# INTERNATIONAL STANDARD

# IEC 60601-2-37

**Edition 1.1**

2004-10

Edition 1:2001 consolidated with amendment 1:2004

## Medical electrical equipment –

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



Reference number
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## Publication numbering

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# CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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# MEDICAL ELECTRICAL EQUIPMENT –

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

## 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.
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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.

This consolidated version of IEC 60601-2-37 consists of the first edition (2001) [documents 62B/428/FDIS and 62B/440/RVD] and its amendment 1 (2004) [documents 62B/524/FDIS and 62B/542/RVD].

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience.

It bears the edition number 1.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

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 the base publication and its amendments will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

A bilingual version of this 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, 1998[1] 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)

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

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)



## 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: $\alpha$

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

$\alpha$ 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;

$P_\alpha$ is the ATTENUATED OUTPUT POWER in milliwatts;

$P$ is the OUTPUT POWER in milliwatts measured in water.

Symbol: $P_\alpha$

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

$\alpha$ 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

$\alpha$ 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

$\alpha$ 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

$\alpha$ 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

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

where

| | |
|---|---|
| $\alpha$ | 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; |
| $f_{\mathrm{awf}}$ | is the ACOUSTIC WORKING FREQUENCY in megahertz; |
| $I_{\mathrm{ta},\alpha}(z)$ | is the ATTENUATED TEMPORAL-AVERAGE INTENSITY in milliwatts per centimetre squared; |
| $I_{\mathrm{ta}}(z)$ | is the TEMPORAL-AVERAGE INTENSITY measured in water in milliwatts per centimetre squared. |

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

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 $cm^2$ 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

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

where

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

Symbol: $D_{\mathrm{eq}}$

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

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

where

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

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

$P$ is the OUTPUT POWER in milliwatts;

$I_{\mathrm{zpta}}(z)$ 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: $A_{\mathrm{eq}}(z)$

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

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

where

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

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

Symbol: $d_{\mathrm{eq}}(z)$

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**
the displayed parameter representing potential cavitation bio-effects

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

**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: $A_{\mathrm{aprt}}$

Unit: centimetre squared, cm²

**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: $p_{\mathrm{r}}$

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, Pa$^2$s

**2.1.137**
**PULSE REPETITION RATE**
inverse of the time interval between two successive acoustic pulses
[3.35 of IEC 61102, modified]

Symbol: $prr$

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: $I_{\text{zpta}}(z)$

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: $I_{\text{ta}}(z)$

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.

## 2.101 List of symbols

| | |
|---|---|
| $\alpha$ | ACOUSTIC ATTENUATION COEFFICIENT |
| $A_{\mathrm{aprt}}$ | –12dB OUTPUT BEAM AREA |
| $C_{MI}$ | NORMALIZING COEFFICIENT |
| $D_{\mathrm{eq}}$ | EQUIVALENT APERTURE DIAMETER |
| $d_{-6}$ | PULSE BEAM WIDTH |
| $d_{\mathrm{eq}}$ | EQUIVALENT BEAM DIAMETER |
| $f_{\mathrm{awf}}$ | ACOUSTIC WORKING FREQUENCY |
| $I_{\mathrm{pa}}$ | PULSE-AVERAGE INTENSITY |
| $I_{\mathrm{pa},\alpha}$ | ATTENUATED PULSE-AVERAGE INTENSITY |
| $I_{\mathrm{pi}}$ | PULSE-INTENSITY INTEGRAL |
| $I_{\mathrm{pi},\alpha}$ | ATTENUATED PULSE-INTENSITY INTEGRAL |
| $I_{\mathrm{ta}}(z)$ | TEMPORAL-AVERAGE INTENSITY |
| $I_{\mathrm{ta},\alpha}(z)$ | ATTENUATED TEMPORAL-AVERAGE INTENSITY |
| $I_{\mathrm{zpta}}(z)$ | SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY |
| $I_{\mathrm{zpta},\alpha}(z)$ | ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY |
| $MI$ | MECHANICAL INDEX |
| $P$ | OUTPUT POWER |
| $P_{\alpha}$ | ATTENUATED OUTPUT POWER |
| $P_1$ | BOUNDED OUTPUT POWER |
| $p_{\mathrm{i}}$ | PULSE PRESSURE SQUARED INTEGRAL |
| $p_{\mathrm{r}}$ | PEAK-RAREFACTIONAL ACOUSTIC PRESSURE |
| $p_{\mathrm{ra}}$ | ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE |
| $prr$ | PULSE REPETITION RATE |
| $TI$ | THERMAL INDEX |
| $TIB$ | BONE THERMAL INDEX |
| $TIC$ | CRANIAL-BONE THERMAL INDEX |
| $TIS$ | SOFT-TISSUE THERMAL INDEX |
| $t_{\mathrm{d}}$ | PULSE DURATION |
| $X, Y$ | –12 dB OUTPUT BEAM DIMENSIONS |
| $z$ | DISTANCE FROM THE SOURCE TO A SPECIFIED POINT |
| $z_{\mathrm{b}}$ | DEPTH FOR $TIB$ |
| $z_{\mathrm{bp}}$ | BREAK-POINT DEPTH |
| $z_{\mathrm{s}}$ | DEPTH FOR $TIS$ |

# 3 General requirements

*This clause of the General Standard applies except as follows:*

### *3.101 ESSENTIAL PERFORMANCE

NOTE See 2.1.145 for intended use definition of ULTRASONIC DIAGNOSTIC EQUIPMENT.

The following are the potential sources of harm identified as characterizing the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT:

– noise on a waveform, artefacts, distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;
– the display of inaccurate numerical values associated with the diagnosis to be performed;
– the display of inaccurate safety-related indications;
– the production of unintended or excessive ultrasound output;
– the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
– the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.

In some circumstances the need for the repetition of an ultrasound examination should be evaluated as a potential hazard, for example, intra-corporeal investigation and stress testing for cardiopathic PATIENTS.

# 6 Identification, marking and documents

This clause of the General Standard applies except as follows:

### 6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

*Addition:*

aa) Compliance with EMC requirements

Intra-corporal TRANSDUCER ASSEMBLIES that do not comply with the electromagnetic compliance requirements of clause 36 shall have applied the following IEC symbol to the TRANSDUCER ASSEMBLY: symbol 14 of table DI in annex D of the General Standard.

*Replacement:*

*p) Output

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 51.2 bb), cc) or dd), and which allows the OPERATOR to directly vary the output levels, the action needed to increase or decrease the output levels shall be clear to the OPERATOR. This marking shall be of the nature of an active DISPLAY.

*Replacement*:

q) Physiological effects, symbols and warning statements

MULTI-PURPOSE ULTRASONIC EQUIPMENT capable of ultrasound output levels subject to 51.2 bb) or dd) should carry the marking described as symbol 14 in table DI of annex D of the General Standard, affixed to the CONTROL PANEL or other readily visible location. The purpose of this marking is to alert the OPERATOR to consult the INSTRUCTIONS FOR USE before operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT.

### 6.3 Marking of controls and instruments

*Additional items:*

aa) A display of THERMAL INDEX and MECHANICAL INDEX shall be provided in accordance with the requirements of 51.2, together with the declaration of accuracy described in 6.8.2 and 50.2.

bb) A display of the surface temperature of ULTRASONIC TRANSDUCERS intended for trans-oesophageal use shall be provided in accordance with 42.3, 50.2, and 51.2.

cc) A display relevant to ultrasound output levels (see 51.2) shall be clearly visible from the OPERATOR'S position, with the full name(s) or abbreviation(s) of the index (indices) displayed.

### 6.8.2 INSTRUCTIONS FOR USE

*Additional items:*

aa) INSTRUCTIONS FOR USE shall contain the following:

1) the procedures necessary for safe operation, drawing attention to the safety hazards which may occur as a result of an inadequate electrical installation when the APPLIED PART of the ULTRASONIC DIAGNOSTIC EQUIPMENT is of TYPE B;

2) the type of electrical installation to which the ULTRASONIC DIAGNOSTIC EQUIPMENT may be safely connected, including the connection of any POTENTIAL EQUALIZATION CONDUCTOR;

3) the safe use of internal and external TRANSDUCER ASSEMBLIES, and in particular that the ULTRASONIC DIAGNOSTIC EQUIPMENT is of the correct type for its intended application; for TRANSDUCER ASSEMBLIES intended for intra-corporeal use, a warning in the instructions not to activate the TRANSDUCER ASSEMBLY outside the PATIENT'S body if the TRANSDUCER ASSEMBLY, when so activated, would not comply with electromagnetic compliance requirements and may cause harmful interference with other equipment in the environment. The identification of interference with other equipment and mitigation techniques shall be included in the INSTRUCTIONS FOR USE if a reduction in test levels is claimed by the MANUFACTURER;

4) a description of those parts of the TRANSDUCER ASSEMBLY which may be immersed in water or other liquids either for NORMAL USE or performance assessment purposes;

5) a notice if the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts thereof are provided with protective means against burns to the PATIENT when used with HF surgical equipment. If no such means are incorporated, notice shall be given in the ACCOMPANYING DOCUMENTS and advice shall be given regarding the location and use of the TRANSDUCER ASSEMBLY to reduce the hazard of burns in the event of a defect in the HF surgical neutral electrode connection;

6) a recommendation calling the USER'S attention to the need for regular testing and periodic maintenance, and especially

   – inspection of the TRANSDUCER ASSEMBLY for cracks which allow the ingress of conductive fluid;

   – inspection of the TRANSDUCER ASSEMBLY cables and associated connectors;

7) the appropriate use of the ULTRASONIC DIAGNOSTIC EQUIPMENT to avoid mechanical damage to the TRANSDUCER ASSEMBLY;

8) for MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT capable of ultrasound output levels significantly greater than those typically used for certain intended applications of the ULTRASONIC DIAGNOSTIC EQUIPMENT, instructions regarding the avoidance of unintended acoustic output control settings and levels;

9) a PRUDENT-USE STATEMENT for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 51.2 bb), cc) or dd);

10) in a separate section descriptions of any DISPLAY or means by which the OPERATOR may modify the operation of the EQUIPMENT relevant to ultrasound output (see 8) and 9) above, and 6.8.3);

11) description of any DISPLAY or means by which the OPERATOR may modify the operation of the EQUIPMENT relevant to surface temperature for ULTRASONIC TRANSDUCERS intended for trans-oesophageal use;

12) if the surface temperature of the TRANSDUCER ASSEMBLY can exceed 41 °C, the maximum temperature shall be disclosed.

13) for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 51.2 bb), cc) or dd), information to the USER on how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX (*TI*) and MECHANICAL INDEX (*MI*) according to the guidance given in annex HH.

### 6.8.3 Technical description

*Additional item:*

aa) Technical data regarding acoustic output levels to be required in the OPERATOR'S manual.

For each mode, provide the maximum value of each index (as well as the associated parameters listed for the operating condition resulting in the maximum index value), for which the operating mode in question is the largest (or sole) contributor.

