

Medical electrical equipment —

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

The European Standard EN 60601-2-37:2001, with the incorporation of amendments A1:2005 and A2:2005, has the status of a British Standard

ICS 11.040.55; 17.140.50

National foreword

This British Standard is the official English language version of EN 60601-2-37:2001, including amendments A1:2005 and A2:2005. It is identical with IEC 60601-2-37:2001, including amendments 1:2004 and 2:2005.

The start and finish of text introduced or altered by IEC amendment is indicated in the text by tags **A1** **A1**. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated in the text by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/62/2, Diagnostic imaging equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

The United Kingdom objected to the publication of this standard for the following reasons:

- The UK National Committee believes that there are technical limitations of the proposed method for dealing with ultrasound safety, for example, failure to establish safe levels for the ultrasonic fields.
- It is also believed that the ultrasonic aspects of safety are not based on traceable quantities such as temperature rise which is an absolute biophysical quantity and are therefore not of defined risk.
- It is believed that thermal indices do not take account of complex configurations of the ultrasonic fields generated by modern diagnostic ultrasonic equipment and instead assume there is a single acoustic model which is a great simplification that could lead to inaccurate estimates being made.
- It is believed that the standard imposes an excessive measurement burden on the manufacturing industry.

Summary of pages

This document comprises a front cover, an inside front cover, page i, a blank page, the EN title page, pages 2 to 71 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

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Amendments issued since publication

Amd. No.	Date	Comments
16106	28 April 2006	See national foreword
16491 Corrigendum No. 1	30 June 2006	Correction to formatting errors at printing stage

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

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Medical electrical equipment
Part 2-37: Particular requirements for the safety of
ultrasonic medical diagnostic and monitoring equipment

(includes amendments A1:2005 and A2:2005)
(IEC 60601-2-37:2001 + A1:2004 + A2:2005)

Appareils électromédicaux
Partie 2-37: Règles particulières de
sécurité pour les appareils de diagnostic
et de surveillance médicaux à ultrasons
(inclut les amendements A1:2005 et
A2:2005)
(CEI 60601-2-37:2001 + A1:2004
+ A2:2005)

Medizinische elektrische Geräte
Teil 2-37: Besondere Festlegungen für
die Sicherheit von Ultraschall-Geräten
für die medizinische Diagnose und
Überwachung
(enthält Änderungen A1:2005 und
A2:2005)
(IEC 60601-2-37:2001 + A1:2004
+ A2:2005)

This European Standard was approved by CENELEC on 2001-09-25. Amendment A1:2005 was approved by CENELEC on 2004-12-07. Amendment A2:2005 was approved by CENELEC on 2005-12-01.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62B/428/FDIS, future edition 1 of IEC 60601-2-37, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-37 on 2001-09-25.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2002-07-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2004-10-01

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annexes AA and DD are normative and annexes BB, CC, EE, FF, GG and HH are informative.

In this standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: roman type;
- explanations, advice, notes, general statements and exceptions: smaller roman type;
- *test specifications and headings of subclauses: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-37:2001 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A1

The text of document 62B/524/FDIS, future amendment 1 to IEC 60601-2-37:2001, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-37:2001 on 2004-12-07.

The following dates were fixed:

- latest date by which the amendment has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2005-09-01
- latest date by which the national standards conflicting
with the amendment have to be withdrawn (dow) 2008-01-01

Endorsement notice

The text of amendment 1:2004 to the International Standard IEC 60601-2-37:2001 was approved by CENELEC as an amendment to the European Standard without any modification.

Foreword to amendment A2

The text of document 62B/591/FDIS, future amendment 2 to IEC 60601-2-37:2001, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A2 to EN 60601-2-37:2001 on 2005-12-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2006-09-01
- latest date by which the national standards conflicting
with the amendment have to be withdrawn (dow) 2008-12-01

Endorsement notice

The text of amendment 2:2005 to the International Standard IEC 60601-2-37:2001 was approved by CENELEC as an amendment to the European Standard without any modification.

