5.5 Determination of thermal index in non-scanning mode	51
21	5.5.1 Determination of soft tissue thermal index for non-scanning modes	51
22	5.5.2 Determination of bone thermal index for non-scanning modes	52
23	5.6 Determination of thermal index in scanning modes	53
24	5.6.1 Determination of soft tissue thermal index for scanning modes	53
25	5.6.2 Determination of bone thermal index for scanning modes	53
26	5.7 Considerations for combined-operating mode index calculations.....	54
27	5.7.1 Determination of acoustic working frequency	54
28	5.7.2 Determination of thermal index	54
29	5.7.3 Determination of mechanical index	55
30	5.8 Summary of measured quantities for index determination	55
31	5.9 Application-specific thermal dose index (TDI_{APP}).....	56
32	5.9.1 Calculation of the application-specific thermal dose index	56
33	5.9.2 Determine the values of application-specific thermal dose normalization factor and the TI_{APP} to use	57
34	Annex A (informative) Rationale and derivation of index models	58
35	A.1 Overview	58
36	A.2 General rationale	58
37	A.2.1 Rationale for attenuation coefficient of the tissue path used	58
38	A.2.2 Thermal properties of tissue used in calculation of the thermal index and the thermal dose index.....	58
39	A.2.3 Mechanical properties of tissue used in calculation of the mechanical index	59

48	A.3	Mechanical index (<i>MI</i>).....	59
49	A.3.1	Rationale	59
50	A.3.2	Derivation notes	59
51	A.4	Thermal index (<i>TI</i>)	60
52	A.4.1	Rationales	60
53	A.4.2	Derivation notes - General.....	64
54	A.4.3	Derivation notes for the thermal models used	68
55	Annex B (informative)	Guidance notes for measurement of output power in combined	
56		modes, scanning modes and in 1 cm × 1 cm windows	79
57	B.1	General.....	79
58	B.2	Measurements for combined operating modes	79
59	B.3	Measurement of output power, <i>P</i> , in scanning modes	80
60	B.4	Creating a 1 cm × 1 cm window using a mask of absorbing material or a	
61		1 cm × 1 cm radiation force balance target.....	82
62	B.4.1	General	82
63	B.4.2	1 cm × 1 cm aperture in a mask	83
64	B.4.3	1 cm × 1 cm area radiation-force-balance target	83
65	B.5	Creating a 1 cm × 1 cm window using electronic control or using calculations	85
66	B.6	Measurement of bounded-square output power	85
67	Annex C (informative)	The contribution of transducer self-heating to the temperature	
68		rise occurring during ultrasound exposure	86
69	Annex D (informative)	Guidance on the interpretation of <i>TI</i> and <i>MI</i>	87
70	D.1	General.....	87
71	D.2	Limitations of the indices	87
72	Annex E (informative)	Differences between IEC 62359 editions	89
73	E.1	General.....	89
74	E.2	Differences from IEC 62359 Edition 1	89
75	E.3	Differences from IEC 62359 Edition 2.1 and 3.....	92
76	Annex F (normative)	Rationale and determination of maximum non-attenuated and	
77		attenuated spatial-peak temporal-average intensity and spatial-peak pulse-	
78		average intensity values	93
79	F.1	Rationale	93
80	F.2	Overview	93
81	F.3	Test methods	94
82	F.3.1	Common parameters.....	94
83	F.3.2	Determination of I_{sppa} and $I_{\text{sppa},\alpha}$	97
84	F.3.3	Determination of $I_{\text{spta},\alpha}$ and I_{spta}	98
85	F.4	Additional rationale and derivation notes.....	100
86	F.4.1	Summary steps for measuring each active mode	100
87	F.4.2	Notes regarding determination of $s_{\text{a}}\text{ppsi}(z)$ and $\text{sppi}_{\text{a}}(z)$	101
88	F.4.3	Further information regarding scanning modes	102
89	Annex G (informative)	Information and rationale related to the quasi-linear,	
90		application-specific mechanical index ($MI_{\text{APP,ql}}$)	104
91	G.1	Rationale for quasi-linear estimates of pressure and <i>MI</i>	104
92	G.2	A conservative over-estimate.	104
93	G.3	Simultaneous display of the <i>MI</i> and $MI_{\text{APP,ql}}$ used for operating modes using	
94		'conditionally increased' acoustic output.	104
95	G.4	Values for the application-specific attenuation coefficient	104

96	Annex H (informative) Information and rationale for the thermal dose index (thermally	
97	equivalent time index) <i>TDI</i> (<i>TETI</i>)	106
98	H.1 General.....	106
99	H.2 Thermal dose.....	106
100	H.3 Deriving <i>TDI</i> (<i>TETI</i>) from thermal dose	107
101	H.4 Choosing the application-specific thermal dose normalization factor, N_{APP}	108
102	H.5 Interpretation of the <i>TDI</i> (<i>TETI</i>)	108
103	Annex I (informative) Information and rationale for the spatial averaging correction	
104	applied to the mechanical index, thermal index, attenuated spatial-peak temporal-	
105	average intensity and spatial-peak pulse-average intensity.....	112
106	Bibliography.....	114
107		
108	Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field	22
109	Figure A.1 – Focusing transducer with a f-number of about 7	65
110	Figure A.2 – Strongly focusing transducer with a low f-number of about 1	65
111	Figure A.3 – Focusing transducer (f-number ≈ 10) with severe undulations close to the	
112	transducer	66
113	Figure A.4 – Focusing transducer	72
114	Figure A.5 – Focusing transducer with smaller aperture than that of Figure A.4	73
115	Figure A.6 – Focusing transducer with a weak focus near z_{bp}	73
116	Figure A.7 – Weakly focusing transducer	73
117	Figure B.1 – Example of curved linear array in scanning mode	81
118	Figure B.2 – Suggested 1 cm $\times$ 1 cm square-aperture mask.....	84
119	Figure B.3 – Suggested orientation of transducer, mask aperture and RFB target	84
120	Figure B.4 – Suggested orientation of transducer and 1 cm-square RFB target.....	85
121	Figure H.1 – <i>TI</i> plotted against t for <i>TDI</i> = 1	109
122	Figure H.2 – <i>TDI</i> plotted against t for <i>TI</i> = 1	110
123	Figure H.3 – <i>TDI</i> plotted against t for <i>TI</i> = 3	110
124		
125	Table 1 – values of application-specific acoustic attenuation coefficients for $MI_{APP,ql}$ –	
126	listed per Application + Mode	46
127	Table 2 – Summary of combination formulae for each of the thermal index categories	55
128	Table 3 – Summary of the acoustic quantities required for the determination of the	
129	indices	56
130	Table 4 – Recommended values for the application-specific thermal dose normalization	
131	factor and the <i>TI</i> (<i>TIS</i> , <i>TIB</i> , <i>TIC</i>)	57
132	Table A.1 – Thermal index categories and models	64
133	Table A.2 – Consolidated thermal index formulae	69
134	Table E.1 – Summary of differences	91
135	Table H.1 – Values of the dwell time, t , in minutes at which the <i>TDI</i> reaches one for <i>TI</i>	
136	= 1 to 5, and N_{APP} = 64, 512, and 1024 (from Formula (H.4))......	109

137

138

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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.

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

Major changes with respect to the previous editions 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) [14] and were intended to yield identical results. The 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 the second edition of IEC 62359 was “missing” *TI* formulas. In Edition 1 there were not enough formulas to make complete “at-surface” and “below-surface” summations for *TIS* and *TIB* in combined-operating modes. Thus, major changes with respect to edition 1 were related to the introduction of new calculations of thermal indices to take into account both “at-surface” and “below-surface” thermal effects. Also added in the second edition were the explicit determination of attenuated spatial peak temporal average intensity, I_{spta} , and attenuated spatial peak pulse average intensity, I_{sppa} .

This third edition of IEC 62539 constitutes a technical revision.

In this third edition four primary changes with respect to the previous editions include the following:

- The first is with regard to syntax. Spatial-peak parameters have been given new labels and symbols, to better distinguish between ‘local’ spatial peaks on a given plane, at depth z perpendicular to the beam axis, and ‘global’ spatial peak values.
- The second change is making normative the determination methods given in Annex F for the determination of spatial-peak temporal-average intensity (I_{spta}), attenuated spatial-peak temporal-average intensity ($I_{\text{spta},\alpha}$), spatial-peak pulse-average intensity (I_{sppa}) and attenuated spatial-peak pulse-average intensity ($I_{\text{sppa},\alpha}$).
- The third change is the addition of determination methods for application-specific ‘thermal dose index’ (TDI_{APP}) and for quasi-linear application-specific mechanical indices, $MI_{\text{APP,ql}}$.
The TDI_{APP} definition originates from references 45 and 46. Its introduction is intended to address limitations in Edition 1 and 2, by providing information to the clinical user indicating that thermal risk is related linearly to duration of tissue temperature rise (dwell time) and exponentially to magnitude of temperature rise.
The quasi-linear application-specific mechanical index, $MI_{\text{APP,ql}}$, is introduced to provide an indicator of mechanical bioeffect risk which both allows for the assignment of tissue-specific attenuation assumptions, and also places limits on the amount of non-linear distortion and saturation (loss of energy) allowed to occur in the acoustic pressure waveform measured in water, a problem which gets worse as the source acoustic pressure increases.
- The fourth change is the additional information and direction on the application of spatial averaging corrections to the measured values of parameters covered by this standard.

For the specific technical changes involved please see sections 5.3 and 5.9, and Annexes G, H and I.

