IEC 60601-2-37

Edition 3.0 2024-07
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 60601-2-37:2024-07 RLV(en)

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

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

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, …). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

IEC Products & Services Portal - products.iec.ch
Discover our powerful search engine and read freely all the publications previews, graphical symbols and the glossary. With a subscription you will always have access to up to date content tailored to your needs.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC 60601-2-37

Edition 3.0 2024-07
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.55; 17.140.50

ISBN 978-2-8322-9372-0

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the basic safety and essential performance 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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-37:2007+AMD1:2015 CSV. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 60601-2-37 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2007 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) technical and editorial changes resulting from the amended general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and its collateral standards IEC 60601-1-xx,
b) technical and editorial changes as a result of maintenance to normative references;
c) technical and editorial changes resulting from relevant developments in TC 87 Ultrasonics standards. In particular, Clause 201.11 about protection against excessive temperatures and other hazards has been fully revised.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1318/CDV	62B/1348/RVC

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

In this document, safety requirements additional to those in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

A general guidance and rationale for the requirements of this document are given in Annex AA.

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

The approach and philosophy used in drafting this document for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in standards of 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 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 ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

~~INTRODUCTION TO AMENDMENT 1~~

~~The second edition of IEC 60601-2-37 was published in 2007. Since that publication, the parent standard, IEC 60601-1:2005, entered maintenance, under which an amendment (IEC 60601-1:2005/AMD1:2012) and a consolidated edition 3.1 (IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012) were published. This amendment to IEC 60601-2-37:2007 addresses three issues:~~

1) ~~technical changes proposed by National Committees as a result of 4 years of practical usage,~~
2) ~~technical and editorial changes resulting from the amended general standard IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its collateral standards IEC 60601-1-xx, and~~
3) ~~technical changes as a result of maintenance to normative references.~~

MEDICAL ELECTRICAL EQUIPMENT –

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

~~The clauses and subclauses of the general standard apply except as follows:~~

201.1 Scope, object and related standards

Clause 1 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 *Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217, hereinafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in ~~7.2.13 and 8.4.1 of this standard~~ 201.7.2.13.

~~NOTE See also subclause 4.2 of this standard.~~

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

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply as modified in Clause 202 and Clause 212 respectively. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

~~For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.~~

The numbering of sections, clauses and subclauses of this document corresponds to that of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.6 in this document addresses the content of Clause 6 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by this document.

"*Addition*" means that the text of this document is additional to the requirements of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the ~~general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, the section, clause or subclause of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012~~[1]~~
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-18:2009, *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

IEC 62127-1:~~2007~~2022, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields* ~~*up to 40 MHz*~~
~~IEC 62127-1:2007/AMD1:2013[2]~~

IEC 62359:2010, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*
IEC 62359:2010/AMD1:2017

CISPR 11:2024, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and in IEC 62359 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this document is found in Table 201.101.

~~[1] There exists a consolidated edition (3.1) including IEC 60601-1:2005 and its Amendment 1 (2012).~~

~~[2] There exists a consolidated edition (1.1) including IEC 62127-1:2007 and its Amendment 1 (2013).~~

Addition:

201.3.201
BONE THERMAL INDEX
TIB
THERMAL INDEX for applications such as foetal (second and third trimester), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.17, modified – ~~The definition no longer refers to neonatal cephalic applications, and~~ The original notes have been deleted.]

201.3.202
COMBINED-OPERATING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that combines more than one DISCRETE-OPERATING MODE

201.3.203
CRANIAL-BONE THERMAL INDEX
TIC
THERMAL INDEX for applications, in which the ultrasound beam passes through bone near the beam entrance into the body, such as paediatric and adult cranial or neonatal cephalic applications

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.21, modified – ~~The definition now includes a reference to neonatal cephalic applications, and~~ The original notes have been deleted.]

201.3.204
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

201.3.205
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 utilise only one diagnostic methodology

201.3.206
FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT
means by which the ULTRASONIC DIAGNOSTIC EQUIPMENT manages the acoustic output independent of direct OPERATOR control

201.3.207
INVASIVE TRANSDUCER ASSEMBLY
transducer which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

201.3.208
MECHANICAL INDEX
~~the displayed parameter representing potential cavitation bioeffects~~

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

Symbol: *MI*

Unit: None

Note 1 to entry: See IEC 62359 for methods of determining the MECHANICAL INDEX.

201.3.209
MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT
ULTRASONIC DIAGNOSTIC EQUIPMENT that is intended for more than one clinical application

201.3.210
NON-SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to ultrasonic scan lines that follow the same acoustic path

201.3.211
PRUDENT USE STATEMENT
affirmation of the principle that only necessary clinical information should be acquired and that high exposure levels and long exposure times should be avoided

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.40~~, modified – The definition has been reworded.~~]

201.3.212
SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to scan lines that do not follow the same acoustic path

201.3.213
SOFT TISSUE THERMAL INDEX
TIS
THERMAL INDEX related to soft tissues

Unit: None

[SOURCE: IEC 62359:2010, 3.52, modified – The original notes have been deleted.]

201.3.214
THERMAL INDEX
TI
indicator of the risk of bioeffect due to thermal mechanisms expressed as the ratio of ATTENUATED OUTPUT POWER at a specified point to the ATTENUATED OUTPUT POWER required to raise the temperature at that point in a specific tissue model by 1 °C

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.56, modified – ~~The term "ATTENUATED ACOUSTIC POWER" has been replaced twice by the term "ATTENUATED OUTPUT POWER"~~ Addition of “indicator of the risk of bioeffect due to thermal mechanisms expressed as the”, and the original note has been deleted.]

201.3.215
TRANSDUCER ASSEMBLY
those parts of ULTRASONIC DIAGNOSTIC EQUIPMENT comprising either the ULTRASONIC TRANSDUCER and/or the ULTRASONIC TRANSDUCER ELEMENT GROUP, or both, together with any integral components, such as an acoustic lens or integral stand-off

Note 1 to entry: The TRANSDUCER ASSEMBLY is usually separable from the ultrasound instrument console.

[SOURCE: IEC 62127-1:2007, 3.69 IEC 62359:2010 and IEC 62359:2010AMD1:2017, 3.57, modified – the original term "medical diagnostic ultrasound equipment" has been replaced by "ULTRASONIC DIAGNOSTIC EQUIPMENT" in the definition.]

201.3.216
TRANSMIT PATTERN
combination of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodisation 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

[SOURCE: IEC 62359:2010, 3.58]

201.3.217
ULTRASONIC DIAGNOSTIC EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT that is intended for ultrasonic medical examination

201.3.218
ULTRASONIC TRANSDUCER
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and/or reciprocally of converting mechanical energy to electrical energy

[SOURCE: IEC 62127-1:2007/AMD1:2013, 3.73 IEC 62127-1:2022, 3.88]

201.3.219
ATTENUATED PULSE-AVERAGE INTENSITY
$I_{pa,\alpha}$
value of the acoustic PULSE-AVERAGE INTENSITY after attenuation and at a specified point, and given by

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

$$I_{pa,\alpha}(z) = I_{pa}(z)10^{(-\alpha z f_{awf}/10\,dB)} \quad (1)$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT as defined in IEC 62359:2010, definition 3.1;

z is the distance from the EXTERNAL TRANSDUCER APERTURE to the point of interest;

f_{awf} is the ACOUSTIC WORKING FREQUENCY as defined in IEC 62359:2010 and IEC 62359:2010/AMD1:2017, definition 3.4;

$I_{pa}(z)$ is the PULSE-AVERAGE INTENSITY measured in water as defined in IEC 62127-1:2007 and IEC 62127-1:2007/AMD1:2013, definition 3.47 IEC 62127-1:2022, 3.53.

Unit: W m^{-2}

201.3.220
NUMBER OF PULSES PER ULTRASONIC SCAN LINE
n_{pps}
number of acoustic pulses travelling along a particular ULTRASONIC SCAN LINE

Note 1 to entry: Here ULTRASONIC SCAN LINE refers to the path of acoustic pulses on a particular BEAM AXIS in SCANNING and NON-SCANNING MODES.

Note 2 to entry: This number can be used in the calculation of any ultrasound temporal average value from HYDROPHONE measurements.

Note 3 to entry: The following shows an example of the NUMBER OF PULSES PER ULTRASONIC SCAN LINE and the NUMBER OF ULTRASONIC SCAN LINES (";" indicates the end of a frame):

1 2 3 4; 1 2 3 4; 1 2 3 4... n_{pps} = 1; n_{sl} = 4

1 1 2 2 3 3 4 4; 1 1 2 2 3 3 4 4; ... n_{pps} = 2; n_{sl} = 4

1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; ... n_{pps} = 4; n_{sl} = 4

1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; 1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; ... n_{pps} = 5; n_{sl} = 4 (within one frame the pulses down each line may not occur contiguously).

Within one frame, all scan lines may not have the same n_{pps} value. An example is: 1 2 2 3 3 4; 1 2 2 3 3 4; ... avg n_{pps} = 1,5; max n_{pps} = 2; n_{sl} = 4

[SOURCE: IEC 61157:2007/AMD1:2013, 3.45, modified – The fourth example in the Note 3 to entry has been corrected.]

201.3.221
ULTRASOUND ENDOSCOPE
ENDOSCOPE with built-in ULTRASOUND TRANSDUCERS

201.3.222
ENDOSCOPE
medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis or therapy

Note 1 to entry: ENDOSCOPES may be of rigid, flexible or capsule type, each of which may have different image pick-up systems (e.g. via lenses or electronic/ultrasonic sensors) and different image transmission systems (e.g. optical (via lenses or fibre bundles), or electrical/electronic).

Note 2 to entry: Note 1 to entry differs from NOTE 1 of definition 3.1 in ISO 8600-1 in order to include 'capsule' endoscopes.

[SOURCE: IEC 60601-2-18:2009, 201.3.203]

201.3.223
DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL
z_{pii}
~~position of maximum SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY for NON-SCANNING MODE components, determined beyond the BREAK-POINT DEPTH, z_{bp}, on the BEAM-AXIS~~

depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} from the external transducer aperture to the plane of maximum PULSE-INTENSITY INTEGRAL (pii) as approximated by the PULSE-PRESSURE-SQUARED INTEGRAL ($ppsi$)

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.24, modified — Notes to entry 1, 2 and 3 deleted.]

201.3.224
DEPTH FOR PEAK ATTENUATED PULSE-INTENSITY INTEGRAL

$z_{pii,\ \alpha}$

~~position of maximum ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY for NON-SCANNING MODE components, determined beyond the BREAK-POINT DEPTH, z_{bp}, on the BEAM-AXIS~~

depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak ATTENUATED PULSE-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.71, modified — Main term “depth for maximum $_{pii,\ \alpha}$” replaced with “depth for peak attenuated pulse-intensity integral”, Notes to entry 1, 2 and 3 deleted and addition of a new Note to entry.]

201.3.225
DEPTH FOR PEAK SUM OF PULSE-INTENSITY INTEGRALS

z_{sii}

~~position of maximum SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY for SCANNING MODE components, determined beyond THE BREAK-POINT DEPTH, z_{bp}, on the BEAM-AXIS~~

depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak SCAN-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

Note 2 to entry: The subscript '*sii*' indicates the scan intensity integral (sii). The *sii* for SCANNING MODE components at a particular point is determined from the sum over a complete scan frame of the PULSE-INTENSITY INTEGRALS of the ULTRASONIC SCAN LINES that make up the scanning components of a combined mode. Non-scanned components are excluded from the sum. See IEC 62359 and IEC 62127-1 for more details.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.74, modified — Main term “depth for maximum sii” replaced with “depth for peak sum of pulse-intensity integrals”, Notes to entry 1, 2 and 3 deleted and addition of new Notes 1 and 2 to entry.]

201.3.226
DEPTH FOR PEAK SUM OF ATTENUATED PULSE-INTENSITY INTEGRALS

$z_{sii,\alpha}$

~~position of maximum ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY for SCANNING MODE components, determined beyond the BREAK-POINT DEPTH, z_{bp}, on THE BEAM-AXIS~~

depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak ATTENUATED SCAN-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

Note 2 to entry: The subscript "sii" indicates the "scan intensity integral" that is the sum at a particular point of the PULSE-INTENSITY INTEGRALS of the ULTRASONIC SCAN LINES comprising a SCANNING MODE component. See IEC 62359 and IEC 62127-1 for additional details.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.75, modified — Main term “depth for maximum sii_{α}” replaced with “depth for peak sum of attenuated pulse-intensity integrals”, addition of “peak” in the definition, Notes to entry 1, 2 and 3 deleted and addition of new Notes 1 and 2 to entry.]

201.3.227
DEPTH FOR MECHANICAL INDEX
z_{MI}
depth on the BEAM-AXIS from the EXTERNAL TRANSDUCER APERTURE to the plane of maximum ~~ATTENUATED PULSE INTENSITY INTEGRAL (pii_{α})~~ ATTENUATED PULSE-PRESSURE-SQUARED-INTEGRAL ($ppsi_{\alpha}$)

Unit: m

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.23]

201.3.228
THERMAL OFFSET
ΔT_{offset}
difference between a) the temperature of the APPLIED PART of the TRANSDUCER ASSEMBLY at steady-state in the measurement setting before transmitting begins and b) the steady-state temperature at the same location in the measurement setting when the TRANSDUCER ASSEMBLY was not present

Note 1 to entry: The value of the THERMAL OFFSET can be positive, negative or zero.

201.3.229
ULTRASOUND
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

Table 201.101 – List of symbols

Symbol	Term	Reference
A_{aprt}	= –12 dB OUTPUT BEAM AREA	IEC 62359
d_{eq}	= EQUIVALENT BEAM DIAMETER	IEC 62359
f_{awf}	= ACOUSTIC WORKING FREQUENCY	IEC 62359
$I_{\text{pa},\alpha}$	= ATTENUATED PULSE-AVERAGE INTENSITY	
pii	= PULSE-INTENSITY INTEGRAL	IEC 62359
pii_{α}	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359
$I_{\text{sppa},\alpha}$	= ATTENUATED SPATIAL-PEAK PULSE-AVERAGE INTENSITY	IEC 62359
I_{spta}	= SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359
$I_{\text{spta},\alpha}$	= ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359
$I_{\text{ta},\alpha}(z)$	= ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359
MI	= MECHANICAL INDEX	IEC 62359
n_{pps}	= NUMBER OF PULSES PER ULTRASONIC SCAN LINE	IEC 61157
P	= OUTPUT POWER	IEC 62359
$P_{1\text{x}1}$	= BOUNDED-SQUARE OUTPUT POWER	IEC 62359
P_{α}	= ATTENUATED OUTPUT POWER	IEC 62359
$p_{\text{r},\alpha}$	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
p_{r}	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
prr	= PULSE REPETITION RATE	IEC 62359

Symbol	Term	Reference
srr	= SCAN REPETITION RATE	IEC 62127-1
TI	= THERMAL INDEX	IEC 62359
TIB	= BONE THERMAL INDEX	IEC 62359
TIC	= CRANIAL-BONE THERMAL INDEX	IEC 62359
TIS	= SOFT-TISSUE THERMAL INDEX	IEC 62359
t_d	= PULSE DURATION	IEC 62359
X,*Y*	= –12 dB OUTPUT BEAM DIMENSIONS	IEC 62359
z_b	= DEPTH FOR BONE THERMAL INDEX	IEC 62359
z_{bp}	= BREAK-POINT DEPTH	IEC 62359
z_{pii}	= DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL	IEC 62359
z_{MI}	= DEPTH FOR MECHANICAL INDEX	IEC 62359
$z_{pii,\alpha}$	= DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL	IEC 62359
z_{sii}	= DEPTH FOR PEAK SUM OF PULSE INTENSITY INTEGRALS	IEC 62359
$z_{sii,\alpha}$	= DEPTH FOR PEAK SUM OF ATTENUATED PULSE INTENSITY INTEGRALS	IEC 62359
z_s	= DEPTH FOR TIS	IEC 62359
ΔT_{offset}	= THERMAL OFFSET	
ΔT_{tx}	= temperature rise caused by the TRANSDUCER ASSEMBLY transmitting	

201.4 General requirements

Clause 4 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

An ULTRASOUND ENDOSCOPE where the imaging means is limited to ultrasound shall be considered an ULTRASOUND TRANSDUCER and shall meet the requirements of this document.

NOTE 1 Examples of such ULTRASOUND TRANSDUCERS include transvaginal, transesophageal (TEE), rectal, laparoscopic and other similar intra-cavity probes.

An ULTRASOUND ENDOSCOPE having imaging means in addition to ultrasound shall also meet the requirements of 201.11.6.5 of IEC 60601-2-18:2009.

NOTE 2 Examples of such additional imaging means include optical and CCD.

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT and the subclauses in which the requirements are found.

Table 201.102 – Distributed essential performance requirements

Requirement	Subclause
Free from 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~~ can alter the diagnosis.	~~202.6.2.1.10~~202.8.1
Free from the display of incorrect numerical values associated with the diagnosis to be performed [a].	~~202.6.2.1.10~~202.8.1
Free from the display of incorrect safety-related indications.[a]	201.12.4.2 ~~202.6.2.1.10~~202.8.1
Free from the production of unintended or excessive ultrasound output.	201.10.101 ~~202.6.2.1.10~~202.8.1
Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.	~~202.6.2.1.10~~202.8.1
Free from the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.	~~202.6.2.1.10~~202.8.1
[a] "incorrect" in the sense that the displayed value differs from what is calculated (having been altered during data transfer), or the calculation itself is not correct.	

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

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2.9 IP classification

Addition:

If the specified IPX classification is applicable for only part of the TRANSDUCER ASSEMBLY, the marking of the IPX code on the TRANSDUCER ASSEMBLY is not required.

201.7.2.13 *Physiological effects (SAFETY SIGNS and warning statements)

Addition:

A description of the means used to limit the surface heating of INVASIVE TRANSDUCER ASSEMBLIES to no more than 43 °C in the event of a SINGLE FAULT CONDITION shall be provided in accordance with the requirements of Clause 12.

Additional subclause:

201.7.2.101 *Acoustic output

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2 and which allows the OPERATOR to directly vary the output levels, the effect of adjusting the control which varies the output level shall be clear. The marking shall be of the nature of an active display.

A display of THERMAL INDEX and MECHANICAL INDEX shall be provided in accordance with the requirements of Clause 201.12, together with the declaration of accuracy described in ~~201.7.9 and~~ Clause 201.12.

A display relevant to ultrasound output levels (Clause 201.12) shall be clearly visible from the OPERATOR'S position, with the full name(s) or abbreviation(s) of the index (indices) displayed.

201.7.9.2.2 *Warning and safety notices

Addition:

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to Clause 201.12, information shall be provided to the OPERATOR on how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX (*TI*) and MECHANICAL INDEX (*MI*) according to the guidance given in Annex CC.

The procedures necessary for safe operation shall be provided, drawing attention to the safety hazards that ~~may~~ can occur as a result of an inadequate electrical installation when the APPLIED PART of the ULTRASONIC DIAGNOSTIC EQUIPMENT is a TYPE B APPLIED PART.

Instruction on the safe use of TRANSDUCER ASSEMBLIES shall be provided, and, in particular, instructions to ensure 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~~ can cause harmful interference with other equipment in the environment. The identification of interference with other equipment and mitigation techniques shall be included in the ACCOMPANYING DOCUMENTS if the MANUFACTURER claims a reduction in test levels.

A notice shall be provided if the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts thereof are provided with protective means against burns to the PATIENT when used with high frequency (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.

A PRUDENT USE STATEMENT shall be provided for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2.

Descriptions shall be provided of any display or means relevant to ultrasound output by which the OPERATOR ~~may~~ can modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT. These descriptions shall be in a separate section.

A description of any display or means by which the OPERATOR may modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT relevant to surface temperature for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use shall be provided.

A description of those parts of the TRANSDUCER ASSEMBLY that are permitted to be immersed in water or other liquids either for NORMAL USE or performance assessment purposes shall be provided.

A recommendation calling the OPERATOR'S attention to the need for regular testing and periodic maintenance including inspection of the TRANSDUCER ASSEMBLY for cracks that allow the ingress of conductive fluid shall be provided.

Instructions shall be provided regarding the avoidance of unintended control settings and acoustic output levels.

Output limits selected according to 201.12.4.5.1 shall be declared in the ACCOMPANYING DOCUMENTS. For MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT the output limits shall be declared for each application.

Transesophageal probes shall be removed from the PATIENT *prior* to application of a defibrillator.

The outer surface of the portions of TRANSDUCER ASSEMBLY which is intended to be inserted into a PATIENT should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which ~~may~~ can cause harm.