CONTENTS

FOREWORD	6
INTRODUCTION	8

SECTION ONE: GENERAL

1 Scope and object	9
2 Terminology and definitions	11
3 General requirements	21
6 Identification, marking and documents	21

SECTION TWO: ENVIRONMENTAL CONDITIONS

SECTION THREE: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	24
20 Dielectric strength	25

SECTION FOUR: PROTECTION AGAINST MECHANICAL HAZARDS

SECTION FIVE: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

*35 Acoustical energy (including ultrasonic)	25
*36 Electromagnetic compatibility	25

SECTION SIX: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES

SECTION SEVEN: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures	27
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection	30

SECTION EIGHT: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

50 Accuracy of operating data	31
51 Protection against hazardous output	31

SECTION NINE: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN: CONSTRUCTIONAL REQUIREMENTS

Annex AA (normative) Terminology – Index of defined terms	33
Annex BB (informative) Guidance and rationale for particular subclauses	35
Annex CC (informative) Guidance in classification according to CISPR 11	39
Annex DD (normative) Test methods for determining the MECHANICAL INDEX and the THERMAL INDEX	40
Annex EE (informative) Relationships with other standards	45
Annex FF (informative) Guidance notes for measurement of OUTPUT POWER in SCANNING MODE	46
Annex GG (informative) Rationale and derivation of index models	50
Annex HH (informative) Guidance on the interpretation of <i>TI</i> and <i>MI</i> to be used to inform the OPERATOR	64
Annex II (informative) Example set-up to measure surface temperature for externally applied transducers	67
Bibliography	70
Figure FF.1 – Suggested 1 cm-wide aperture mask	48
Figure FF.2 – Suggested orientation of probe, mask slit, and RFB target	48
Figure FF.3 – Suggested orientation of probe, mask slit, and 1 cm RFB target	48
Figure GG.2a – Focused transducer with a large aperture	62
Figure GG.2b – Focused transducer with smaller aperture ($\geq 1 \text{ cm}^2$)	62
Figure GG.2c – Focused transducer with a weak focus ($A_{\text{eq}} > 1 \text{ cm}^2$)	63
Figure GG.2d – Weakly focused transducer	63
Figure II.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers	69
Table 101 – Acoustic output reporting table	24
Table 102 – Overview of the tests noted under 42.3	30
Table DD.1 – Summary of combination formulae for each of the THERMAL INDEX categories	44
Table DD.2 – Summary of the acoustic quantities required for the determination of the indices	44
Table GG.1 – THERMAL INDEX categories and models	52
Table GG.2 – THERMAL INDEX formulae	56
Table HH.1 – Relative importance of maintaining low exposure indices in various scanning situations	65
Table II.1 – Acoustic and thermal properties of tissues and materials	67
Table II.2 – Preparation of the soft tissue mimicking material (TMM)	68

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the safety of ultrasonic diagnostic and monitoring equipment

FOREWORD

- 1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The 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 the 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 National Committees.
- 3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-37 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/428/FDIS	62B/440/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annexes AA and DD form an integral part of this Particular Standard.

Annexes BB, CC, EE, FF, GG and HH are for information only.

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*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IEC 60601-1: IN SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2002. At this date, the publication will be

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

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

INTRODUCTION

In this Particular Standard, safety requirements additional to those in the General Standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

Guidance and a rationale for the requirements of this Particular Standard are given below.

Knowledge of the reasons for these requirements will not only facilitate the proper application of this Particular Standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology.

General guidance and rationale

The approach and philosophy used in drafting this particular standard for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in current standards in the IEC 60601-2 series that apply to other diagnostic modalities, such as X-ray equipment and magnetic resonance systems.

In each case, the safety standard is intended to require increasing sophistication of output display indicators and/or controls with increasing energy levels in the interrogating field of diagnosis. Thus, for all such diagnostic modalities, it is the responsibility of the OPERATOR to understand the risk of the output of the equipment, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

 It should be noted that although UD-3 Rev.1, 1998¹ was developed as a national standard, it has since been referenced by numerous countries worldwide and by all internationally operating manufacturers and test houses; regulatory authorities also follow the standard, as it has become a *de facto* international standard. The material taken from UD-3 Rev.1, 1998 forms only a part of this Particular Standard.

This standard contains normative measurement methodologies. These clauses may be replaced in a future revision by reference to an appropriate future measurement standard.

This standard does not cover ultrasonic therapeutic equipment. Equipment used for the imaging and diagnosis of body structures by ultrasound in conjunction with other medical procedure is covered.

¹ See reference [19] in the Bibliography. 