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

This standard is intended to 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.

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 to Editions 1 and 2

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 diagnostic ultrasonic equipment** intended for these purposes.

INTRODUCTION to Amendment – Edition 2.1

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.

INTRODUCTION to Edition 3

As acknowledged in the introductions to edition 1 and 2 of this standard, limitations to the **thermal** and **mechanical indices** were intended to be addressed in future revisions. One of these limitations was the lack of **thermal dose** information; information which relates thermal bioeffect risk linearly with increasing **dwelt time** and exponentially with magnitude of temperature rise. Edition 3 introduces the **application-specific thermal dose index** (TDI_{APP}) to address this limitation in a relatively simple manner, by integrating the TI value over time and normalizing the value of this integral by dividing by an **application-specific thermal dose normalization factor** (N_{APP}).

The TDI_{APP} itself has limitations, one of the biggest being the assumption that the region of tissue being exposed does not change during the exam, when usually it does change as clinicians and sonographers move the **ultrasonic transducer** to obtain various diagnostic views. This limitation can be partially offset by providing a ' **TDI reset**' function on the **medical diagnostic ultrasound systems**, which the informed clinician or sonographer can apply.

A **quasi-linear application-specific mechanical index**, $MI_{APP,qI}$, is introduced in this edition. Its determination uses the same simple model as the MI ; with the **attenuated peak-rarefactional acoustic pressure** divided by the square root of the **acoustic working**

frequency, $MI = \frac{p_{r,\alpha}(z_{MI}) f_{awf}^{-1/2}}{C_{MI}}$. The difference is that the $MI_{APP,qI}$ formulas allow for the

use of ‘application-specific’ value of **attenuation coefficient**, α_{APP} , and a ‘quasi-linear’ estimate of the **peak-rarefactional pressure**, in calculating the **quasi-linear application-specific peak-rarefactional pressure**, $p_{r,\alpha APP,qI}$, used in the $MI_{APP,qI}$ formulation.

Similar to the TDI_{APP} , there are limitations on the applicability of the $MI_{APP,qI}$. The assumption of quasi-linear propagation of ultrasonic pressure waveforms in tissue is considered conservative in nature. And the chosen values of tissue attenuation values used, should also be conservative. One of the chief advantages of the $MI_{APP,qI}$ will be that its value should increase and decrease linearly with increases and decreases in the acoustic source pressure **source acoustic pressure** near the radiating aperture of the **external transducer aperture**, whereas the current MI is more subject to non-linear distortion and saturation effects, which worsen as the **source acoustic pressure** increases.

For many years, the existing **mechanical index** and **thermal index** described in Ed. 1 and Ed. 2 have been considered sufficient from a regulatory and safety standpoint for **medical diagnostic ultrasonic equipment** with acoustic output that remains below the de-facto worldwide limits of the **mechanical index** of 1,9 and **attenuated spatial-peak temporal-average intensity**, $I_{Spta,\alpha} = 720 \text{ mW/cm}^2$.

However, if regulatory standards such as IEC 60601-2-37, or regulatory bodies or Investigational Review Boards (IRBs) are to allow ‘conditionally increased’ acoustic output that exceeds these longstanding de-facto limits for specific clinical applications, additional real-time safety information to the clinical user can possibly be required. The TDI_{APP} and $MI_{APP,qI}$ are intended to provide such additional information.

Annexes G and H provide additional information and rationale for the **quasi-linear application-specific mechanical index** and the **thermal dose index**.

Note too that the TDI_{APP} and $MI_{APP,qI}$ could also be used, if deemed necessary, for sensitive applications where regulations call for conditionally decreased output.

In addition edition 3 contains changes to syntax for improved clarity, spatial-peak parameters have been given new labels and symbols to better distinguish between ‘local’ spatial peaks on a given plane at depth z perpendicular to the **beam axis**, and ‘global’ spatial peak values in the ultrasonic field.

Also, edition 3 makes normative the methods given in Annex F for determination of maximum non-attenuated and **attenuated spatial-peak temporal-average intensity** and **spatial-peak pulse-average intensity** values.

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

1 Scope

This document is applicable to medical diagnostic ultrasound fields.

This document establishes

- parameters related to thermal and non-thermal exposure aspects of diagnostic ultrasonic fields;
- methods for the determination of exposure parameters 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 document, SI units are used (per ISO/IEC Directives, Part 2) in the Notes below definitions of certain parameters, such as beam areas and intensities; it can 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 can 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 $0,3 \text{ dBcm}^{-1}\text{MHz}^{-1}$ attenuation model” [1]¹⁾ and possibly are not 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 61161:2013, *Ultrasonics – Power measurement – Radiation force balances and performance requirements*

IEC 61828:2020, *Ultrasonics - Transducers - Definitions and measurement methods regarding focusing for the transmitted fields.*

IEC 62127-1:2022, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields*

¹⁾ Figures in square brackets refer to Bibliography.

363 IEC 62127-2:2007, *Ultrasonics – Hydrophones – Part 2: Calibration for ultrasonic fields up to*
364 *40 MHz*
365 IEC 62127-2:2007/AMD1:2013/AMD2:2017

366 IEC 62127-3:2022, *Ultrasonics – Hydrophones – Part 3: Properties of hydrophones for*
367 *ultrasonic fields*

368 IEC TS 61949: 2007, *Ultrasonics – Field characterization – in situ exposure estimation in finite-*
369 *amplitude ultrasonic beams*

370 ISO/IEC Guide 98-3:2008, *Uncertainty of measurement – Part 3: Guide to the expression of*
371 *uncertainty in measurement (GUM:1995)*

372 **3 Terms and definitions**

373 For the purposes of this document, the terms and definitions given in IEC 60601-2-37,
374 IEC 62127-1, IEC 62127-2, IEC 62127-3, IEC 61157 and IEC 61161 apply. Several of these
375 are repeated below for convenience and others are listed because they have been modified for
376 application to this standard.

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

380 **3.1** 381 **acoustic attenuation coefficient**

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

385 Note 1 to entry: A linear dependence on frequency is assumed.

386 Note 2 to entry: **Acoustic attenuation coefficient** is expressed in units of decibel per metre per hertz
387 ($\text{dB m}^{-1} \text{Hz}^{-1}$).

388 **3.2** 389 **acoustic absorption coefficient**

390 μ_0
391 coefficient intended to account for ultrasonic absorption of tissue in the region of interest

392 Note 1 to entry: A linear dependence on frequency is assumed.

393 Note 2 to entry: **Acoustic absorption coefficient** is expressed in units of neper per metre per hertz ($\text{Np m}^{-1} \text{Hz}^{-1}$).

394 **3.3** 395 **acoustic repetition period**

396 arp
397 time interval between corresponding points of consecutive cycles, pulses or scans, depending
398 on the current operating mode

399 Note 1 to entry: The **acoustic repetition period** is equal to the **pulse repetition period** for non-automatic scanning
400 systems and to the **scan repetition period** for automatic scanning systems.

401 Note 2 to entry: For continuous wave modes, the **acoustic repetition period** is the time interval between
402 corresponding points of consecutive cycles

403 Note 3 to entry: For **combined operating modes** where transmit pulsing of the constituent modes can be
404 interrupted, the arp determination should take into account non-pulsing time to calculate an average period.

405 Note 4 to entry: The **acoustic repetition period** is expressed in seconds (s).

[SOURCE: IEC 62127-1:2022, definition 3.2, modified – definition has been changed to general wording and application dependent details have been moved to Notes 1 to 3 to entry]

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 on the **beam axis**, beyond the **break-point depth**, corresponding to the **depth for peak pulse-intensity integral** z_{pii} .

Note 1 to entry: The signal is analysed using either the **zero-crossing acoustic-working frequency** technique or spectrum analysis methods. Specific acoustic-working frequencies are defined in 3.4.1 to 3.4.3.

Note 2 to entry: For pulsed waveforms the **acoustic-working frequency** shall be measured at the **depth for peak pulse-intensity integral**.

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

[SOURCE: IEC 62127-1:2022, definition 3.3, modified – position of measurement has been changed]

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 to entry: Any half-cycle in which the waveform shows evidence of phase change shall not be counted.

Note 2 to entry: 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 to entry: This frequency is determined according to the procedure specified in IEC TR 60854.

Note 4 to entry: 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 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 level.

[SOURCE: IEC 62127-1:2022, definition 3.3.2]

3.4.3

magnitude-weighted acoustic-working frequency

f_{awf}

frequency weighted with the spectral acoustic pressure magnitude in the frequency range where the spectral pressure level is equal or larger than 3 dB below the peak level

$$f_{awf} = \frac{\int f |P(f)| df}{\int |P(f)| df} \quad \text{with} \quad |P(f)| = \begin{cases} |P(f)| & \text{if } L_P(f) \geq \max L_P(f) - 3 \text{ dB} \\ 0 & \text{otherwise} \end{cases} \quad (1)$$

where:

f is the frequency of the acoustic pressure waveform;

$|P(f)|$ is the modulus of the complex-valued spectrum of the **acoustic pulse waveform**;

$L_P(f)$ is the pressure level spectrum given from $L_P(f) = 20 \log_{10} \left(\frac{|P(f)|}{P_{\text{ref}}} \right)$ dB, with $P_{\text{ref}} = 1$ Pa.