As the use of ULTRASONIC DIAGNOSTIC EQUIPMENT is increasing in the home care area, special attention should be paid to provide information to this type of user. How this is addressed should be documented in the RISK MANAGEMENT FILE. See IEC 60601-1-11.

201.7.9.2.10 Messages

Replacement of the first paragraph:

The instructions for use shall list all system messages, error messages and fault messages that are generated and are visible to the OPERATOR, unless these messages are self-explanatory.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

After second dashed item, add:

– a list of the pertinent parts, components and~~/or~~ functions that should be checked after each cleaning, disinfection or sterilization cycle, and method(s) of inspection.

NOTE This list of parameters is neither exhaustive nor mandatory.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 *Technical data regarding acoustic output levels

For each mode, provide the maximum value of each THERMAL and MECHANICAL INDEX. These data shall be provided following Table 201.103 and listed in the ACCOMPANYING DOCUMENTS.

Numerical values shall be entered in the cells indicated with "✓".

The equipment setting related to each index shall be entered in the "operating control conditions" section of Table 201.103.

For a TRANSDUCER ASSEMBLY and ultrasound instrument console that satisfies all of the exemption conditions cited in 201.12.4.2 a) and ~~b~~c), information declared in the ACCOMPANYING DOCUMENTS shall state that the THERMAL INDICES are 0,7 or less and the MECHANICAL INDEX is 1,0 or less for all device settings. If 201.12.4.2 b) and c) are satisfied instead of a) and c), the value of 0,7 for THERMAL INDICES in this statement shall be replaced with 1,0.

NOTE 1 For Table 201.103, see Annex AA for a description of "Maximum Index Value' and (for *TIS* and *TIB*) 'Index Component Values'.

NOTE 2 An operating mode can be interpreted to be any DISCRETE-OPERATING MODE (like B, M) as well as any COMBINED-OPERATING MODE (like B+D+CFM).

NOTE 3 Per IEC 62359:2010 and IEC 62359:2010/AMD1:2017, the z_s and z_b values are entered for non-scanned (component) modes.

NOTE 4 According to 201.3.201, in the *TIB* model the bone tissue is located below a soft tissue. Therefore the "*TIB* at surface" component is equal to the "*TIS* at surface" component, not *TIC*.

NOTE 5 Annex EE provides an example table to allow 3rd parties to recalculate the *TI* and *MI* values for each operating mode, including the contributions from each mode in COMBINED-OPERATING MODES.

Table 201.103 – Acoustic output reporting table

MODE ____________

Index label			*MI*	*TIS* At surface	*TIS* Below surface	*TIB* At surface	*TIB* Below surface	*TIC*
Maximum index value			✓	✓		✓		✓
Index component value				✓	✓	✓	✓	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	✓					
	P	(mW)		✓		✓		✓
	P_{1x1}	(mW)		✓	~~✓~~	✓ (added)		
	z_s	(cm)			✓			
	z_b	(cm)					✓	
	z_{MI}	(cm)	✓					
	$z_{pii,\alpha}$	(cm)	✓					
	f_{awf}	(MHz)	✓	✓		✓		✓
Other Information	*prr*	(Hz)	✓					
	srr	(Hz)	✓					
	n_{pps}		✓					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm^2)	✓					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm^2)	✓					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm^2)	✓					
	p_r at z_{pii}	(MPa)	✓					
Operating control conditions	Control 1							
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	…							
	Control x							

NOTE 1 Only one operating condition per index.

NOTE 2 Data ~~should be entered~~ for "at surface" and "below surface" are entered in both the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) or b) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.~~2b~~2c) are met, it is not required to enter any data in the column related to *MI*.

~~NOTE 6 "✓" indicates cells where a numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.~~

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows*:*

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

aa) *For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.*

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Addition:

For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.

201.8.8.3 Dielectric strength

Addition:

aa) *For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.*

201.8.9.3.4 Thermal cycling

Addition, at the end of the first paragraph:

and, for ultrasonic transducer assemblies only, where T_1 is

– *10 °C above the maximum allowable temperature specified in the ACCOMPANYING DOCUMENTS for cleaning, disinfection, sterilization, normal use or storage.*

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

Addition:

This subclause does not apply to ULTRASONIC TRANSDUCER ASSEMBLIES.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows*:*

Additional subclause:

201.10.101 *Ultrasonic energy

The MANUFACTURER shall address the RISKS associated with ultrasonic energy in the RISK MANAGEMENT PROCESS as described in the text of this document.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Acoustic output shall be switched off when the signal acquisition is stopped (i.e.: the "freeze" feature is enabled).

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1.2.2 *APPLIED PARTS not intended to supply heat to a PATIENT

Addition:

TRANSDUCER ASSEMBLIES applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 43 °C in NORMAL CONDITIONS when measured under test conditions 201.11.1.3.101.1.

TRANSDUCER ASSEMBLIES applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 50 °C when measured under test conditions 201.11.1.3.101.2.

Compliance is checked by operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT and temperature tests as described in 201.11.1.3.

NOTE PATIENT contact surface includes any part of the APPLIED PART, not just the radiating surface, but excluding the cable.

201.11.1.3 *Measurements

Addition:

For the applied part of the TRANSDUCER ASSEMBLY, replace the third paragraph and the remaining text of the subclause with the following:

Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE.

201.11.1.3.101 Test conditions

For the purposes of this test, thermal steady state is considered reached when the rate of change of temperature is < 0,12 °C per minute for three consecutive minutes.

The TRANSDUCER ASSEMBLY shall be tested under the following conditions:

201.11.1.3.101.1 * Simulated use

The APPLIED PART of the TRANSDUCER ASSEMBLY shall be coupled acoustically to, and be initially in thermal ~~equilibrium~~ steady-state with, a test object such that the ultrasound emitted from the active surface of the TRANSDUCER ASSEMBLY enters the test object.

The ~~positioning, and~~ heating or cooling of the TRANSDUCER ASSEMBLY and the positioning of TRANSDUCER ASSEMBLY relative to the test object shall resemble those corresponding to the intended application of that TRANSDUCER ASSEMBLY. This includes using a typical amount of ultrasound coupling medium appropriate to the intended application.

The temperature shall be measured at the point on the APPLIED PART of the ULTRASONIC TRANSDUCER ASSEMBLY that contacts the PATIENT *during NORMAL USE and where the temperature is a maximum.*

The test object shall have thermal and acoustical properties mimicking those of an appropriate tissue. In the case where the TRANSDUCER ASSEMBLY is intended for external use this test object shall account for a skin layer.

For soft tissue, the material of the test object shall have the following properties:

– *specific heat capacity:* *(3 500 ± 500) J/(kg·K);*
– *thermal conductivity:* *(0,5 ± 0,1) W/(m·K);*
– *attenuation at 5 MHz:* *(2,5 ± 1,0) dB/cm.*

NOTE 1 A general guidance for the acoustic properties of appropriate tissue is given in ICRU report 61[1][3].

NOTE 2 As heat develops differently in tissue surfaces containing skin, bone or soft tissue, ~~careful consideration should be given~~ it is important to consider the choice of the model in relation to the intended use of the APPLIED PART. Additional guidance can be found in Annex DD and [2].

~~NOTE 3 For the purposes of this test, thermal equilibrium may be considered reached when the rate of change of temperature of the APPLIED PART is <= 0,2 °C per minute for three consecutive minutes.~~

The test object shall be designed (for example, using acoustic absorbers) to reduce heating the surface of the TRANSDUCER ASSEMBLY by minimizing ultrasound reflections.

Test method a) or b) specified below shall be selected.

Test method a) shall be used where the ULTRASOUND DIAGNOSTIC EQUIPMENT uses a closed loop temperature monitoring system, as the use of test method b) could result in inappropriate results.

- *the temperature of the test object should be stable,*
- *and after contact with each other, the temperature at the test object / APPLIED PART interface should be stable before the measurement is started.*

a) *Test criteria based on peak temperature measurements.*

The ambient temperature shall be 23 °C ± 3 °C.

For TRANSDUCER ASSEMBLIES intended for external use, the surface of the test object before contacting the APPLIED PART should be not less than 33°°C and stable.

As a good measurement practice, the temperature of the test object should not cool down during the test.

For invasive TRANSDUCER ASSEMBLIES, the temperature of the point of contact of the test object before contacting the APPLIED PART should be not less than 37 °C.

3 Numbers in square brackets refer to the Bibliography.

To meet the requirements of this test, the temperature of the surface of the APPLIED PART shall not exceed 43 °C.

b) *Test criteria based upon temperature rise measurements*

The ambient temperature shall be 23 °C ± 3 °C. Any THERMAL OFFSET existing at thermal steady state shall be a known, stable value (see Annex AA and 201.3.228).

For TRANSDUCER ASSEMBLIES intended for external use,

- *the initial temperature of the surface of the test object at the object-transducer interface before contacting the APPLIED PART shall be between 20 °C and 33 °C,*
- *the temperature measured under these test conditions shall be equal to the sum of 33 °C plus the THERMAL OFFSET plus the measured temperature rise.*

For INVASIVE TRANSDUCER ASSEMBLIES,

- *the initial temperature of the point of contact of the test object before contacting the APPLIED PART shall be between 20 °C and 37 °C,*
- *the temperature measured under these test conditions shall be equal to the sum of 37 °C plus the THERMAL OFFSET plus the measured temperature rise.*

To meet the requirements of this clause, the calculated temperature shall not exceed 43 °C.

For TRANSDUCER ASSEMBLIES intended for external use,

$$\Delta T_{tx} + \Delta T_{offset} + 33\ °C \le 43\ °C \quad (2)$$

For invasive transducer assemblies,

$$\Delta T_{tx} + \Delta T_{offset} + 37\ °C \le 43\ °C \quad (3)$$

NOTE 1 When following this test method, the temperature rise is defined as the difference between the temperature of the TRANSDUCER ASSEMBLY just before the transducer is activated acoustically and the maximum temperature of the TRANSDUCER ASSEMBLY measured during the test.

NOTE 2 The term "THERMAL OFFSET" is defined in 201.3.228. See also Figure AA.1.

~~201.11.1.3.1.1.1 Test methods~~

~~*Test method a) or b) specified below shall be selected.*~~

~~Test method a) shall be used where the ULTRASOUND DIAGNOSTIC EQUIPMENT uses a closed loop temperature monitoring system, as the use of test method b) could result in inappropriate results.~~

~~*a) Test criteria based on test object near human temperatures.*~~

- ~~*For TRANSDUCER ASSEMBLIES 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.*~~
- ~~*For INVASIVE TRANSDUCER ASSEMBLIES, 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 of this test, the temperature of the surface of the APPLIED PART shall not exceed 43 °C.*~~

~~*b) Test criteria based upon temperature rise measurements*~~

– *The ambient temperature shall be 23 °C ± 3 °C. For TRANSDUCER ASSEMBLIES intended for external use, the initial temperature of the surface of the test object at the object-transducer interface shall be between 20 °C and 33 °C, and the surface temperature rise of the APPLIED PART shall not exceed 10 °C. For INVASIVE TRANSDUCER ASSEMBLIES, the initial temperature of the surface of the test object at the object-transducer interface shall be between 20 °C and 37 °C, and the surface temperature rise shall not exceed 6 °C.*

For TRANSDUCER ASSEMBLIES intended for external use, the temperature measured under the test conditions of 201.11.1.3.1.1 shall be equal to the sum of 33 °C plus the measured temperature rise.

For INVASIVE TRANSDUCER ASSEMBLIES, the temperature measured under the test conditions of 201.11.1.3.1.1 shall be equal to the sum of 37 °C plus the measured temperature rise.

To meet the requirements of this clause, the calculated temperature shall not exceed 43 °C.

NOTE When following this test method, the temperature rise is defined as the difference between the temperature of the TRANSDUCER ASSEMBLY just before the test and the maximum temperature of the TRANSDUCER ASSEMBLY during the test as measured according to 201.11.1.3.1.1.

201.11.1.3.101.2 * Still air

Suspend the TRANSDUCER ASSEMBLY with a clean surface (no coupling gel applied) in still air or place it in a stationary position in an environmental chamber with minimal airflow across the APPLIED PART of the TRANSDUCER ASSEMBLY.

"In still air" means an environment without air movement (flow) and an air temperature of 23 °C ± 3 °C stable within 0,5 °C.

Test criteria are based upon temperature rise measurements.

The ambient temperature shall be 23 °C ± 3 °C and the initial temperature of the APPLIED PART of the TRANSDUCER ASSEMBLY shall be the ambient temperature or shall be offset from the ambient temperature by a known, stable value at thermal steady state (see Annex AA *and 201.3.228). During the test the sum of the* temperature rise *+ THERMAL OFFSET of the APPLIED PART 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, the THERMAL OFFSET, and 23 °C shall be regarded as the surface temperature under test conditions 201.11.1.3.101.2.

NOTE "In still air" means an environment without air movement (flow) and an air temperature of 23 °C ± 3 °C stable within 0,5 °C. Otherwise it is recommended that one corrects for temperature drift.

$$\Delta T_{tx} + \Delta T_{offset} + 23\,°C \leq 50\,°C \qquad (4)$$

201.11.1.3.2102 Operating settings

Operate the ULTRASONIC DIAGNOSTIC EQUIPMENT at a setting that gives the highest surface temperature of APPLIED PART of the TRANSDUCER ASSEMBLY. The transmit parameters of the test shall be recorded in the test report.

201.11.1.3.3103 Test duration

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

The test according to 201.11.1.3.101.1 shall be conducted for 30 min or until the thermal steady state is reached.

For the purposes of this test, thermal steady state can be considered reached when the rate of change of temperature of the APPLIED PART is < 0,12 °C per minute for three consecutive minutes.

The test according to 201.11.1.3.101.2 shall be conducted ~~for the shorter of~~:

a) *for 30 min; or*

b) *for twice the time period limited by an automatic output hold or "freeze" function in the case where the OPERATOR is not able to switch off that function; or*

c) *until thermal steady-state is reached.*

~~NOTE~~ If the ULTRASONIC DIAGNOSTIC EQUIPMENT automatically "freezes" or halts its output earlier than the time period given in this subclause, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be switched on again immediately.

201.11.1.3.~~4~~104 *Temperature measurement

The temperature of the TRANSDUCER ASSEMBLY should be measured by any appropriate means such as infra-red radiometry or thermocouple methods.

If a thermographic camera is used, see Annex AA *for further details.*

If a thermocouple is used, the thermocouple junction and adjacent thermocouple lead wire should be securely held in good thermal contact with the surface being measured. The thermocouple should be positioned and secured in such a way that it has a negligible effect on the temperature rise of the area being measured.

The size of the temperature measurement area of the sensor, or the focus size in case of an infra-red measurement system, should be such that any averaging effect is minimized.

The temperature shall be measured on the surface of the applied part of the TRANSDUCER ASSEMBLY in those areas that give the highest surface temperature.

The measurement uncertainty shall be recorded in the test report.

~~NOTE 1~~ *As part of measurement uncertainty determination, the measurement set-up can be used to make surface temperature measurements of ULTRASONIC TRANSDUCERS of known maximum surface temperature. It is recommended that the measurement set-up be validated.*

~~NOTE 2~~ *For the estimation of uncertainties, the ISO/IEC Guide 98-1 to the expression of uncertainty in measurement should be used [3].*

NOTE 1 Any means to measure the temperature can be a type that is not overly sensitive to direct ultrasonic heating (for example, if a thermocouple is used, it can be a thin film or fine wire). Additional factors, such as effects of conductive losses, ultrasonic heating and spatial averaging on the measurement sensors or its connecting cables after "averaging", are also relevant when assessing the measurement uncertainty.

NOTE 2 Example means for measuring surface temperature of externally applied TRANSDUCER ASSEMBLIES is provided in Annex DD of this document.

201.11.1.3.~~5~~105 Test criteria

The TRANSDUCER ASSEMBLY shall operate throughout the test as specified in 201.11.1.3.~~3~~103. During the test, the maximum temperature or the maximum temperature rise shall not exceed the limits specified.

Table 201.104 provides an overview of the tests and limits outlined in 201.11.1.3.

Table 201.104 – Overview of the tests noted under 201.11.1.3

~~Transducer type →~~ ~~Test to be applied ↓~~		~~External use~~	~~Invasive use~~
~~201.11.1.3.1.1~~ ~~Simulated use test~~	~~a) Temperature~~	~~*Initially temperature of the surface of the test object at the object / transducer interface shall not be less than 33 °C and shall be in thermal equilibrium.*~~ ~~The temperature shall not exceed 43 °C~~	~~*Initially test object maintained at not less than 37 °C*~~ ~~The temperature shall not exceed 43 °C~~
	~~b) Temperature rise~~	~~*Initially the temperature at the object-transducer interface shall be between 20 and 33°C and shall be in thermal equilibrium.*~~ ~~*The ambient temperature shall be 23 °C ± 3 °C.*~~ ~~The temperature rise shall not exceed 10 °C.~~	~~*Initially the temperature at the object-transducer interface shall be between 20 °C and 37°C.*~~ ~~*The ambient temperature shall be 23 °C ± 3 °C.*~~ ~~The temperature rise shall not exceed 6 °C.~~
~~201.11.1.3.1.2~~ ~~Still air test (no gel)~~	~~Temperature rise~~	~~*The ambient temperature shall be 23 ± 3 °C and shall be in thermal equilibrium.*~~ ~~*Initially the temperature at the surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature*~~ ~~The temperature rise shall not exceed 27 °C.~~	

Test to be applied		Transducer type	
		External use	Invasive use
201.11.1.3.101.1 Simulated use test	a) Temperature	*The surface of the test object before contacting the applied part should be not less than 33 °C and the temperature of the test object should be stable.* The temperature shall not exceed 43 °C	*The point of contact of the test object before contacting the applied part should be not less than 37 °C and the temperature of the test object should be stable.* The temperature shall not exceed 43 °C.
	b) Temperature rise	*Initially the temperature at the object-transducer interface shall be between 20 °C and 33 °C and shall be in thermal steady state.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise plus the THERMAL OFFSET shall not exceed 10 °C.	*Initially the temperature at the object-transducer interface shall be between 20 °C and 37 °C and shall be in thermal steady state.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise plus the THERMAL OFFSET shall not exceed 6 °C.
201.11.1.3.101.2 Still air test (no gel)	Temperature rise	*The ambient temperature shall be 23 ± 3 °C and shall be in thermal steady state.* *Initially the temperature at the surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature.* The temperature rise plus the THERMAL OFFSET shall not exceed 27 °C.	

201.11.6.5 *Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

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.*

Compliance is checked by the test ~~prescribed~~ required 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.

Parts of the TRANSDUCER ASSEMBLIES specified by the MANUFACTURER as intended to be immersed during NORMAL USE, shall meet the requirements of watertight equipment (IPX7).

NOTE 1 For this clause, NORMAL USE includes cleaning and disinfection.

Compliance is checked by the test ~~prescribed~~ required in IEC 60529:1989 for IPX7, with the exception of 14.2.7 a) and b).

NOTE 2 Parts of the TRANSDUCER ASSEMBLIES not intended to be immersed during NORMAL USE ~~may~~ can be temporarily protected for the purposes of the test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

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

– any display indicating THERMAL INDEX (TI) and MECHANICAL INDEX (MI); see 201.7.9.2.2, 201.7.2.101 and 201.12.4.2.

– technical data; see 201.7.9.3.101.

The accuracy of the data and controls specific to the surface temperature of INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use shall be specified, including any display of surface temperature, if provided; see 201.7.9.2.2 and 201.12.4.2.

NOTE Guidance for the estimation of uncertainties can be found in the ISO/IEC Guide 98-1 *Guide to the expression of uncertainty in measurement* ~~*should be used*~~ [3].

For hydrophone measurements on diagnostic systems that fulfil the 'low output' criteria of a) and c) or b) and c) in 201.12.4.2, the narrowband approximation of IEC 62127-1 can be applied even if the criteria of 5.1.7.1 in IEC 62127-1:2022 cannot be fulfilled. When using this simplification, the additional measurement uncertainty reflecting the limitations of a narrowband measurement of a broadband signal shall be considered, in particular, when comparing output data against thresholds.

See IEC 62127-1 for additional details.

201.12.4.2 Indication ~~of parameters~~ relevant to safety

Addition:

a) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not capable of exceeding either a SOFT TISSUE THERMAL INDEX of 0,7, a bone THERMAL INDEX of 0,7 or, for ULTRASONIC DIAGNOSTIC EQUIPMENT intended for transcranial or neonatal cephalic applications, a cranial THERMAL INDEX of 0,7, in any mode of operation, then no display of the THERMAL INDEX is required (see also Annex AA concerning 201.7.2.101).

b) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not intended for obstetric (including gynecologic when pregnancy is possible), neonatal transcranial, or neonatal spinal applications, and is not capable of exceeding either a SOFT TISSUE THERMAL INDEX of 1,0, a BONE THERMAL INDEX of 1,0 or, for ULTRASONIC DIAGNOSTIC EQUIPMENT intended for transcranial ~~or neonatal cephalic~~ applications, a CRANIAL THERMAL INDEX of 1,0, in any mode of operation, then no display of the THERMAL INDEX is required (see also Annex AA concerning 201.7.2.101).