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment

SECTION ONE: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies particular safety requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 2.1.145.

This standard does not cover ultrasonic therapeutic equipment; however, equipment used for the imaging of body structures by ultrasound in conjunction with therapeutic modalities is covered.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of ULTRASONIC DIAGNOSTIC EQUIPMENT and those aspects thereof which are directly related to safety.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as the “General Standard”, consisting of

IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety* and its Amendments 1 (1991) and 2 (1995)

☐_{A1} IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests* ☐_{A1}

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1-4: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems* and its Amendment 1 (1999)

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

“Addition” means that the text of this Particular Standard is additional to the requirements of the General Standard.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk (*). These rationales can be found in an informative annex BB. Annex BB should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or of a Collateral Standard takes precedence over the corresponding general requirement(s).

1.3.101 Related international standards

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61102:1991, *Measurement and characterisation of ultrasonic fields using hydrophones in the frequency range 0,5 MHz to 15 MHz*

IEC 61157:1992, *Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment*

IEC 61161:1992, *Ultrasonic power measurement in liquids in the frequency range 0,5 MHz to 25 MHz*

Amendment 1 (1998)

 ISO 14971:2000, *Medical devices – Application of risk management to medical devices*
Amendment 1 (2003) 

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.1.101

ACOUSTIC ATTENUATION COEFFICIENT

coefficient intended to account for ultrasonic attenuation of tissue between the source and a specified point

Symbol: α

Unit: decibels per centimetre per megahertz, dB cm⁻¹ MHz⁻¹

2.1.102

ACOUSTIC WORKING FREQUENCY

arithmetic mean of the most widely separated frequencies f_1 and f_2 at which the amplitude of the pressure spectrum of the acoustic signal is 3 dB lower than the peak amplitude [3.4.2 of IEC 61102, modified]

Symbol: f_{awf}

Unit: megahertz, MHz

2.1.103

ATTENUATED OUTPUT POWER

value of the acoustic OUTPUT POWER after attenuation and at a specified distance from the transducer, and given by

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

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

P_{α} is the ATTENUATED OUTPUT POWER in milliwatts;

P is the OUTPUT POWER in milliwatts measured in water.

Symbol: P_{α}

Unit: milliwatts, mW

2.1.104

ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE

value of the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE after attenuation and at a specified point, and given by

$$p_{ra}(z) = p_r(z) 10^{(-\alpha z f_{awf}/20)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest, in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$p_r(z)$ is the PEAK-RAREFACTIONAL ACOUSTIC PRESSURE measured in water.

Symbol: p_{ra}

Unit: megapascals, MPa

2.1.105

ATTENUATED PULSE-AVERAGE INTENSITY

value of the acoustic PULSE-AVERAGE INTENSITY after attenuation and at a specified point, and given by

$$I_{pa,\alpha} = I_{pa}(z) 10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY, at distance z in megahertz;

$I_{pa}(z)$ is the PULSE-AVERAGE INTENSITY measured in water, in milliwatts per centimetre squared.

Symbol: $I_{pa,\alpha}$

Unit: watts per centimetre squared, W cm⁻²

2.1.106

ATTENUATED PULSE-INTENSITY INTEGRAL

value of the PULSE-INTENSITY INTEGRAL after attenuation and at a specified point, and given by

$$I_{pi,\alpha} = I_{pi} 10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$I_{pi,\alpha}$ is the ATTENUATED PULSE-INTENSITY INTEGRAL in millijoules per centimetre squared;

I_{pi} is the PULSE-INTENSITY INTEGRAL measured in water in millijoules per centimetre squared.

Symbol: $I_{pi,\alpha}$

Unit: millijoules per centimetre squared, mJ cm⁻²

2.1.107

ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY

value of the SPATIAL-PEAK TEMPORAL AVERAGE INTENSITY after attenuation and at a specified distance z , and given by

$$I_{zpta,\alpha}(z) = I_{zpta}(z) 10^{(-\alpha z f_{awf}/10)}$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$I_{zpta}(z)$ is the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, at a specified distance z in milliwatts per centimetre squared measured in water.