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

Note 2 to entry: The integrals in (1) are definite, to be taken from the minimum to the maximum of the acquired signal spectrum

Note 3 to entry: It is recommended to use definition 3.4.3 whenever possible, as it leads to more stable acoustic-working frequency results than definition 3.4.2 if there are peaks in the acoustic pressure spectrum close to the -3 dB threshold. This is particularly relevant when, as is shown in this standard, the determination of derated field parameters is done using a single derating factor determined from a single value of the **acoustic-working frequency**.

[SOURCE: IEC 62127-1:2022, definition 3.3.3, modified – Note 1 to entry has been omitted]

3.5 application-specific acoustic attenuation coefficient

α_{APP}

coefficient intended to account for ultrasonic attenuation of application-specific tissue between the **external transducer aperture** and a specified point

Note 1 to entry: A linear dependence on frequency is assumed.

Note 2 to entry: The definition is the same as the **acoustic attenuation coefficient** but supports the MI_{APP} by allowing the assignment of different, tissue-specific, attenuation values.

Note 3 to entry: See table 1 in section 5.3.2 for a listing of approved **application-specific acoustic attenuation coefficients**

Note 4 to entry: **Application-specific acoustic attenuation coefficient** is expressed in units of decibel per metre per hertz (dB m⁻¹ Hz⁻¹).

3.6 application-specific attenuated instantaneous acoustic pressure

$p_{\alpha_{\text{APP}}}(z, t)$

value of the **instantaneous acoustic pressure** after application-specific attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**

$$p_{\alpha_{\text{APP}}}(z, t) = p(z, t) 10^{(-\alpha_{\text{APP}} z f_{\text{awf}} / 20 \text{ dB})} \quad (2)$$

where

$p(z, t)$ is the **instantaneous acoustic pressure** at depth z ;

α_{APP} is the **application-specific acoustic attenuation coefficient**;

z is the distance from the source to the point (plane) of interest;

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

Note 1 to entry: **Application-specific attenuated instantaneous acoustic pressure** is expressed in pascals (Pa).

Note 2 to entry: See 3.59 for the definition of **instantaneous acoustic pressure**.

3.7

application-specific attenuated pulse-pressure-squared integral

$ppsi_{\alpha,APP}(z)$

value of the **pulse-pressure-squared integral** after application-specific attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**

$$ppsi_{\alpha_{APP}}(z) = \int p_{\alpha_{APP}}^2(z, t) dt = \int \left[p(z, t) 10^{(-\alpha_{APP} z f_{awf} / 20 \text{ dB})} \right]^2 dt = ppsi(z) \times 10^{(-\alpha_{APP} z f_{awf} / 10 \text{ dB})} \quad (3)$$

where

$p(z, t)$ is the **instantaneous acoustic pressure** at depth z ;

$p_{\alpha_{APP}}(z, t)$ is the **application-specific attenuated instantaneous acoustic pressure** at depth z ;

α_{APP} is the **application-specific acoustic attenuation coefficient**;

z is the distance from the source to the point (plane) of interest;

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

$ppsi$ is the **pulse-pressure-squared integral**.

Note 1 to entry: **Application-specific attenuated pulse-pressure-squared integral** is expressed in units of pascal squared times second (Pa^2s).

Note 2 to entry: This is the same as Formula (13) in 3.18, except with the use of the application-specific attenuation coefficient.

3.8

application-specific attenuated quasi-linear peak-rarefactional acoustic pressure

$p_{r,\alpha_{APP},ql}(z)$

value of the **quasi-linear peak-rarefactional acoustic pressure** after application-specific attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the **external transducer aperture**

$$p_{r,\alpha_{APP},ql}(z) = p_{r,ql}(z) 10^{(-\alpha_{APP} z f_{awf} / 20 \text{ dB})} \quad (4)$$

where

α_{APP} is the **application-specific 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**;

$p_{r,ql}(z)$ is the **quasi-linear peak-rarefactional acoustic pressure** measured in water.

Note 1 to entry: **Application-specific attenuated quasi-linear peak-rarefactional acoustic pressure** is expressed in pascals (Pa).

Note 2 to entry: This follows Formula (2), with the replacement of $p_r(z)$ with $p_{r,ql}(z)$ and α with α_{APP} .

Note 3 to entry: This is the same as Formula (11) in 3.16, except with the use of the application-specific attenuation coefficient and quasi-linear pressure values.

3.9

application-specific attenuated quasi-linear pulse-pressure-squared integral

$ppsi_{\alpha_{APP},ql}(z)$

528 value of the **quasi-linear pulse-pressure-squared integral** after application-specific
 529 attenuation, on a plane perpendicular to the **beam axis** at a specified distance z from the
 530 **external transducer aperture**

$$531 \quad ppsi_{\alpha_{APP},ql}(z) = ppsi_{ql}(z) \times 10^{(-\alpha_{APP} z f_{awf}/10 \text{ dB})} \quad (5)$$

532 where

533 α_{APP} is the **application-specific acoustic attenuation coefficient**;

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

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

537 $ppsi_{ql}(z)$ is the **quasi-linear pulse-pressure-squared integral** measured in water.

538 Note 1 to entry: **Application-specific attenuated quasi-linear pulse-pressure-squared integral** is expressed in
 539 units of pascal squared times second (Pa^2s).

540 Note 2 to entry: This is the same as Formula (13) in 3.18, except with the use of the **application-specific**
 541 **attenuation coefficient** and **quasi-linear pressure values**

542 **3.10** 543 **application specific quasi-linear mechanical index**

544 $MI_{APP,ql}$

545 indicator of the risk for bioeffects due to mechanical or nonthermal mechanisms, such as
 546 cavitation, based on **quasi-linear peak-rarefactional acoustic pressure** for specific
 547 applications of **medical diagnostic ultrasound equipment**

$$548 \quad MI_{APP,ql} = \frac{p_{r,\alpha_{APP,ql}}(z_{MI_{APP}} p_{\text{source,target}}) f_{awf}^{-1/2}}{C_{MI}} \quad (6)$$

549 where

550 $C_{MI} = 1 \text{ MPa} \cdot \text{MHz}^{-1/2}$;

551 $p_{r,\alpha_{APP,ql}}(z_{MI_{APP}} p_{\text{source,target}})$ is the **application-specific attenuated quasi-linear peak-**
 552 **rarefactional acoustic pressure at depth** $z_{MI_{APP}}$ and at the **target**
 553 **source acoustic pressure**;

554 f_{awf} is the **acoustic-working frequency**.

555

556 Note 1 to entry: If the **application-specific quasi-linear mechanical index** is adopted in safety standards or
 557 regulatory agency documents, then 'APP' might be replaced by a designated label. For example, for Liver
 558 applications ' $MI_{\text{Liver},ql}$ ' might be displayed

559 Note 2 to entry: This is the same as Formula (25) in 3.63, except with the use of the **application-specific**
 560 **attenuation coefficient** and **quasi-linear pressure values**.

561 Note 3 to entry: See Annex G for rationale and derivation notes.

562

563 **3.11** 564 **application-specific thermal dose index** 565 **application-specific thermally equivalent time index**

566 TDI_{APP} (Or $TETI_{APP}$)

567 application-specific thermal risk indicator representing the risk for thermal bioeffect as
 568 increasing exponentially with tissue temperature rise and linearly with exposure time

569

570

$$TDI_{APP}(t) = \frac{1}{N_{APP}} \int_{t'=0}^t 4^{TI_{APP}(t')} dt' \quad (7)$$

where

- t is **dwelt time**, in minutes, since the last **thermal dose index reset time**;
 $TI_{APP}(t)$ is the value of the thermal index (*TIS*, *TIB* or *TIC*) indicated for the selected application;
 N_{APP} is the **application-specific thermal dose normalization factor**.

Note 1 to entry: To account for varying values of *TI* with time, as the clinician or sonographer changes transmit conditions, an integral form is used. For a constant value of *TI*, Formula (7) simplifies to

$$TDI_{APP}(t) = \frac{4^{TI_{APP}} \cdot t}{N_{APP}} \quad (8)$$

Note 2 to entry: Formulas (7) and (8) are the same as Formulas (31) and (32) in 3.102, but with the use of the **thermal index** (*TIS*, *TIB* or *TIC*) most appropriate for the diagnostic application and with the use of an **application-specific thermal dose normalization factor**.

Note 3 to entry: See Annex H for a rational and derivation notes of the **thermal dose index**.

Note 4 to entry: See 3.12 and Annex H for a discussion of **application-specific thermal dose normalization factors**.

Note 5 to entry: See Table 4, subclause 5.9.2, for values of N_{APP} and *TI* to use by application in the *TDI* formula.

Note 6 to entry: **Thermal dose index** is expressed in units of 1.

3.12 application-specific thermal dose normalization factor

N_{APP}

application-specific constant used in the **thermal dose index** formulas

Note 1 to entry: N_{APP} is a conservative estimate of the time, t_{43} for a thermal bioeffect to occur in tissue representative of the selected application, when the temperature of that tissue is sustained at a constant value of 43 °C.

Note 2 to entry: See Annex H for a rational and derivation notes, including discussion of t_{43} .

Note 3 to entry: See Table 4, subclause 5.9.2, for values of N_{APP} to use by application.

Note 4 to entry: The **thermal dose normalization factor** is expressed in units of time (minutes).

3.13 attenuated bounded-square output power

$P_{1 \times 1, \alpha}(z)$

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

Note 2 to entry: **Attenuated bounded-square output power** is expressed in watts (W).