NOTE 1 ULTRASONIC DIAGNOSTIC EQUIPMENT for which the OUTPUT POWER divided by the −12 dB OUTPUT BEAM AREA is less than 20 mW/cm^2 and the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY (I_{spta}) is less than 100 mW/cm^2 (cfr. low acoustic output criteria in 4.2.5 of IEC 61157:2007 and IEC 61157:2007/AMD1:2013 [38]) is not expected to exceed a THERMAL INDEX of 1,0 if, for all operation conditions, both f_{awf} < 10,5 MHz, and A_{aprt} < 1,25 cm^2. Consequently, the requirement listed in 201.12.4.2 b) is fulfilled.

c) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not capable of exceeding a MECHANICAL INDEX of 1,0 in any mode of operation, then no display of the MECHANICAL INDEX is required.

NOTE 2 ULTRASONIC DIAGNOSTIC EQUIPMENT for which the peak-rarefactional acoustic pressure (p_r) is less than 1 MPa is not capable of exceeding a mechanical index of 1,0 if, for all operation conditions, f_{awf} > 1,0 MHz. Consequently, the requirement listed in Clause 201.12.4.2 c) is fulfilled.

d) If the ULTRASONIC DIAGNOSTIC EQUIPMENT ~~is capable of exceeding either SOFT TISSUE THERMAL INDEX, BONE THERMAL INDEX of a value of 1,0 or, for ULTRASONIC DIAGNOSTIC EQUIPMENT intended for transcranial or neonatal cephalic applications, a CRANIAL THERMAL INDEX of 1,0, when any operational mode is active~~ does not meet the criteria in a) or b) for omitting a THERMAL INDEX display, then the capability shall be available for the OPERATOR to display the SOFT TISSUE THERMAL INDEX (when exceeding a value of 0,4), the BONE THERMAL INDEX (when exceeding a value of 0,4) or a CRANIAL THERMAL INDEX (when exceeding a value of 0,4), but not necessarily simultaneously, in such operational mode.

e) 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 it exceeds a value of 0,4 and is capable of exceeding a value of 1,0.

f) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of exceeding a MECHANICAL INDEX of 1,0 in any mode of operation, then the MECHANICAL INDEX shall be displayed when it equals or exceeds a value of 0,4 in such an operational mode.

g) The ULTRASONIC DIAGNOSTIC EQUIPMENT shall allow the OPERATOR to display simultaneously both a THERMAL INDEX (according to the requirements of a), b), d), and e) above) and the MECHANICAL INDEX (according to the requirements of c) and f) above).

h) The increments for the display of THERMAL INDICES, if displayed (see a) – g)), shall be no more than 0,2 over the entire range of display.

i) The increment for the display of MECHANICAL INDEX, if displayed (see a) – g)), shall be no more than 0,2 over the entire range of display.

j) 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 201.11.1.3).

201.12.4.3 Accidental selection of excessive output values

Replacement:

a) 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~~ can be reconfigured by the OPERATOR.

b) 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.

201.12.4.5.1 *Limits

Addition:

Acoustic output shall be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety related parameters specified in this document and other relevant information such as clinical experience.

NOTE For guidance on the relevance of the safety related parameters specified in this document, see Annex CC.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.13.1.2 * Emissions, deformation of ENCLOSURE or exceeding maximum temperature

Addition at the end of the third dash:

As an exception, for TRANSDUCER ASSEMBLIES intended for external use, the APPLIED PART temperature may can exceed the value in 201.11.1.2.2 of this document by up to 5 °C during a SINGLE FAULT CONDITION, if an alarm or indication is provided to the OPERATOR, as described in 12.3 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, indicating that a SINGLE FAULT CONDITION causing the temperature rise has occurred.

NOTE This exception is valid ONLY for TRANSDUCER ASSEMBLIES intended for application to the skin surface.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 ME SYSTEMS

Clause 16 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.6 ELECTROMAGNETIC COMPATIBILITY

Clause 6 of IEC 60601-1-2:2007 applies, except as follows:

202.6.1.1 Protection of radio services

202.6.1.1.1 Requirements

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 CISPR 11 is reported in Annex BB.

202.6.2 IMMUNITY

202.6.2.1 General

202.6.2.1.6 *Variable gain

Addition:

NOTE See Annex AA for gain adjustment technique.

202.6.2.1.10 *Compliance criteria

Amendment:

Replacement of dashes 8 through 11 as follows:

– the disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which may be attributed to a physiological effect and which may alter the diagnosis.
– the disturbance shall not produce an error in a display of incorrect numerical values associated with the diagnosis to be performed after 1st dash.
– the disturbance shall not produce an error in a displayed safety related indication
– the disturbance shall not produce unintended or excessive ultrasound output
– the disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature
– the disturbance shall not produce unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use

202.6.2.3 Radiated RF electromagnetic fields

202.6.2.3.2 Tests

Replacement of item c):

c) *According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 000 Hz modulation frequency (physiological simulation frequency), whichever represents the worst case condition. The modulation frequency adopted shall be disclosed in the test report.

202.6.2.6 Conducted disturbances, induced by RF fields

202.6.2.6.2 Tests

Replacement of item c):

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

The TRANSDUCER ASSEMBLY of the ULTRASONIC DIAGNOSTIC EQUIPMENT 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.*

– *TRANSDUCER ASSEMBLY 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 16-2.*

Replacement of item f):

f) **According to the intended use the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested using a 2 Hz or 1 000 Hz modulation frequency whichever represents the worst-case condition. The modulation frequency adopted shall be disclosed in the test report.*

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

202.6.2.7.1 Requirements

Replacement of item a):

a) ULTRASONIC DIAGNOSTIC EQUIPMENT shall comply with the requirements of 6.2.1.10 of IEC 60601-1-2 as modified by clause 202.6.2.1.10 of this standard at the IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2. Deviation from the requirements of 6.2.1.10 of IEC 60601-1-2 is allowed at the IMMUNITY TEST LEVELS specified in Table 10 of IEC 60601-1-2, 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 10 of IEC 60601-1-2.

202.7.1 Protection of radio services and other equipment

202.7.1.1 General

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 CISPR 11 is reported in Annex BB.

202.7.1.2 Operating modes

Replacement:

During EMISSIONS testing, the ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS.

The ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested in scanning mode unless the manufacturer concludes that standby mode is the most likely to result in an unacceptable risk.

The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report.

202.8.1 * General

Amendment:

Addition to 8.1 General, before NOTE 5:

The following pass/fail criteria shall be considered during and after the IMMUNITY tests of ULTRASONIC DIAGNOSTIC EQUIPMENT:

– the disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which can be attributed to a physiological effect and which may alter the diagnosis;
– the disturbance shall not produce an error in a display of incorrect numerical values associated with the diagnosis to be performed;
– the disturbance shall not produce an error in a displayed safety related indication;
– the disturbance shall not produce unintended or excessive ultrasound output;
– the disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
– the disturbance shall not produce unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.

202.8.2 PATIENT physiological simulation

Addition:

The use of a mimicking phantom is recommended to monitor the performance of the ULTRASONIC DIAGNOSTIC EQUIPMENT during testing.

202.8.9 * IMMUNITY TEST LEVELS

Addition to note c) in Table 4, e) in Table 5, e) in Table 6 and c) in Table 8:

According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT should be tested using a 2 Hz or 1 000 Hz modulation frequency (physiological simulation frequency), whichever is identified by the RISK MANAGEMENT PROCESS. The modulation frequency adopted shall be disclosed in the test report.

202.8.11 IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

Addition:

Add the following note at the end of the paragraph:

NOTE ULTRASONIC DIAGNOSTIC EQUIPMENT are likely to be sensitive to disturbances in the frequency range of the IMMUNITY test to proximity magnetic fields. The manufacturer RISK ANALYSIS will document the applicability of the test according to the intended use of the ULTRASONIC DIAGNOSTIC EQUIPMENT. The immunity pass/fail criteria in 202.8.1 will be applied.

212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (EMS)

IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply, except as follows:

212.4.2.2.2 Transient operating conditions

Addition:

If the instructions for use state a more restricted range of transient environmental operating conditions or an operation time shorter than 20 minutes at the transient environmental operating conditions, these conditions shall be justified in the RISK MANAGEMENT FILE.

A reduction of the test duration is allowed but not less than 5 min.

Annexes

The annexes of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

Annex AA
(informative)

Particular guidance and rationale

Clause 201.1.1 – Scope

The content of this document has largely been determined to cover ultrasonic medical diagnostic and monitoring equipment including ultrasonic echo ranging devices (both manual and automatic scanning), Doppler echo ULTRASONIC DIAGNOSTIC 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 ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of being used with numerous different types, power ratings and frequencies of TRANSDUCER ASSEMBLIES to cover a wide variety of applications. This has been taken into account in drafting this document.

It is anticipated that later editions of this document 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.

Subclause 201.7.2.13 – Physiological effects (SAFETY SIGNS and warning statements)

The transeosophageal INVASIVE TRANSDUCER ASSEMBLY is considered a unique case requiring special consideration due to its additional use in lengthy monitoring applications.

Subclause 201.7.2.101 – Acoustic output

With certain ULTRASONIC DIAGNOSTIC EQUIPMENT in some operating modes, ten 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~~ shall be avoided in many cases, as with MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT (see 201.12.4.3).

On most ULTRASONIC DIAGNOSTIC EQUIPMENT, there is generally provided a single control means for changing the amplitude of the acoustic output, while leaving other parameters (such as pulse length, duty cycle, etc.) unchanged. Often, the OPERATOR ~~must~~ shall 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 ULTRASONIC DIAGNOSTIC EQUIPMENT not capable of generating output levels producing unacceptable risk at any possible output level has been implemented in 201.12.4.2.

Subclause 201.7.9.2.2 – Warning and safety notices

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.

Subclause 201.7.9.3.101 – Technical data regarding acoustic output levels

Maximum index value

For the THERMAL INDEX: following 5.6.2 of IEC 62359:2010 and IEC 62359:2010/AMD1:2017, including Table 1:

For *TIS* and *TIB*, the Maximum Index Value is the larger of the sum of the 'at surface' Index Component Values and the sum of the 'below-surface' Index Component Values;

For *TIC,* the Maximum Index Value is the sum of the 'at-surface' non-scanned and scanned *TIC* Index Component Values.

For *MI*, following 5.6.3 of IEC 62359:2010 and IEC 62359:2010/AMD1:2017, the maximum index value is the largest MECHANICAL INDEX of all active TRANSMIT PATTERNS. i.e. the maximum index value is the largest of the MI index component values of the active DISCRETE-OPERATING MODES in a COMBINED-OPERATING MODE.

Subclause 201.10.101 – Ultrasonic energy

This document places the responsibility for establishing upper limits of allowed levels of acoustic output on the MANUFACTURER based on RISK ANALYSIS.

Concerns with possible excessive levels are addressed by requiring an interactive real-time display of acoustic output such as the THERMAL INDICES and MECHANICAL INDEX as included in this document.

Subclause 201.11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

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

NOTE General guidance for the acoustic properties of appropriate tissue is available in the literature [1].

When carrying out a risk analysis for the ULTRASOUND DIAGNOSTIC EQUIPMENT, the user of this document ~~must~~ shall take into account that the temperature limit of 43 °C in ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 is only applicable for long-term (more than 10 min) contact with healthy skin of adults. Special consideration should be taken 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~~ 10 min) inside the body is currently not well investigated. It is assumed 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 based on clinical experience.

The allowable maximum temperature of 43 °C for parts having contact with the PATIENT for more than 10 min is consistent with ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. This represents a safety factor of 2 relative to the threshold for thermally induced chronic damage to the kidney, one of the most sensitive mammalian tissues [4].

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 INVASIVE TRANSDUCER ASSEMBLY 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 transport effects such as blood perfusion, 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 temperature, 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.

Subclause 201.11.1.3 – Measurements

In the still-air test of 11.1.3 of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, essentially all of the electrical energy would be converted into heat within a 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 would drop quickly. The modification of 201.11.1.3 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 11.1.1, Table 24 of the ~~general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.)

This is also true for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use. Although contact with the internal surface of the oesophagus is prolonged, the time in which the initial transducer temperature is in contact with a single tissue site is relatively short. Furthermore, the transducer area that 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 [5], 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.

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 at the surface;
– a model consisting of a soft tissue mimic.

The test object should be designed such that increasing the size will have a negligible effect on the surface temperature of the TRANSDUCER ASSEMBLY.

When the TRANSDUCER ASSEMBLY 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~~ can 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.

Subclause 201.11.1.3.101.1 – Simulated use

The following figures show the thermal offset depending on probe types and depending on measurement method a) or measurement method b) for external probes.

Figure AA.1 shows the thermal behavior if the measurement is performed according to method a).

Figure AA.2 visualizes the thermal behavior during measurement according to method b) of a probe with internal heat source (left) and the thermal behavior of a probe with temperature drop after probe coupling to the tissue-mimicking material (right). The later one might occur for all probes where the probe works like a heat sink and transfers heat away from the tissue-mimicking material. In this example, the measurement is done at tissue-mimicking material temperature slightly below 33 °C.

Figure AA.3 shows the same scenario when the tissue-mimicking material is at environmental temperature. The right part of Figure AA.3 does not show a thermal drop, because the tissue-mimicking material is in thermal steady state with the probe and the surrounding air. Therefore, no heat transfer from the tissue-mimicking material to any other material occurs.

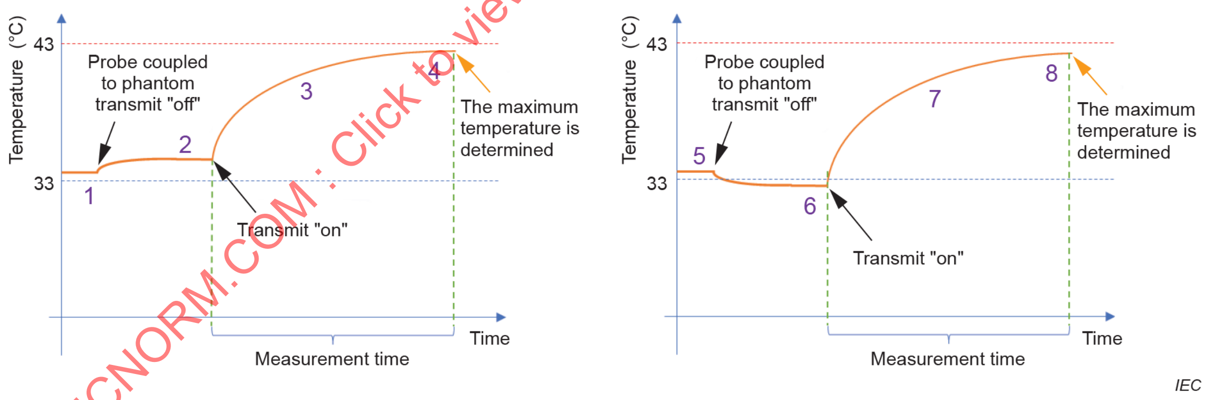


Figure AA.1a) – With heat source **Figure AA.1b) – Without heat source**

Figure AA.1 – Method a) for an external probe

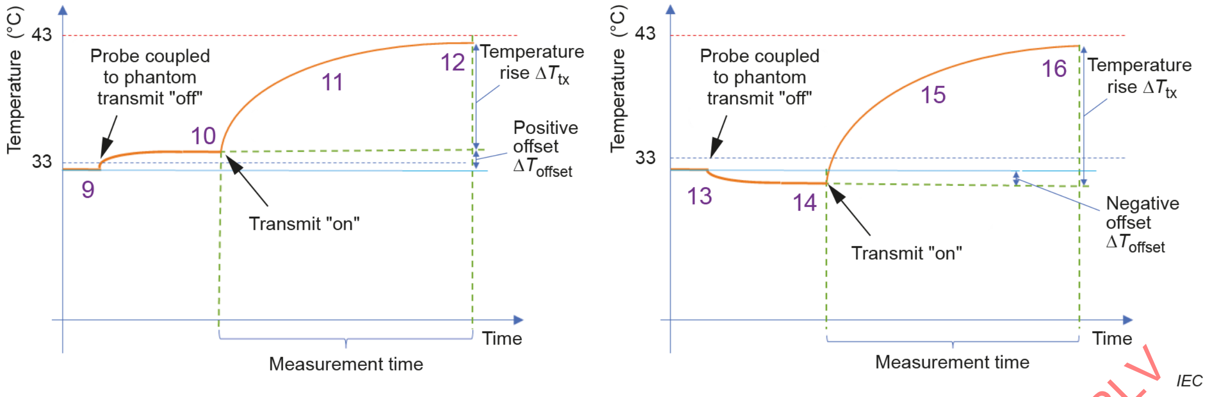


Figure AA.2a) – With heat source **Figure AA.2b) – Without heat source**

Figure AA.2 – Method b) for an external probe

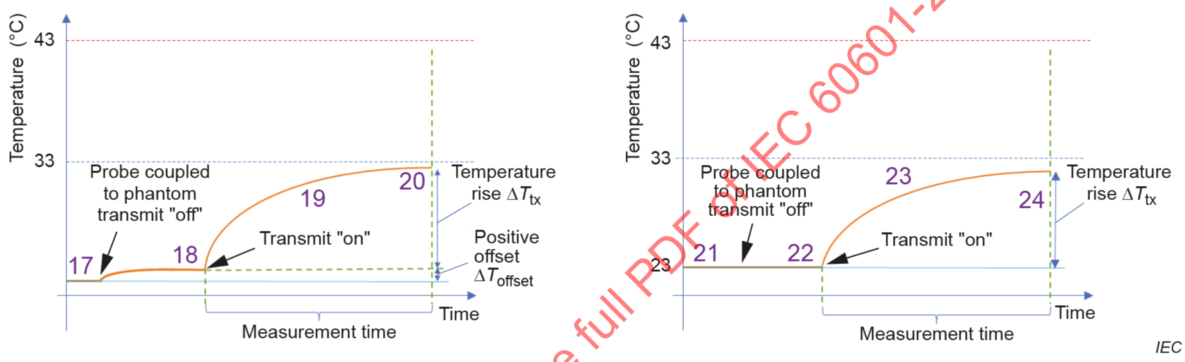


Figure AA.3a) – With heat source at room temperature **Figure AA.3b) – Without heat source at room temperature**

Figure AA.3 – Method b) for an external probe

Method a) for a probe **with** heat sources.

1) TMM surface is >33 °C before the probe is coupled to the TMM.

2) The applied part – TMM surface interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (3) is started.

3) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

4) The maximum temperature during the measurement cycle is determined.

Method a) for a probe **without** heat sources.

5) TMM surface is >33 °C before the probe is coupled to.

6) The applied part – TMM interface drops slightly because heat is transferred away from the TMM. The probe acts like a heat sink and moves heat away from the TMM. The amount depends on the probe heat capacity, thermal conductivity, and probe handle surface area. For some probes, the effect might be negligible. A steady state condition shall be reached before (7) is started.

7) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

8) The maximum temperature during the measurement cycle is determined.

Method b) for a probe **with** heat sources, where method b) is used at temperatures close to method a)

9) TMM surface is <33 °C before the probe is coupled to.

10) The applied part – TMM interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (11) is started.

11) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached.

12) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, can help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **without** heat sources, where method b) is used at temperatures close to method a)

13) TMM surface is <33 °C before the probe is coupled to.

14) The applied part – TMM interface drops slightly because heat is transferred away from the TMM. The probe acts like a heat sink and moves heat away from the TMM. The amount depends on the probe heat capacity, thermal conductivity, and probe handle surface area. A steady state condition shall be reached before (15) is started.

15) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached.

16) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **with** heat sources, where method b) is used at room temperature

17) TMM surface is ~23 °C before the probe is coupled to.

18) The applied part – TMM surface interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (19) is started.

19) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

20) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **without** heat sources, where method b) is used at room temperature

21) TMM surface is ~23 °C before the probe is coupled to.

22) The applied part – TMM interface does not drop because the phantom, probe and environment are in thermal steady state. A steady state condition shall be reached before (23) is started.

23) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

24) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the temperature rise. The second sensor is visualized as a light blue line.