**Table 101 – Acoustic output reporting table**

| Index label | | | *MI* | *TIS* | | | *TIB* | *TIC* |
|---|---|---|---|---|---|---|---|---|
| | | | | Scan | Non-scan | | Non-scan | |
| | | | | | $A_{aprt} \leq 1\ cm^2$ | $A_{aprt} > 1\ cm^2$ | | |
| Maximum index value | | | X | X | X | X | X | X |
| Associated acoustic parameters | $p_{ra}$ | | X | | | | | |
| | $P$ | | | X | X | | X | X |
| | Min. of $[P_\alpha(z_s), I_{ta,\alpha}(z_s)]$ | | | | | X | | |
| | $z_s$ | | | | | X | | |
| | $z_{bp}$ | | | | | X | | |
| | $z_b$ | | | | | | X | |
| | $z$ at max. $I_{pi,\alpha}$ | | X | | | | | |
| | $d_{eq}\ (z_b)$ | | | | | | X | |
| | $f_{awf}$ | | X | X | X | X | X | X |
| | Dim of $A_{aprt}$ | X | | X | X | X | X | X |
| | | Y | | X | X | X | X | X |
| Other information | $t_d$ | | X | | | | | |
| | *prr* | | X | | | | | |
| | $p_r$ at max. $I_{pi}$ | | X | | | | | |
| | $d_{eq}$ at max. $I_{pi}$ | | | | | | X | |
| | $I_{pa,\alpha}$ at max. *MI* | | X | | | | | |
| Operating control conditions | Control 1 | | X | X | X | X | X | X |
| | Control 2 | | X | X | X | X | X | X |
| | Control 3 | | X | X | X | X | X | X |
| | … | | … | … | … | … | … | … |

NOTE 1 Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

NOTE 2 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 3 Information on *MI* and *TI* need not be provided if the equipment meets both exemption clauses given in 51.2 aa) and 51.2 dd).



## SECTION TWO: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

## SECTION THREE: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

### 19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

*Addition:*

**19.4** *g)5) For testing the TRANSDUCER ASSEMBLIES a saline solution in which the APPLIED PART is immersed shall be used.*

*Addition:*

**19.4** *h)9) For testing the TRANSDUCER ASSEMBLIES a saline solution in which the APPLIED PART is immersed shall be used.*

## 20 Dielectric strength

*Addition:*

**20.4** *h) For testing the TRANSDUCER ASSEMBLIES a saline solution in which the APPLIED PART is immersed shall be used.*

SECTION FOUR: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION FIVE: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

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

## *35 Acoustical energy (including ultrasonic)

*Replacement*:

**35.1** For requirements and recommendations specific to markings, DISPLAYS and technical descriptions relevant to emission of ultrasound, see Section One.

**35.2** For requirements and recommendations specific to accuracy of acoustic output data and protection against hazardous or undesired output levels, see Section Eight.

**35.3** Acoustic output shall be switched off when the image freeze facility is enabled.

## *36 Electromagnetic compatibility

*Addition:*

ULTRASONIC DIAGNOSTIC EQUIPMENT shall comply with the requirements of IEC 60601-1-2 with the following modifications.

### 36.201.1 Protection of radio services

*Replacement:*

ULTRASONIC DIAGNOSTIC EQUIPMENT shall be classified as Group 1 and class A or class B, in accordance with CISPR 11, as per their intended use, specified by the MANUFACTURER in the INSTRUCTIONS FOR USE. Guidance for classification according to CISPR 11 is reported in Annex CC of this standard.

## 36.202 IMMUNITY

### *36.202.1 f) Variable gain

*Addition:*

NOTE See Annex BB of this standard for gain adjustment technique.

### *36.202.1 j) Compliance criteria

*Replace the eighth to eleventh dashed items with the following:*

– noise on a waveform or artefacts or distortion in an image or error of a displayed numerical value which cannot be attributed to a physiological effect and which may alter the diagnosis;

– an error in a displayed safety related indication;

– unintended or excessive ultrasound output;

– unintended or excessive TRANSDUCER ASSEMBLY surface temperature;

– unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use;

### * 36.202.3 Radiated RF electromagnetic fields

b) Tests

*Replacement:*

3) According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 kHz modulation frequency (physiological simulation frequency), whichever represents the worst case condition. The modulation frequency adopted shall be disclosed in the test report.

### *36.202.6 Conducted disturbances, induced by RF fields

b) Tests

*Replacement:*

*3) PATIENT-coupled cables including the ULTRASOUND TRANSDUCER cable shall be tested using a current clamp. All PATIENT-coupled cables including the ULTRASOUND TRANSDUCER cable may be tested simultaneously using a single current clamp.*

*The ULTRASOUND TRANSDUCER of the ULTRASONIC DIAGNOSTIC EQUIPMENT and SYSTEM shall be terminated during the test as specified below. In all cases, no intentional decoupling device shall be used between the injection point and the PATIENT coupling point.*

– *For PATIENT coupling points that have conductive contact to the PATIENT, terminal M of the RC element (see CISPR 16-1-2) shall be connected directly to the conductive PATIENT connection, and the other terminal of the RC element shall be connected to the ground reference plane. If normal operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT cannot be verified with terminal M of the artificial hand connected to the coupling point, a PATIENT simulator may be used between terminal M of the artificial hand and the PATIENT coupling point or points.*

– *ULTRASOUND TRANSDUCERS shall be terminated with the artificial hand and RC element specified in CISPR 16-1-2. The metal foil of the artificial hand shall be sized and placed to simulate the approximate area of PATIENT and OPERATOR coupling in NORMAL USE.*

– *For ULTRASONIC DIAGNOSTIC EQUIPMENT that have multiple PATIENT coupling points intended to be connected to a single PATIENT, each artificial hand shall be tied to a single common connection and this common connection shall be connected to terminal M of the RC element, as specified in CISPR 16-1-2.*

*Replacement:*

6) *According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 kHz modulation frequency, whichever represents the worst-case condition. The modulation frequency adopted shall be disclosed in the test report.*

**36.202.7 Voltage dips, short interruptions and voltage variations on power supply input lines**

*a) Requirements

*Replacement:*

1) ULTRASONIC DIAGNOSTIC EQUIPMENT shall comply with the requirements of 36.202.1 j) at the IMMUNITY TEST LEVELS specified in Table 210. Deviation from the requirements of 36.202.1 j) is allowed at the IMMUNITY TEST LEVELS specified in Table 210, provided the ULTRASONIC DIAGNOSTIC EQUIPMENT remains safe, experiences no component failures and is restorable to the pre-test state with OPERATOR intervention. Determination of compliance is based upon performance of the ULTRASONIC DIAGNOSTIC EQUIPMENT during and after application of the test sequence. ULTRASONIC DIAGNOSTIC EQUIPMENT for which the RATED input current exceeds 16 A per phase are exempt from the testing specified in Table 210.

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

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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



## 42 Excessive temperatures

This clause of the General Standard applies except as follows:

**42.3** *Replacement:*

***42.3** ULTRASONIC TRANSDUCERS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 43 °C when measured under test conditions a)1) below.

In addition, ULTRASONIC TRANSDUCERS applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 50 °C when measured under test conditions a)2) below.

*Compliance is checked by operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT and temperature tests as follows.*

a) *Test conditions*

1) *The ULTRASONIC TRANSDUCER shall be tested under simulated use conditions.*

*Test conditions for simulated use include:*

– *the ULTRASONIC TRANSDUCER shall be coupled acoustically to and be initially in thermal equilibrium with a test object such that the ultrasound emitted from the active surface of the ULTRASONIC TRANSDUCER enters the test object;*

– *the position and heating and/or cooling of the ULTRASONIC TRANSDUCER shall resemble those corresponding to the intended application of that ULTRASONIC TRANSDUCER;*

– *the position at which the temperature is measured shall be at the active surface of the ULTRASONIC TRANSDUCER;*

– *the test object shall have thermal and acoustical properties mimicking those of an appropriate tissue. In the case where the ULTRASONIC TRANSDUCER is intended for external use this test object shall account for a skin layer. The test object shall have values for the specific heat capacity, thermal conductivity and attenuation coefficient as specified in Note 1.*

NOTE 1 A general guidance for the acoustic properties of appropriate tissue is given in ICRU report 61 of the International Commission of Radiation Units and Measurements [28]. For test objects mimicking soft tissue, the material of the test object shall have the following properties:

– specific heat capacity: (3 500 ± 500) J $kg^{-1}$ $K^{-1}$;
– thermal conductivity: (0,5 ± 0,1) W $m^{-1}$ $K^{-1}$;
– attenuation at 5 MHz: (2,5 ± 1,0) dB $cm^{-1}$.

NOTE 2 As temperature changes occur at different rates in tissue surfaces containing skin, bone or soft tissue, careful consideration should be given to the choice of the model in relation to the intended use of the ULTRASONIC TRANSDUCER. Additional guidance can be found in Annex BB and in the TNO report PG/TG/2001.246 [30].

– *the test object shall be designed (for example, using acoustic absorbers) to minimize ultrasound reflections that could result in heating the surface of the ULTRASONIC TRANSDUCER;*

– *the minimum size of the test object should be such that increasing the size will have a negligible effect on the surface temperature of the TRANSDUCER ASSEMBLY;*

*Test methods: either test method A) or B) specified below shall be selected.*

NOTE 3 Because test method B) could yield inappropriate results where the ULTRASOUND DIAGNOSTIC EQUIPMENT uses a closed loop temperature monitoring system, test method A) shall be used for these cases.

***Test method A):*** *Test criteria based upon temperature measurements*

*In the case where the ULTRASONIC TRANSDUCER is intended for external use, the initial temperature of the surface of the test object at the object-transducer interface shall be not less than 33 °C and the ambient temperature shall be 23 °C ± 3 °C.*

*In the case where the ULTRASONIC TRANSDUCER is intended for internal/invasive use, the initial temperature of the surface of the test object material at the object-transducer interface shall be not less than 37 °C and the ambient temperature shall be 23 °C ± 3 °C.*

*To meet the requirements, the temperature of the radiating surface of the TRANSDUCER ASSEMBLY shall not exceed 43 °C during the test.*

***Test method B):*** *Test criteria based upon temperature rise measurements.*

NOTE 4 When following test method B), the temperature rise is defined as the difference between the surface temperature of the ultrasonic transducer just before the test and the maximum surface temperature of the ultrasonic transducer during the test.