3.14 attenuated instantaneous acoustic pressure

$p_{\alpha}(z, t)$

value of the **instantaneous acoustic pressure** at time *t* after attenuation on a plane perpendicular to the **beam axis** at a specified distance *z* from the source, and given by

$$p_{\alpha}(z, t) = p(z, t) 10^{(-\alpha z f_{\text{awf}} / 20 \text{ dB})}$$

612 where

613 α is the **acoustic attenuation coefficient**;

614 z is the distance from the source to the point (plane) of interest;

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

616 $p(z,t)$ is the **instantaneous acoustic pressure**.

617 Note 1 to entry: **Attenuated instantaneous acoustic pressure** is expressed in pascals (Pa).

618 3.15

619 attenuated output power

620 $P_{\alpha}(z)$

621 value of the **acoustic output power** after attenuation, at a specified distance from the **external**
622 **transducer aperture**, and given by

$$623 \quad P_{\alpha}(z) = P 10^{(-\alpha z f_{\text{awf}}/10 \text{ dB})} \quad (10)$$

624 where

625 α is the **acoustic attenuation coefficient**;

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

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

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

629 Note 1 to entry: **Attenuated output power** is expressed in watts (W).

630 Note 2 to entry: In the case of stand-offs the P represents the **output power** emanating from the stand-off.

631 3.16

632 attenuated peak-rarefactional acoustic pressure

633 $p_{r,\alpha}(z)$

634 value of the **peak-rarefactional acoustic pressure** after attenuation, on a plane perpendicular
635 to the **beam axis** at a specified distance z from the **external transducer aperture**, and given
636 by

$$637 \quad p_{r,\alpha}(z) = p_r(z) 10^{(-\alpha z f_{\text{awf}}/20 \text{ dB})} \quad (11)$$

638 where

639 α is the **acoustic attenuation coefficient**;

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

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

643 $p_r(z)$ is the **peak-rarefactional acoustic pressure** measured in water.

644 Note 1 to entry: **Attenuated peak-rarefactional acoustic pressure** is expressed in pascals (Pa).

645 3.17

646 attenuated pulse-intensity integral

647 $p_{ii,\alpha}(z)$

648 value of the **pulse-intensity integral** after attenuation, on a plane perpendicular to the **beam**
649 **axis** at a specified distance z from the **external transducer aperture**, and given by

$$650 \quad p_{ii,\alpha}(z) = p_{ii} 10^{(-\alpha z f_{\text{awf}}/10 \text{ dB})} \quad (12)$$

651 where

652 α is the **acoustic attenuation coefficient**;

- 653 z is the distance from the **external transducer aperture** along the **beam axis** to the plane
 654 containing the point of interest;
 655 f_{awf} is the **acoustic working frequency**;
 656 p_{ii} is the **pulse-intensity integral** measured in water.

657 Note 1 to entry: **Attenuated pulse-intensity integral** is expressed in units of joule per metre squared (J m^{-2}).

658 Note 2 to entry: For measurement purposes of this standard, p_{ii_α} is equivalent to $1/(\rho c)$ times the **attenuated**
 659 **pulse-pressure-squared integral** at depth z , with ρc denoting the characteristic acoustic impedance of pure water.

660 3.18 661 attenuated pulse-pressure-squared integral

662 $ppsi_\alpha(z)$
 663 time integral of the square of the **attenuated instantaneous acoustic pressure**, integrated
 664 over the acoustic pulse waveform, on a plane perpendicular to the **beam axis** at a specified
 665 distance z in an acoustic field

$$666 \quad ppsi_\alpha(z) = \int p_\alpha^2(z, t) dt = \int [p(z, t) 10^{(-\alpha z f_{\text{awf}} / 20 \text{ dB})}]^2 dt = ppsi(z) \times 10^{(-\alpha z f_{\text{awf}} / 10 \text{ dB})} \quad (13)$$

667 where

- 668 $p(z, t)$ is the **instantaneous acoustic pressure** at depth z .
 669 α is the **acoustic attenuation coefficient**;
 670 z is the distance from the source to the point (plane) of interest;
 671 f_{awf} is the **acoustic working frequency**;
 672 $ppsi$ is the **pulse-pressure-squared integral**.

673 Note 1 to entry: **Attenuated pulse-pressure-squared integral** is expressed in units of pascal squared times
 674 second (Pa^2s).

675 Note 2 to entry: See definition 3.76 for the non-attenuated version; with the addition here of the perpendicular
 676 plane at depth z .

677 3.19 678 attenuated scan intensity integral

679 $sii_\alpha(z)$
 680 sum of the **attenuated pulse intensity integrals** in one scan (one frame of **ultrasonic scan**
 681 **lines**) at depth z

682 Note 1 to entry: **Attenuated scan intensity integral** is expressed in units of joule per metre squared (J m^{-2}).

683 Note 2 to entry: For measurement purposes of this standard, $sii_\alpha(z)$ is equivalent to $1/(\rho c)$ times the **sum of**
 684 **attenuated pulse-pressure-squared integrals** at depth z , for $z \geq z_{\text{bp}}$, with ρc denoting the characteristic acoustic
 685 impedance of pure water.

686 Note 3 to entry: See definition 3.87 for the non-attenuated version.

687 3.20 688 attenuated spatial-average temporal-average intensity

689 $I_{\text{sata}, \alpha}(z)$
 690 value of the **spatial-average temporal-average intensity** after attenuation, on a plane
 691 perpendicular to the **beam axis** at a specified distance z from the **external transducer**
 692 **aperture**, and given by

$$693 \quad I_{\text{sata}, \alpha}(z) = I_{\text{sata}} 10^{(-\alpha z f_{\text{awf}} / 10 \text{ dB})} \quad (14)$$

694 where

- 695 α is the **acoustic attenuation coefficient**;
- 696 z is the distance from the **external transducer aperture** along the **beam axis** to the plane
- 697 containing the point of interest;
- 698 f_{awf} is the **acoustic working frequency**;
- 699 I_{sata} is the **spatial-average temporal-average intensity**, at a specified distance z measured
- 700 in water.

701 Note 1 to entry: **Attenuated spatial-average temporal-average intensity** is expressed in units of watt per metre

702 squared (W m^{-2}).

703 3.21

704 attenuated spatial-peak pulse-average intensity

- 705 $I_{\text{sppa},\alpha}(z)$
- 706 maximum value of the **spatial-peak pulse-average intensity** after attenuation, on a plane
- 707 perpendicular to the **beam axis** at a specified distance z from the source, and given by

$$708 \quad I_{\text{sppa},\alpha}(z) = \frac{1}{t_d(z)} pii_{\alpha}(z) \quad (15)$$

709 where

- 710 $t_d(z)$ is the **pulse duration** at the same depth z ;
- 711 $pii_{\alpha}(z)$ is the **attenuated pulse-intensity integral** at depth z .

712 Note 1 to entry: **Attenuated spatial-peak pulse-average intensity** is expressed in units of watts per metre

713 squared (Wm^{-2}).

714 Note 2 to entry: For measurement purposes of this standard, $pii_{\alpha}(z)$ is equivalent to $1/(\rho c)$ times the **attenuated**

715 **pulse-pressure-squared integrals** at depth z , $ppsi_{\alpha}(z)$, for $z \geq z_{\text{bp}}$, with ρc denoting the characteristic acoustic

716 impedance of pure water.

717 Note 3 to entry: See definition 3.96 for the non-attenuated version.

718 3.22

719 attenuated spatial-peak temporal-average intensity

- 720 $I_{\text{spta},\alpha}(z)$
- 721 value of the **spatial-peak temporal-average intensity** after attenuation, on a plane
- 722 perpendicular to the **beam axis** at a specified distance z from the **external transducer**
- 723 **aperture**, and given by

$$724 \quad I_{\text{spta},\alpha}(z) = I_{\text{spta}} 10^{(-\alpha z f_{\text{awf}}/10 \text{ dB})} \quad (16)$$

725 where

- 726 α is the **acoustic attenuation coefficient**;
- 727 z is the distance from the **external transducer aperture** along the **beam axis** to the plane
- 728 containing the point of interest;
- 729 f_{awf} is the **acoustic working frequency**;
- 730 I_{spta} is the **spatial-peak temporal-average intensity**, at a specified distance z measured in
- 731 water.

732 Note 1 to entry: **Attenuated spatial-peak temporal-average intensity** is expressed in units of watt per metre

733 squared (W m^{-2}).

3.23**attenuated sum of pulse-pressure-squared integrals** $s_{\alpha ppsi}(z)$

attenuated value of the sum of **pulse-pressure-squared integrals** in one scan (one frame of **ultrasonic scan lines**) at depth z

Note 1 to entry: **Attenuated sum of pulse-pressure-squared integrals** is expressed in units of pascal squared times second (Pa^2s).

Note 2 to entry: The **attenuated sum of pulse-pressure-squared integrals** at depth z will be equal to the **sum of attenuated pulse-pressure-squared integrals** if each **ultrasonic scan line** in the frame which is included in the sum has the same **acoustic working frequency**.

Note 3 to entry: See F.3.1.4.2 for additional explanation.

Note 4 to entry: See definition 3.100 for the non-attenuated version.

3.24**attenuated temporal-average intensity** $I_{ta,\alpha}(z)$

value of the **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

$$I_{ta,\alpha}(z) = I_{ta}(z) 10^{(-\alpha z f_{awf}/10 \text{ dB})} \quad (17)$$

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**;

$I_{ta}(z)$ is the **temporal-average intensity** measured in water.

Note 1 to entry: **Attenuated temporal-average intensity** is expressed in units of watt per metre squared (W m^{-2}).

3.25**beam area** $A_b(z)$

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 **spatial-peak temporal-peak acoustic pressure** 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** can be replaced by **temporal average intensity**.