Subclause 201.11.1.3.101.2 – Still air

For some TRANSDUCER ASSEMBLIES such as mechanically rocked 3D probes, or solid state probes with integrated multiplexing electronics, the temperature of the APPLIED PART (surface temperatures) may not stabilize at an initial steady-state temperature equal to the air-ambient temperature when the acoustic power is 'off' (i.e.: non-energized transducer elements). Rather, a fixed offset temperature may exist.

In such cases, the initial APPLIED PART temperature shall be the ambient temperature plus ~~a steady-state OFFSET temperature~~ the THERMAL OFFSET, and the final surface temperature shall be considered as the sum of the measured APPLIED PART temperature rise obtained during the 30 min test plus the offset temperature plus 23 °C.

Note that the THERMAL OFFSET might be eliminated by completely disconnecting the TRANSDUCER ASSEMBLY from the ULTRASONIC DIAGNOSTIC EQUIPMENT when the acoustic power is off.

Subclause 201.11.1.3.104 – Temperature measurement

Temperature measurement with thermographic camera (infrared camera) under the still air condition should be conducted with reference to IEC TS 63070:2019 which covers measurement on both diagnostic and therapeutic (physiotherapy and HITU) equipment [52].

Subclause 201.11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS

All TRANSDUCER ASSEMBLIES are assumed to require some contact with fluids during normal operation. Some TRANSDUCER ASSEMBLIES 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 TRANSDUCER ASSEMBLIES, employed for contact scanning, need only minimal contact with some coupling gel at the TRANSDUCER ASSEMBLY'S active surface. The MANUFACTURER is expected to specify, through knowledge of the application and TRANSDUCER ASSEMBLY design, the parts of the TRANSDUCER ASSEMBLY that ~~may~~ can be wetted in NORMAL USE, see 201.7.9.2.2.

The requirement and test as specified are considered suitable for this ULTRASONIC DIAGNOSTIC EQUIPMENT and avoid conflict with the WATERTIGHT requirements of ~~the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. The tests specified are documented in IEC 60529. The IPX1 code indicates protection of equipment against the 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.

Subclause 201.12.4.5.1 – Limits

While this document places no upper limits on permitted levels of acoustic output, all EQUIPMENT is limited for technical reasons, compliance with local regulatory requirements, or reasons resulting from the MANUFACTURER'S RISK MANAGEMENT. On the one hand the MANUFACTURERS should continuously track the scientific discussions on safety of ultrasonic fields for diagnostic ultrasound, on the other hand the OPERATORS should know about the – possibly application-dependent – limits of their EQUIPMENT as selected by the MANUFACTURER.

Compliance with 201.12.4.5.1 ~~may~~ can be checked by inspection of the relevant documentation of the results of the RISK MANAGEMENT process provided by the MANUFACTURER, including relevant information such as clinical experience.

Clause 201.17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

ULTRASONIC DIAGNOSTIC EQUIPMENT is categorised 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 ~~has to~~ shall be categorised as class B. For further details, see Annex BB.

ULTRASONIC DIAGNOSTIC EQUIPMENT, which is the subject of this document, is classified in Group 1 (under Annex C.2, IEC 60601-1-2:2014), since the device ~~must~~ shall intentionally generate radio frequency 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.

For INVASIVE TRANSDUCER ASSEMBLIES, radiated and conducted emissions per IEC 60601-1-2 should be performed both with and without the transducer active to ensure compliance when the transducer is outside the body and not activated, and secondly, when the transducer is inside the body and activated. The condition "inside the body and activated" should be simulated using a phantom having the same attenuation as human tissue in the frequency pass band of the transducer. The phantom should only be used while making radiated ~~and/~~or conducted emission measurements in the frequency pass band of the transducer unless the phantoms frequency characteristics are known over the entire frequency range of 150 kHz to 1 000 MHz.

~~**Concerning 202.6.2.1.6 – Variable gain**~~

~~ULTRASONIC DIAGNOSTIC EQUIPMENT that incorporates a variable gain shall be tested at the typical user gain. This should be determined using a tissue mimicking and/or flow phantom appropriate for the application to adjust the gain and other image enhancement adjustments to represent typical user settings. The phantom shall be removed prior to IMMUNITY testing in accordance with 101.6.2 of IEC 60601-1-2.~~

~~If this requirement can be met with the normal software of the ULTRASONIC DIAGNOSTIC EQUIPMENT, the test shall be performed using the normal software. If this requirement cannot be met using the normal software of the ULTRASONIC DIAGNOSTIC EQUIPMENT, 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 ~~202.6.2.1.10~~ 202.8.1 – ~~Compliance criteria~~ General

There is common agreement that it is not possible to require that nothing 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 ~~6.2 of IEC 60601-1-2~~ 8.1 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Examples of conformance to the compliance criteria:

– 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.

~~**Concerning 202.6.2.3.2 c) and 202.6.2.6.2 f)**~~

~~Table 9 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 1 000 Hz 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 on the order of kHz).~~

Subclause 202.8.9 – IMMUNITY TEST LEVELS

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 on the order of kHz). 2 Hz modulation frequency is intended to test the former, while 1 kHz modulation frequency is intended for the latter.

Annex BB
(informative)

Guidance in classification according to CISPR 11

Rules for classification and separation into groups of equipment are contained in CISPR 11. ULTRASONIC DIAGNOSTIC EQUIPMENT that is the subject of this document is classified in Group 1 (under Annex C.2, IEC 60601-1-2:2014), since the device ~~must~~ shall 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.

- Subclause ~~4~~5.2 of CISPR 11:2024

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.~~

– Class A equipment is equipment suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

– Class B equipment is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Annex CC
(informative)

Guidance to the MANUFACTURER on the interpretation of *TI* and *MI* to be used to inform the OPERATOR

CC.1 Guidance

It is the responsibility of the OPERATOR to understand the risk of the output of the ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the patient. To be able to do so the manufacturer of the device should provide information to the user regarding how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX and MECHANICAL INDEX. Brief reviews of the rationale and derivation of MI and TI are available in the literature [14, 19]. A detailed rationale and derivation of *TI* and *MI* models is reported in Annex A of IEC 62359:2010, while brief reviews are available in the literature [6], [7]. This annex provides guidance on subjects that should be taken into account in drawing up a PRUDENT USE STATEMENT to be used in the instructions for use as specified in 201.7.9.2.2 of this document.

The relationship of various acoustic output parameters (e.g., acoustic intensity, pressure, power, etc) to biological endpoints is not presently fully understood. Evidence to date has identified two fundamental mechanisms, thermal and mechanical, by which ultrasound may can induce bioeffects [8], [9], [5], [10], [11], [12] and, in certain cases, alteration or damage to tissue.

The temperature rise and the possibility of cavitation seem to depend on such factors as the total energy output, the mode, the shape of the ultrasound beam, the position of the focus, the centre frequency, the shape of the waveform, the pulse repetition frequency, and the duty factor. The *TI* and *MI* are indices designed to give the user instant information about the potential for thermal or mechanical bioeffects. Because the *MI* and *TI* reflect instantaneous output conditions, they do not take into account the cumulative effects (especially heating) of the total examination time. It is relevant to indicate that shortening insonation times can give a large safety margin under some conditions (wide, scanning beams in soft tissue) but no significant margin under other conditions (narrow, non-scanning beams on bone) [13].

As far as cavitation is concerned there is agreement that the potential for biological effects rises with a rising peak rarefactional pressure. There is lesser agreement about the frequency dependence of the occurrence of cavitation in tissue [9], [10], [14], [15], [16], [17]. Nevertheless, the *MI* is intended to give a relative indication of the potential for mechanical bioeffects such as cavitation.

The *TI* gives a relative indication of the potential for temperature increase at a specific point along the ultrasound beam. The reason for the term "relative" is that the assumed conditions for heating in tissue are complex such that any single index or model cannot be expected to give the actual increase in temperature for all possible conditions and tissue types. Thus, for a particular beamshape, a *TI* of 2 represents a higher temperature rise than a *TI* of 1 but does not necessarily represent a rise of 2 °C. The important point about the *TI* is that it is designed to make the OPERATOR aware of the possible temperature rise at a particular point in tissue. To inform the OPERATOR, limitations about the use of the indices are given below.

Subclause 201.12.4.5.1 of this document requires that acoustic output be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety related parameters specified in this document. The indices do not presently provide absolute safety limits. Safety limits based on biological effects remain a topic of research for consideration in future standards. The demarcation between safe levels and levels where there exists a potential for biological effects is of importance for the OPERATOR.

The WFUMB [5] gives some guidelines: embryonic and foetal *in situ* temperature above 41 °C (4 °C above normal temperature) for 5 min or more should be considered potentially hazardous.

The same is true if the anticipated acoustic pressure amplitude at the surface of the postnatal lung tissue exceeds 1 MPa. However, the actual threshold for effects in the lungs of mammalian laboratory species is a complex combination of the values of the acoustic output parameters [18]

What the indices do provide is an indication of the conditions that are more likely than others to produce thermal ~~and/~~or mechanical effects.

For example, *TI* values towards the upper end of the range (over 1,0) might best be avoided in obstetric applications. Such a restriction allows a reasonable safety margin considering the WFUMB recommendation that a temperature increase of 4 °C for 5 min or more should be considered as potentially hazardous to embryonic and foetal tissue [5]. However, if a particular clinical result cannot be obtained with lower values, increased output may be warranted, but particular attention should be paid to limiting the exposure time. Any extra thermal load to the foetus when the mother has a fever is also unwise, and again note should be made to avoid high *TI* values [19]. ISUOG [20] states that doppler ultrasound should not be used routinely on foetuses between 11 and 14 weeks of pregnancy, in addition *TI* should not exceed 1 when doppler ultrasound is performed, and that the exposure time should be kept as short as possible and should not exceed 60 min (usually 5 min to 10 min).

BMUS [21] presents recommended maximum *TI* and *MI* values for each application, as well as maximum recommended scanning times for a range of *TI* values. AIUM [22] also has published recommended maximum scanning times for displayed *TI* values. These two safe use guidelines agree for obstetrical, neonatal trans-cranial, and neonatal spinal exams. However, for all other exams, the AIUM recommendations are less conservative, as explained in Harris et al. 2016 [23]. For obstetric, neonatal transcranial, and neonatal spinal exams, both safe use guidelines begin at *TI*=0,7 (i.e., they state that there is no scanning time limit if *TI* ≤ 0,7).

The modelling for predicting *TI* assumes some cooling by blood perfusion. For applications where poorly perfused tissues are expected, the *TI* may underestimate the possible worst-case temperature rise, and again the *TI* should be maintained at a lower value. Conversely, when scanning organs known to be well perfused, such as hepatic, cardiac or vascular structures, the value of *TI* may overestimate the temperature rise.

In clinical applications where the *TIS* has been selected to be shown on the screen, it may well be more appropriate to inform the OPERATOR to pay attention to the value of *TIB*. Examples are for breast scanning, when ribs may be exposed, and for vascular studies when vessels lie close to bone surfaces.

The assumption is made that the surface heating in soft tissue SCANNING MODE is always larger than the worst-case bone heating at depth. This assumption may not be universally true, and for this reason *TI* values in both B-mode and Doppler imaging modes in second and third trimester scanning ~~must~~ shall be interpreted with caution.

The *TI* values in SCANNING MODE predict heating in tissue next to the transducer surface due only to the energy absorbed from the beam. No correction is made for the heating of the transducer itself. The same is true for transcranial transducers and smaller unscanned transducers where the heating is also predicted next to the transducer.

The *MI* becomes important at a gas/soft tissue interface, for example in cardiac scanning where the lung surface ~~may~~ can be exposed. Most critically, however, it is with the use of contrast materials when most attention should be made to limit *MI*.

There are always limitations due to measurement and parameter determination imperfections when utilizing mathematical models. Specific limitations of the *MI* and *TI* are identified in IEC 62359. These limitations should be taken into account when drawing up guidance to the user on the interpretation of the indices.

The EFSUMB Clinical Safety Statement for Diagnostic Ultrasound [24] is useful information. For example, B mode including coded transmission technology, spectral pulse wave Doppler and Doppler imaging modes (such as color flow imaging and power Doppler imaging, etc.) can produce more tissue heating and higher *TIS*.

Attention should be paid to the use of long-duration waveforms with higher outputs than normal diagnostic ultrasound, such as shear wave elastography [25], which evaluates the elasticity of shear waves using acoustic radiation forces. If there is bone tissue near the focal point, there is a concern of a significant temperature rise [26] [27]. In animal studies, it has been reported that exposed ultrasound to the heart with contrast agents causes premature ventricular contractions [28], and when exposed ultrasound to lung tissue, pulmonary haemorrhage occurs [29] [30] [31]. It may not be appropriate or valid to apply the current *TI* models in the shear wave elastography: the *TI* and *MI* displayed for these applications may represent an underestimate of the temperature rises and mechanical effects to be expected [25]. So far, no specific risk indicator has been developed, thus the duration of the shear wave elastography should be kept as low as possible to reduce the thermal stress to the targeted tissue.

Table CC.1 summarizes the relative importance of maintaining low index values in specific scanning situations.

Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations

	Of greater importance	**Of less importance**
MECHANICAL INDEX	With contrast material Cardiac scanning (lung exposure) Abdominal scanning (bowel gas)	In the absence of gas bodies: i.e. in most tissue imaging
THERMAL INDEX	First trimester scanning Foetal skull and spine Neonatal head PATIENT with fever In any poorly perfused tissue Ophthalmic scanning (requires different risk estimate) If ribs or bone is exposed: *TIB*	In well perfused tissue i.e. liver, spleen In cardiac scanning In vascular scanning

CC.2 Prudent use

It is conventional to consider all biological effects of ultrasound as deterministic effects, in contrast to the assumption for ionizing radiation, for which it is known that some effects are stochastic and act without threshold. For some effects, e.g., those due to inertial cavitation, this reflects the fact that the responsible physical mechanism does not occur below a particular exposure level. For other effects, e.g., those due to increased temperature, this ~~may~~ can reflect the difficulty of observing a small increase in the rate of occurrence of rare events. In order for an apparent threshold of this type to be exceeded, a biological effect ~~must~~ shall occur frequently enough for an observer to be aware of having "observed" an effect. A temperature rise from 37 °C to 40 °C for quite a long time may be deemed sub-threshold because it produces too low an increased incidence to be observed, whereas a temperature rise to 42 °C for any duration may not be acceptable, i.e., it may produce an observable effect. An appropriate guide to the user would be that although there may be a biological effect, not all biological effects result in a hazard. Healthy human cells are obviously able to survive small temperature rises. Apart from the fact that the science evaluating the hazard is incomplete at the moment, there is enough evidence about thermal teratology, exposure levels, and temperature rise to carry out a basic risk analysis.

A prudent starting-point for each examination would be first to set the machine for the lowest index setting and then modify from this level until a satisfactory image or Doppler signal is obtained, keeping track of the *TI* and~~/or~~ *MI*; and second, the exposure time, during one examination, should be kept as short as possible. A safety guideline on this should be included [19].

Annex DD
(informative)

Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES

DD.1 General

The test object set-up described below is a result of measurements presented in the report [32]. For at least 10 different transducers, the surface temperatures of the transducers as measured when radiating into human under-arms were compared with the set-up described.

Basically, the set-up consists of a piece of soft tissue mimicking material (TMM) covered by a slab of silicone rubber on which a (thin film) thermocouple is placed (see Figure DD.1). The TMM is placed on a piece of material that absorbs all acoustic energy.

The properties of the materials used will be those of silicon and TMM as listed in Table DD.1:

Table DD.1 – Acoustic and thermal properties of tissues and materials

Tissue/ material	Velocity *c* m/s	Density *ρ* kg/m³	Attenuation coefficient *α* dB/cm-MHz	Acoustic impedance *Z* 10^6 kg/m²-s	Spec. Heat capacity *C* J/kg-K	Thermal Conductivity *κ* W/ kg-K	Thermal Diffusivity *D* 10^{-6} m²/s	Source
Skin	1 615	1 090	2,3 to 4,7 3,5 ~~7)~~	1,76	3 430	0,335	0,09	ICRU rep. 61, 1998 [1] Chivers 1978 [33]
Soft tissue	1 575	1 055	0,6 to 2,24 [a]	1,66	3 550	0,525	0,150	ICRU rep. 61. 1998 [1]
Soft tissue fatty	1 465	985	0,4	1,44	3 000	0,350	0,135	ICRU rep. 61, 1998 [1]
Cortical bone[b]	3 635	1 920	14 to 22	6,98	1 300	0,3 to 0,79	0,32	ICRU rep. 61, 1998 [1]
Silicone	1 021	1 243	1,8[c]	1,3		0,25		TNO / Dow Corning[32]
TMM	1 540	1 050	0,5[c]	1,6	3 800	0,58	0,15	TNO (Soft Tissue Model)

[a] Frequency dependence: $f^{1,2}$.

[b] Wide uncertainty has been reported in bone properties [34].

[c] Determined at 3 MHz.

DD.2 Preparation of the soft tissue mimicking material (TMM)

A mixture is made from the materials provided in Table DD.2 (weight % pure components).

Table DD.2 – Weight % pure components

Component	Weight %
Glycerol	11,21
Water	82,95
Benzalkonium chloride	0,47
Silicon Carbide (SiC (-400 mesh))	0,53
Aluminium Oxide (Al_2O_3 (0,3 µm))	0,88
Aluminium Oxide (Al_2O_3 (3 µm))	0,94
Agar	3,02
Sum	100,00

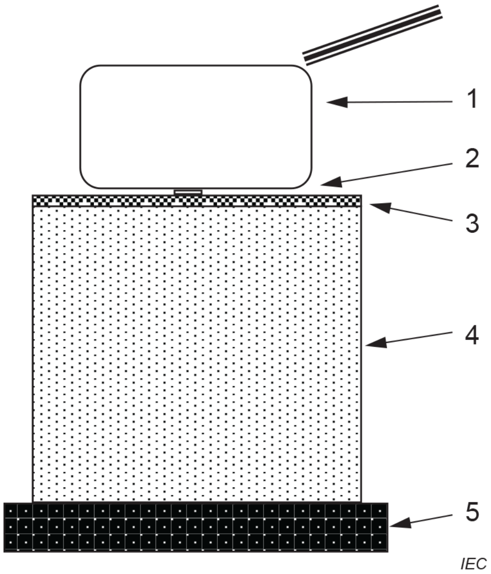
- Recipe to prepare the soft tissue mimicking material and the set-up
  1) Mix all components listed in the table and degas at laboratory temperature.
  2) Heat, while stirring, until 90 °C

     To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
  3) Cool the substance, while stirring as long as the viscosity allows, until about 47 °C,

     To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
  4) Pour the substance quickly in a mould and let it further cool down while the mould is covered.
  5) The TMM is now ready for use. To prepare the total measurements set-up, the TMM should be covered with a slab of silicone rubber with a thickness of 1,5 mm. Take care that there is no air between the TMM and the silicon rubber. (This will result in about equal measurement results as when using human under-arms). Although Figure DD.1 shows a set-up for a flat transducer surface, a curved surface is easily obtained by cutting the curvature in the TMM.
  6) A (thin film) thermocouple ~~is to~~ shall be placed on top of the silicone rubber layer.
  7) Finally the transducer under test ~~has to~~ shall be placed, coupled with acoustic coupling gel.
- Maintenance

The material should be stored in a closed container under normal laboratory conditions (18 °C to 25 °C). While stored, keep the material in a water/glycerol mixture to prevent it from drying out and to avoid air contact. This mixture contains 88,1 % (weight) demineralised water and 11,9 % (weight) glycerol (purity >99 %).

The shelf life of the material if it is preserved without air contact is at least one year. The addition of a 0,5 % (weight) solution of benzalkonium chloride acts as an antifungal agent extending the life of the phantom. With produced samples shelf lives over 2 years were found.



Key

1 ULTRASONIC TRANSDUCER under test, coupled to the test object using acoustic coupling gel

2 Thermal sensor, e.g. thin film thermocouple

3 Silicone rubber, thickness: 1,5 mm

4 Soft tissue mimicking material (TMM)

5 Acoustic absorber

Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers

Annex EE
(informative)

Acoustic output table intended for third parties

Table EE.1 provides an example acoustic output table to allow 3rd parties to recalculate the *TI* and *MI* values for each operating mode, including the contributions from each mode in COMBINED-OPERATING MODES.

The 'index component values' for *MI* and *TIC* are the index values for each DISCRETE-OPERATING MODE comprising the operating mode.

The 'index component values' for *TIS* and *TIB* are the values of the 'at-surface' and below-surface' *TI* formulations for each DISCRETE-OPERATING MODE comprising the operating mode. "✓" indicates cells where to enter one or more numerical values. The equipment setting related to the index is entered in the operating control section.