*The initial temperature of the surface of the test object at the object-transducer interface shall be the ambient temperature and the ambient temperature shall be 23 °C ± 3 °C. In the case where the ULTRASONIC TRANSDUCER is intended for external use, the surface temperature rise of the ULTRASONIC TRANSDUCER shall not exceed 10 °C during the test. In the case where the ULTRASONIC TRANSDUCER is not intended for external use, the surface temperature rise of the ULTRASONIC TRANSDUCER shall not exceed 6 °C during the test.*

*In the case of an ULTRASONIC TRANSDUCER which is intended for external use, the surface temperature under test conditions 42.3 a)1) is equal to the sum of 33 °C and the measured temperature rise. In the case of an ULTRASONIC TRANSDUCER which is not intended for external use, the surface temperature under test conditions 42.3 a)1) is equal to the sum of 37 °C and the measured temperature rise.*

*To meet the requirements of this standard, the surface temperature calculated in this way shall not exceed 43 °C during the test.*

2) *Suspend the ULTRASONIC TRANSDUCER with a clean surface (no coupling gel applied) in still air or place it in a stationary position in an environmental chamber with minimal air flow to the surface of the ULTRASONIC TRANSDUCER.*

*Test criteria are based upon temperature rise measurements.*

*The ambient temperature shall be 23 °C ± 3 °C and the initial temperature of the radiating surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature. During the test the temperature rise of the radiating surface of the TRANSDUCER ASSEMBLY shall not exceed 27 °C.*

*To meet the requirements of not exceeding a surface temperature of 50 °C, the sum of the surface temperature rise obtained under these test conditions and 23 °C shall be regarded as the surface temperature under test conditions a)2).*

b) *Operating settings*

*Operate the ULTRASONIC DIAGNOSTIC EQUIPMENT at a setting which gives the highest surface temperature of the ULTRASONIC TRANSDUCER. The tests of a)1) and a)2) shall be performed under the same driving condition. The test driving condition shall be listed in the test report. The maximum temperature shall be disclosed in the instructions for use.*

c) *Duty cycle*

*The* ULTRASONIC DIAGNOSTIC EQUIPMENT *is continually operated for the duration of the test.*

1) *The test according to 42.3 a)1) is conducted for 30 min.*

NOTE When the ULTRASONIC DIAGNOSTIC EQUIPMENT automatically freezes its output earlier than the time period given in c)1), the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be switched on again immediately.

2) *The test according to 42.3 a)2) is conducted for the shorter of*

– *30 min or*

– *twice the time period limited by an automatic output freezing capability in case the* OPERATOR *is not able to switch off that capability.*

d) *Temperature measurement*

*The temperature of the* ULTRASONIC TRANSDUCER *can be measured by any appropriate means, including radiometry and thermocouple methods.*

*When a thermocouple is used, the thermocouple junction and adjacent thermocouple lead wire are to be securely held in good thermal contact with the surface of the material whose temperature is being measured. Position and secure the thermocouple in such a way that it will have negligible effect on the temperature rise of the area being measured.*

*The temperature shall be measured on the surface of the* ULTRASONIC TRANSDUCER *in those areas that give the highest surface temperature.*

*The measurement uncertainty shall be declared.*

NOTE 1 For the estimation of uncertainties, the ISO *Guide to the expression of uncertainty in measurement* should be used [18].

NOTE 2 Any means to measure the temperature should be a type that is not very sensitive to direct ultrasonic heating (for example, use a thin film or fine wire thermocouple). Also, the size of its sensitive area should be such that any averaging effect will be minimised. The effects of conductive losses, ultrasonic heating and spatial averaging should be taken into account when accessing the measurement uncertainty.

e) *Test criteria*

*The* ULTRASONIC TRANSDUCER *shall operate through the test at the duty cycle and for the duration specified in item c) above. During the test, the maximum temperature recorded or the maximum temperature rise recorded shall not have exceeded the limits specified.*

**Table 102 – Overview of the tests noted under 42.3**

| **Transducer type ➔** / **Test to be applied ➔** | | **External use** | **Non-external use** |
|---|---|---|---|
| **a) 1) Simulated use test** | **A) Temperature** | *Test object maintained at not less than 33 °C.*<br>The temperature shall not exceed 43 °C. | *Test object maintained at not less than 37 °C.*<br>The temperature shall not exceed 43 °C. |
| | **B) Temperature rise** | *Initially the temperature at the object-transducer interface shall be the ambient temperature.*<br>*The ambient temperature shall be 23 °C ± 3 °C.*<br>The temperature rise shall not exceed 10 °C. | *Initially the temperature at the object-transducer interface shall be the ambient temperature.*<br>*The ambient temperature shall be 23 °C ± 3 °C.*<br>The temperature rise shall not exceed 6 °C. |
| **a) 2) Still air test (no gel)** | **Temperature rise** | *The ambient temperature shall be 23 °C ± 3 °C.*<br>*Initially the temperature at the surface of* THE TRANSDUCER ASSEMBLY *shall be the ambient temperature*<br>The temperature rise shall not exceed 27 °C. | |

## 44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection

This clause of the General Standard applies except as follows:

### *44.6 Ingress of liquids

*Additional items:*

aa) Those parts of the TRANSDUCER ASSEMBLY specified by the MANUFACTURER which in NORMAL USE are likely to come into contact with the OPERATOR or PATIENT shall meet the requirements of DRIP-PROOF EQUIPMENT (IPX1). Connectors of the TRANSDUCER ASSEMBLIES shall be excluded from this requirement.

NOTE Cleaning and disinfection is included in NORMAL USE.

*Compliance is checked by the test prescribed for the second characteristic, numeral 1 of IEC 60529, with the TRANSDUCER ASSEMBLIES configured as in NORMAL USE, including the connection of any cables, but excluding the condition when the TRANSDUCER ASSEMBLY is disconnected from the ultrasound console.*

bb) Parts of the TRANSDUCER ASSEMBLIES specified by the MANUFACTURER intended to be immersed in NORMAL USE shall meet the requirements of WATERTIGHT EQUIPMENT (IPX7).

*Compliance is checked by the test prescribed for the second characteristic, numeral 7 of IEC 60529, with the exception of 14.2.7 a) and b).*

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

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

## 50 Accuracy of operating data

This clause of the General Standard applies except as follows:

### 50.2 Accuracy of controls and instruments

*Replacement*:

aa) The accuracy of the data and controls specific to acoustic output shall be specified, including the following:

– any DISPLAY indicating the ACOUSTIC OUTPUT POWER, if provided; see 6.3 and 51.2.

– technical data; see 6.8.3.

bb) The accuracy of the data and controls specific to the surface temperature of ULTRASONIC TRANSDUCERS intended for trans-oesophageal use shall be specified, including any display of surface temperature, if provided; see 6.3 and 51.2.

NOTE For the estimation of uncertainties, the ISO *Guide to the expression of uncertainty in measurement* should be used [18][1].

[1] Figures in square brackets refer to the bibliography.

## 51 Protection against hazardous output

This clause of the General Standard applies except as follows:

### 51.2 Indication of parameters relevant to safety

*Replacement*:

aa) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not capable of exceeding either a SOFT TISSUE THERMAL INDEX of 1,0, or a BONE THERMAL INDEX of 1,0 in any mode of operation then no display of the THERMAL INDEX is required (see also annex BB concerning 6.1p))

ULTRASONIC DIAGNOSTIC EQUIPMENT which meets the requirements for the declaration exemption under clause 6 of IEC 61157 is not expected to be capable of exceeding either a SOFT TISSUE THERMAL INDEX of 1,0, or a BONE THERMAL INDEX of 1,0, if, for all operating conditions, both $f_{awf}$ < 10,5 MHz, and $A_{aprt}$ < 1,25 cm$^2$. Consequently, there is no requirement to display the TI.

bb) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of exceeding either SOFT TISSUE THERMAL INDEX or BONE THERMAL INDEX of a value of 1,0, when any operational mode is active, then the capability shall be available for the OPERATOR to display both the SOFT TISSUE INDEX (*TIS*) (when exceeding a value of 0,4) and the BONE THERMAL INDEX (*TIB*) (when exceeding a value of 0,4), but not necessarily simultaneously, in such operational mode.

cc) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is intended solely for adult cephalic applications, then the THERMAL INDEX display need only include the CRANIAL-BONE THERMAL INDEX when equal to, or exceeding, a value of 1,0.

dd) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of exceeding a MECHANICAL INDEX of 1,0 in real-time B-mode operation (when no other mode is active), then the MECHANICAL INDEX shall be displayed when it equals or exceeds a value of 0,4 in such an operational mode.

ULTRASONIC DIAGNOSTIC EQUIPMENT which meets the requirements for the declaration exemption under clause 6 of IEC 61157 is not expected to be capable of exceeding a MECHANICAL INDEX of 1,0 if, for all operation conditions, $f_{awf}$ > 1,0 MHz. Consequently, there is no requirement to display the *MI*.

ee) For SYSTEMS that are not capable of real-time (B-mode) imaging, the SYSTEM shall allow the OPERATOR to display both a THERMAL INDEX (according to the requirements of aa) – cc) above) and the MECHANICAL INDEX (according to the requirements of dd) above), but need not be capable of displaying both indices simultaneously.

ff) The increments for the display of THERMAL INDICES, if displayed (see aa) – ee)), shall be no more than 0,2 for values of indices up to 2,0 and 0,5 for values of indices above 2,0.

gg) The increment for each display of MECHANICAL INDICES, if displayed (see aa) – ee)), shall be no more than 0,2 over the entire range of display.

hh) If an ULTRASONIC TRANSDUCER intended for trans-oesophageal use is capable of exceeding a surface temperature of 41 °C, then the surface temperature shall be displayed or some other indication provided to the OPERATOR when the surface temperature equals or exceeds a value of 41 °C (see 42.3).

**51.4 Accidental selection of excessive output values**

*Replacement:*

aa) For ULTRASONIC DIAGNOSTIC EQUIPMENT in which the design allows FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall switch to an appropriate DEFAULT SETTING upon power-up, entry of new PATIENT identification data or change from a non-foetal to a foetal application. These DEFAULT SETTING levels shall be established by the MANUFACTURER but may be reconfigured by the OPERATOR.

bb) For MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT in which the design does not allow FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall provide upon power-up, entry of new PATIENT identification data or change from a non-foetal to a foetal application, a reminder to the OPERATOR to check (and reset or change, if appropriate) the acoustic output and the MECHANICAL INDEX and/or THERMAL INDEX displayed.

SECTION NINE: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply.

SECTION TEN: CONSTRUCTIONAL REQUIREMENTS

The clauses and subclauses of this section of the General Standard apply.

# Annex AA
(normative)

## Terminology – Index of defined terms

# Annex BB
(informative)

## Guidance and rationale for particular subclauses

**concerning 1.1 Scope**

The content of this Particular Standard has largely been determined to cover ultrasonic medical diagnostic and monitoring EQUIPMENT including ULTRASONIC echo ranging devices (both manual and automatic scanning), Doppler echo EQUIPMENT and combinations thereof.

The scope has been kept general to encompass as much of the wide range of (non-therapeutic) medical ULTRASONIC DIAGNOSTIC EQUIPMENT as possible. For example, some EQUIPMENT is capable of being used with numerous different types, power ratings and frequencies of ULTRASONIC TRANSDUCER to cover a wide variety of applications. This has been taken into account in drafting this Particular Standard.

It is anticipated that later editions of this Particular Standard may well specify different or additional parameters for specification relative to safety, reflecting the state of biophysical understanding and measurement technology as will develop in the future.

**concerning 6.1 p) Output**

With certain EQUIPMENT in some operating modes, 10 or more different controls can affect ultrasound output levels. While small changes in output level are not of concern to the OPERATOR, inadvertent large increases are to be avoided in many cases, as with MULTI-PURPOSE EQUIPMENT. (See 6.3c) and 51.4 of the General Standard.)

On most EQUIPMENT, a single control means is generally provided for changing the amplitude of the acoustic output, while leaving other parameters (such as pulse length, duty cycle, etc.) unchanged. Often, the OPERATOR must have some understanding of the operation of this control for effective use of the device, aside from concerns with safety. This requirement addresses the need to effectively indicate to the OPERATOR the control (or controls) whose primary function is to affect ultrasound output levels, and the action needed to increase or decrease output by manipulating this direct control means.