Symbol: $I_{zpta,\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm⁻²

2.1.108

ATTENUATED TEMPORAL-AVERAGE INTENSITY

value of the TEMPORAL-AVERAGE INTENSITY after attenuation and at a specified point, and given by

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

where

α is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz;

z is the distance from the source to the point of interest in centimetres;

f_{awf} is the ACOUSTIC WORKING FREQUENCY in megahertz;

$I_{\text{ta},\alpha}(z)$ is the ATTENUATED TEMPORAL-AVERAGE INTENSITY in milliwatts per centimetre squared;

$I_{\text{ta}}(z)$ is the TEMPORAL-AVERAGE INTENSITY measured in water in milliwatts per centimetre squared.

Symbol: $I_{\text{ta},\alpha}(z)$

Unit: milliwatts per centimetre squared, mW cm⁻²

2.1.109

BEAM AREA

area in a specified plane perpendicular to the BEAM-ALIGNMENT AXIS consisting of all points at which the PULSE-INTENSITY INTEGRAL is greater than a specified fraction of the maximum PULSE-INTENSITY INTEGRAL in that plane

[3.6 of IEC 61102, modified]

NOTE For measurement purposes the PULSE INTENSITY INTEGRAL can be taken as being proportional to the PULSE PRESSURE-SQUARED INTEGRAL

2.1.110

BEAM ALIGNMENT AXIS

straight line joining the points of maximum PULSE INTENSITY INTEGRAL measured at several different distances in the far field. For the purposes of alignment, this line may be projected to the face of the ULTRASONIC TRANSDUCER

[3.5 of IEC 61102, modified]

2.1.111

BONE THERMAL INDEX

THERMAL INDEX for applications, such as foetal (second and third trimester) or neonatal cephalic (through the fontanelle), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

Symbol: TIB

Unit: None

NOTE See annex DD.4.2 and DD.5.2 for methods of determining the BONE THERMAL INDEX.

2.1.112

BOUNDED OUTPUT POWER

OUTPUT POWER emitted in SCANNING MODE from a region of the active area of the transducer whose width in the scan plane is limited to 1 cm

Symbol: P_1

Unit: milliwatts, mW

2.1.113

BREAK-POINT DEPTH

value equal to 1,5 times the EQUIVALENT APERTURE DIAMETER, and given by

$$z_{bp} = 1,5 D_{eq}$$

where

D_{eq} is the EQUIVALENT APERTURE DIAMETER.

Symbol: z_{bp}

Unit: centimetres, cm

2.1.114

COMBINED-OPERATING MODE

mode of operation of an EQUIPMENT which combines more than one DISCRETE-OPERATING MODE [3.6 of IEC 61157]

2.1.115

CRANIAL-BONE THERMAL INDEX

THERMAL INDEX for applications, such as paediatric and adult cranial applications, in which the ultrasound beam passes through bone near the beam entrance into the body

Symbol: *TIC*

Unit: None

NOTE See annex DD.4.3 for methods of determining the CRANIAL BONE THERMAL INDEX.

2.1.116

DEFAULT SETTING

specific state of control, the ULTRASONIC DIAGNOSTIC EQUIPMENT will enter upon power-up, new PATIENT select or change from non-foetal to foetal applications

2.1.117

DEPTH FOR BONE THERMAL INDEX

distance from the plane where the -12 dB OUTPUT BEAM DIMENSIONS are determined along the BEAM ALIGNMENT AXIS to the plane where the product of ATTENUATED OUTPUT POWER and ATTENUATED PULSE-INTENSITY INTEGRAL is maximum

Symbol: z_b

Unit: centimetres, cm

2.1.118

DEPTH FOR SOFT-TISSUE THERMAL INDEX

distance from the plane where the -12 dB OUTPUT BEAM DIMENSIONS are determined along the BEAM ALIGNMENT AXIS to the plane at which the lower value of the ATTENUATED OUTPUT POWER and the product of the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY and 1 cm² is maximized over the distance range equal to, or more than, 1,5 times the EQUIVALENT APERTURE DIAMETER

Symbol: z_s

Unit: centimetres, cm

NOTE In this Particular Standard, the restricted definition of SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY from 3.49 of IEC 61102 relating to a specified plane is used where SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY is replaced by ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY.