NOTE 1 See Annex AA for descriptions of "maximum index value' and 'index component values'.

NOTE 2 An operating mode can be interpreted to be any DISCRETE-OPERATING MODE (like B, M) as well as any COMBINED-OPERATING MODE (like B+D+CFM).

NOTE 3 According to 201.3.201, the bone tissue is located deeper position in the *TIB* model. Therefore "*TIB* at surface" is equal to "*TIS* at surface", not *TIC*.

Table EE.1 – Example of acoustic output table for third parties

MODE: ______________________

Index label		*MI*	*TIS*			*TIB*			*TIC*	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Maximum index value		✓	✓			✓			✓	
Index component value		✓	✓	✓	✓	✓	✓	✓	✓	✓
Associated acoustic parameters	$p_{r,\alpha}$ at z_{MI} (MPa)	✓								
	P (mW)		✓	✓		✓	✓		✓	✓
	P_{1x1} (mW)		✓	✓	✓	✓	✓			
	Min. of $[P_\alpha(z_s), I_{ta,\alpha}(z_s) \times 1\ cm^2]$(mW)				✓					
	z_s (cm)				✓					
	z_{bp} (cm)				✓			✓		
	z_b (cm)							✓		
	z_{pii} (cm)	✓			✓			✓		
	z_{MI} (cm)	✓								
	d_{eq} at $_{zb}$ (cm)							✓		
	f_{awf} (MHz)	✓	✓	✓		✓	✓		✓	✓
	Dim of A_{aprt} X (cm)		✓	✓		✓	✓		✓	✓
	Dim of A_{aprt} Y (cm)		✓	✓		✓	✓		✓	✓

Index label			*MI*	*TIS*			*TIB*			*TIC*	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Other information	Mode components		✓	✓	✓		✓	✓		✓	✓
	t_d	(µsec)	✓								
	prr	(Hz)	✓								
	srr	(Hz)	✓								
	p_r at z_{pii}	(MPa)	✓								
	d_{eq} at z_{pii}	(cm)							✓		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	✓								
	Focal length	*FLx* (cm)	✓			✓			✓		
		FLy (cm)	✓			✓			✓		
Operating control conditions	Control 1										
	Control 2										
	Control 3										
	Control 4										
	Control 5										
	…										
	Control x										

NOTE 1 Only one operating condition per index.

NOTE 2 Data can be entered for each component transmit pattern active in COMBINED-OPERATING MODES.

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) or b) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2c) are met, it is not required to enter any data in the column related to *MI*.

NOTE 6 Focal Length is a NOMINAL value.

~~NOTE 7 "✓" indicates cells where one or more numerical value should be entered. The equipment setting related to the index has to be entered in the operating control section.~~

NOTE 7 "Mode component" identifies the DISCRETE-OPERATING MODES in a COMBINED-OPERATING MODE. As an example of the labelling of mode components, see 4.1 of IEC 61157:2007.

NOTE 8 'Dim of A_{aprt}' is, for scanning modes, the dimensions of the SCANNED APERTURE AREA and, for non-scanning mode, the dimensions of the OUTPUT BEAM AREA, see definition section of IEC 62359.

Bibliography

[1] International Commission on Radiation Units and Measurements (ICRU), *Tissue substitutes, phantoms and computational modelling in medical ultrasound*, report 61, 1998, ISBN 0-913394-60-2

[2] HEKKENBERG, RT. and BEZEMER, RA. *Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers.* TNO report: PG/TG/2001.246, Leiden, 2002, ISBN 90-5412-078-9

[3] ISO/IEC Guide 98-1:2024, *Guide to the expression of uncertainty in measurement – Part 1: Introduction*

[4] DEWEY, WC. Arrhenius relationships from the molecule and cell to the clinic. *Intl J Hyperthermia*, 1994, 10(4): pp. 457-483

[5] World Federation for Ultrasound in Medicine and Biology (WFUMB), *Conclusions and Recommendations on Thermal and Non-thermal Mechanisms for Biological Effects of Ultrasound*. Report of the 1996 WFUMB Symposium on Safety of Ultrasound in Medicine. Barnett, S. B (ed). *Ultrasound in Medicine and Biology*, Vol 24, suppl 1, 1998

[6] ABBOTT, JG. Rational and Derivation of MT and TI – a Review. *Ultrasound in Med & Biol*, 1999, Vol. 25, No. 3, pp 431 – 441

[7] DUCK, FA. The meaning of Thermal Index (TI) and Mechanical Index (MI) values. *BMUS Bulletin*, Nov. 1997, pp. 36-40

[8] American Institute of Ultrasound in Medicine (AIUM). Bio-effects considerations for the safety of diagnostic ultrasound. *J Ultrasound Med 7*: supplement (1988)

[9] APFEL, RE. and HOLLAND, CK. Gauging the likelihood of cavitation from short-pulse low-duty cycle diagnostic ultrasound. *Ultrasound Med Biol*, 1991, 17: p.179-185

[10] American Institute of Ultrasound in Medicine (AIUM), Mechanical Bioeffects from Diagnostic Ultrasound: AIUM Consensus Statement. *J. Ultrasound Med*., 2000, Vol. 19, No. 2 or 3

[11] SALVESEN, KA. *Epidemiological studies of diagnostic ultrasound. Chapter 9, In: The safe use of ultrasound in medical diagnosis.* British Medical Ultrasound Society/British Institute of Radiology. Editors ter Haar, G.R. and Duck, F.A., 2000, pp. 86-93

[12] National Council on Radiation Protection and Measurements (NCRP), *Exposure criteria for medical diagnostic ultrasound: II. Criteria based on all known mechanisms*, NCRP Report No. 140, National Council on Radiation Protection and Measurements, Bethesda MD (2002)

[13] LUBBERS J., HEKKENBERG, RT., BEZEMER, RA. Time to Threshold (TT), a safety parameter for heating by diagnostic ultrasound. *Ultrasound in Med. & Biol.*, May 2003, Vol. 29, 5, pp.755-764

[14] CHURCH, CC. Spontaneous Homogeneous Nucleation, Inertial Cavitation and the Safety of Diagnostic Ultrasound. *Ultrasound Med. and Biol.*, 2001, 28(10), 1349-1364

[15] CHURCH, CC. Frequency, pulse length, and the mechanical index. *Acoust Res Lett Online,* 2005, 6(3):162-168

[16] ŠPONER, J. Dependence of the cavitation threshold on the ultrasonic frequency. *Czech. J. Phys.*, 1990, 40: pp. 1123–1132

[17] ŠPONER, J. Theoretical estimation of the cavitation threshold for very short pulses of ultrasound. *Ultrasonics,* 1991, 29: pp. 376–380

[18] CHURCH, CC., O'BRIEN, WC. Evaluation of the Threshold for Lung Hemorrhage by Diagnostic Ultrasound and a Proposed New Safety Index. *Ultrasound Med Biol,* 2007, 33

[19] BARNETT, SB, ter HAAR, GR., ZISKIN, MC., ROTT, H-D., DUCK, FA., MAEDA, K. International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine. *Ultrasound in Medicine and Biology*, 2000, Vol. 26, No. 3

[20] Bioeffect and Safety Committee of ISUOG. ISUOG statement on the safe use of Doppler in the 11 to 13 + 6-week fetal ultrasound examination, *Ultrasound Obstet Gynecol.* 37:628 (2011)

[21] British Medical Ultrasound Society. Guidelines for the safe use of diagnostic ultrasound equipment. *Ultrasound 2010*; 18:52–59

[22] AIUM (American Institute of Ultrasound in Medicine). *Official Statement: Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values*. Approved: 10/30/2016; Reapproved: 09/26/2022

[23] HARRIS G.R., CHURCH C.C., DALECKI D., ZISKIN M.C., BAGLEY J.E. Comparison of Thermal Safety Practice Guidelines for Diagnostic Ultrasound Exposures. *Ultrasound in Med. Biol*. 42, No. 2, pp. 345–357 (2016)

[24] KOLLMANN, C., JENDERKA, K. V., MORAN, C. M., DRAGHI, F., JIMENEZ DIAZ, J. F., & SANDE, R. (2020). EFSUMB Clinical Safety Statement for Diagnostic Ultrasound – (2019 revision). *Ultraschall in der Medizin* (Stuttgart, Germany: 1980), 41(4), 387–389. https://doi.org/10.1055/a-1010-6018

[25] SHIINA, T. et al, WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 1: basic principles and terminology, *Ultrasound Med Biol.* 2015; 41:1126-47

[26] B. A. HERMAN AND G. R. HARRIS, Models and regulatory considerations for transient temperature rise during diagnostic ultrasound pulses, *Ultrason. in Med. & Biol.*, vol. 28, pp. 1217-1224,2002

[27] N. NITTA, Y. ISHIGURO, H. SASANUMA, N.TANIGUCHI, I. AKIYAMA, In Vivo Measurement of Temperature Rise in Living Rabbit's Liver Exposed to Ultrasound with Acoustic Radiation Force*. Proceedings of the IEEE International Ultrasonics Symposium,* 2014, pp. 1175 – 1178

[28] KAZUMA RIFU, et.al, An acoustic radiation force impulse under clinical conditions with a single infusion of an ultrasound contrast agent evokes arrhythmias in the rabbit heart, *J. Med. Ultrasonics* (2021)

[29] DOUGLAS L. MILLER. et.al. Pulmonary Capillary Hemorrhage Induced by Super Sonic Shear Wave Elastography in Rats. *Ultrasound Med Biol,* 2019, 45: p.2993-3004

[30] N. TAKAYAMA, Y. ISHIGURO, et.al, The effect of ultrasound with acoustic radiation force on rabbit lung tissue: a preliminary study, *J. Med. Ultrasonics* (2016) 43:pp. 481 – 485

[31] Y. ISHIGURO, N. NITTA, N. TANIGUCHI, et.al. Ultrasound exposure (mechanical index 1.8) with acoustic radiation force impulse evokes extrasystolic waves in rabbit heart under concomitant administration of an ultrasound contrast agent. *J. Med. Ultrasonics* (2016) 43:pp. 3 – 7

[32] HEKKENBERG, RT., BEZEMER, RA. *Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers, part 2: on a human and artificial tissue*, TNO report: PG/TG/2003.134, ISBN 90-5412-085-1, Leiden, 2003

[33] CHIVERS, RC., PARRY, RJ. Ultrasonic velocity and attenuation in mammalian tissues. *J. Acoust. Soc. Am.*, 1978, 63, pp. 940-953

[34] DUCK, FA. *Physical properties of tissue – a comprehensive reference book*. Academic Press, London. ISBN 0-12-222800-6, 1990

[35] O'BRIEN, WD. and ELLIS, DS. *IEEE Trans. Ultrasonics Freq. Control*, vol 46, no. 6 November 1999, pp. 1459-1476

[36] World Federation for Ultrasound in Medicine and Biology (WFUMB) Symposium on Safety and Standardisation in Medical Ultrasound, Synopsis. *Ultrasound in Med & Biol*, 1992, 18, 733-737

[37] American Institute of Ultrasound in Medicine (AIUM), *Bio-effects and safety of diagnostic ultrasound*, American Institute of Ultrasound in Medicine, 1470 Sweitzer Lane, suite 100, Laurel MD 20707-5906 (1993)

[38] CARSTENSEN, EL., CHILD, SZ., CRANE, C., PARKER, KJ. Lysis of cells in Elodea leaves by pulsed and continuous wave ultrasound. *Ultrasound Med Biol*, 1990a, 16:p.167-173

[39] CARSTENSEN, EL., CHILD, SZ., NORTON, S., NYBORG, WL. Ultrasonic heating of the skull. *J Acous Soc Am*, 1990b, 87: p.1310-1317

[40] CHILD, SZ., HARTMAN, CL. McHALE, LA. CARSTENSEN, EL. Lung damage from exposure to pulsed ultrasound. *Ultrasound Med Biol*, 1990, 16: p.817-825

[41] CURLEY, MG. Soft tissue temperature rise caused by scanned, diagnostic ultrasound. *IEEE Trans Ultrasonics, Ferroelectrics and Frequency Control*, 1993, 49:p.59-66

[42] HOLLAND, CK., APFEL, RE. Thresholds for transient cavitation produced by pulsed ultrasound in a controlled nuclei environment. *J Acoust Soc Am*, 1989, 88:p.2059-2069

[43] National Council on Radiation Protection and Measurements (NCRP), *Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms*, NCRP Report No. 113, National Council on Radiation Protection and Measurements, Bethesda MD (1992)

[44] SEKINS, KM., EMERY, AF. "Thermal science for physical medicine", chapter 3:70-132, in *Therapeutic Heat and Cold*, Lehmann JF editor. Williams & Wilkins, Baltimore, MD, 1982

[45] World Federation of Ultrasound in Medicine and Biology (WFUMB), Second world federation of ultrasound in medicine and biology symposium on safety and standardization in medical ultrasound. *Ultrasound Med Biol,* 1989, 15:supplement

[46] American Institute of Ultrasound in Medicine (AIUM), *Medical Ultrasound Safety,* AIUM, 14750 Sweitzer Lane, Suite 100, Laurel MD 20707 – 5906, USA, 1994

[47] American Institute of Ultrasound in Medicine (AIUM), National Electrical Manufacturers Association (NEMA), *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,* Rev.1. American Institute of Ultrasound in Medicine & National Electrical Manufacturers Association, 2004

[48] CHRISTOPHER, T., CARSTENSEN, EL. Finite amplitude distortion and its relationship to linear derating formulae for diagnostic ultrasound systems. *Ultrasound in Med. and Biol.*, 1996, 22, pp.1103-1116

[49] SHAW, A., PAY, NM. and PRESTON, RC. *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment – Stages II and III: experimental assessment of scanner/transducer combinations,* NPL Report CMAM 12, The National Physical Laboratory, Teddington, Middlesex TW11 OLW, UK, 1998

[50] IEC 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*
IEC 61157:2007/AMD1:2013[4]

[51] IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

[52] IEC TS 63070:2019, *Ultrasonics – Field characterization – Infrared imaging techniques for determining temperature elevation in tissue-mimicking material and at the radiation surface of a transducer in still air*

[53] IEC 60050-802:2011, *International Electrotechnical Vocabulary (IEV) – Part 802: Ultrasonics*

[54] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[4] There exists a consolidated edition (2.1) including IEC 61157:2007 and its Amendment 1 (2013).

Index of defined terms

IEC 60601-2-37

Edition 3.0 2024-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

Appareils électromédicaux –
Partie 2-37: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons

IEC 60601-2-37:2024-07(en-fr)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-37: Particular requirements for the basic safety and essential performance 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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60601-2-37 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2007 and Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) technical and editorial changes resulting from the amended general standard IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and its collateral standards IEC 60601-1-xx,

b) technical and editorial changes as a result of maintenance to normative references;
c) technical and editorial changes resulting from relevant developments in TC 87 Ultrasonics standards. In particular, Clause 201.11 about protection against excessive temperatures and other hazards has been fully revised.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1318/CDV	62B/1348/RVC

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

In this document, safety requirements additional to those in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

A general guidance and rationale for the requirements of this document are given in Annex AA.

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

The approach and philosophy used in drafting this document for safety of ULTRASONIC DIAGNOSTIC EQUIPMENT are consistent with those in standards of 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 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 ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the PATIENT.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 *Scope

Replacement:

This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217, hereinafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 201.7.2.13.

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

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply as modified in Clause 202 and Clause 212 respectively. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of sections, clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.6 in this document addresses the content of Clause 6 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding section, clause or subclause in this document, the section, clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-18:2009, *Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment*

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

IEC 62359:2010, *Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*
IEC 62359:2010/AMD1:2017

CISPR 11:2024, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and in IEC 62359 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE 1 An index of defined terms is given after the Bibliography.

NOTE 2 A list of symbols used in this document is found in Table 201.101.

Addition:

201.3.201
BONE THERMAL INDEX
TIB
THERMAL INDEX for applications such as foetal (second and third trimester), in which the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.17, modified – The original notes have been deleted.]

201.3.202
COMBINED-OPERATING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that combines more than one DISCRETE-OPERATING MODE

201.3.203
CRANIAL-BONE THERMAL INDEX
TIC
THERMAL INDEX for applications, in which the ultrasound beam passes through bone near the beam entrance into the body, such as paediatric and adult cranial or neonatal cephalic applications

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.21, modified – The original notes have been deleted.]

201.3.204
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

201.3.205
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 utilise only one diagnostic methodology

201.3.206
FULL SOFTWARE CONTROL OF ACOUSTIC OUTPUT
means by which the ULTRASONIC DIAGNOSTIC EQUIPMENT manages the acoustic output independent of direct OPERATOR control

201.3.207
INVASIVE TRANSDUCER ASSEMBLY
transducer which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body

201.3.208
MECHANICAL INDEX
Indicator of the risk for bioeffects due to mechanical or nonthermal mechanisms, such as cavitation

Symbol: *MI*

Unit: None

Note 1 to entry: See IEC 62359 for methods of determining the MECHANICAL INDEX.

201.3.209
MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT
ULTRASONIC DIAGNOSTIC EQUIPMENT that is intended for more than one clinical application

201.3.210
NON-SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to ultrasonic scan lines that follow the same acoustic path

201.3.211
PRUDENT USE STATEMENT
affirmation of the principle that only necessary clinical information should be acquired and that high exposure levels and long exposure times should be avoided

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.40]

201.3.212
SCANNING MODE
mode of operation of ULTRASONIC DIAGNOSTIC EQUIPMENT that involves a sequence of ultrasonic pulses that give rise to scan lines that do not follow the same acoustic path

201.3.213
SOFT TISSUE THERMAL INDEX
TIS
THERMAL INDEX related to soft tissues

Unit: None

[SOURCE: IEC 62359:2010, 3.52, modified – The original notes have been deleted.]

201.3.214
THERMAL INDEX
TI
indicator of the risk of bioeffect due to thermal mechanisms expressed as the ratio of ATTENUATED OUTPUT POWER at a specified point to the ATTENUATED OUTPUT POWER required to raise the temperature at that point in a specific tissue model by 1 °C

Unit: None

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.56, modified – Addition of “indicator of the risk of bioeffect due to thermal mechanisms expressed as the”, and the original note has been deleted.]

201.3.215
TRANSDUCER ASSEMBLY
those parts of ULTRASONIC DIAGNOSTIC EQUIPMENT comprising either the ULTRASONIC TRANSDUCER and the ULTRASONIC TRANSDUCER ELEMENT GROUP, or both, together with any integral components, such as an acoustic lens or integral stand-off

Note 1 to entry: The TRANSDUCER ASSEMBLY is usually separable from the ultrasound instrument console.

[SOURCE: IEC 62359:2010 and IEC 62359:2010AMD1:2017, 3.57, modified – "medical diagnostic ultrasound equipment" has been replaced by "ULTRASONIC DIAGNOSTIC EQUIPMENT" in the definition.]

201.3.216
TRANSMIT PATTERN
combination of a specific set of transducer beam-forming characteristics (determined by the transmit aperture size, apodisation 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

[SOURCE: IEC 62359:2010, 3.58]

201.3.217
ULTRASONIC DIAGNOSTIC EQUIPMENT
MEDICAL ELECTRICAL EQUIPMENT that is intended for ultrasonic medical examination

201.3.218
ULTRASONIC TRANSDUCER
device capable of converting electrical energy to mechanical energy within the ultrasonic frequency range and reciprocally of converting mechanical energy to electrical energy

[SOURCE: IEC 62127-1:2022, 3.88]

201.3.219
ATTENUATED PULSE-AVERAGE INTENSITY
$I_{pa,\alpha}$
value of the acoustic PULSE-AVERAGE INTENSITY after attenuation and at a specified point, and given by

$$I_{pa,\alpha}(z) = I_{pa}(z)10^{(-\alpha z f_{awf}/10\,dB)} \quad (1)$$

where

α is the ACOUSTIC ATTENUATION COEFFICIENT as defined in IEC 62359:2010, definition 3.1;

z is the distance from the EXTERNAL TRANSDUCER APERTURE to the point of interest;

f_{awf} is the ACOUSTIC WORKING FREQUENCY as defined in IEC 62359:2010 and IEC 62359:2010/AMD1:2017, definition 3.4;

$I_{pa}(z)$ is the PULSE-AVERAGE INTENSITY measured in water as defined in IEC 62127-1:2022, 3.53.

Unit: W m^{-2}

201.3.220
NUMBER OF PULSES PER ULTRASONIC SCAN LINE
n_{pps}
number of acoustic pulses travelling along a particular ULTRASONIC SCAN LINE

Note 1 to entry: Here ULTRASONIC SCAN LINE refers to the path of acoustic pulses on a particular BEAM AXIS in SCANNING and NON-SCANNING MODES.