An exemption for EQUIPMENT not capable of generating output levels subject to 51.2 bb) or dd), has been implemented, since it is assumed that such devices are equally safe at all possible output levels.

**concerning 6.8.2 aa) 13)**

Written instructions, as well as pre-programmed application-specific default levels, are appropriate means for informing the OPERATOR of appropriate ultrasound output levels for different clinical uses.

**concerning 35 Acoustical energy (including ultrasonic)**

This Particular Standard places no upper limits on permitted levels of acoustic output

Concerns with possible excessive levels are addressed by requiring an interactive real-time DISPLAY of acoustic output, expressed in clinically meaningful parameters, such as the THERMAL INDICES and MECHANICAL INDICES as included in this standard.

**concerning 36 Electromagnetic compatibility**

**Subclause 36.201.1**

ULTRASONIC DIAGNOSTIC EQUIPMENT is categorized as class A (under IEC 60601-1-2) when the environment for the intended use as defined by the MANUFACTURER is in a hospital or a similar environment. For the extension of the intended use into a residential environment the ULTRASONIC DIAGNOSTIC EQUIPMENT is categorized as class B. For further details, see Annex CC.

**Subclause 36.202.1 f)**

ULTRASONIC DIAGNOSTIC EQUIPMENT that incorporates a variable gain shall be tested at the typical gain applied by the USER. This setting should be determined by using a tissue mimicking material or a flow phantom, appropriate for the application to adjust the gain and the other image enhancement adjustments to represent the typical settings applied by the USER. The phantom shall be removed prior to IMMUNITY testing in accordance with subclause 36.202 of IEC 60601-1-2.

If this requirement can be met with the normal software of the EQUIPMENT or SYSTEM, the test shall be performed using the normal software. If this requirement cannot be met using the normal software of the EQUIPMENT or SYSTEM, a method shall be provided to implement this operational mode. The use of special software may be required. If special software is used, it shall not inhibit changes in gain that may occur as a result of testing.

**Subclause 36.202.1 j)**

There is common agreement that it is not reasonable to require that nothing will happen when an electromagnetic disturbance is applied to an ULTRASOUND DIAGNOSTIC EQUIPMENT which is intended to acquire signals in the µV range by means of a transducer whose cable length is more than 2 m.

The sense of the requirement is that under the test conditions specified in 36.202, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Examples of conformance to the compliance criteria include:

- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image that may have regular dots or dashes or lines produced by the disturbance, but in a way that is recognisable as other than physiologic and that would not affect diagnosis;
- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image that may have lines on a Doppler trace, but in a way that is recognisable as other than physiologic and that would not affect diagnosis;
- ULTRASONIC DIAGNOSTIC EQUIPMENT displays an image and Doppler traces which may be covered with noise signals, but in a way that is recognisable as other than physiologic and that would not affect diagnosis.

**36.202.3 b)3) and 36.202.6 b)6)**

Table 209 of IEC 60601-1-2 lists a 2 Hz modulation frequency when the intended use of the device is “control, monitor or measure a physiological parameter” and 1 kHz modulation frequency for “all other” intended use. Ultrasound diagnostic devices are intended to analyse both slow physiological parameters, like heart wall motion, and relatively fast phenomena, like blood velocity (detected as Doppler shift in the range of the kHz).

**concerning 42.3 Excessive temperatures**

Diagnostic ULTRASONIC TRANSDUCERS are not intended to supply heat but do so because of energy loss within the TRANSDUCER ASSEMBLY and ultrasound absorption in the PATIENT.

In the still-air test of 42.3 of the General Standard, essentially all of the electrical energy is converted into heat within the TRANSDUCER ASSEMBLY, since ultrasound radiation into air (unlike that into the body) is highly inefficient. Due to the use of coupling gel and the usually low heat capacity of the ULTRASONIC TRANSDUCER surface layer, it can be expected that from the free-air situation into the normal use situation the surface temperature drops quickly. A modification of 42.3 to allow for a 50 °C limit in the still-air test is appropriate to ensure that in normal use conditions the temperature can drop to 43 °C within 1 min. (See 42.1, table Xa of the General Standard.)

This also counts for TRANSDUCER ASSEMBLIES intended for trans-oesophageal use. Although contact with the internal surface of the oesophagus is prolonged, the time in which the TRANSDUCER ASSEMBLY at its initial temperature is in contact with a single tissue site is relatively short. Furthermore, the transducer area which is heated is relatively small, providing little heat capacity, and the resulting heat is rapidly drawn away from the transducer as it passes through the mouth and into the oesophagus. As a result, no tissue encounters a temperature in excess of the steady-state temperature for clinical scanning for other than a brief moment. In the case of foetal endovaginal use, while exposure time plays an important role [17], because of intervening tissue and fluid structures and the same transient contact discussed for trans-oesophageal applications, the surface temperature of an endovaginal transducer does not translate directly to the temperature ultimately affecting the foetus.

When carrying out a risk analysis for the ULTRASOUND DIAGNOSTIC EQUIPMENT the USER of this standard has to take into account that the temperature limit of 43°C in the current draft of the third edition of IEC 60601-1 is only applicable for long term (more than 10 min) contact with healthy skin of adults. Special consideration should be given for an application on children. The influence of drugs and the condition of the PATIENT are factors that should be also considered in the risk-benefit analysis. With respect to further not foreseeable developments the safety of a long-term use of transducers (more than 41°C) inside the body is currently not well investigated. The standard committee assume that the safe use of temperatures higher than 41 °C on children, inside the body and on PATIENTS with possible risky conditions should also be a subject of the clinical evaluation.

Net tissue temperature rise results from the following mechanisms:

– heat conduction from the transducer;
– absorption of ultrasound in the tissue;
– cooling by heat conduction to other parts of the tissue;
– cooling by heat transport due to blood perfusion.

All TRANSDUCER ASSEMBLIES require test conditions and criteria appropriate to the unique clinical scanning environment encountered by the device.

As ultrasound diagnostic devices generally are used in temperature controlled locations the ambient temperature of 23 °C ± 3 °C has been chosen for the environment during the measurement of transducer surface temperature.

In NORMAL USE, a trans-oesophageal or other endo-cavitary transducer operates surrounded by tissue, such that the ambient temperature is the PATIENT's internal body temperature. Unlike the conditions encountered when operating the TRANSDUCER ASSEMBLY in still air, both ultrasound energy and heat from the TRANSDUCER ASSEMBLY are efficiently transferred into the adjoining tissue. Both the heat directly conducted from the TRANSDUCER ASSEMBLY, as well as the heat resulting from ultrasound absorption within the tissue, are carried off by heat transport effects such as blood perfusion, heat conduction and radiation.

In NORMAL USE, typically hand-held probes do not operate while surrounded by tissue; the body of the probe assembly is in contact with ambient air, while only the small portion of the probe intended to contact the patient will be exposed to an ambient temperature determined by patient's core body temperature.

*Explanatory notes concerning the test object setup are as follows:*

- *tissue-mimicking material (TMM) with thermal and acoustical properties similar to human tissue most appropriate to the typical use of the ULTRASONIC TRANSDUCER under test should be used. The TMM is intended both to inhibit cooling by convection and to model the acoustic properties of a specific tissue. The use of three different types of models can be justified:*
  - *a model with a bone mimic close to the surface;*
  - *a model with a skin mimic to the surface;*
  - *a model consisting of a soft tissue mimic.*
- *when the ULTRASONIC TRANSDUCER is intended for intra-cavity use the TRANSDUCER ASSEMBLY should be potted in a tissue-mimicking material (TMM) to a depth such that increasing the depth will have a negligible effect on the surface temperature of the TRANSDUCER ASSEMBLY;*
- *when the surface of the ULTRASONIC TRANSDUCER is curved, care should be taken to ensure that the whole surface is in contact with the model used to mimic the intended use.*
- *alternative materials may be used where the results can be shown to be comparable; most significantly, however, the material used shall exhibit an ultrasonic absorption coefficient and thermal properties appropriate to the intended model.*

*General guidance for the acoustic properties of appropriate tissue is given in ICRU report 61: Tissue substitutes, phantoms and computational modelling in medical ultrasound, 1998, ISBN 0-913394-60-2.*

*Directions for preparation and characterization of an appropriate liquid TMM is described by R. B. Chin, et al, "A reusable perfusion supporting tissue-mimicking material for ultrasound hyperthermia phantoms," Medical Physics, Vol. 17, No. 3, May/June 1990.*

*Alternative materials may be used where the results can be shown to be comparable; most significantly, however, the material used shall exhibit an ultrasonic absorption coefficient appropriate to the intended model.*

**concerning 44.6 Ingress of liquids**

All TRANSDUCER ASSEMBLIES are assumed to require some contact with fluids during normal operation. Some ULTRASONIC TRANSDUCER are designed to be immersed in water baths wherein the water bath provides a link in the acoustic coupling path to the PATIENT while other ULTRASONIC TRANSDUCER, employed for contact scanning, need only minimal contact with some coupling gel at the active surface of the PROBE. The MANUFACTURER is expected to specify, through knowledge of the application and PROBE design, the parts of the PROBE that may be wetted in NORMAL USE (see 6.8.2).

The requirement and test as specified are considered suitable for this EQUIPMENT and avoid conflict with the WATERTIGHT requirements of the General Standard. The tests specified are documented in IEC 60529. The IPX1 code indicates protection of EQUIPMENT against ingress of water with harmful effects by dripping; the IPX7 code indicates protection of EQUIPMENT against ingress of water with harmful effects by temporary immersion.

# Annex CC
(informative)

## Guidance in classification according to CISPR 11

Rules for classification and separation into groups of equipment are contained in CISPR 11. EQUIPMENT that is the subject of this Particular Standard is classified in Group 1 (under IEC 60601-1-2), since the device must intentionally generate radiofrequency energy and transmit it through a shielded external cable (up to 2 m or longer in length) to a TRANSDUCER ASSEMBLY at the end of the cable. The purpose of this annex is to provide summarized information for the assignment of the ULTRASONIC DIAGNOSTIC EQUIPMENT to the appropriate CISPR 11 class.

According to the subclause, **Groups** are separated as follows:

– *Group 1 ISM equipment*: group 1 contains all ISM equipment in which there is intentionally generated and/or used conductively coupled RF energy that is necessary for the internal functioning of the equipment itself.

– *Group 2 ISM equipment*: group 2 contains all ISM equipment in which RF energy is intentionally generated and/or used in the form of electromagnetic radiation for the treatment of material, and spark erosion equipment.

Subclause 4.2 of CISPR 11

According to the subclause, division into **Classes** is as follows:

– *Class A equipment* is equipment suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

  NOTE Although class A limits have been derived for industrial and commercial establishments, administrations may allow, with whatever additional measures are necessary, the installation and use of class A ISM equipment in domestic establishments or in an establishment connected directly to the public low-voltage power supply network.