2.1.119

DISCRETE-OPERATING MODE

mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT in which the purpose of the excitation of the ULTRASONIC TRANSDUCER or ULTRASONIC TRANSDUCER element group is to utilize only one diagnostic methodology
[3.7 of IEC 61157]

2.1.120

EQUIVALENT APERTURE DIAMETER

diameter of a circle whose area is the –12 dB OUTPUT BEAM AREA and given by

$$D_{eq} \equiv \sqrt{\frac{4}{\pi} A_{aprt}}$$

where

A_{aprt} is the –12 dB OUTPUT BEAM AREA.

Symbol: D_{eq}

Unit: centimetres, cm

NOTE This formula gives the diameter of a circle whose area is the –12 dB OUTPUT BEAM AREA. It is used in the calculation of the CRANIAL-BONE THERMAL INDEX and the SOFT TISSUE THERMAL INDEX.

2.1.121

EQUIVALENT BEAM AREA

value of the area of the acoustic beam at the distance z in terms of power and intensity, and given by

$$A_{eq}(z) \equiv \frac{P_{\alpha}}{I_{zpta,\alpha}(z)} = \frac{P}{I_{zpta}(z)}$$

where

$P_{\alpha}(z)$ is the ATTENUATED OUTPUT POWER, at the distance z , in milliwatts;

$I_{zpta,\alpha}(z)$ is the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, at the distance z , in milliwatts per square centimetre;

P is the OUTPUT POWER in milliwatts;

$I_{zpta}(z)$ is the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, at the distance z , in milliwatts per square centimetre; and

z is the distance from the source to the specified point in centimetres.

Symbol: $A_{eq}(z)$

Unit: centimetres squared, cm²

2.1.122

EQUIVALENT BEAM DIAMETER

value of the diameter of the acoustic beam at the distance z in terms of the EQUIVALENT BEAM AREA, and given by

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

where

$A_{eq}(z)$ is the EQUIVALENT BEAM AREA;

z is the distance from the source to the specified point.

Symbol: $d_{eq}(z)$

Unit: centimetres, cm

2.1.123

FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT

means by which the EQUIPMENT establishes values of the acoustic output quantities independent of direct OPERATOR control

2.1.124

MECHANICAL INDEX

A_1 the displayed parameter representing potential cavitation bio-effects

NOTE See DD.2.2 for methods of determining the MECHANICAL INDEX. A_1

2.1.125

MULTI-PURPOSE ULTRASONIC EQUIPMENT

ultrasonic equipment which is intended for more than one clinical application

2.1.126

NON-SCANNING MODE

mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses which give rise to ultrasonic scan lines that follow the same acoustic path [3.12 of IEC 61157, modified]

2.1.127

–12 dB OUTPUT BEAM AREA

area of the ultrasonic beam derived from the –12 dB OUTPUT BEAM DIMENSIONS [3.13 of IEC 61157, modified]

Symbol: A_{aprt}

Unit: centimetre squared, cm^2

2.1.128

–12 dB OUTPUT BEAM DIMENSIONS

dimensions of the ultrasonic beam (–12 dB PULSE BEAM WIDTH) in specified directions normal to the BEAM ALIGNMENT AXIS and at the transducer output face [3.14 of IEC 61157, modified]

NOTE 1 For reasons of measurement accuracy the –12 dB OUTPUT BEAM DIMENSIONS 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 (3.14 of IEC 61157, modified).

NOTE 2 For contact transducers, these dimensions can be taken as the dimensions of the radiating element.

Symbol: X, Y

Unit: centimetres, cm

2.1.129

OUTPUT POWER

time-average power radiated by an ULTRASONIC TRANSDUCER into an approximately free field under specified conditions in a specified medium, preferably water [3.5 of IEC 61161, modified]

Symbol: P

Unit: milliwatts, mW

2.1.130

PEAK-RAREFACTIONAL ACOUSTIC PRESSURE

maximum of the modulus of the negative instantaneous acoustic pressure in an acoustic field during an acoustic repetition period
[3.34 of IEC 61157, modified]

Symbol: p_r

Unit: megapascals, MPa

2.1.131

PRUDENT-USE STATEMENT

affirmation of the principle advising avoidance of primarily high exposure levels and secondarily long exposure times while acquiring necessary clinical information