Note 2 to entry: This number can be used in the calculation of any ultrasound temporal average value from HYDROPHONE measurements.

Note 3 to entry: The following shows an example of the NUMBER OF PULSES PER ULTRASONIC SCAN LINE and the NUMBER OF ULTRASONIC SCAN LINES (";" indicates the end of a frame):

1 2 3 4; 1 2 3 4; 1 2 3 4… n_{pps} = 1; n_{sl} = 4

1 1 2 2 3 3 4 4; 1 1 2 2 3 3 4 4; … n_{pps} = 2; n_{sl} = 4

1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; … n_{pps} = 4; n_{sl} = 4

1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; 1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; … n_{pps} = 5; n_{sl} = 4 (within one frame the pulses down each line may not occur contiguously).

Within one frame, all scan lines may not have the same n_{pps} value. An example is: 1 2 2 3 3 4; 1 2 2 3 3 4; … avg n_{pps} = 1,5; max n_{pps} = 2; n_{sl} = 4

[SOURCE: IEC 61157:2007/AMD1:2013, 3.45, modified – The fourth example in the Note 3 to entry has been corrected.]

201.3.221
ULTRASOUND ENDOSCOPE
ENDOSCOPE with built-in ULTRASOUND TRANSDUCERS

201.3.222
ENDOSCOPE
medical instrument having viewing means, with or without optics, introduced into a body cavity through a natural or surgically created body opening for examination, diagnosis or therapy

Note 1 to entry: ENDOSCOPES may be of rigid, flexible or capsule type, each of which may have different image pick-up systems (e.g. via lenses or electronic/ultrasonic sensors) and different image transmission systems (e.g. optical (via lenses or fibre bundles), or electrical/electronic).

Note 2 to entry: Note 1 to entry differs from NOTE 1 of definition 3.1 in ISO 8600-1 in order to include 'capsule' endoscopes.

[SOURCE: IEC 60601-2-18:2009, 201.3.203]

201.3.223
DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL
z_{pii}
depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} from the external transducer aperture to the plane of maximum PULSE-INTENSITY INTEGRAL (pii) as approximated by the PULSE-PRESSURE-SQUARED INTEGRAL ($ppsi$)

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.24, modified — Notes to entry 1, 2 and 3 deleted.]

201.3.224
DEPTH FOR PEAK ATTENUATED PULSE-INTENSITY INTEGRAL
$z_{pii,\ \alpha}$
depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak ATTENUATED PULSE-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.71, modified — Main term "depth for maximum $_{pii,\ \alpha}$" replaced with "depth for peak attenuated pulse-intensity integral", Notes to entry 1, 2 and 3 deleted and addition of a new Note to entry.]

201.3.225
DEPTH FOR PEAK SUM OF PULSE-INTENSITY INTEGRALS
z_{sii}
depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak SCAN-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

Note 2 to entry: The subscript '*sii*' indicates the scan intensity integral (sii). The *sii* for SCANNING MODE components at a particular point is determined from the sum over a complete scan frame of the PULSE-INTENSITY INTEGRALS of the ULTRASONIC SCAN LINES that make up the scanning components of a combined mode. Non-scanned components are excluded from the sum. See IEC 62359 and IEC 62127-1 for more details.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.74, modified — Main term "depth for maximum sii" replaced with "depth for peak sum of pulse-intensity integrals", Notes to entry 1, 2 and 3 deleted and addition of new Notes 1 and 2 to entry.]

201.3.226
DEPTH FOR PEAK SUM OF ATTENUATED PULSE-INTENSITY INTEGRALS
$z_{sii,\alpha}$
depth z on the BEAM AXIS and beyond the BREAK-POINT DEPTH z_{bp} of peak ATTENUATED SCAN-INTENSITY INTEGRAL

Unit: m

Note 1 to entry: BEAM-AXIS and BREAK-POINT DEPTH are defined in IEC 62359.

Note 2 to entry: The subscript "sii" indicates the "scan intensity integral" that is the sum at a particular point of the PULSE-INTENSITY INTEGRALS of the ULTRASONIC SCAN LINES comprising a SCANNING MODE component. See IEC 62359 and IEC 62127-1 for additional details.

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.75, modified — Main term "depth for maximum sii_{α}" replaced with "depth for peak sum of attenuated pulse-intensity integrals", addition of "peak" in the definition, Notes to entry 1, 2 and 3 deleted and addition of new Notes 1 and 2 to entry.]

201.3.227
DEPTH FOR MECHANICAL INDEX
z_{MI}
depth on the BEAM-AXIS from the EXTERNAL TRANSDUCER APERTURE to the plane of maximum ATTENUATED PULSE-PRESSURE-SQUARED-INTEGRAL ($ppsi_{\alpha}$)

Unit: m

[SOURCE: IEC 62359:2010 and IEC 62359:2010/AMD1:2017, 3.23]

201.3.228
THERMAL OFFSET
ΔT_{offset}
difference between a) the temperature of the APPLIED PART of the TRANSDUCER ASSEMBLY at steady-state in the measurement setting before transmitting begins and b) the steady-state temperature at the same location in the measurement setting when the TRANSDUCER ASSEMBLY was not present

Note 1 to entry: The value of the THERMAL OFFSET can be positive, negative or zero.

201.3.229
ULTRASOUND
acoustic oscillation whose frequency is above the high-frequency limit of audible sound (about 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

Table 201.101 – List of symbols

Symbol	Term	Reference
A_{aprt}	= –12 dB OUTPUT BEAM AREA	IEC 62359
d_{eq}	= EQUIVALENT BEAM DIAMETER	IEC 62359
f_{awf}	= ACOUSTIC WORKING FREQUENCY	IEC 62359
$I_{\text{pa},\alpha}$	= ATTENUATED PULSE-AVERAGE INTENSITY	
pii	= PULSE-INTENSITY INTEGRAL	IEC 62359
pii_{α}	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359
$I_{\text{sppa},\alpha}$	= ATTENUATED SPATIAL-PEAK PULSE-AVERAGE INTENSITY	IEC 62359
I_{spta}	= SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359
$I_{\text{spta},\alpha}$	= ATTENUATED SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY	IEC 62359
$I_{\text{ta},\alpha}(z)$	= ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359
MI	= MECHANICAL INDEX	IEC 62359
n_{pps}	= NUMBER OF PULSES PER ULTRASONIC SCAN LINE	IEC 61157
P	= OUTPUT POWER	IEC 62359
$P_{1\text{x}1}$	= BOUNDED-SQUARE OUTPUT POWER	IEC 62359
P_{α}	= ATTENUATED OUTPUT POWER	IEC 62359
$p_{\text{r},\alpha}$	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
p_{r}	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
prr	= PULSE REPETITION RATE	IEC 62359
srr	= SCAN REPETITION RATE	IEC 62127-1

Symbol	Term	Reference
TI	= THERMAL INDEX	IEC 62359
TIB	= BONE THERMAL INDEX	IEC 62359
TIC	= CRANIAL-BONE THERMAL INDEX	IEC 62359
TIS	= SOFT-TISSUE THERMAL INDEX	IEC 62359
t_d	= PULSE DURATION	IEC 62359
X, *Y*	= –12 dB OUTPUT BEAM DIMENSIONS	IEC 62359
z_b	= DEPTH FOR BONE THERMAL INDEX	IEC 62359
z_{bp}	= BREAK-POINT DEPTH	IEC 62359
z_{pii}	= DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL	IEC 62359
z_{MI}	= DEPTH FOR MECHANICAL INDEX	IEC 62359
$z_{pii,\alpha}$	= DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL	IEC 62359
z_{sii}	= DEPTH FOR PEAK SUM OF PULSE INTENSITY INTEGRALS	IEC 62359
$z_{sii,\alpha}$	= DEPTH FOR PEAK SUM OF ATTENUATED PULSE INTENSITY INTEGRALS	IEC 62359
z_s	= DEPTH FOR TIS	IEC 62359
ΔT_{offset}	= THERMAL OFFSET	
ΔT_{tx}	= temperature rise caused by the TRANSDUCER ASSEMBLY transmitting	

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition:

An ULTRASOUND ENDOSCOPE where the imaging means is limited to ultrasound shall be considered an ULTRASOUND TRANSDUCER and shall meet the requirements of this document.

NOTE 1 Examples of such ULTRASOUND TRANSDUCERS include transvaginal, transesophageal (TEE), rectal, laparoscopic and other similar intra-cavity probes.

An ULTRASOUND ENDOSCOPE having imaging means in addition to ultrasound shall also meet the requirements of 201.11.6.5 of IEC 60601-2-18:2009.

NOTE 2 Examples of such additional imaging means include optical and CCD.

201.4.3 ESSENTIAL PERFORMANCE

Additional subclause:

201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements

Table 201.102 lists the potential sources of unacceptable risk identified to characterize the ESSENTIAL PERFORMANCE of ULTRASONIC DIAGNOSTIC EQUIPMENT and the subclauses in which the requirements are found.

Table 201.102 – Distributed essential performance requirements

Requirement	Subclause
Free from 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 can alter the diagnosis.	202.8.1
Free from the display of incorrect numerical values associated with the diagnosis to be performed [a].	202.8.1
Free from the display of incorrect safety-related indications.[a]	201.12.4.2 202.8.1
Free from the production of unintended or excessive ultrasound output.	201.10.101 202.8.1
Free from the production of unintended or excessive TRANSDUCER ASSEMBLY surface temperature.	202.8.1
Free from the production of unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.	202.8.1
[a] "incorrect" in the sense that the displayed value differs from what is calculated (having been altered during data transfer), or the calculation itself is not correct.	

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

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2.9 IP classification

Addition:

If the specified IPX classification is applicable for only part of the TRANSDUCER ASSEMBLY, the marking of the IPX code on the TRANSDUCER ASSEMBLY is not required.

201.7.2.13 *Physiological effects (SAFETY SIGNS and warning statements)

Addition:

A description of the means used to limit the surface heating of INVASIVE TRANSDUCER ASSEMBLIES to no more than 43 °C in the event of a SINGLE FAULT CONDITION shall be provided in accordance with the requirements of Clause 12.

Additional subclause:

201.7.2.101 *Acoustic output

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2 and which allows the OPERATOR to directly vary the output levels, the effect of adjusting the control which varies the output level shall be clear. The marking shall be of the nature of an active display.

A display of THERMAL INDEX and MECHANICAL INDEX shall be provided in accordance with the requirements of Clause 201.12, together with the declaration of accuracy described in Clause 201.12.

A display relevant to ultrasound output levels (Clause 201.12) shall be clearly visible from the OPERATOR'S position, with the full name(s) or abbreviation(s) of the index (indices) displayed.

201.7.9.2.2 *Warning and safety notices

Addition:

For ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to Clause 201.12, information shall be provided to the OPERATOR on how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX (*TI*) and MECHANICAL INDEX (*MI*) according to the guidance given in Annex CC.

The procedures necessary for safe operation shall be provided, drawing attention to the safety hazards that can occur as a result of an inadequate electrical installation when the APPLIED PART of the ULTRASONIC DIAGNOSTIC EQUIPMENT is a TYPE B APPLIED PART.

Instruction on the safe use of TRANSDUCER ASSEMBLIES shall be provided, and, in particular, instructions to ensure 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 can cause harmful interference with other equipment in the environment. The identification of interference with other equipment and mitigation techniques shall be included in the ACCOMPANYING DOCUMENTS if the MANUFACTURER claims a reduction in test levels.

A notice shall be provided if the ULTRASONIC DIAGNOSTIC EQUIPMENT or parts thereof are provided with protective means against burns to the PATIENT when used with high frequency (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.

A PRUDENT USE STATEMENT shall be provided for ULTRASONIC DIAGNOSTIC EQUIPMENT capable of generating output levels subject to 201.12.4.2.

Descriptions shall be provided of any display or means relevant to ultrasound output by which the OPERATOR can modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT. These descriptions shall be in a separate section.

A description of any display or means by which the OPERATOR may modify the operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT relevant to surface temperature for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use shall be provided.

A description of those parts of the TRANSDUCER ASSEMBLY that are permitted to be immersed in water or other liquids either for NORMAL USE or performance assessment purposes shall be provided.

A recommendation calling the OPERATOR'S attention to the need for regular testing and periodic maintenance including inspection of the TRANSDUCER ASSEMBLY for cracks that allow the ingress of conductive fluid shall be provided.

Instructions shall be provided regarding the avoidance of unintended control settings and acoustic output levels.

Output limits selected according to 201.12.4.5.1 shall be declared in the ACCOMPANYING DOCUMENTS. For MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT the output limits shall be declared for each application.

Transesophageal probes shall be removed from the PATIENT *prior* to application of a defibrillator.

The outer surface of the portions of TRANSDUCER ASSEMBLY which is intended to be inserted into a PATIENT should be checked to ensure that there are no unintended rough surfaces, sharp edges or protrusions which can cause harm.

As the use of ULTRASONIC DIAGNOSTIC EQUIPMENT is increasing in the home care area, special attention should be paid to provide information to this type of user. How this is addressed should be documented in the RISK MANAGEMENT FILE. See IEC 60601-1-11.

201.7.9.2.10 Messages

Replacement of the first paragraph:

The instructions for use shall list all system messages, error messages and fault messages that are generated and are visible to the OPERATOR, unless these messages are self-explanatory.

201.7.9.2.12 Cleaning, disinfection and sterilization

Addition:

After second dashed item, add:

– a list of the pertinent parts, components and functions that should be checked after each cleaning, disinfection or sterilization cycle, and method(s) of inspection.

NOTE This list of parameters is neither exhaustive nor mandatory.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 *Technical data regarding acoustic output levels

For each mode, provide the maximum value of each THERMAL and MECHANICAL INDEX. These data shall be provided following Table 201.103 and listed in the ACCOMPANYING DOCUMENTS.

Numerical values shall be entered in the cells indicated with "✓".

The equipment setting related to each index shall be entered in the "operating control conditions" section of Table 201.103.

For a TRANSDUCER ASSEMBLY and ultrasound instrument console that satisfies all of the exemption conditions cited in 201.12.4.2 a) and c), information declared in the ACCOMPANYING DOCUMENTS shall state that the THERMAL INDICES are 0,7 or less and the MECHANICAL INDEX is 1,0 or less for all device settings. If 201.12.4.2 b) and c) are satisfied instead of a) and c), the value of 0,7 for THERMAL INDICES in this statement shall be replaced with 1,0.

NOTE 1 For Table 201.103, see Annex AA for a description of "Maximum Index Value' and (for *TIS* and *TIB*) 'Index Component Values'.

NOTE 2 An operating mode can be interpreted to be any DISCRETE-OPERATING MODE (like B, M) as well as any COMBINED-OPERATING MODE (like B+D+CFM).

NOTE 3 Per IEC 62359:2010 and IEC 62359:2010/AMD1:2017, the z_s and z_b values are entered for non-scanned (component) modes.

NOTE 4 According to 201.3.201, in the *TIB* model the bone tissue is located below a soft tissue. Therefore the "*TIB* at surface" component is equal to the "*TIS* at surface" component, not *TIC*.

NOTE 5 Annex EE provides an example table to allow 3rd parties to recalculate the *TI* and *MI* values for each operating mode, including the contributions from each mode in COMBINED-OPERATING MODES.

Table 201.103 – Acoustic output reporting table

MODE ____________

Index label			*MI*	*TIS* At surface	*TIS* Below surface	*TIB* At surface	*TIB* Below surface	*TIC*
Maximum index value			✓	✓		✓		✓
Index component value				✓	✓	✓	✓	
Acoustic Parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	✓					
	P	(mW)		✓		✓		✓
	P_{1x1}	(mW)		✓		✓		
	z_s	(cm)			✓			
	z_b	(cm)					✓	
	z_{MI}	(cm)	✓					
	$z_{pii,\alpha}$	(cm)	✓					
	f_{awf}	(MHz)	✓	✓		✓		✓
Other Information	*prr*	(Hz)	✓					
	srr	(Hz)	✓					
	n_{pps}		✓					
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	✓					
	$I_{spta,\alpha}$ at $z_{pii,\alpha}$ or $z_{sii,\alpha}$	(mW/cm²)	✓					
	I_{spta} at z_{pii} or z_{sii}	(mW/cm²)	✓					
	p_r at z_{pii}	(MPa)	✓					
Operating control conditions	Control 1							
	Control 2							
	Control 3							
	Control 4							
	Control 5							
	…							
	Control x							

NOTE 1 Only one operating condition per index.

NOTE 2 Data for "at surface" and "below surface" are entered in both the columns related to *TIS* or *TIB*.

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) or b) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2c) are met, it is not required to enter any data in the column related to *MI*.

NOTE 6 The depths z_{pii} and $z_{pii,\alpha}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,\alpha}$ apply to SCANNING MODES.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows*:*

201.8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

Addition:

aa) *For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.*

201.8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

Addition:

For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.

201.8.8.3 Dielectric strength

Addition:

aa) *For testing the TRANSDUCER ASSEMBLIES, the APPLIED PART shall be immersed in a 0,9 % saline solution.*

201.8.9.3.4 Thermal cycling

Addition, at the end of the first paragraph:

and, for ultrasonic transducer assemblies only, where T_1 is

– *10 °C above the maximum allowable temperature specified in the ACCOMPANYING DOCUMENTS for cleaning, disinfection, sterilization, normal use or storage.*

201.8.10.4 Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

Addition:

This subclause does not apply to ULTRASONIC TRANSDUCER ASSEMBLIES.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows*:*

Additional subclause:

201.10.101 *Ultrasonic energy

The MANUFACTURER shall address the RISKS associated with ultrasonic energy in the RISK MANAGEMENT PROCESS as described in the text of this document.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Acoustic output shall be switched off when the signal acquisition is stopped (i.e.: the "freeze" feature is enabled).

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1.2.2 *APPLIED PARTS not intended to supply heat to a PATIENT

Addition:

TRANSDUCER ASSEMBLIES applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 43 °C in NORMAL CONDITIONS when measured under test conditions 201.11.1.3.101.1.

TRANSDUCER ASSEMBLIES applied to the PATIENT shall have a PATIENT contact surface temperature not exceeding 50 °C when measured under test conditions 201.11.1.3.101.2.

Compliance is checked by operation of the ULTRASONIC DIAGNOSTIC EQUIPMENT and temperature tests as described in 201.11.1.3.

NOTE PATIENT contact surface includes any part of the APPLIED PART, not just the radiating surface, but excluding the cable.

201.11.1.3 *Measurements

Addition:

For the applied part of the TRANSDUCER ASSEMBLY, replace the third paragraph and the remaining text of the subclause with the following:

Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE.

201.11.1.3.101 Test conditions

For the purposes of this test, thermal steady state is considered reached when the rate of change of temperature is < 0,12 °C per minute for three consecutive minutes.

The TRANSDUCER ASSEMBLY shall be tested under the following conditions:

201.11.1.3.101.1 * Simulated use

The APPLIED PART of the TRANSDUCER ASSEMBLY shall be coupled acoustically to, and be initially in thermal steady-state with, a test object such that the ultrasound emitted from the active surface of the TRANSDUCER ASSEMBLY enters the test object.

The heating or cooling of the TRANSDUCER ASSEMBLY and the positioning of TRANSDUCER ASSEMBLY relative to the test object shall resemble those corresponding to the intended application of that TRANSDUCER ASSEMBLY. This includes using a typical amount of ultrasound coupling medium appropriate to the intended application.

The temperature shall be measured at the point on the APPLIED PART of the ULTRASONIC TRANSDUCER ASSEMBLY that contacts the PATIENT *during NORMAL USE and where the temperature is a maximum.*

The test object shall have thermal and acoustical properties mimicking those of an appropriate tissue. In the case where the TRANSDUCER ASSEMBLY is intended for external use this test object shall account for a skin layer.

For soft tissue, the material of the test object shall have the following properties:

– *specific heat capacity:* *(3 500 ± 500) J/(kg·K);*
– *thermal conductivity:* *(0,5 ± 0,1) W/(m·K);*
– *attenuation at 5 MHz:* *(2,5 ± 1,0) dB/cm.*

NOTE 1 A general guidance for the acoustic properties of appropriate tissue is given in ICRU report 61[1][1].

NOTE 2 As heat develops differently in tissue surfaces containing skin, bone or soft tissue, it is important to consider the choice of the model in relation to the intended use of the APPLIED PART. Additional guidance can be found in Annex DD and [2].

The test object shall be designed (for example, using acoustic absorbers) to reduce heating the surface of the TRANSDUCER ASSEMBLY by minimizing ultrasound reflections.

Test method a) or b) specified below shall be selected.

Test method a) shall be used where the ULTRASOUND DIAGNOSTIC EQUIPMENT uses a closed loop temperature monitoring system, as the use of test method b) could result in inappropriate results.