Note 3 to entry: Some specified levels 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 units of metre squared (m^2).

[SOURCE: IEC 62127-1:2022, definition 3.7, modified – the symbol subscript has been changed]

3.26**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 aperture

Note 1 to entry: See Figure 1.

Note 2 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 3 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 scan frame is not available the term **pulse-pressure-squared integral** can be replaced by **temporal average intensity**.

[SOURCE: IEC 62127-1:2022, definition 3.8]

3.27**beam centrepoint**

position determined by the 2D centroid of a set of **pulse-pressure-squared integrals** measured over the -6 dB beam-area in a specified plane

Note 1 to entry: Methods for determining 2D centroids are described in Annex C and D of IEC 61828:2020.

3.28**beamwidth midpoint**

linear average of the coordinates of the locations midway between each pair of points determining a **beamwidth** in a specified plane

Note 1 to entry: The average is taken over as many **beamwidth** levels given in C.2 of IEC 61828:2020 as signal level permits.

[SOURCE: IEC 62127-1:2022, definition 3.10, modified – the wording has been changed to comprise “of the coordinates”, “midway between each pairs” and “specified”]

3.29**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

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.:

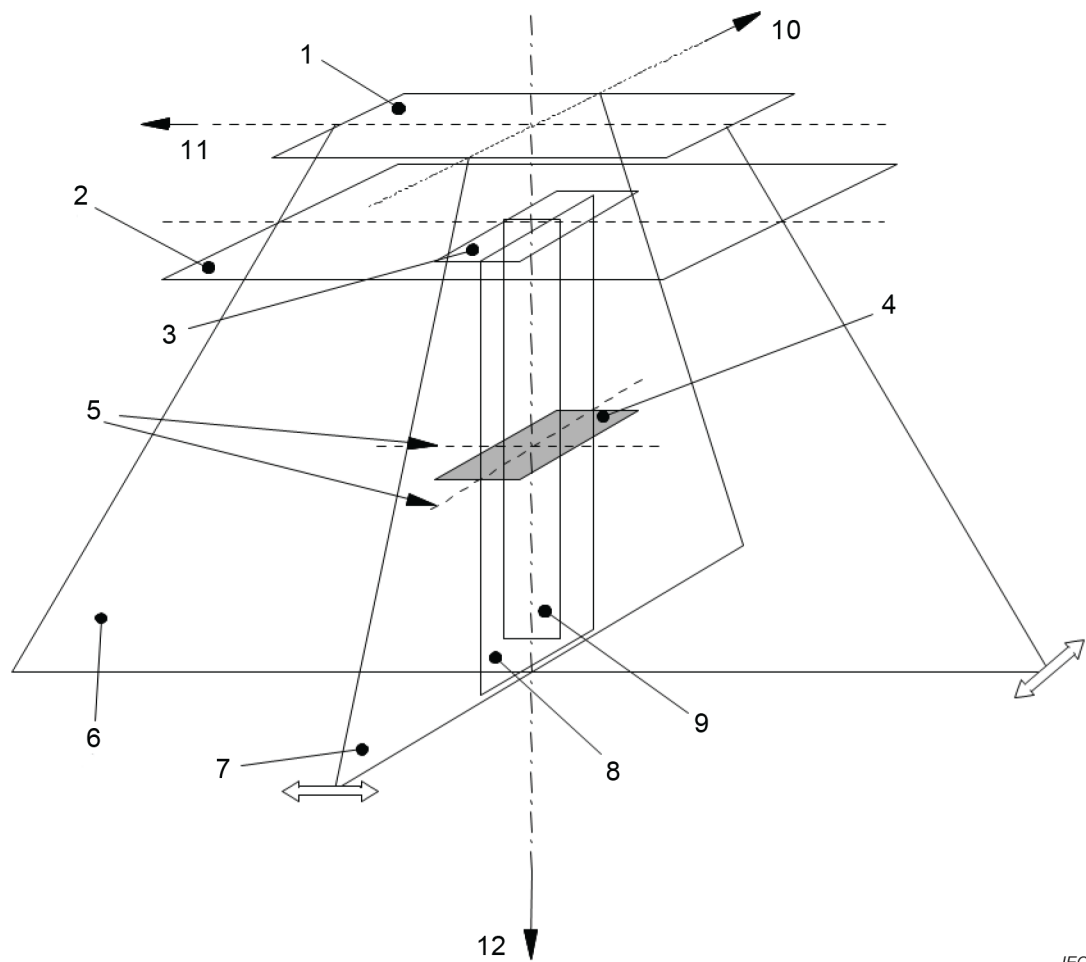
a) in the case of a continuous wave signal the term **pulse-pressure-squared integral** is replaced by mean square acoustic pressure as defined in IEC 61689,

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

Note 2 to entry: Commonly used **beamwidths** are specified at -6 dB, -12 dB and -20 dB levels below the maximum. The decibel calculation implies taking 10 times the logarithm to the base of 10 of the ratios of the integrals.

Note 3 to entry: **Beamwidth** is expressed in metres (m).

[SOURCE: IEC 62127-1:2022, definition 3.11]



- Key**
- | | | | |
|---|-----------------------------------|----|------------------------------|
| 1 | external transducer surface plane | 7 | azimuth plane, scan plane |
| 2 | source aperture plane | 8 | principal longitudinal plane |
| 3 | source aperture | 9 | longitudinal plane |
| 4 | beam area plane | 10 | X, azimuth axis |
| 5 | beamwidth lines | 11 | Y, elevation axis |
| 6 | elevation plane | 12 | Z, beam axis |

[SOURCE: IEC 61828:2020]

Figure 1 – Schematic diagram of the different planes and lines in an ultrasonic field

3.30
bone thermal index
TIB

thermal index for applications, such as foetal (second and third trimester), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

Note 1 to entry: See 5.5.2.2 and 5.6.2.2 for methods of determining the bone thermal index.

Note 2 to entry: See Annex A for rationale and derivation notes.

3.31
bounded-square output power
 P_{1x1}

837 maximum value of the time average **acoustic output power** emitted from any one-centimetre
 838 square region of the active area of the transducer, the one-centimetre square region having
 839 1 cm dimensions in the x - and y -directions

840 Note 1 to entry: The side of the 1 cm × 1 cm square should be aligned with the azimuth axis in accordance with
 841 Figure 1. See A.4.1.4 and Annex B for more detail.

842 Note 2 to entry: **Bounded-square output power** is expressed in watts (W).

843 3.32 844 break-point depth

845 z_{bp}

846 closest distance, to the solid surface of the transducer or the enclosure of any stand-off path,
 847 used during a search to determine below-surface *TIS* and *TIB* **acoustic working frequency**
 848 and intensity parameters (such as **attenuated spatial-peak temporal-average intensity**)

$$849 \quad z_{bp} = 1,5 \times D_{eq} \quad (18)$$

850 where D_{eq} is the **equivalent aperture diameter** for **non-scanning modes**.

851 Note 1 to entry: Specifically, for the **mechanical index**: the search should continue till the depth z_{MI} . Reasonable
 852 care should be taken not to go so close to the transducer face as to risk the integrity of the hydrophone or the validity
 853 of the measurement.

854 Note 2 to entry: For **scanning modes**, use the **non-scanning mode** D_{eq} value calculation (Formula (19)). Do this
 855 using the **output beam area** of one **ultrasonic scan line**; the central scan line, corresponding to the **beam axis** (i.e.
 856 the line where p_{ii} , MI , and f_{awf} are measured).

857 Note 3 to entry: See Annex A for rationale and derivation notes.

858 Note 4 to entry: **Breakpoint depth** is expressed in metres (m).

859 3.33 860 combined-operating mode 861 mode of operation of an **equipment** that combines more than one **discrete-operating mode**

862 [SOURCE: IEC 61157:2007, definition 3.17.1]

863 3.34 864 cranial-bone thermal index

865 *TIC*

866 **thermal index** for applications in which the ultrasound beam passes through bone near the
 867 beam entrance into the body, such as paediatric and adult cranial or neonatal cephalic
 868 applications

869 Note 1 to entry: See 5.5.2.1 and 5.6.2.1 for methods of determining the **cranial bone thermal index**.

870 Note 2 to entry: See Annex A for rationale and derivation notes.

871 3.35 872 default setting

873 specific state of control that the **medical diagnostic ultrasonic equipment** will enter upon
 874 power-up, new **patient** selection or change from non-foetal to foetal applications

875 3.36 876 depth for application-specific quasi-linear mechanical index

877 z_{MIAPP}

878 depth on the **beam axis** from the **external transducer aperture** to the plane of maximum
 879 **application-specific attenuated quasi-linear pulse-pressure-squared-integral**

880 $ppsi_{\alpha_{APP},ql}(z)$

881

882 Note 1 to entry: Because $z_{MI_{APP}}$ can occur closer to the transducer than the **break-point depth** z_{bp} , use of $ppsi_{\alpha}$
 883 rather than $p_{ii_{\alpha}}$ is technically more appropriate. If $z_{ppsi_{\alpha}}$ is larger than z_{bp} , then $z_{ppsi_{\alpha}}$ and $z_{p_{ii_{\alpha}}}$ are equal.