– *Class B equipment* is equipment suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

# Annex DD
(normative)

# Test methods for determining the MECHANICAL INDEX and the THERMAL INDEX

## DD.1 Introduction

This clause defines methods for determining an exposure parameter relating to temperature rise in theoretical tissue-equivalent models, and also an exposure parameter for non-thermal effects. These exposure parameters, referred to as indices, are related to the safety of ULTRASONIC DIAGNOSTIC EQUIPMENT.

These indices shall be determined in accordance with DD.2 to DD.5 for a particular ultrasonic field configuration generated by a DISCRETE-OPERATING MODE of a specific ULTRASONIC DIAGNOSTIC EQUIPMENT. For COMBINED OPERATING MODES, the procedures specified in DD.6 shall be used.

Acoustic output measurements shall be undertaken using test methods based on the use of hydrophones in accordance with IEC 61102 or the use of radiation force balances for power measurements in accordance with IEC 61161. All such measurements shall be made in water (see also annex FF).

In all cases where BOUNDED OUTPUT POWER is determined, the location of the bounding mask or equivalent means (see annex FF) shall be such as to determine the largest value.

The value of the ACOUSTIC ATTENUATION COEFFICIENT shall be 0,3 dB cm$^{-1}$ MHz$^{-1}$. This value is selected as an appropriate attenuating coefficient for a homogeneous model intended to be equivalent to the attenuation in reasonable worst-case conditions of clinical use. The meaning of “reasonable worst case” is taken as that given by the World Federation for Ultrasound in Medicine and Biology [14], namely “that set of tissue properties and dimensions such that less than 2,5 % of patients have a higher calculated temperature increase or other thermal endpoint if their actual tissue properties or thickness differ from those employed in the calculations”.

NOTE The model used is not always applicable. Recent literature suggests that sometimes other models should be used [1].

The –12 dB OUTPUT BEAM AREA may be determined by using a raster scanned hydrophone.

## DD.2 Determination of MECHANICAL INDEX

### DD.2.1 Determination of attenuated peak-rarefactional pressure

The calculation of MECHANICAL INDEX requires the determination of the ATTENUATED PEAK-RAREFACTIONAL PRESSURE. This shall be determined at the location of the maximum ATTENUATED PULSE-INTENSITY INTEGRAL. This location should be determined according to the procedures set out in IEC 61102 for the location of peak PULSE-PRESSURE-SQUARED INTEGRAL, with the addition that for all measurement locations an ACOUSTIC ATTENUATION COEFFICIENT shall be applied to the PULSE-PRESSURE SQUARED INTEGRAL.

### DD.2.2 Calculation of MECHANICAL INDEX

The MECHANICAL INDEX shall be calculated from the expression as defined under 2.1.124:

$$MI = \frac{p_{ra} f_{awf}^{-1/2}}{C_{MI}}$$

where

$C_{MI}$ = 1 MPa MHz$^{-1/2}$;

$p_{ra}$ is the ATTENUATED PEAK-RAREFACTIONAL PRESSURE in megapascal;

$f_{awf}$ is the ACOUSTIC WORKING FREQUENCY in megahertz.

## DD.3 Determination of THERMAL INDEX – general

The method of determination of the THERMAL INDEX depends upon whether the field is formed in SCANNING MODE or NON-SCANNING MODE. Also for the SOFT-TISSUE THERMAL INDEX in NON-SCANNING MODE the method of determination depends on the –12 dB OUTPUT BEAM AREA. Each determination method is set out in the following sections.

## DD.4 Determination of THERMAL INDEX in NON-SCANNING MODE

### DD.4.1 Determination of SOFT-TISSUE THERMAL INDEX, *TIS*, for NON-SCANNING MODES

When the –12 dB OUTPUT BEAM AREA for the particular TRANSMIT PATTERN satisfies the condition $A_{aprt} \leq 1{,}0$ cm$^2$ then the SOFT-TISSUE THERMAL INDEX shall be determined following the procedures described in DD.4.1.3. Otherwise, the SOFT-TISSUE THERMAL INDEX shall be determined according to the procedures given in DD.4.1.1 and DD.4.1.2 below.

#### DD.4.1.1 Determination of the DEPTH FOR *TIS*, $z_s$, in NON-SCANNING MODE

The DEPTH FOR *TIS*, $z_s$, shall be determined as the depth at which the lower value of $P_\alpha$ and $I_{zpta,\alpha}(z) \times 1$ cm$^2$ is maximized over $z$, where $z \geq 1{,}5\ D_{eq}$. For this determination, $P_\alpha$ shall be in milliwatts and $I_{zpta,\alpha}(z)$ shall be in milliwatts per centimetre squared.

#### DD.4.1.2 Determination of SOFT-TISSUE THERMAL INDEX, *TIS*, for $A_{aprt}$ > 1 cm$^2$

The SOFT-TISSUE THERMAL INDEX, *TIS*, shall be calculated at the DEPTH FOR *TIS*, $z_s$, from:

$$TIS = \frac{P_\alpha f_{awf}}{C_{TIS1}}$$

or

$$TIS = \frac{I_{zpta,\alpha}(z_s) f_{awf}}{C_{TIS2}}$$

whichever is the lesser,

where

$C_{TIS1}$ = 210 mW MHz;

$C_{TIS2}$ = 210 mW cm$^{-2}$ MHz;

$P_\alpha$ is the ATTENUATED OUTPUT POWER in milliwatts;

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

$I_{zpta,\alpha}(z_s)$ is the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY in milliwatts per centimetre squared at the depth of *TIS*, $z_s$.

### DD.4.1.3 Determination of SOFT-TISSUE THERMAL INDEX, $TIS$, for $A_{aprt} \le 1$ cm2

If the –12 dB OUTPUT BEAM AREA satisfies the condition $A_{aprt} \le 1$ cm2, the SOFT-TISSUE THERMAL INDEX shall be calculated from

$$TIS = \frac{P\, f_{awf}}{C_{TIS1}}$$

where

$C_{TIS1}$ = 210 mW MHz;

$P$ is the OUTPUT POWER in milliwatts;

$f_{awf}$ is the ACOUSTIC WORKING FREQUENCY in megahertz.

### DD.4.2 Determination of BONE THERMAL INDEX, $TIB$, for NON-SCANNING MODES

The location of DEPTH FOR $TIB$, $z_b$, shall be carried out by determining the variation with the distance of the ATTENUATED OUTPUT POWER multiplied by the ATTENUATED PULSE-INTENSITY INTEGRAL. The position of the maximum value of this parameter shall be $z_b$.

The ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, $I_{zpta,\alpha}(z_b)$, at the DEPTH FOR $TIB$, $z_b$, shall be calculated from

$$I_{zpta,\alpha}(z_b) = I_{pi,\alpha}(z_b)\,prr$$

where

$I_{pi,\alpha}(z_b)$ is the ATTENUATED PULSE-INTENSITY INTEGRAL at the DEPTH FOR $TIB$, $z_b$, in millijoules per centimetre squared;

$prr$ is the PULSE REPETITION RATE in Hertz.

The BONE THERMAL INDEX, $TIB$, for the model where the insonified bone is near the focus, shall be calculated from:

$$TIB = \frac{\sqrt{P_\alpha(z)\, I_{zpta,\alpha}(z)}}{C_{TIB1}}$$

or

$$TIB = \frac{P_\alpha(z_b)}{C_{TIB2}}$$

whichever is the lesser;

where

$C_{TIB1}$ = 50 mW cm−1;

$C_{TIB2}$ = 4,4 mW;

$P_\alpha(z_b)$ is the ATTENUATED OUTPUT POWER, at the DEPTH FOR $TIB$, $z_b$, in milliwatts;

$I_{zpta,\alpha}(z_b)$ is the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY, at the DEPTH FOR $TIB$, $z_b$, in milliwatts per centimetre squared.

### DD.4.3 Determination of CRANIAL-BONE THERMAL INDEX, *TIC*, for NON-SCANNING MODES

The CRANIAL-BONE THERMAL INDEX shall be calculated from

$$TIC = \frac{P / D_{eq}}{C_{TIC}}$$

where

$C_{TIC}$ = 40 mW cm$^{-1}$;

$P$ is the OUTPUT POWER in milliwatts;

$D_{eq}$ is the EQUIVALENT APERTURE DIAMETER in centimetres.

## DD.5 Determination of THERMAL INDEX in SCANNING MODE

### DD.5.1 Determination of SOFT TISSUE THERMAL INDEX, *TIS*, for SCANNING MODES

For each TRANSMIT PATTERN in a SCANNING MODE, the soft-tissue THERMAL INDEX shall be calculated from

$$TIS = \frac{P_1 f_{awf}}{C_{TIS1}}$$

where

$C_{TIS1}$ = 210 mW MHz;

$P_1$ is the BOUNDED OUTPUT POWER in milliwatts;

$f_{awf}$ is the ACOUSTIC WORKING FREQUENCY in megahertz.

### DD.5.2 Determination of BONE THERMAL INDEX, *TIB*, for SCANNING MODE

The determination of BONE THERMAL INDEX for SCANNING MODE shall be identical to that for soft-tissue THERMAL INDEX for SCANNING MODE, as specified in DD.5.1.

### DD.5.3 Determination of CRANIAL-BONE THERMAL INDEX, *TIC*, for SCANNING MODE

In a SCANNING MODE the CRANIAL-BONE THERMAL INDEX for a particular TRANSMIT PATTERN shall be calculated with the same parameters as for NON-SCANNING MODE

## DD.6 Calculations for COMBINED-OPERATING MODE

### DD.6.1 ACOUSTIC WORKING FREQUENCY

In a COMBINED-OPERATING MODE with more than one type of TRANSMIT PATTERN employed during the scan period, the ACOUSTIC WORKING FREQUENCY shall be considered separately for each different TRANSMIT PATTERN as appropriate in calculating the THERMAL INDEX or the MECHANICAL INDEX.

### DD.6.2 THERMAL INDEX

For COMBINED-OPERATING MODES, the THERMAL INDEX for the contribution of each discrete mode shall be calculated separately and the individual values summed appropriately, as shown in table DD.1. The location of the maximum temperature increase is near the surface of the TRANSDUCER ASSEMBLY for SCANNING MODE in all three categories, *TIS*, *TIB* and *TIC*. The location of maximum temperature is also near the surface for NON-SCANNING MODE for *TIS* when $A_{aprt} \leq 1{,}0$ cm$^2$, and for *TIC*. The location is at greater depth for NON-SCANNING MODE for *TIB* and for *TIS* when $A_{aprt} > 1{,}0$ cm$^2$. Table DD.1 summarizes the combination formulae for each of the THERMAL INDEX categories.

**Table DD.1 – Summary of combination formulae for each of the THERMAL INDEX categories**

| THERMAL INDEX categories | Combining discrete mode values of THERMAL INDEX |
|---|---|
| *TIC*, *TIS* for $A_{aprt} \leq$ 1,0 $cm^2$ | THERMAL INDEX at the surface = $\Sigma$(THERMAL INDEX values for all modes) |
| *TIB*, *TIS* for $A_{aprt}$ > 1,0 $cm^2$ | Maximum of THERMAL INDEX at surface or THERMAL INDEX at depth, i.e. the maximum of $\Sigma$(THERMAL INDEX values for SCANNING MODES)<br>or<br>$\Sigma$(THERMAL INDEX values for NON-SCANNING MODES) |

### DD.6.3 MECHANICAL INDEX

For COMBINED-OPERATING MODE, the MECHANICAL INDEX shall be that for the DISCRETE-OPERATING MODE with the largest MECHANICAL INDEX.