- *the temperature of the test object should be stable,*
- *and after contact with each other, the temperature at the test object / APPLIED PART interface should be stable before the measurement is started.*

a) *Test criteria based on peak temperature measurements.*

The ambient temperature shall be 23 °C ± 3 °C.

For TRANSDUCER ASSEMBLIES intended for external use, the surface of the test object before contacting the APPLIED PART should be not less than 33°°C and stable.

As a good measurement practice, the temperature of the test object should not cool down during the test.

For invasive TRANSDUCER ASSEMBLIES, the temperature of the point of contact of the test object before contacting the APPLIED PART should be not less than 37 °C.

To meet the requirements of this test, the temperature of the surface of the APPLIED PART shall not exceed 43 °C.

b) *Test criteria based upon temperature rise measurements*

The ambient temperature shall be 23 °C ± 3 °C. Any THERMAL OFFSET existing at thermal steady state shall be a known, stable value (see Annex AA and 201.3.228).

[1] Numbers in square brackets refer to the Bibliography.

For TRANSDUCER ASSEMBLIES intended for external use,

- *the initial temperature of the surface of the test object at the object-transducer interface before contacting the APPLIED PART shall be between 20 °C and 33 °C,*
- *the temperature measured under these test conditions shall be equal to the sum of 33 °C plus the THERMAL OFFSET plus the measured temperature rise.*

For INVASIVE TRANSDUCER ASSEMBLIES,

- *the initial temperature of the point of contact of the test object before contacting the APPLIED PART shall be between 20 °C and 37 °C,*
- *the temperature measured under these test conditions shall be equal to the sum of 37 °C plus the THERMAL OFFSET plus the measured temperature rise.*

To meet the requirements of this clause, the calculated temperature shall not exceed 43 °C.

For TRANSDUCER ASSEMBLIES intended for external use,

$$\Delta T_{tx} + \Delta T_{offset} + 33\ °C \leq 43\ °C \qquad (2)$$

For invasive transducer assemblies,

$$\Delta T_{tx} + \Delta T_{offset} + 37\ °C \leq 43\ °C \qquad (3)$$

NOTE 1 When following this test method, the temperature rise is defined as the difference between the temperature of the TRANSDUCER ASSEMBLY just before the transducer is activated acoustically and the maximum temperature of the TRANSDUCER ASSEMBLY measured during the test.

NOTE 2 The term "THERMAL OFFSET" is defined in 201.3.228. See also Figure AA.1.

201.11.1.3.101.2 * Still air

Suspend the TRANSDUCER ASSEMBLY with a clean surface (no coupling gel applied) in still air or place it in a stationary position in an environmental chamber with minimal airflow across the APPLIED PART of the TRANSDUCER ASSEMBLY.

"In still air" means an environment without air movement (flow) and an air temperature of 23 °C ± 3 °C stable within 0,5 °C.

Test criteria are based upon temperature rise measurements.

The ambient temperature shall be 23 °C ± 3 °C and the initial temperature of the APPLIED PART of the TRANSDUCER ASSEMBLY shall be the ambient temperature or shall be offset from the ambient temperature by a known, stable value at thermal steady state (see Annex AA and 201.3.228). During the test the sum of the temperature rise + THERMAL OFFSET of the APPLIED PART 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, the THERMAL OFFSET, and 23 °C shall be regarded as the surface temperature under test conditions 201.11.1.3.101.2.

$$\Delta T_{tx} + \Delta T_{offset} + 23\,°C \leq 50\,°C \qquad (4)$$

201.11.1.3.102 Operating settings

Operate the ULTRASONIC DIAGNOSTIC EQUIPMENT at a setting that gives the highest surface temperature of APPLIED PART of the TRANSDUCER ASSEMBLY. The transmit parameters of the test shall be recorded in the test report.

201.11.1.3.103 Test duration

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

The test according to 201.11.1.3.101.1 shall be conducted for 30 min or until the thermal steady state is reached.

For the purposes of this test, thermal steady state can be considered reached when the rate of change of temperature of the APPLIED PART is < 0,12 °C per minute for three consecutive minutes.

The test according to 201.11.1.3.101.2 shall be conducted:

a) for 30 min; or

b) for twice the time period limited by an automatic output hold or "freeze" function in the case where the OPERATOR is not able to switch off that function; or

c) until thermal steady-state is reached.

If the ULTRASONIC DIAGNOSTIC EQUIPMENT automatically "freezes" or halts its output earlier than the time period given in this subclause, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be switched on again immediately.

201.11.1.3.104 *Temperature measurement

The temperature of the TRANSDUCER ASSEMBLY should be measured by any appropriate means such as infra-red radiometry or thermocouple methods.

If a thermographic camera is used, see Annex AA for further details.

If a thermocouple is used, the thermocouple junction and adjacent thermocouple lead wire should be securely held in good thermal contact with the surface being measured. The thermocouple should be positioned and secured in such a way that it has a negligible effect on the temperature rise of the area being measured.

The size of the temperature measurement area of the sensor, or the focus size in case of an infra-red measurement system, should be such that any averaging effect is minimized.

The temperature shall be measured on the surface of the applied part of the TRANSDUCER ASSEMBLY in those areas that give the highest surface temperature.

The measurement uncertainty shall be recorded in the test report.

As part of measurement uncertainty determination, the measurement set-up can be used to make surface temperature measurements of ULTRASONIC TRANSDUCERS of known maximum surface temperature. It is recommended that the measurement set-up be validated.

For the estimation of uncertainties, the ISO/IEC Guide 98-1 to the expression of uncertainty in measurement should be used [3].

NOTE 1 Any means to measure the temperature can be a type that is not overly sensitive to direct ultrasonic heating (for example, if a thermocouple is used, it can be a thin film or fine wire). Additional factors, such as effects of conductive losses, ultrasonic heating and spatial averaging on the measurement sensors or its connecting cables after "averaging", are also relevant when assessing the measurement uncertainty.

NOTE 2 Example means for measuring surface temperature of externally applied TRANSDUCER ASSEMBLIES is provided in Annex DD of this document.

201.11.1.3.105 Test criteria

The TRANSDUCER ASSEMBLY shall operate throughout the test as specified in 201.11.1.3.103. During the test, the maximum temperature or the maximum temperature rise shall not exceed the limits specified.

Table 201.104 provides an overview of the tests and limits outlined in 201.11.1.3.

Table 201.104 – Overview of the tests noted under 201.11.1.3

Test to be applied		Transducer type	
		External use	**Invasive use**
201.11.1.3.101.1 Simulated use test	a) Temperature	*The surface of the test object before contacting the applied part should be not less than 33 °C and the temperature of the test object should be stable.* The temperature shall not exceed 43 °C	*The point of contact of the test object before contacting the applied part should be not less than 37 °C and the temperature of the test object should be stable.* The temperature shall not exceed 43 °C.
	b) Temperature rise	*Initially the temperature at the object-transducer interface shall be between 20 °C and 33 °C and shall be in thermal steady state.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise plus the THERMAL OFFSET shall not exceed 10 °C.	*Initially the temperature at the object-transducer interface shall be between 20 °C and 37 °C and shall be in thermal steady state.* *The ambient temperature shall be 23 °C ± 3 °C.* The temperature rise plus the THERMAL OFFSET shall not exceed 6 °C.
201.11.1.3.101.2 Still air test (no gel)	Temperature rise	*The ambient temperature shall be 23 ± 3 °C and shall be in thermal steady state.* *Initially the temperature at the surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature.* The temperature rise plus the THERMAL OFFSET shall not exceed 27 °C.	

201.11.6.5 *Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

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.

Compliance is checked by the test required 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.

Parts of the TRANSDUCER ASSEMBLIES specified by the MANUFACTURER as intended to be immersed during NORMAL USE, shall meet the requirements of watertight equipment (IPX7).

NOTE 1 For this clause, NORMAL USE includes cleaning and disinfection.

Compliance is checked by the test required in IEC 60529:1989 for IPX7, with the exception of 14.2.7 a) and b).

NOTE 2 Parts of the TRANSDUCER ASSEMBLIES not intended to be immersed during NORMAL USE can be temporarily protected for the purposes of the test.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

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

– any display indicating THERMAL INDEX (TI) and MECHANICAL INDEX (MI); see 201.7.9.2.2, 201.7.2.101 and 201.12.4.2.

– technical data; see 201.7.9.3.101.

The accuracy of the data and controls specific to the surface temperature of INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use shall be specified, including any display of surface temperature, if provided; see 201.7.9.2.2 and 201.12.4.2.

NOTE Guidance for the estimation of uncertainties can be found in the ISO/IEC Guide 98-1 *Guide to the expression of uncertainty in measurement* [3].

For hydrophone measurements on diagnostic systems that fulfil the 'low output' criteria of a) and c) or b) and c) in 201.12.4.2, the narrowband approximation of IEC 62127-1 can be applied even if the criteria of 5.1.7.1 in IEC 62127-1:2022 cannot be fulfilled. When using this simplification, the additional measurement uncertainty reflecting the limitations of a narrowband measurement of a broadband signal shall be considered, in particular, when comparing output data against thresholds.

See IEC 62127-1 for additional details.

201.12.4.2 Indication relevant to safety

Addition:

a) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not capable of exceeding either a SOFT TISSUE THERMAL INDEX of 0,7, a bone THERMAL INDEX of 0,7 or, for ULTRASONIC DIAGNOSTIC EQUIPMENT intended for transcranial or neonatal cephalic applications, a cranial THERMAL INDEX of 0,7, in any mode of operation, then no display of the THERMAL INDEX is required (see also Annex AA concerning 201.7.2.101).

b) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not intended for obstetric (including gynecologic when pregnancy is possible), neonatal transcranial, or neonatal spinal applications, and is not capable of exceeding either a SOFT TISSUE THERMAL INDEX of 1,0, a BONE THERMAL INDEX of 1,0 or, for ULTRASONIC DIAGNOSTIC EQUIPMENT intended for transcranial applications, a CRANIAL THERMAL INDEX of 1,0, in any mode of operation, then no display of the THERMAL INDEX is required (see also Annex AA concerning 201.7.2.101).

NOTE 1 ULTRASONIC DIAGNOSTIC EQUIPMENT for which the OUTPUT POWER divided by the −12 dB OUTPUT BEAM AREA is less than 20 mW/cm^2 and the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY (I_{spta}) is less than 100 mW/cm^2 (cfr. low acoustic output criteria in 4.2.5 of IEC 61157:2007 and IEC 61157:2007/AMD1:2013 [38]) is not expected to exceed a THERMAL INDEX of 1,0 if, for all operation conditions, both f_{awf} < 10,5 MHz, and A_{aprt} < 1,25 cm^2. Consequently, the requirement listed in 201.12.4.2 b) is fulfilled.

c) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is not capable of exceeding a MECHANICAL INDEX of 1,0 in any mode of operation, then no display of the MECHANICAL INDEX is required.

NOTE 2 ULTRASONIC DIAGNOSTIC EQUIPMENT for which the peak-rarefactional acoustic pressure (p_r) is less than 1 MPa is not capable of exceeding a mechanical index of 1,0 if, for all operation conditions, f_{awf} > 1,0 MHz. Consequently, the requirement listed in Clause 201.12.4.2 c) is fulfilled.

d) If the ULTRASONIC DIAGNOSTIC EQUIPMENT does not meet the criteria in a) or b) for omitting a THERMAL INDEX display, then the capability shall be available for the OPERATOR to display the SOFT TISSUE THERMAL INDEX (when exceeding a value of 0,4), the BONE THERMAL INDEX (when exceeding a value of 0,4) or a CRANIAL THERMAL INDEX (when exceeding a value of 0,4), but not necessarily simultaneously, in such operational mode.

e) 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 it exceeds a value of 0,4 and is capable of exceeding a value of 1,0.

f) If the ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of exceeding a MECHANICAL INDEX of 1,0 in any mode of operation, then the MECHANICAL INDEX shall be displayed when it equals or exceeds a value of 0,4 in such an operational mode.

g) The ULTRASONIC DIAGNOSTIC EQUIPMENT shall allow the OPERATOR to display simultaneously both a THERMAL INDEX (according to the requirements of a), b), d), and e) above) and the MECHANICAL INDEX (according to the requirements of c) and f) above).

h) The increments for the display of THERMAL INDICES, if displayed (see a) – g)), shall be no more than 0,2 over the entire range of display.

i) The increment for the display of MECHANICAL INDEX, if displayed (see a) – g)), shall be no more than 0,2 over the entire range of display.

j) 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 201.11.1.3).

201.12.4.3 Accidental selection of excessive output values

Replacement:

a) 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 can be reconfigured by the OPERATOR.

b) 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 THERMAL INDEX displayed.

201.12.4.5.1 *Limits

Addition:

Acoustic output shall be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety related parameters specified in this document and other relevant information such as clinical experience.

NOTE For guidance on the relevance of the safety related parameters specified in this document, see Annex CC.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.13.1.2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature

Addition at the end of the third dash:

As an exception, for TRANSDUCER ASSEMBLIES intended for external use, the APPLIED PART temperature can exceed the value in 201.11.1.2.2 of this document by up to 5 °C during a SINGLE FAULT CONDITION, if an alarm or indication is provided to the OPERATOR, as described in 12.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, indicating that a SINGLE FAULT CONDITION causing the temperature rise has occurred.

NOTE This exception is valid ONLY for TRANSDUCER ASSEMBLIES intended for application to the skin surface.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.7.1 Protection of radio services and other equipment

202.7.1.1 General

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 CISPR 11 is reported in Annex BB.

202.7.1.2 Operating modes

Replacement:

During EMISSIONS testing, the ME EQUIPMENT or ME SYSTEM shall be tested in the modes that maximize EMISSIONS.

The ULTRASONIC DIAGNOSTIC EQUIPMENT shall be tested in scanning mode unless the manufacturer concludes that standby mode is the most likely to result in an unacceptable risk.

The operating modes selected for testing should be documented in the test plan and shall be documented in the test report.

Compliance is checked by inspection of the test report.

202.8.1 * General

Amendment:

Addition to 8.1 General, before NOTE 5:

The following pass/fail criteria shall be considered during and after the IMMUNITY tests of ULTRASONIC DIAGNOSTIC EQUIPMENT:

– the disturbance shall not produce noise on a waveform or artifacts or distortion in an image or error of a displayed numerical value which can be attributed to a physiological effect and which may alter the diagnosis;
– the disturbance shall not produce an error in a display of incorrect numerical values associated with the diagnosis to be performed;
– the disturbance shall not produce an error in a displayed safety related indication;
– the disturbance shall not produce unintended or excessive ultrasound output;
– the disturbance shall not produce unintended or excessive TRANSDUCER ASSEMBLY surface temperature;
– the disturbance shall not produce unintended or uncontrolled motion of TRANSDUCER ASSEMBLIES intended for intra-corporeal use.

202.8.2 PATIENT physiological simulation

Addition:

The use of a mimicking phantom is recommended to monitor the performance of the ULTRASONIC DIAGNOSTIC EQUIPMENT during testing.

202.8.9 * IMMUNITY TEST LEVELS

Addition to note c) in Table 4, e) in Table 5, e) in Table 6 and c) in Table 8:

According to the intended use, the ULTRASONIC DIAGNOSTIC EQUIPMENT should be tested using a 2 Hz or 1 000 Hz modulation frequency (physiological simulation frequency), whichever is identified by the RISK MANAGEMENT PROCESS. The modulation frequency adopted shall be disclosed in the test report.

202.8.11 IMMUNITY to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz

Addition:

Add the following note at the end of the paragraph:

NOTE ULTRASONIC DIAGNOSTIC EQUIPMENT are likely to be sensitive to disturbances in the frequency range of the IMMUNITY test to proximity magnetic fields. The manufacturer RISK ANALYSIS will document the applicability of the test according to the intended use of the ULTRASONIC DIAGNOSTIC EQUIPMENT. The immunity pass/fail criteria in 202.8.1 will be applied.

212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (EMS)

IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020 apply, except as follows:

212.4.2.2.2 Transient operating conditions

Addition:

If the instructions for use state a more restricted range of transient environmental operating conditions or an operation time shorter than 20 minutes at the transient environmental operating conditions, these conditions shall be justified in the RISK MANAGEMENT FILE.

A reduction of the test duration is allowed but not less than 5 min.

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

Annex AA
(informative)

Particular guidance and rationale

Clause 201.1.1 – Scope

The content of this document has largely been determined to cover ultrasonic medical diagnostic and monitoring equipment including ultrasonic echo ranging devices (both manual and automatic scanning), Doppler echo ULTRASONIC DIAGNOSTIC 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 ULTRASONIC DIAGNOSTIC EQUIPMENT is capable of being used with numerous different types, power ratings and frequencies of TRANSDUCER ASSEMBLIES to cover a wide variety of applications. This has been taken into account in drafting this document.

It is anticipated that later editions of this document 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.

Subclause 201.7.2.13 – Physiological effects (SAFETY SIGNS and warning statements)

The transeosophageal INVASIVE TRANSDUCER ASSEMBLY is considered a unique case requiring special consideration due to its additional use in lengthy monitoring applications.

Subclause 201.7.2.101 – Acoustic output

With certain ULTRASONIC DIAGNOSTIC EQUIPMENT in some operating modes, ten 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 shall be avoided in many cases, as with MULTI-PURPOSE ULTRASONIC DIAGNOSTIC EQUIPMENT (see 201.12.4.3).

On most ULTRASONIC DIAGNOSTIC EQUIPMENT, there is generally provided a single control means for changing the amplitude of the acoustic output, while leaving other parameters (such as pulse length, duty cycle, etc.) unchanged. Often, the OPERATOR shall 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 ULTRASONIC DIAGNOSTIC EQUIPMENT not capable of generating output levels producing unacceptable risk at any possible output level has been implemented in 201.12.4.2.

Subclause 201.7.9.2.2 – Warning and safety notices

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.

Subclause 201.7.9.3.101 – Technical data regarding acoustic output levels

Maximum index value

For the THERMAL INDEX: following 5.6.2 of IEC 62359:2010 and IEC 62359:2010/AMD1:2017, including Table 1:

For *TIS* and *TIB*, the Maximum Index Value is the larger of the sum of the 'at surface' Index Component Values and the sum of the 'below-surface' Index Component Values;

For *TIC,* the Maximum Index Value is the sum of the 'at-surface' non-scanned and scanned *TIC* Index Component Values.

For *MI*, following 5.6.3 of IEC 62359:2010 and IEC 62359:2010/AMD1:2017, the maximum index value is the largest MECHANICAL INDEX of all active TRANSMIT PATTERNS. i.e. the maximum index value is the largest of the MI index component values of the active DISCRETE-OPERATING MODES in a COMBINED-OPERATING MODE.

Subclause 201.10.101 – Ultrasonic energy

This document places the responsibility for establishing upper limits of allowed levels of acoustic output on the MANUFACTURER based on RISK ANALYSIS.

Concerns with possible excessive levels are addressed by requiring an interactive real-time display of acoustic output such as the THERMAL INDICES and MECHANICAL INDEX as included in this document.

Subclause 201.11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

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

NOTE General guidance for the acoustic properties of appropriate tissue is available in the literature [1].

When carrying out a risk analysis for the ULTRASOUND DIAGNOSTIC EQUIPMENT, the user of this document shall take into account that the temperature limit of 43 °C in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 is only applicable for long-term (more than 10 min) contact with healthy skin of adults. Special consideration should be taken 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 10 min) inside the body is currently not well investigated. It is assumed 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 based on clinical experience.

The allowable maximum temperature of 43 °C for parts having contact with the PATIENT for more than 10 min is consistent with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. This represents a safety factor of 2 relative to the threshold for thermally induced chronic damage to the kidney, one of the most sensitive mammalian tissues [4].

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 INVASIVE TRANSDUCER ASSEMBLY 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 transport effects such as blood perfusion, 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 temperature, 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.

Subclause 201.11.1.3 – Measurements

In the still-air test of 11.1.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, essentially all of the electrical energy would be converted into heat within a 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 would drop quickly. The modification of 201.11.1.3 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 11.1.1, Table 24 of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.)

This is also true for INVASIVE TRANSDUCER ASSEMBLIES intended for trans-oesophageal use. Although contact with the internal surface of the oesophagus is prolonged, the time in which the initial transducer temperature is in contact with a single tissue site is relatively short. Furthermore, the transducer area that 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 [5], 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.

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 at the surface;
– a model consisting of a soft tissue mimic.

The test object should be designed such that increasing the size will have a negligible effect on the surface temperature of the TRANSDUCER ASSEMBLY.

When the TRANSDUCER ASSEMBLY 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 can 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.