884 Note 2 to entry: **Depth for application-specific mechanical index** is expressed in metres (m).

885 3.37

886 **depth for I_{sppa}**

887 z_{sppa}

888 depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of **spatial-peak pulse-**
 889 **average intensity**

890 Note 1 to entry: **Depth for I_{sppa}** is expressed in metres (m).

891 Note 2 to entry: This depth is equivalent to the **depth for peak p_{ii}** .

892 3.38

893 **depth for $I_{sppa,\alpha}$**

894 $z_{sppa,\alpha}$

895 depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of **attenuated spatial-peak**
 896 **pulse-average intensity**

897 Note 1 to entry: **Depth for $I_{sppa,\alpha}$** is expressed in metres (m).

898 Note 2 to entry: This depth is equivalent to the **depth for peak $p_{ii_{\alpha}}$** .

899 3.39

900 **depth for I_{spta}**

901 z_{spta}

902 depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of **spatial-peak temporal-**
 903 **average intensity**

904 Note 1 to entry: **Depth for I_{spta}** is expressed in metres (m).

905 Note 2 to entry: For **non-scanning modes**, this depth is equivalent to the **depth for peak p_{ii}** . For **scanning modes**,
 906 it is equivalent to the **depth for peak s_{ii}** .

907 3.40

908 **depth for $I_{spta,\alpha}$**

909 $z_{spta,\alpha}$

910 depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of **attenuated spatial-peak**
 911 **temporal-average intensity**

912 Note 1 to entry: **Depth for $I_{spta,\alpha}$** is expressed in metres (m).

913 Note 2 to entry: For **non-scanning modes**, this depth is equivalent to the **depth for peak $p_{ii_{\alpha}}$** . For **scanning**
 914 **modes**, it is equivalent to the **depth for peak $s_{ii_{\alpha}}$** .

915 3.41

916 **depth for mechanical index**

917 z_{MI}

918 depth on the **beam axis** from the **external transducer aperture** to the plane of maximum
 919 **attenuated pulse-pressure-squared-integral** ($ppsi_{\alpha}$)

920 Note 1 to entry: Because z_{MI} can occur closer to the transducer than the **break-point depth** z_{bp} , use of $ppsi_{\alpha}$ rather
 921 than $p_{ii_{\alpha}}$ is technically more appropriate. If $z_{ppsi_{\alpha}}$ is larger than z_{bp} , then $z_{ppsi_{\alpha}}$ and $z_{p_{ii_{\alpha}}}$ are equal.

922 Note 2 to entry: **Depth for mechanical index** is expressed in metres (m).

3.42**depth for peak $ppsi_{\alpha_{APP,ql}}$** $z_{ppsi,\alpha_{APP,ql}}$ **depth z on the beam axis of peak application-specific attenuated quasi-linear pulse-pressure-squared integral**Note 1 to entry: **Depth for peak $ppsi_{\alpha_{APP,ql}}$** is expressed in metres (m).Note 2 to entry: This depth is the **depth for application-specific mechanical index**, z_{MI_APP} (see 3.36).**3.43****depth for peak p_{ii}_{α}** $z_{p_{ii},\alpha}$ **depth z on the beam axis and beyond the break-point depth z_{bp} of peak attenuated pulse-intensity integral**Note 1 to entry: **Depth for peak p_{ii}_{α}** is expressed in metres (m).Note 2 to entry: This depth is equivalent to the **depth for peak $ppsi_{\alpha}$** , $z_{ppsi,\alpha}$, when $z_{ppsi,\alpha}$ occurs beyond the **break-point depth** (see 3.45).**3.44****depth for peak $ppsi$** z_{ppsi} **depth z on the beam axis of peak pulse-pressure-squared integral**Note 1 to entry: **Depth for peak $ppsi$** is expressed in metres (m).Note 2 to entry: When it occurs beyond the **break-point depth**, this depth is equivalent to the **depth for peak p_{ii}** , $z_{p_{ii}}$ (see 3.46).**3.45****depth for peak $ppsi_{\alpha}$** $z_{ppsi,\alpha}$ **depth z on the beam axis of peak attenuated pulse-pressure-squared integral**Note 1 to entry: **Depth for peak $ppsi_{\alpha}$** is expressed in metres (m).Note 2 to entry: When it occurs beyond the **break-point depth**, this depth is equivalent to the **depth for peak p_{ii}_{α}** , $z_{p_{ii},\alpha}$ (i.e. depth for peak **attenuated pulse-intensity integral**).Note 3 to entry: This depth is the **depth for mechanical index**, z_{MI} (see 3.41).**3.46****depth for peak pulse intensity integral** $z_{p_{ii}}$ **depth z on the beam axis and beyond the break-point depth z_{bp} from the external transducer aperture to the plane of maximum pulse-intensity integral (p_{ii}) as approximated by the pulse-pressure-squared integral ($ppsi$)**Note 1 to entry: **Depth for peak p_{ii}** is expressed in metres (m).Note 2 to entry: At this depth the **acoustic working frequency** is determined.

3.47**depth for peak s_{ii}** $z_{s_{ii}}$

depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of peak **scan-intensity integral**

Note 1 to entry: **Depth for peak s_{ii}** is expressed in metres (m).

Note 2 to entry: This depth is equivalent to the **depth for peak s_{ppsi}** , $z_{s_{ppsi}}$, when $z_{s_{ppsi}}$ occurs beyond the **break-point depth** (see 3.39).

Note 3 to entry: **Depth for peak s_{ii}** is termed "depth for peak sum of pulse-intensity integrals" in IEC 60601-2-37:2007+IEC 60601-2-37:2007/AMD1:2015.

3.48**depth for peak $s_{ii\alpha}$** $z_{s_{ii,\alpha}}$

depth z on the **beam axis** and beyond the **break-point depth** z_{bp} of peak **attenuated scan-intensity integral**

Note 1 to entry: **Depth for peak $s_{ii\alpha}$** is expressed in metres (m).

Note 2 to entry: This depth is equivalent to the **depth for peak $s_{ppsi\alpha}$** , $z_{s_{ppsi,\alpha}}$, when $z_{s_{ppsi,\alpha}}$ occurs beyond the **break-point depth** (see 3.50).

Note 3 to entry: **Depth for peak $s_{ii\alpha}$** is termed "depth for peak sum of attenuated pulse-intensity integrals" in IEC 60601-2-37:2007+IEC 60601-2-37:2007/AMD1:2015.

3.49**depth for peak s_{ppsi}** $z_{s_{ppsi}}$

depth z on the **beam axis** of peak **sum of pulse-pressure-squared integrals**

Note 1 to entry: **Depth for peak s_{ppsi}** is expressed in metres (m).

Note 2 to entry: When it occurs beyond the **break-point depth**, this depth is equivalent to the **depth for peak s_{ii}** , $z_{s_{ii}}$ (see 3.47).

Note 3 to entry: **Depth for peak s_{ppsi}** is termed "depth for peak sum of pulse-intensity integrals" in IEC 60601-2-37:2007+IEC 60601-2-37:2007/AMD1:2015.

3.50**depth for peak $s_{ppsi\alpha}$** $z_{s_{ppsi,\alpha}}$

depth z on the **beam axis** of peak **sum of attenuated pulse-pressure-squared integrals**

Note 1 to entry: **Depth for peak $s_{ppsi\alpha}$** is expressed in metres (m).

Note 2 to entry: When it occurs beyond the **break-point depth**, this depth is equivalent to the **depth for peak $s_{ii\alpha}$** , $z_{s_{ii,\alpha}}$ (see 3.48).

Note 3 to entry: **Depth for peak $s_{ppsi\alpha}$** is termed "depth for peak sum of attenuated pulse-intensity integrals" in IEC 60601-2-37:2007+IEC 60601-2-37:2007/AMD1:2015.

3.51**depth for scaling** z_{sc}

separation distance from the **external transducer aperture** to the depth at which the **scaling factor** is determined by hydrophone or RFB target

1007 Note 1 to entry: Clause 5.3.3.3 conditions a, b and c provide details on the **depth for scaling** to be applied.

1008 Note 2 to entry: **Depth for scaling** is expressed in metres (m).

1009 **3.52** 1010 **depth for TIB**

1011 $z_{b,ns}$

1012 <for **non-scanning modes**> the distance along the **beam axis** from the **external transducer**
1013 **aperture** to the plane where the product of **attenuated output power** and **attenuated**
1014 **temporal-average intensity** is a maximum over the distance range equal to, or greater than,
1015 the **break-point depth**, z_{bp}

1016 Note 1 to entry: **Depth for TIB** is expressed in metres (m).

1017 Note 2 to entry: See Annex A for rationale and derivation notes.

1018 **3.53** 1019 **depth for TIS**

1020 $z_{s,ns}$

1021 <for **non-scanning modes**> the distance along the **beam axis** from the **external transducer**
1022 **aperture** to the plane at which the lower value of the **attenuated output power** and the product
1023 of the **attenuated temporal-average intensity** and 1 cm^2 is maximized over the distance range
1024 equal to, or greater than, the **break-point depth**, z_{bp}

1025 Note 1 to entry: **Depth for TIS** is expressed in metres (m).

1026 Note 2 to entry: See Annex A for rationale and derivation notes.

1027 **3.54** 1028 **discrete-operating mode**

1029 mode of operation of **medical diagnostic ultrasonic equipment** in which the purpose of the
1030 excitation of the **ultrasonic transducer** or **ultrasonic transducer** element group is to utilize
1031 only one diagnostic methodology

1032 [SOURCE: IEC 61157:2007, definition 3.17.2, modified – NOTE 1 has been omitted]

1033 **3.55** 1034 **dwelt time**

1035 the total time that a specified anatomic structure is continuously exposed to the ultrasound
1036 beam during an ultrasound examination

1037 Note 1 to entry: From 'dwelt time' definition in [55], which emphasizes that "t" in the *TI* vs. *t* recommendations is not
1038 simply the duration of the examination, but the time the beam is exposing one location.