## DD.7 Summary of measured quantities for index determination

Table DD.2 gives a summary of the acoustic quantities required for the determination of each of the defined safety indices. Since attenuated quantities are derived by calculation from associated measured free-field quantities, both attenuated and free-field quantities are included.

**Table DD.2 – Summary of the acoustic quantities required for the determination of the indices**

| Index | *MI* | *TIS* | *TIS* | *TIS* | *TIB* | *TIB* | *TIC* |
|---|---|---|---|---|---|---|---|
| Mode | | Scanning | Non-scanning | Non-scanning | Scanning | Non-scanning | |
| | | | $A_{aprt} \leq$ 1 $cm^2$ | $A_{aprt}$ > 1 $cm^2$ | | | |
| $f_{awf}$ | x | x | x | x | x | x | |
| $P$ | | | x | x | | x | x |
| $P_1$ | | x | | | x | | |
| $P_\alpha$ | | | | x | | x | |
| $I_{zpta}$ | | | | x | | x | |
| $I_{zpta,\alpha}$ | | | | x | | x | |
| $I_{pi}$ | x | | | | | x | |
| $I_{pi,\alpha}$ | x | | | | | x | |
| $p_r$ | x | | | | | | |
| $p_{r,\alpha}$ | x | | | | | | |
| $A_{aprt}$ | | | x | x | | | x |
| $D_{eq}$ | | | | x | | | x |
| $z_s$ | | | | x | | | |
| $z_b$ | | | | | | x | |
| $z$ at max. $I_{pi,\alpha}$ | x | | | | | | |

# Annex EE
(informative)

## Relationships with other standards

The methods of determinations set out in this standard are intended to yield identical results to those contained in *UD-3 Rev.1:1998 Standard for real-time* DISPLAY *of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment*, American Institute of Ultrasound in Medicine/ National Electrical Manufacturers Association.

The models on which these determinations are based and the measurement and calculation rationale are contained in the document *UD-3 Rev:1-1998* and in its secondary references. This document has been followed in this standard (see annex GG).

# Annex FF
(informative)

## Guidance notes for measurement of OUTPUT POWER in SCANNING MODE

This annex deals primarily with the exceptions that must be made for SCANNING MODES from the standard acoustic measurement procedures set out in IEC 61102 and IEC 61161.

### FF.1 Measurement of OUTPUT POWER, $P$, in SCANNING MODES

This standard requires the measurement of the OUTPUT POWER transmitted from the 1 cm linear length of the active array which transmits the most power. This is termed the BOUNDED OUTPUT POWER.

The following paragraphs provide guidance for the measurement of OUTPUT POWER in addition to the requirements set out in IEC 61161 and when these requirements are inappropriate.

(a) In a COMBINED-OPERATING MODE with more than one type of TRANSMIT PATTERN employed during the scan period, the OUTPUT POWER may be considered separately for different TRANSMIT PATTERNS when necessary to permit accurate measurement of OUTPUT POWER and determination of THERMAL INDEX by combining values appropriately as shown in table DD.1. Such an approach may, for example, enable the appropriate acoustic-working frequency to be used for each calculation. Caution is needed to ensure that the selected single TRANSMIT PATTERN is identical to that used during COMBINED-OPERATING MODE.

(b) When performing these measurements in NON-SCANNING MODE with the beam scan arrested (when possible), the measured OUTPUT POWER should be corrected to compensate for any beam-former related output variability, dependent on beam scan angle and/or linear position. Hydrophone measurements of OUTPUT POWER should be performed either with the beam scan arrested, or by making use of a synchronizing system to synchronize the transmitted acoustic signal with the measurement system.

In phased arrays, OUTPUT POWER is often increased for non-normal scan angles because of decreased element (reception) sensitivity off axis.

(c) When performing these measurements in SCANNING MODE, the radiation force balance target and source should be such that the effective BEAM AREA intercepts the target over the entire extent of the beam. The alignment of the beam axis, the direction of sensing of the radiation-force balance and the axis of the aperture should be co-linear to within ±10°. The associated error in measurement will depend upon the specific geometry of the transducer and radiation-force-balance target, and no general guidance can be given.

The following sections describe windowing techniques using a 1 cm-wide slit absorber, a 1 cm-wide radiation force balance target or electronic masking techniques.

### FF.2 Creating a 1 cm azimuthal wide window using a mask of absorbing material or a 1 cm-wide radiation force balance target

When a radiation force balance target is used to limit the azimuth (image plane) aperture, its geometry and composition should be such as to detect all forward emissions from a 1 cm-wide strip immediately in front of the scan-head and not to detect emissions from outside that 1 cm-wide strip.

The two techniques in this section have somewhat different sources of error. Agreement of the two methods of defining the apertures should give reasonable confidence that the aperture is defined accurately. Use of an absorbing mask or limited-width radiation-force-balance absorber to limit detection to a 1 cm linear length at the front surface of the active scan aperture is recommended for mechanical sector probes, or third-party testing of all ULTRASONIC TRANSDUCER.

**FF.2.1 1 cm aperture in a mask**

When a mask is used, its geometry and composition should be such as to eliminate transmitted acoustic power except that emitted by the designated 1 cm length of the active area, to allow passage of all forward emissions from that 1 cm length and to agree with the accuracy and other requirements of this standard.

The scan-head front surface should be coplanar with the mask surfaces as illustrated in figure FF.1. This recommendation maintains consistency with FF.2.2. The ultrasonic attenuation of the mask should be at least 30 dB and its window's inside walls should be lined with a material of at least 90 % reflectance to prevent loss by the walls. The length of the slit should be at least twice the elevation dimension of the TRANSDUCER ASSEMBLY under test.

BOUNDED OUTPUT POWER measurements should be made with two mask thickness demonstrating no or marginal influence of the mask thickness. Figure FF.1 presents a sketch of a suggested geometry. A material with a maximum attenuation coefficient and minimum impedance mismatch with water is recommended. Materials are available commercially which are well matched to water (reflection coefficient –30 dB) and have a loss in the range of 45 dB/cm at 3,5 MHz. Additional attenuation can be provided by sandwiching a stainless steel, closed pore foam or other high- or low-impedance reflector between two layers of the ultrasonic attenuating material.

For measurement of the BOUNDED OUTPUT POWER, the mask slit should be aligned with respect to the TRANSDUCER ASSEMBLY under test and its imaging plane, as illustrated in figure FF.2. With mechanical sector scanners and curvilinear arrays, lateral positioning is critical. Scan-head probe holders and jigs will be helpful in this regard. It is anticipated that a BEAM-ALIGNMENT AXIS alignment within ±5° of the normal to the mask plane and target plane, and a scan plane alignment within ±5° of the normal to the sides of the slit are sufficient for the purposes of this test (see figure FF.2).

**FF.2.2 1 cm-wide radiation-force-balance target**

As an alternative to the use of an aperture-limiting mask, the measurement of the bounded acoustic power may be made using a 1 cm-wide radiation-force target. When the 1 cm-wide radiation-force-balance (RFB) target is used, it should be placed immediately in front of the scan-head, and its geometry and composition should be such that it detects all of, and only, the acoustic emissions from a 1 cm-wide strip of the scan-head.

The accuracy and linearity of the measurement of bounded acoustic power should conform to IEC 61161.

BOUNDED OUTPUT POWER measurements should have an accuracy of 20 % (95 % confidence level).

To minimize measurement errors due to reverberations, caution should be used to ensure that reflected acoustic energy does not reflect back onto the target. Further, the orientation of the target's long axis should remain perpendicular to the scan plane, as illustrated in figure FF.3.

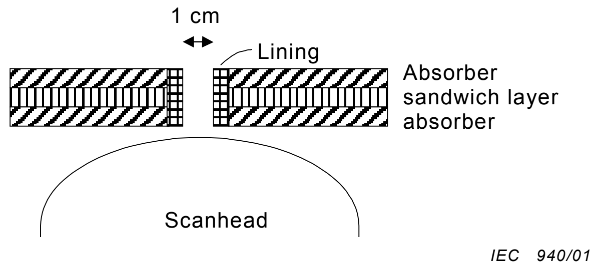


**Figure FF.1 – Suggested 1 cm-wide aperture mask**

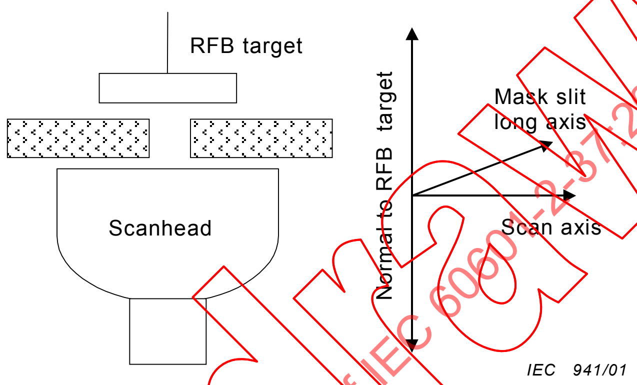


**Figure FF.2 – Suggested orientation of probe, mask slit, and RFB target**

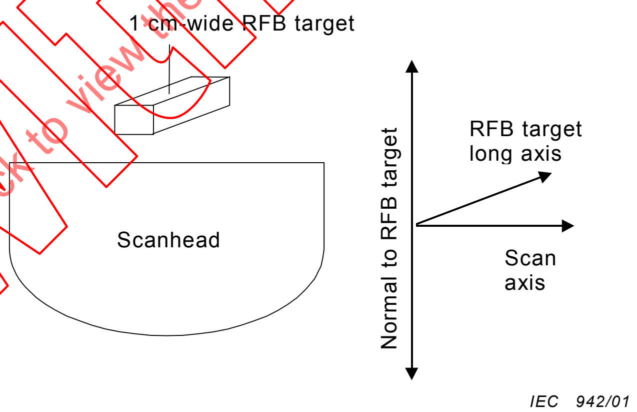


**Figure FF.3 – Suggested orientation of probe, mask slit, and 1 cm RFB target**

## FF.3 Creating a 1 cm azimuthal window using electronic control

Where the EQUIPMENT control scheme and transducer geometry allows, masking a 1 cm linear length aperture may be accomplished electronically by de-energizing the aperture outside this area, provided that the OUTPUT POWER emitted within the 1 cm linear length aperture is not affected by the electronic masking.

Electronic means for masking the active aperture for a 1 cm linear length aperture is recommended where feasible with electronically controllable linear arrays (sequenced, phased, or combination).

## FF.4 Measurement of BOUNDED OUTPUT POWER

While using the methods of FF.2.1 or FF.2.2 to mask all the OUTPUT POWER except that originating within a 1 cm azimuthal linear length of the –12 dB OUTPUT BEAM AREA in SCANNING MODE, the remaining BOUNDED OUTPUT POWER should be measured according to the procedures in IEC 61161.

In locating the mask used in either FF.2.1 or FF.2.2, the 1 cm linear length aperture emitting the largest BOUNDED OUTPUT POWER, should be exposed.