2.1.132

PULSE-AVERAGE INTENSITY

ratio of the PULSE INTENSITY INTEGRAL I_{pi} to the PULSE DURATION t_d

Symbol: I_{pa}

Unit: watts per square centimetre, $W\ cm^{-2}$

2.1.133

PULSE BEAM-WIDTH

distance between two points, on a specified surface in a specified direction passing through the point of maximum PULSE-PRESSURE-SQUARED INTEGRAL (p_i) in that surface, at which the PULSE-PRESSURE-SQUARED INTEGRAL is a specified fraction of the maximum value in that surface
[3.18 of IEC 61157, modified]

Symbol: d_{-6} (for PULSE BEAM-WIDTH defined at -6dB)

Unit: centimetres, cm

2.1.134

PULSE DURATION

1,25 times the interval between the time when the time integral of intensity in an acoustic pulse at a point reaches 10 % and when it reaches 90 % of the PULSE INTENSITY INTEGRAL
[3.30 of IEC 61102, modified]

Symbol: t_d

Unit: seconds, s

2.1.135

PULSE-INTENSITY INTEGRAL

time integral of the instantaneous intensity at a particular point in an acoustic field integrated over the acoustic pulse waveform
[3.31 of IEC 61102]

Symbol: I_{pi}

Unit: millijoules per centimetre squared, $mJ\ cm^{-2}$

2.1.136

PULSE-PRESSURE-SQUARED INTEGRAL

time integral of the square of the instantaneous acoustic pressure at a particular point in an acoustic field integrated over the acoustic pulse waveform
[3.33 of IEC 61102]

Symbol: p_i

Unit: Pascal squared seconds, Pa²s

2.1.137

PULSE REPETITION RATE

inverse of the time interval between two successive acoustic pulses
[3.35 of IEC 61102, modified]

Symbol: pr_r

Unit: hertz, Hz

2.1.138

SCANNING MODE

mode of operation of an ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses which give rise to scan lines that do not follow the same acoustic path
[3.21 of IEC 61157, modified]

2.1.139

SOFT TISSUE THERMAL INDEX

THERMAL INDEX related to soft tissues

Symbol: TIS

Unit: None

NOTE 1 See annex DD.5.1 and the following for methods of determination of the SOFT-TISSUE THERMAL INDEX.

NOTE 2 For the purposes of this document, soft tissue includes all body tissues and fluids but excludes skeletal tissues

2.1.140

SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY

maximum value of the TEMPORAL-AVERAGE INTENSITY in a specified plane at a specified distance z from the transducer
[3.49 of IEC 61102, modified]

Symbol: $I_{zpta}(z)$

Unit: milliwatts per centimetre squared, mW cm⁻²

NOTE In this standard the restricted definition from 3.49 of IEC 61102 relating to a specified plane is used.

2.1.141

TEMPORAL-AVERAGE INTENSITY

time-average of the instantaneous intensity at a particular point in an acoustic field
[3.53 of IEC 61102, modified]

Symbol: $I_{ta}(z)$

Unit: milliwatts per centimetre squared, mW cm⁻²

2.1.142

THERMAL INDEX

ratio of attenuated acoustic power at a specified point to the attenuated acoustic power required to raise the temperature at that point in a specific tissue model by 1 °C

Symbol: *TI*

Unit: None

2.1.143

TRANSDUCER ASSEMBLY

transducer housing (probe), any associated electronic circuitry and any liquids contained in the housing and the integral cable which connects the transducer probe to an ultrasound console [see 3.22 of IEC 61157]

2.1.144

TRANSMIT PATTERN

combination of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodization shape and relative timing/phase delay pattern across the aperture, resulting in a specific focal length and direction), and an electrical drive waveform of a specific fixed shape but variable amplitude

2.1.145

ULTRASONIC DIAGNOSTIC EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT which is intended for *in vivo* ultrasonic and monitoring examination for obtaining a medical diagnosis

NOTE See also definition 3.11 of IEC 61157: medical diagnostic ultrasonic equipment (or system) – combination of the ultrasound instrument console and the TRANSDUCER ASSEMBLY making up a complete diagnostic system.

2.1.146

ULTRASONIC TRANSDUCER

device capable of converting electrical energy to mechanical energy and/or mechanical energy to electrical energy, both within the ultrasonic frequency range

2.1.147

ESSENTIAL PERFORMANCE

performance characteristics necessary to maintain the RESIDUAL RISK within acceptable limits

[IEC 60601-1-2, definition 2.210]

NOTE See also 3.201.2 of IEC 60601-1-2. 