1039 1040 **3.56** 1041 **equivalent aperture diameter**

1042 D_{eq}

1043 diameter of the circular area *A* which is the –12 dB **output beam area** A_{ob} for **non-scanning**
1044 **modes** and the –12 dB **scanned aperture area** A_{sa} for **scanning modes**

$$1045 \quad D_{eq} = \sqrt{\frac{4}{\pi} A} \quad (19)$$

1046 Note 1 to entry: Formula (19) is used in the calculation of the **cranial-bone thermal index**; for **non-scanning**
1047 **modes** with $A = A_{ob}$ and for **scanning modes** with $A = A_{sa}$.

1048 Note 2 to entry: Formula (19) with $A = A_{ob}$ is also used in calculating the **break-point depth**.

1049 Note 3 to entry: **Equivalent aperture diameter** is expressed in metres (m).

3.57**equivalent beam area** $A_{\text{eq}}(z)$ area of the acoustic beam at the distance z in terms of power and intensity

$$A_{\text{eq}}(z) = \frac{P_{\alpha}(z)}{I_{\text{ta},\alpha}(z)} = \frac{P}{I_{\text{ta}}} \quad (20)$$

where

 $P_{\alpha}(z)$ is the **attenuated output power**, at the distance z ; $I_{\text{ta},\alpha}(z)$ is the **attenuated temporal-average intensity** on the beam axis, at the distance z ; P is the **output power**; $I_{\text{ta}}(z)$ is the **temporal-average intensity** on the beam axis, at the distance z ; z is the distance from the **external transducer aperture** to the specified point.Note 1 to entry: **Equivalent beam area** is expressed in units of metre squared (m^2).**3.58****equivalent beam diameter** $d_{\text{eq}}(z)$ diameter of the acoustic beam at the distance z in terms of the **equivalent beam area**

$$d_{\text{eq}}(z) = \sqrt{\frac{4}{\pi} A_{\text{eq}}(z)} \quad (21)$$

where

 $A_{\text{eq}}(z)$ is the **equivalent beam area**; z is the distance from the **external transducer aperture** to the specified point.Note 1 to entry: **Equivalent beam diameter** is expressed in metres (m).**3.59****external transducer aperture**part of the surface of the **ultrasonic transducer** or **ultrasonic transducer** element group assembly that emits ultrasonic radiation into the propagation medium

See: Figure 1

Note 1 to entry: This surface is assumed to be either directly in contact with the patient or in contact with a water or liquid path to the patient.

Note 2 to entry: The **ultrasonic transducer** element group is usually offset from this surface by a lens, matching layers and possibly fluid.

[SOURCE: IEC 62127-1:2022, definition 3.28, modified – Notes to entry have been changed]

3.60**instantaneous acoustic pressure** $p(t)$

pressure minus the ambient pressure at a particular instant in time and at a particular point in an acoustic field

Note 1 to entry: **Instantaneous acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC 62127-1:2022, 3.35, modified – The reference to IEC 801-01-19 has been removed in the definition]

3.61**local area factor** F_a

square root of the ratio of the **source aperture area** of one **ultrasonic scan line**, the central scan line, to the **beam area** of that same **ultrasonic scan line** at the point of interest

$$F_a = \sqrt{\frac{A_{SAeff}}{A_b}} \quad (22)$$

Note 1 to entry: The relevant local **beam area**, A_b , is that for which the **pulse-pressure-squared integral** is greater than 0,135 (that is, $1/e^2$) times the maximum value in the cross-section.

Note 2 to entry: If the beam profile is approximately Gaussian at the distance of interest and the area at the -6 dB level, $A_{b,6}$, is known, the local **beam area** can be calculated as $A_b = A_{b,6}/0,69$: ($0,69 = 3 \ln(10)/10$): $F_a = \sqrt{\frac{0,69 A_{SAeff}}{A_{b,6}}}$

[SOURCE: IEC 62127-1:2022, 3.37, modified – The **source aperture area** and the **beam area** are for one **ultrasonic scan line**.]

3.62**local distortion factor** σ_q

index which permits the prediction of nonlinear distortion of ultrasound for a specific **ultrasonic transducer**

$$\sigma_q = z p_m \frac{2\pi f_{awf} \beta}{\rho \cdot c^3} \frac{1}{\sqrt{F_a}} \quad (23)$$

where

z is the axial distance of the point of interest to the transducer face;

p_m is the **mean-peak acoustic pressure** at the point in the acoustic field corresponding to the **spatial-peak temporal-peak acoustic pressure**;

β is the nonlinearity parameter ($\beta = 1 + B/2A = 3,5$ for pure water at 20 °C);

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

F_a is the **local area factor**.

Note 1 to entry: If the transmitting system comprises an internal standoff utilizing a water or water-equivalent propagation medium, the offset distance between the transducer element and the transducer face increases the actual path length z to be considered. The nominal distance between the **beam axis**'s intersection with the crystal and the transducer face can be used.

Note 2 to entry: Under some conditions, a value for the **local area factor** can not be available conveniently. Under these conditions a conservative value $F_a = 2$ can be used.

Note 3 to entry: The approximation of **local area factor** described in definition 3.61 and 5.3.3.1 can be used to save measurement time in determining the **local distortion factor**.

[SOURCE: IEC 62127-1:2022, 3.38, modified – Notes 2 and 3 to entry have been added.]

3.63**mean peak acoustic pressure** p_m

The average of the **peak-compressional acoustic pressure** and the **peak-rarefactional acoustic pressure** in an acoustic field or in a specified plane during an acoustic repetition period

$$p_m(z) = \frac{p_c(z) + p_r(z)}{2} \quad (24)$$

Note 1 to entry: **Mean peak acoustic pressure** is expressed in pascals (Pa).

[SOURCE: IEC TS 61949:2007, definition 3.13, modified – specifications “in an acoustic field or in a specified plane during an acoustic repetition period” and the formula have been added]

3.64 mechanical index

MI

indicator of the risk for bioeffects due to mechanical or nonthermal mechanisms, such as cavitation

$$MI = \frac{p_{r,\alpha}(z_{MI}) f_{awf}^{-1/2}}{C_{MI}} \quad (25)$$

where

$C_{MI} = 1 \text{ MPa} \cdot \text{MHz}^{-1/2}$

$p_{r,\alpha}(z_{MI})$ is the **attenuated peak-rarefactional acoustic pressure** at the depth z_{MI}

f_{awf} is the **acoustic-working frequency**.

Note 1 to entry: See Annex A for rationale and derivation notes.

Note 2 to entry: **Mechanical index** is expressed in units of 1.

3.65 medical diagnostic ultrasonic equipment (or system)

combination of the **ultrasound instrument console** and the **transducer assembly** making up a complete diagnostic system

Note 1 to entry: For the purpose of this standard, **medical diagnostic ultrasonic equipment (or system)** means **electrical equipment** that is intended for *in vivo* ultrasonic examination and monitoring for obtaining a medical diagnosis.

Note 2 to entry: IEC 60601-2-37:2007 uses the term “ultrasonic diagnostic equipment” instead of **medical diagnostic ultrasonic equipment**.

[SOURCE: IEC 61157:2007, definition 3.15, modified – Notes to entry have been added.]

3.66 non-scanning mode

mode of operation of **medical diagnostic ultrasonic equipment** that involves a sequence of ultrasonic pulses which give rise to **ultrasonic scan lines** that follow the same acoustic path

[SOURCE: IEC 62127-1:2022, definition 3.45.4]

3.67 output beam area

A_{ob}

area of the ultrasonic beam derived from the –12 dB **beam area** at the **external transducer aperture**

Note 1 to entry: For reasons of measurement accuracy, the –12 dB **output beam area** can be derived from measurements at a distance chosen to be as close as possible to the face of the transducer, and, if possible, no more than 1 mm from the face.

Note 2 to entry: For contact transducers, this area can be taken as the geometrical area of the **ultrasonic transducer** or **ultrasonic transducer** element group.

Note 3 to entry: The **output beam area** is expressed in units of metre squared (m²).

Note 4 to entry: Methodologies for finding beam areas for focused fields are described in clause 5.2.9 of IEC 61828:2020.

1172 [SOURCE: IEC 62127-1:2022, definition 3.46, modified - Note 4 to entry has been added]

1173 **3.68**

1174 **output beam dimensions**

1175 X_{ob} , Y_{ob}

1176 dimensions of the ultrasonic beam (–12 dB **beamwidth**) in specified directions perpendicular
1177 to each other and in a direction normal to the **beam axis** and at the **external transducer**
1178 **aperture**

1179 Note 1 to entry: For reasons of measurement accuracy, the –12 dB **output beam dimensions** can be derived from
1180 measurements at a distance chosen to be as close as possible to the face of the transducer and, if possible, no more
1181 than 1 mm from the face.

1182 Note 2 to entry: For contact transducers, these dimensions can be taken as the geometrical dimensions of the
1183 **ultrasonic transducer** or **ultrasonic transducer** element group.