The measurement accuracy from the 1 cm linear length aperture should be verified as allowing forward passage of all the acoustic power from the central 1 cm linear length aperture of the transducer within ±20 %.

# Annex GG
(informative)

## Rationale and derivation of index models

This annex provides a summary rationale and derivation guidance for the formulas presented in the body of this standard for MECHANICAL INDEX and THERMAL INDEX. Numerous references are made to the root publications from which the formulas were derived. As will be discussed in the derivation notes that follow, key parts of the $MI$ and $TI$ models rely heavily on experimental data. This annex does not attempt to do more than describe relevant results of the experiments. A thorough reading of the referenced papers is strongly recommended in order to obtain a full understanding of the model derivation notes presented herein.

The relationship of various acoustic output parameters (for example, acoustic intensity, pressure, power, etc.) to biological endpoints is not well understood at the present time. Evidence to date has identified two fundamental mechanisms, thermal and mechanical, by which ultrasound may induce bio-effects [3], [17]. This standard provides a uniform means for the calculation of acoustic output parameters relevant to these potential biological effects. The rationale behind these calculation methods is twofold:

1. that information be provided that is representative of what is occurring *in vivo* with regard to mechanical and thermal bio-effects. It is for this reason that indices were chosen as opposed to absolute quantities not shown to have a direct correlation to bio-effects;
2. that ultrasonically induced heating and acoustic pressure levels should be maintained at a level as low as practical while still providing acceptable diagnostic information.

### GG.1 Definition specific to this annex

The definitions given under 2.1 apply, if not noted otherwise. As an additional definition, POWER PARAMETER is used in this informative annex.

#### GG.1.1 POWER PARAMETER

beam-related power quantity used in the numerator of the general THERMAL INDEX relationship

$$P_p = TI\ P_{deg} \qquad \text{(GG.1.1-1)}$$

where

$TI$ is the THERMAL INDEX;

$P_p$ is the POWER PARAMETER in milliwatts; and

$P_{deg}$ is the estimated power in milliwatts necessary to raise the target tissue 1 °C, based on the thermal models discussed in annex DD.

Symbol: $P_p$

Unit: milliwatt, mW

#### GG.1.2 Additional list of symbols used in this annex

$I_{sata}$ = spatial-average, TEMPORAL-AVERAGE INTENSITY

$K$ = thermal conductivity

$P_p$ = POWER PARAMETER

## GG.2 MECHANICAL INDEX (*MI*)

### GG.2.1 Rationale

A MECHANICAL INDEX is selected as the value to be calculated as an indicator related to mechanical effects. The index is intended to estimate the potential for mechanical bio-effects. Examples of mechanical effects include motion (or streaming) around compressible gas bubbles as ultrasound pressure waves pass through tissues, and energy released in the collapse, via cavitation, of transient gas bubbles.

While no adverse mechanical bio-effects have been reported to date in humans from exposure to ultrasound output levels typical of ULTRASONIC DIAGNOSTIC EQUIPMENT, several observations have contributed to the development of the MECHANICAL INDEX.

– In lithotripsy, mechanical bio-effects are induced by ultrasound with peak pressures in the same range as are sometimes used in diagnostic imaging, albeit at markedly different frequencies.
– *In vitro* experiments and observations with lower organisms have demonstrated the possibility of cavitation at ultrasound peak pressures and frequencies in ranges in some ULTRASONIC DIAGNOSTIC EQUIPMENT [6].
– Lung haemorrhage has been demonstrated in mice exposed to levels of pulsed ultrasound similar to those used in ULTRASONIC DIAGNOSTIC EQUIPMENT (although this has been demonstrated in adult mice, similar effects have not been found in foetuses) [8].

No clear conclusion has been drawn on the relevance of these laboratory studies to human exposure to diagnostic ultrasound. However, the results raise sufficient concern that the calculation of a MECHANICAL INDEX will raise in users' minds an appropriate awareness of the possibility of mechanical effects and of the conditions in which the possibility is more likely.

### GG.2.2 Derivation notes

The conditions that affect the likelihood of mechanical effects are not yet well understood; however, it is generally agreed that the likelihood increases as PEAK-RAREFACTIONAL ACOUSTIC PRESSURE increases, and decreases as the ultrasound frequency increases. Further, it is generally believed to be a threshold effect such that no effect occurs unless a certain output level is exceeded [10].

While the existing limited experimental data [5] suggest a linear frequency relationship, a more conservative root-frequency relationship is selected. The MECHANICAL INDEX is defined as

$$MI = \frac{p_{\mathrm{ra}} f_{\mathrm{awf}}^{-1/2}}{C_{MI}} \quad \text{for } f_{\mathrm{awf}} < 4\,\mathrm{MHz} \qquad \text{(GG.2.2-1)}$$

where

$C_{MI}$ = 1 MPa MHz$^{-1/2}$; and

$$MI = \frac{p_{\mathrm{ra}}}{2\,C_{MI}} \quad \text{for } f_{\mathrm{awf}} \geq 4\,\mathrm{MHz} \qquad \text{(GG.2.2-2)}$$

where

$C_{MI}$ = 1 Mpa;

$p_{\mathrm{ra}}$ is the ATTENUATED PEAK-RAREFACTIONAL PRESSURE in megapascals;

$f_{\mathrm{awf}}$ is the ACOUSTIC-WORKING FREQUENCY in megahertz.

The choice of a homogeneous tissue model and a derating factor of 0,3 dB cm$^{-1}$ MHz$^{-1}$ is a compromise. Other attenuation models were evaluated and rejected, such as fixed distance models [11] and the use of a homogeneous tissue model with an attenuation factor of 0,5 dB cm$^{-1}$ MHz$^{-1}$, a value more representative of many radiological and cardiac imaging applications. However, use of more than one attenuation model would entail an increase in EQUIPMENT complexity and could create a further need for user input to select appropriate attenuation schemes.

It is not felt that the extra complexity in attenuation modelling is justified given the level of understanding of the conditions required to produce mechanical bio-effects. With the selected, compromise attenuation model, the MECHANICAL INDEX is simple to implement and use and, most importantly, sufficient to allow users to minimize acoustic output and any corresponding potential mechanical bio-effects.



## GG.3 THERMAL INDEX (*TI*)

### GG.3.1 Rationale

The relationship between thermal rise and tissue bio-effects is well established (numerous studies [11] and while present acoustic output measurement parameters, such as

$P$ OUTPUT POWER,

$I_{ta}$ TEMPORAL-AVERAGE INTENSITY, and

$I_{spta}$ SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY

are not individually suitable as indicators or estimators of ultrasound-induced temperature rise, combinations of these parameters, along with specific geometric information, can be used to calculate indices which provide an estimate of temperature rise in soft tissue or bone.

Because of the difficulties of anticipating and thermally modelling the many possible ultrasound scan planes of the human body, simplified models based on average conditions are used. Three user-selectable THERMAL INDEX categories corresponding to different anatomical combinations of soft tissue and bone encountered in imaging applications are defined (see table GG.1). Each category uses one or more *TI* models which are calculated on the basis of information on the EQUIPMENT, including transducer aperture or acoustic beam dimensions and the imaging mode.

**Table GG.1 – THERMAL INDEX categories and models**

| THERMAL INDEX category | THERMAL INDEX models | |
|---|---|---|
| | Scanned mode | Non-scanned mode |
| *TIS* (soft tissue) | A. Soft tissue at surface | B. Large aperture<br>C. Small aperture |
| *TIB* (bone at focus) | A. Soft tissue at surface | D. Bone at focus |
| *TIC* (bone at surface) | E. Bone at surface | |

The SOFT-TISSUE THERMAL INDEX (*TIS*) is based on three soft tissue models. Two models cover small and large aperture cases for NON-SCANNING MODES, such as Doppler and M-mode. The remaining model covers SCANNED MODES, such as colour flow mapping and B-mode.

The BONE THERMAL INDEX (*TIB*) uses, for NON-SCANNING MODES, a model in which bone is located in a focal region (such as may occur in second and third trimester foetal applications). For SCANNED MODES, the soft tissue model is used because the temperature increase at the surface is typically greater than, or about the same as, with the bone at the focus.

The cranial BONE THERMAL INDEX ($TIC$) is based on a model with bone located close to the surface (such as in adult cranial applications). The cranial bone model is used with both the NON-SCANNING MODE and the SCANNED MODE.

### GG.3.2 General derivation of the parameters

#### GG.3.2.1 THERMAL INDEX

In this annex the THERMAL INDEX, $TI$, is defined by the relationship

$$TI = \frac{P_{\mathrm{p}}}{P_{\mathrm{deg}}} \qquad \text{(GG.3.2-1)}$$

where

$P_{\mathrm{p}}$ is the POWER PARAMETER as defined in this annex, and

$P_{\mathrm{deg}}$ is the estimated power necessary to raise the target tissue 1 °C, based on the thermal models discussed in this annex.

The derivation of the temperature rise estimation models requires the understanding of four key concepts/parameters.

#### GG.3.2.2 ATTENUATED OUTPUT POWER and intensity

These parameters are functions of the non-attenuated values, depth and the ACOUSTIC ATTENUATION COEFFICIENT. ATTENUATED OUTPUT POWER and intensities are denoted by the subscript $\alpha$. Parameters without the subscript refer to non-attenuated values measured in water. Thus the ATTENUATED OUTPUT POWER $P_\alpha$ at a distance $z$ is defined as

$$P_\alpha(z) = P\,10^{(-\alpha f_{\mathrm{awf}}\, z/10)} \quad \text{(mW)} \qquad \text{(GG.3.2-2)}$$

where

$P$ is the OUTPUT POWER in milliwatts,

$\alpha$ is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz,

$f_{\mathrm{awf}}$ is the ACOUSTIC-WORKING FREQUENCY in megahertz, and

$z$ is the distance from the source to the specified plane in centimetres.

The ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY is denoted:

$$I_{\mathrm{zpta},\alpha}(z) = I_{\mathrm{zpta}}(z)\,10^{(-\alpha f_{\mathrm{awf}}\, z/10)} \quad (\text{mW cm}^{-2}) \qquad \text{(GG.3.2-3)}$$

where

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

$\alpha$ is the ACOUSTIC ATTENUATION COEFFICIENT in decibels per centimetre per megahertz,

$f_{\mathrm{awf}}$ is the ACOUSTIC-WORKING FREQUENCY in megahertz, and

$z$ is the distance from the source to the specified plane in centimetres.

**GG.3.2.3 Derivation of the EQUIVALENT BEAM AREA**

The EQUIVALENT BEAM AREA, $A_{eq}$, is defined as

$$A_{eq}(z) \equiv \frac{P_\alpha(z)}{I_{zpta,\alpha}(z)} = \frac{P}{I_{zpta}(z)} \quad (cm^2) \qquad (GG.3.2\text{-}4)$$

where

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

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

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

**GG.3.2.4 Derivation of the EQUIVALENT BEAM DIAMETER**

The EQUIVALENT BEAM DIAMETER, $d_{eq}$, is defined as

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

$$= 2{,}0\sqrt{\frac{P_\alpha}{\pi I_{zpta,\alpha}}} \quad (cm) \qquad (GG.3.2\text{-}5a)$$

where

$A_{eq}$ is the EQUIVALENT BEAM AREA in square centimetres,

$P_\alpha$ is the ATTENUATED OUTPUT POWER in milliwatts, and

$I_{zpta,\alpha}$ is the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY in milliwatts per square centimetre.