1184 Note 3 to entry: **Output beam dimensions** are expressed in metres (m).

1185 Note 4 to entry: Methodologies for finding beam areas for focused fields are described in clause 7.2.9 of IEC
1186 61828:2020

1187 [SOURCE: IEC 62127-1:2022, definition 3.47, modified - Note 4 to entry has been added]

1188 **3.69**

1189 **output power**

1190 P

1191 time-average ultrasonic power emitted by an **ultrasonic transducer** into an approximately free
1192 field under specified conditions in a specified medium, preferably water

1193 Note 1 to entry: "Time-average" means averaged over an integral multiple of the temporal periodicity.

1194 Note 2 to entry: **Output power** is expressed in watts (W).

1195 [SOURCE: IEC 61161:2013, definition 3.3]

1196 **3.70**

1197 **peak-rarefactional acoustic pressure**

1198 p_r

1199 maximum of the modulus of the negative **instantaneous acoustic pressure** in an acoustic field
1200 or in a specified plane during an **acoustic repetition period**

1201 Note 1 to entry: **Peak-rarefactional acoustic pressure** is expressed as a positive number.

1202 Note 2 to entry: **Peak-rarefactional acoustic pressure** is expressed in pascals (Pa).

1203 Note 3 to entry: The definition of **peak-rarefactional acoustic pressure** also applies to peak-negative acoustic
1204 pressure which is also in use in literature.

1205 [SOURCE: IEC 62127-1:2022, definition 3.51]

1206 **3.71**

1207 **peak-compressional acoustic pressure**

1208 p_c

1209 maximum positive instantaneous **acoustic pressure** in an acoustic field or in a specified plane
1210 during an acoustic repetition period

1211 Note 1 to entry: **Peak-compressional acoustic pressure** is expressed in pascals (Pa).

1212 Note 2 to entry: The definition of peak-compressional acoustic pressure also applies to peak-positive acoustic
1213 pressure, which is also in use in literature.

1214 [SOURCE: IEC 62127-1:2022, definition 3.50]

1215 **3.72**1216 **power parameter**1217 P_p 1218 beam-related power quantity used in the numerator of the general **thermal index** relationship

1219 Note 1 to entry: See Formula A.4.

1220 Note 2 to entry: The meaning of this quantity depends on the *TI* to be evaluated, see A.5.1 and A.5.2. In general
1221 terms, it will be the measured quantity responsible for the estimation of the specific temperature rise.1222 Note 3 to entry: **Power parameter** is expressed in watts (W).1223 **3.73**1224 **prudent-use statements**1225 affirmations of the principle that only necessary clinical information should be acquired and that
1226 high exposure levels and long exposure times should be avoided

1227 Note 1 to entry: See Bibliography [3],[4],[5],[6].

1228 **3.74**1229 **pulse-average intensity**1230 I_{pa} 1231 quotient of the **pulse-intensity integral** to the **pulse duration** at a particular point in an
1232 acoustic field

1233 Note 1 to entry: This definition applies to pulses and bursts.

1234 Note 2 to entry: **Pulse-average intensity** is expressed in units of watt per metre squared (Wm^{-2}).

1235 [SOURCE: IEC 62127-1:2022, definition 3.53]

1236 **3.75**1237 **pulse duration**1238 t_d 1239 1,25 times the interval between the time when the time integral of the square of the
1240 **instantaneous acoustic pressure** reaches 10 % and 90 % of its final value1241 Note 1 to entry: The final value of the time integral of the square of the **instantaneous acoustic pressure** is the
1242 **pulse-pressure-squared integral**.1243 Note 2 to entry: **Pulse duration** is expressed in seconds (s).

1244 Note 3 to entry: See Figure 4 of IEC 62127-1.

1245 [SOURCE: IEC 62127-1:2022, definition 3.54]

1246 **3.76**1247 **pulse-intensity integral**1248 p_{ii} 1249 time integral of the **instantaneous intensity** at a particular point in an acoustic field integrated
1250 over the **acoustic pulse waveform**1251 Note 1 to entry: For measurement purposes referred to in this International Standard, **pulse-intensity integral** is
1252 proportional to **pulse-pressure-squared integral**.1253 Note 2 to entry: The **pulse-intensity integral** is expressed in units of joule per metre squared (Jm^{-2}).

1254 [SOURCE: IEC 62127-1:2022, definition 3.55]

1255 **3.77**1256 **pulse-pressure-squared integral**1257 pp_{si} 1258 time integral of the square of the **instantaneous acoustic pressure** at a particular point in an
1259 acoustic field integrated over the **acoustic pulse waveform**

1260 Note 1 to entry: The **pulse-pressure-squared integral** is expressed in units of pascal squared times second
1261 (Pa²s).

1262 [SOURCE: IEC 62127-1:2022, definition 3.56]

1263 3.78

1264 **pulse repetition period**

1265 *prp*

1266 time interval between equivalent points on successive pulses or tone-bursts

1267 Note 1 to entry: In general, for **non-scanning modes** the **pulse repetition period** needs to be adjusted to
1268 represent a 'per-second' average taking into account interruptions-in, or non-constant, pulsing; e.g. such as can
1269 occur in **combined operating modes**.

1270 Note 2 to entry: The **pulse repetition period** is expressed in seconds (s).

1271 [SOURCE: IEC 62127-1:2022, definition 3.57, modified - Note 1 to entry has been added.]

1272 3.79

1273 **pulse repetition rate**

1274 *prr*

1275 reciprocal of the **pulse repetition period**

1276 Note 1 to entry: The **pulse repetition rate** is expressed in hertz (Hz).

1277 [SOURCE: IEC 62127-1:2022, definition 3.58]

1278 3.80

1279 **quasi-linear instantaneous acoustic pressure**

1280 $p_{ql}(t)$

1281 scaled pressure minus the ambient pressure at a particular instant in time and at a particular
1282 point in an acoustic field

1283 Note 1 to entry: Following the methods of IEC TS 61949, with modifications as noted here, quasi-linear pressure
1284 values are determined for any source pressure value by applying a **scaling factor**, determined at a location close to
1285 the transducer, to the values of **instantaneous acoustic pressure** obtained with **local distortion parameter** value
1286 $\leq 1,0$ at the point in the acoustic field or in a specified plane.

1287 Note 2 to entry: **Quasi-linear instantaneous acoustic pressure** is expressed in pascals (Pa).

1288 Note 3 to entry: The chosen threshold value of 1,0 for the **local distortion parameter** is higher than the value of
1289 0,5 in IEC TS 61949:2007.

1290 3.81

1291 **quasi-linear peak-rarefactional acoustic pressure**

1292 $p_{r,ql}$

1293 maximum value of the modulus of the scaled negative **instantaneous acoustic pressure** in an
1294 acoustic field or in a specified plane during an **acoustic repetition period**

1295 Note 1 to entry: Following the methods of IEC TS 61949, with modifications as noted here, the value is determined
1296 by applying a **scaling factor**, determined at a location close to the transducer, to the values of **peak-rarefactional**
1297 **acoustic pressure** obtained with **local distortion parameter** value ≤ 1.0 at the point in the acoustic field or in a
1298 specified plane.

1299 Note 2 to entry: **Quasi-linear peak-rarefactional acoustic pressure** is expressed as a positive number.

1300 Note 3 to entry: **Quasi-linear peak-rarefactional acoustic pressure** is expressed in pascals (Pa).

1301 Note 4 to entry: The chosen threshold value of 1.0 for the **local distortion parameter** is higher than the value of
1302 0.5 in IEC TS 61949:2007.

3.82**quasi-linear pulse-pressure-squared integral** $ppsi_{ql}$

time integral of the square of the **quasi-linear instantaneous acoustic pressure** at a particular point in an acoustic field integrated over the acoustic pulse waveform

$$ppsi_{ql} = \int p_{ql}^2(t) dt \quad (26)$$

Note 1 to entry: The **quasi-linear pulse-pressure-squared integral** is expressed in units of pascal squared times second (Pa²s).

3.83**quasi-linear source acoustic pressure** $p_{source,ql}$

for a given **transmit pattern**, the **source acoustic pressure** corresponding to **quasi-linear transmit conditions**

3.84**quasi-linear transmit conditions**

for a given **transmit pattern**, and for a selected location in the acoustic field, **quasi-linear transmit conditions** exist, at that location, when the value of the **local distortion factor**, σ_q , is $\leq 1,0$ for the acoustic pressure waveform corresponding to the **transmit pattern**

Note 1 to entry: The chosen threshold value of 1,0 for the **local distortion parameter** is higher than the value of 0,5 in IEC TS 61949:2007.

3.85**scaling factor**

for a given **transmit pattern**, the ratio of the value of an acoustic parameter measured at the **depth for scaling** (a location close to the transducer) to the value of the same parameter measured at the same location under quasi-linear conditions

Note 1 to entry: Quasi-linearity ($\sigma_q \leq 1,0$) is determined at the point of interest, per the definition for **quasi-linear transmit conditions**.

Note 2 to entry: Either a hydrophone or a RFB target is used at the **depth for scaling** for determining **scaling factors**.

Note 3 to entry: Definition 3.51 defines the **depth for scaling** and considerations to include in choosing it.

Note 4 to entry: The underlying concept of scaling goes back to IEC TS 61949:2007. The definition of the **scaling factor**, however, has been substantially modified and expanded here to accommodate the three specific implementations of 3.85.1, 3.85.2 and 3.85.3.

3.85.1**pressure based scaling factor** S_p

source acoustic pressure of interest (the **target source pressure**) divided by the **source acoustic pressure** under **quasi-linear transmit conditions**

$$S_p = \frac{p_{source,target}}{p_{source,ql}} \quad (27)$$

3.85.2**power based scaling factor** S_p

acoustic power corresponding to the **target source acoustic pressure** of interest divided by the **acoustic power** under **quasi-linear transmit conditions**