A minimum beam-width of one millimetre (0,1 cm) is assumed because of the practical difficulty of holding a small beam steady on one target location. Therefore, for these derivations

$$d_{eq}(z) \equiv \max\left(\sqrt{\frac{4}{\pi}A_{eq}(z)},\ 0{,}1\right) \quad (cm)$$

$$= \max\left(2{,}0\sqrt{\frac{P_\alpha}{\pi I_{zpta,\alpha}}},\ 0{,}1\right) \quad (cm) \qquad (GG.3.2\text{-}5b)$$

This minimum beam-width assumption is referred to in context in later sections of this annex.

### GG.3.2.5 The location of the maximum temperature increase ($z_{t,max}$)

This parameter depends on the imaging conditions. The maximum temperature increase is assumed to be near the surface if the ultrasound beam passes through bone near the surface or if the ultrasound beam is automatically scanned. For NON-SCANNING MODES with bone in a focal region, the maximum temperature increase will be at the focal region. For NON-SCANNING MODES in soft tissue, the maximum temperature increase may be at the surface or at a deeper location. The interaction between acoustic beam dimensions and the cooling effect of perfusion determines the depth of maximum temperature increase. A low perfusion rate is assumed with a heat perfusion length of 1 cm. This translates to a situation where, for BEAM-AREAS less than 1 $cm^2$, ACOUSTIC POWER is the relevant POWER PARAMETER and for BEAM-AREAS greater than 1 $cm^2$, acoustic intensity multiplied by 1 $cm^2$ is the relevant POWER PARAMETER.

### GG.3.3 Models

As discussed in section GG.3.1 and in table GG.1, three THERMAL INDICES are defined, the *TIS*, the *TIB* and the *TIC*. Five different thermal rise estimation models are used in calculating the *TI*s as defined in annex DD of this standard. For the purposes of discussion and derivation, these five models are identified as noted in table GG.2.

The three soft tissue at surface models (A, B and C) are based on the theoretical and experimental treatise [9], [15]. Accordingly, the mediating factor for temperature rise is the absorbed power per unit scan length, $\mu_o f[P/X]$, which normalizes the effect of frequency on the temperature rise (where $\mu_o$ is the frequency specific absorption coefficient). A series of measurements on 70 transducers of the absorbed power per scan length that causes a 1 °C rise at the skin surface produced results centred about

$$\mu_o f_{awf}\,[P_{deg}/X] = 21\ \text{mW/cm}^2 \qquad \text{(GG.3.3-1)}$$

NOTE This is a key concept in the development of the *TIS* models. A careful study of Curley [9] is strongly recommended to ensure a thorough understanding of this important concept.

For this study, the acoustic absorption factor was selected at $\mu_o$ = 0,8 dB $cm^{-1}$ $MHz^{-1}$, a value typical of soft tissue. The average perfusion rate for soft tissue has been estimated as the cardiac output divided by the body mass, resulting in a corresponding typical perfusion length of 1,0 cm. Selecting the unit scan length, *X*, as the perfusion length and combining these experimental approximations with equation GG.3.3-1 results in the power required to cause a 1 °C temperature rise at the surface as

$$P_{deg} = \frac{(21\ \text{mW / cm}^2)\ (1{,}0\ \text{cm})}{(0{,}1\,\text{dB / cm - MHz})\ (f_{awf}\ \text{MHz})} = \frac{210}{f_{afw}} \quad (\text{mW}) \qquad \text{(GG.3.3-2)}$$

This $P_{deg}$ formula is shared by all three soft tissue models. In this standard, the value of 210 mW MHz is incorporated in constants $C_{TIS1}$ and $C_{TIS2}$.

#### GG.3.3.1 Soft tissue at surface [*TIS*(scanned), *TIB*(scanned)] derivation notes

As noted in GG.3.3, temperature increase is determined by power per unit length in the scan direction.

$$\frac{P}{X} \quad (\text{mW/cm}) \qquad \text{(GG.3.3.1-1)}$$

If the scan width of the active aperture is longer than the assumed heat perfusion length of 1 cm, then the source power may be measured by a force balance using either an intermediary absorbing mask with a 1 cm window in the scan direction or an equivalent electronic window. Power from the central 1 cm of the radiating or active aperture is measured (see figure FF.2). For active apertures having a scan width less than 1 cm, no mask is necessary. The result of these power measurements, the BOUNDED OUTPUT POWER, designated $P_1$, is the POWER PARAMETER used in the numerator of the general *TI* formula (equation GG.3.2-1).

Combining the BOUNDED OUTPUT POWER, $P_1$, with the power required to cause a 1 °C temperature rise, $P_{deg}$, (equation GG.3.3-2) into the general *TI* formula GG.3.2-1 yields the soft tissue at surface model

$$TIS, TIB = \frac{P_1 \, f_{awf}}{C_{TIS1}} \qquad \text{(GG.3.3.1-2)}$$

where

$C_{TIS1}$ = 210 mW MHz.

**Table GG.2 – THERMAL INDEX formulae**

| Name | Formula |
|---|---|
| A. Soft tissue at surface<br>*TIS* (scanned)<br>*TIB* (scanned)<br>(see DD.5.1 and DD.1.5.2) | $TIS, TIB = \frac{P_1 \, f_{awf}}{C_{TIS1}}$ |
| B. Large aperture ($A_{aprt}$ > 1 cm²)<br>*TIS* (non-scanned)<br>(see DD.4.1.2) | $TIS = \max_{z > 1{,}5\, D_{eq}} \left[ \min \left[ \frac{P_\alpha \, f_{awf}}{C_{TIS1}}, \frac{I_{zpta,\alpha} \, f_{awf}}{C_{TIS2}} \right] \right]$ |
| C. Small aperture ($A_{aprt}$ ≤ 1 cm²)<br>*TIS* (non-scanned)<br>(see DD.4.1.3) | $TIS = \frac{P \, f_{awf}}{C_{TIS1}}$ |
| D. Bone at focus<br>*TIB* (non-scanned)<br>(see DD.4.2) | $TIB = \min \left[ \frac{\sqrt{P_\alpha \, I_{zpta,\alpha}}}{C_{TIB1}}, \frac{P_\alpha}{C_{TIB2}} \right]$ |
| E. Bone at surface<br>*TIC*<br>(see DD.4.3) | $TIC = \frac{P / D_{eq}}{C_{TIC}}$ |

### GG.3.3.2 Large aperture ($A_{aprt}$ > 1 cm²) [*TIS*(non-scanned)] derivation notes

The perfusion assumption (1 cm heat perfusion length) is critical to determining the location of maximum temperature increase. Theory derived for a heated cylinder suggests that if the BEAM AREA is less than 1 cm², the power in the beam controls the temperature rise [11]. If the BEAM AREA is greater than 1 cm², intensity controls the temperature rise. Therefore, the POWER PARAMETER *TI* used in the numerator of the general formula (equation GG.3.2-1) for narrow beams [EQUIVALENT BEAM AREA, $A_{eq}$ = 1 cm²] is the ATTENUATED OUTPUT POWER, $P_\alpha$, and for broad beams [$A_{eq}$ > 1 cm²] the POWER PARAMETER is the ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY across 1 cm², $I_{zpta,\alpha}$ × 1 cm². Thus, for any location on the beam axis, the local POWER PARAMETER is

$$\min\left[ (P_\alpha), (I_{zpta,\alpha} \times 1\,\text{cm}^2) \right] \quad \text{(mW)} \qquad \text{(GG.3.3.2-1)}$$

To avoid inaccuracies introduced by attempting to measure intensities in the acoustic near field, a BREAK-POINT DEPTH, $z_{bp}$, is defined equal to one-and-a-half times the EQUIVALENT APERTURE DIAMETER, $D_{eq}$.

$$z_{bp} = 1{,}5\ D_{eq} \quad \text{(cm)} \tag{GG.3.3.2-2}$$

The BREAK-POINT DEPTH, $z_{bp}$, can be derived from the –12 dB OUTPUT BEAM AREA, $A_{aprt}$:

$$z_{bp} = 1{,}5\sqrt{\frac{4}{\pi}A_{aprt}} = 1{,}69\sqrt{A_{aprt}} \quad \text{(cm)} \tag{GG.3.3.2-3}$$

For the purposes of this standard, the maximum temperature increase is assumed to be at the location at or beyond the BREAK-POINT DEPTH, $z_{bp}$, that maximizes the local POWER PARAMETER (equation GG.3.3.2-1). The resulting POWER PARAMETER for the beam becomes

$$\max_{z > 1{,}5\ D_{eq}}\left[\min\left[(P_{\alpha}),(I_{zpta,\alpha} \times 1\ \text{cm}^2)\right]\right] \quad \text{(mW)} \tag{GG.3.3.2-4}$$

NOTE For consistency throughout the body of the standard, the equivalent value of 1,5 $D_{eq}$ has been substituted for $z_{bp}$ in equation GG.3.3.2-4.

Combining the POWER PARAMETER expressed in equation GG.3.3.2-4 with the power required to cause a 1 °C temperature rise, $P_{deg}$, (equation GG.3.3-2) into the general $TI$ formula GG.3.2-1 yields the large aperture ($A_{aprt}$ > 1 cm²) model

$$TIS = \max_{z > 1{,}5\ D_{eq}}\left[\min\left[\frac{P_{\alpha}\ f_{awf}}{C_{TIS1}}, \frac{I_{zpta,\alpha}\ f_{awf}}{C_{TIS2}}\right]\right] \tag{GG.3.3.2-5}$$

where

$C_{TIS1}$ = 210 mW MHz;

$C_{TIS2}$ = 210 mW cm$^{-2}$ MHz.

NOTE For notational purposes, $C_{TIS2}$ combines the 1 cm² factor in equation GG.3.3.2-4 with the 210 mW-MHz factor from equation GG.3.3-2, hence the difference in units between $C_{TIS1}$ and $C_{TIS2}$.

*Examples*

The large aperture ($A_{aprt}$ > 1 cm²) model describes a transducer for which the entrance area is greater than 1 cm². Figures GG.2a, GG.2b, GG.2c, and GG.2d illustrate examples of possible locations and values of the POWER PARAMETER (equation GG.3.3.2-4). These figures demonstrate examples of possible relationships between the intensity ($I_{zpta,\alpha}$ × 1 cm²) and power ($P_{\alpha}$) curves. Values within the region less than the BREAK-POINT DEPTH ($z < z_{bp}$) are not considered.

It is helpful to consider what these curves indicate about beam focusing. The EQUIVALENT BEAM AREA, $A_{eq}$, is the ratio of $P_{\alpha}$ to $I_{zpta,\alpha}$. In regions where the intensity curve is below (less than) the power curve, the EQUIVALENT BEAM AREA is greater than 1 cm². Where the intensity curve is above (greater than) the power curve, the EQUIVALENT BEAM AREA is less than 1 cm². The EQUIVALENT BEAM AREA is 1 cm² where the curves intersect.