Subclause 201.11.1.3.101.1 – Simulated use

The following figures show the thermal offset depending on probe types and depending on measurement method a) or measurement method b) for external probes.

Figure AA.1 shows the thermal behavior if the measurement is performed according to method a).

Figure AA.2 visualizes the thermal behavior during measurement according to method b) of a probe with internal heat source (left) and the thermal behavior of a probe with temperature drop after probe coupling to the tissue-mimicking material (right). The later one might occur for all probes where the probe works like a heat sink and transfers heat away from the tissue-mimicking material. In this example, the measurement is done at tissue-mimicking material temperature slightly below 33 °C.

Figure AA.3 shows the same scenario when the tissue-mimicking material is at environmental temperature. The right part of Figure AA.3 does not show a thermal drop, because the tissue-mimicking material is in thermal steady state with the probe and the surrounding air. Therefore, no heat transfer from the tissue-mimicking material to any other material occurs.

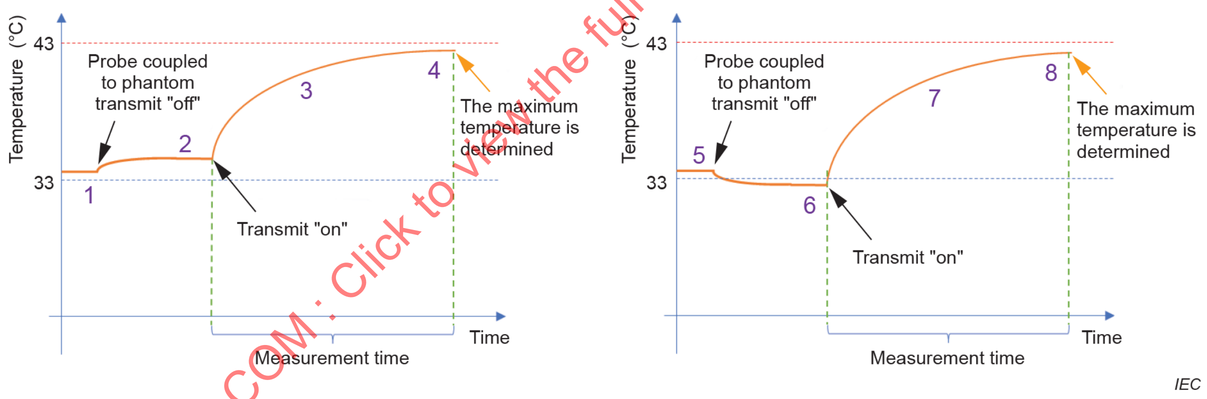


Figure AA.1a) – With heat source **Figure AA.1b) – Without heat source**

Figure AA.1 – Method a) for an external probe

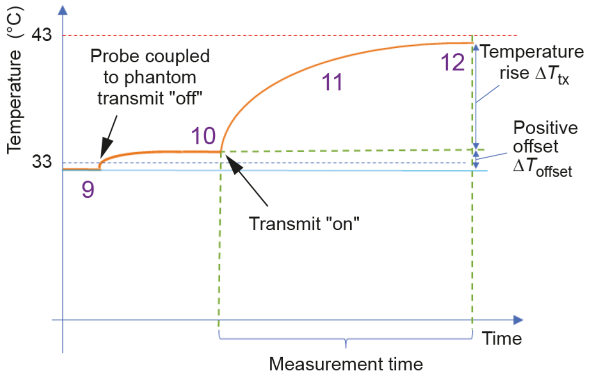


Figure AA.2a) – With heat source

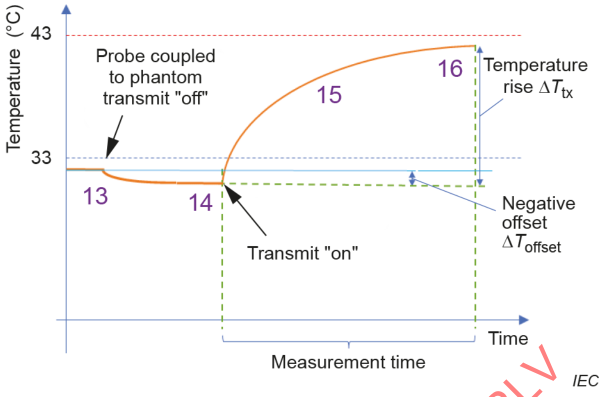


Figure AA.2b) – Without heat source

Figure AA.2 – Method b) for an external probe

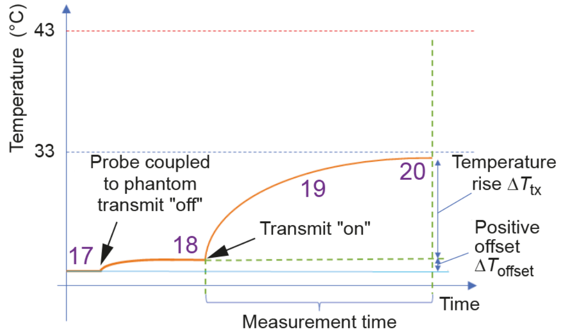


Figure AA.3a) – With heat source at room temperature

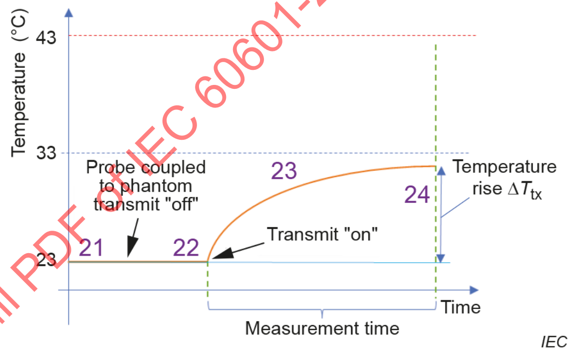


Figure AA.3b) – Without heat source at room temperature

Figure AA.3 – Method b) for an external probe

Method a) for a probe **with** heat sources.

1) TMM surface is >33 °C before the probe is coupled to the TMM.

2) The applied part – TMM surface interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (3) is started.

3) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

4) The maximum temperature during the measurement cycle is determined.

Method a) for a probe **without** heat sources.

5) TMM surface is >33 °C before the probe is coupled to.

6) The applied part – TMM interface drops slightly because heat is transferred away from the TMM. The probe acts like a heat sink and moves heat away from the TMM. The amount depends on the probe heat capacity, thermal conductivity, and probe handle surface area. For some probes, the effect might be negligible. A steady state condition shall be reached before (7) is started.

7) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

8) The maximum temperature during the measurement cycle is determined.

Method b) for a probe **with** heat sources, where method b) is used at temperatures close to method a)

9) TMM surface is <33 °C before the probe is coupled to.

10) The applied part – TMM interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (11) is started.

11) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached.

12) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, can help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **without** heat sources, where method b) is used at temperatures close to method a)

13) TMM surface is <33 °C before the probe is coupled to.

14) The applied part – TMM interface drops slightly because heat is transferred away from the TMM. The probe acts like a heat sink and moves heat away from the TMM. The amount depends on the probe heat capacity, thermal conductivity, and probe handle surface area. A steady state condition shall be reached before (15) is started.

15) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached.

16) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **with** heat sources, where method b) is used at room temperature

17) TMM surface is ~23 °C before the probe is coupled to.

18) The applied part – TMM surface interface increases because heat is transferred to the TMM. A steady state condition shall be reached before (19) is started.

19) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

20) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the offset and temperature rise. The second sensor is visualized as a light blue line.

Method b) for a probe **without** heat sources, where method b) is used at room temperature

21) TMM surface is ~23 °C before the probe is coupled to.

22) The applied part – TMM interface does not drop because the phantom, probe and environment are in thermal steady state. A steady state condition shall be reached before (23) is started.

23) The applied part temperature increases during the 30 min measurement time or until the thermal steady state is reached. In case of closed loop systems, the temperature might not increase continuously.

24) The temperature rise and offset are found as shown by arrows on the graph. A second sensor on the test object, at a sufficient distance to avoid thermal impact from the probe, may help to find the temperature rise. The second sensor is visualized as a light blue line.

Subclause 201.11.1.3.101.2 – Still air

For some TRANSDUCER ASSEMBLIES such as mechanically rocked 3D probes, or solid state probes with integrated multiplexing electronics, the temperature of the APPLIED PART (surface temperatures) may not stabilize at an initial steady-state temperature equal to the air-ambient temperature when the acoustic power is 'off' (i.e.: non-energized transducer elements). Rather, a fixed offset temperature may exist.

In such cases, the initial APPLIED PART temperature shall be the ambient temperature plus the THERMAL OFFSET, and the final surface temperature shall be considered as the sum of the measured APPLIED PART temperature rise obtained during the 30 min test plus the offset temperature plus 23 °C.

Note that the THERMAL OFFSET might be eliminated by completely disconnecting the TRANSDUCER ASSEMBLY from the ULTRASONIC DIAGNOSTIC EQUIPMENT when the acoustic power is off.

Subclause 201.11.1.3.104 – Temperature measurement

Temperature measurement with thermographic camera (infrared camera) under the still air condition should be conducted with reference to IEC TS 63070:2019 which covers measurement on both diagnostic and therapeutic (physiotherapy and HITU) equipment [52].

Subclause 201.11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS

All TRANSDUCER ASSEMBLIES are assumed to require some contact with fluids during normal operation. Some TRANSDUCER ASSEMBLIES 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 TRANSDUCER ASSEMBLIES, employed for contact scanning, need only minimal contact with some coupling gel at the TRANSDUCER ASSEMBLY'S active surface. The MANUFACTURER is expected to specify, through knowledge of the application and TRANSDUCER ASSEMBLY design, the parts of the TRANSDUCER ASSEMBLY that can be wetted in NORMAL USE, see 201.7.9.2.2.

The requirement and test as specified are considered suitable for this ULTRASONIC DIAGNOSTIC EQUIPMENT and avoid conflict with the WATERTIGHT requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. The tests specified are documented in IEC 60529. The IPX1 code indicates protection of equipment against the 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.

Subclause 201.12.4.5.1 – Limits

While this document places no upper limits on permitted levels of acoustic output, all EQUIPMENT is limited for technical reasons, compliance with local regulatory requirements, or reasons resulting from the MANUFACTURER'S RISK MANAGEMENT. On the one hand the MANUFACTURERS should continuously track the scientific discussions on safety of ultrasonic fields for diagnostic ultrasound, on the other hand the OPERATORS should know about the – possibly application-dependent – limits of their EQUIPMENT as selected by the MANUFACTURER.

Compliance with 201.12.4.5.1 can be checked by inspection of the relevant documentation of the results of the RISK MANAGEMENT process provided by the MANUFACTURER, including relevant information such as clinical experience.

Clause 201.17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

ULTRASONIC DIAGNOSTIC EQUIPMENT is categorised 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 shall be categorised as class B. For further details, see Annex BB.

ULTRASONIC DIAGNOSTIC EQUIPMENT, which is the subject of this document, is classified in Group 1 (under Annex C.2, IEC 60601-1-2:2014), since the device shall intentionally generate radio frequency 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.

For INVASIVE TRANSDUCER ASSEMBLIES, radiated and conducted emissions per IEC 60601-1-2 should be performed both with and without the transducer active to ensure compliance when the transducer is outside the body and not activated, and secondly, when the transducer is inside the body and activated. The condition "inside the body and activated" should be simulated using a phantom having the same attenuation as human tissue in the frequency pass band of the transducer. The phantom should only be used while making radiated or conducted emission measurements in the frequency pass band of the transducer unless the phantoms frequency characteristics are known over the entire frequency range of 150 kHz to 1 000 MHz.

Subclause 202.8.1 – General

There is common agreement that it is not possible to require that nothing 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 8.1 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, the ULTRASONIC DIAGNOSTIC EQUIPMENT shall be able to provide the ESSENTIAL PERFORMANCE and remain safe.

Examples of conformance to the compliance criteria:

– 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.

Subclause 202.8.9 – IMMUNITY TEST LEVELS

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 on the order of kHz). 2 Hz modulation frequency is intended to test the former, while 1 kHz modulation frequency is intended for the latter.

Annex BB
(informative)

Guidance in classification according to CISPR 11

Rules for classification and separation into groups of equipment are contained in CISPR 11. ULTRASONIC DIAGNOSTIC EQUIPMENT that is the subject of this document is classified in Group 1 (under Annex C.2, IEC 60601-1-2:2014), since the device shall 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.

- Subclause 5.2 of CISPR 11:2024

According to the subclause, division into classes is as follows:

– Class A equipment is equipment suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

– Class B equipment is equipment suitable for use in locations in residential environments and in establishments directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Annex CC
(informative)

Guidance to the MANUFACTURER on the interpretation of *TI* and *MI* to be used to inform the OPERATOR

CC.1 Guidance

It is the responsibility of the OPERATOR to understand the risk of the output of the ULTRASONIC DIAGNOSTIC EQUIPMENT, and to act appropriately in order to obtain the needed diagnostic information with the minimum risk to the patient. To be able to do so the manufacturer of the device should provide information to the user regarding how to interpret the displayed ultrasonic exposure parameters, THERMAL INDEX and MECHANICAL INDEX. A detailed rationale and derivation of *TI* and *MI* models is reported in Annex A of IEC 62359:2010, while brief reviews are available in the literature [6], [7]. This annex provides guidance on subjects that should be taken into account in drawing up a PRUDENT USE STATEMENT to be used in the instructions for use as specified in 201.7.9.2.2 of this document.

The relationship of various acoustic output parameters (e.g., acoustic intensity, pressure, power, etc) to biological endpoints is not presently fully understood. Evidence to date has identified two fundamental mechanisms, thermal and mechanical, by which ultrasound can induce bioeffects [8], [9], [5], [10], [11], [12] and, in certain cases, alteration or damage to tissue.

The temperature rise and the possibility of cavitation seem to depend on such factors as the total energy output, the mode, the shape of the ultrasound beam, the position of the focus, the centre frequency, the shape of the waveform, the pulse repetition frequency, and the duty factor. The *TI* and *MI* are indices designed to give the user instant information about the potential for thermal or mechanical bioeffects. Because the *MI* and *TI* reflect instantaneous output conditions, they do not take into account the cumulative effects (especially heating) of the total examination time. It is relevant to indicate that shortening insonation times can give a large safety margin under some conditions (wide, scanning beams in soft tissue) but no significant margin under other conditions (narrow, non-scanning beams on bone) [13].

As far as cavitation is concerned there is agreement that the potential for biological effects rises with a rising peak rarefactional pressure. There is lesser agreement about the frequency dependence of the occurrence of cavitation in tissue [9], [10], [14], [15], [16], [17]. Nevertheless, the *MI* is intended to give a relative indication of the potential for mechanical bioeffects such as cavitation.

The *TI* gives a relative indication of the potential for temperature increase at a specific point along the ultrasound beam. The reason for the term "relative" is that the assumed conditions for heating in tissue are complex such that any single index or model cannot be expected to give the actual increase in temperature for all possible conditions and tissue types. Thus, for a particular beamshape, a *TI* of 2 represents a higher temperature rise than a *TI* of 1 but does not necessarily represent a rise of 2 °C. The important point about the *TI* is that it is designed to make the OPERATOR aware of the possible temperature rise at a particular point in tissue. To inform the OPERATOR, limitations about the use of the indices are given below.

Subclause 201.12.4.5.1 of this document requires that acoustic output be limited based on RISK ASSESSMENT and RISK MANAGEMENT following ISO 14971 using the safety related parameters specified in this document. The indices do not presently provide absolute safety limits. Safety limits based on biological effects remain a topic of research for consideration in future standards. The demarcation between safe levels and levels where there exists a potential for biological effects is of importance for the OPERATOR.

The WFUMB [5] gives some guidelines: embryonic and foetal *in situ* temperature above 41 °C (4 °C above normal temperature) for 5 min or more should be considered potentially hazardous.

The same is true if the anticipated acoustic pressure amplitude at the surface of the postnatal lung tissue exceeds 1 MPa. However, the actual threshold for effects in the lungs of mammalian laboratory species is a complex combination of the values of the acoustic output parameters [18]

What the indices do provide is an indication of the conditions that are more likely than others to produce thermal or mechanical effects.

For example, *TI* values towards the upper end of the range (over 1,0) might best be avoided in obstetric applications. Such a restriction allows a reasonable safety margin considering the WFUMB recommendation that a temperature increase of 4 °C for 5 min or more should be considered as potentially hazardous to embryonic and foetal tissue [5]. However, if a particular clinical result cannot be obtained with lower values, increased output may be warranted, but particular attention should be paid to limiting the exposure time. Any extra thermal load to the foetus when the mother has a fever is also unwise, and again note should be made to avoid high *TI* values [19]. ISUOG [20] states that doppler ultrasound should not be used routinely on foetuses between 11 and 14 weeks of pregnancy, in addition *TI* should not exceed 1 when doppler ultrasound is performed, and that the exposure time should be kept as short as possible and should not exceed 60 min (usually 5 min to 10 min).

BMUS [21] presents recommended maximum *TI* and *MI* values for each application, as well as maximum recommended scanning times for a range of *TI* values. AIUM [22] also has published recommended maximum scanning times for displayed *TI* values. These two safe use guidelines agree for obstetrical, neonatal trans-cranial, and neonatal spinal exams. However, for all other exams, the AIUM recommendations are less conservative, as explained in Harris et al. 2016 [23]. For obstetric, neonatal transcranial, and neonatal spinal exams, both safe use guidelines begin at *TI*=0,7 (i.e., they state that there is no scanning time limit if *TI* ≤ 0,7).

The modelling for predicting *TI* assumes some cooling by blood perfusion. For applications where poorly perfused tissues are expected, the *TI* may underestimate the possible worst-case temperature rise, and again the *TI* should be maintained at a lower value. Conversely, when scanning organs known to be well perfused, such as hepatic, cardiac or vascular structures, the value of *TI* may overestimate the temperature rise.

In clinical applications where the *TIS* has been selected to be shown on the screen, it may well be more appropriate to inform the OPERATOR to pay attention to the value of *TIB*. Examples are for breast scanning, when ribs may be exposed, and for vascular studies when vessels lie close to bone surfaces.

The assumption is made that the surface heating in soft tissue SCANNING MODE is always larger than the worst-case bone heating at depth. This assumption may not be universally true, and for this reason *TI* values in both B-mode and Doppler imaging modes in second and third trimester scanning shall be interpreted with caution.

The *TI* values in SCANNING MODE predict heating in tissue next to the transducer surface due only to the energy absorbed from the beam. No correction is made for the heating of the transducer itself. The same is true for transcranial transducers and smaller unscanned transducers where the heating is also predicted next to the transducer.

The *MI* becomes important at a gas/soft tissue interface, for example in cardiac scanning where the lung surface can be exposed. Most critically, however, it is with the use of contrast materials when most attention should be made to limit *MI*.

There are always limitations due to measurement and parameter determination imperfections when utilizing mathematical models. Specific limitations of the *MI* and *TI* are identified in IEC 62359. These limitations should be taken into account when drawing up guidance to the user on the interpretation of the indices.

The EFSUMB Clinical Safety Statement for Diagnostic Ultrasound [24] is useful information. For example, B mode including coded transmission technology, spectral pulse wave Doppler and Doppler imaging modes (such as color flow imaging and power Doppler imaging, etc.) can produce more tissue heating and higher *TIS*.

Attention should be paid to the use of long-duration waveforms with higher outputs than normal diagnostic ultrasound, such as shear wave elastography [25], which evaluates the elasticity of shear waves using acoustic radiation forces. If there is bone tissue near the focal point, there is a concern of a significant temperature rise [26] [27]. In animal studies, it has been reported that exposed ultrasound to the heart with contrast agents causes premature ventricular contractions [28], and when exposed ultrasound to lung tissue, pulmonary haemorrhage occurs [29] [30] [31]. It may not be appropriate or valid to apply the current *TI* models in the shear wave elastography: the *TI* and *MI* displayed for these applications may represent an underestimate of the temperature rises and mechanical effects to be expected [25]. So far, no specific risk indicator has been developed, thus the duration of the shear wave elastography should be kept as low as possible to reduce the thermal stress to the targeted tissue.

Table CC.1 summarizes the relative importance of maintaining low index values in specific scanning situations.

Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations

	Of greater importance	**Of less importance**
MECHANICAL INDEX	With contrast material Cardiac scanning (lung exposure) Abdominal scanning (bowel gas)	In the absence of gas bodies: i.e. in most tissue imaging
THERMAL INDEX	First trimester scanning Foetal skull and spine Neonatal head PATIENT with fever In any poorly perfused tissue Ophthalmic scanning (requires different risk estimate) If ribs or bone is exposed: *TIB*	In well perfused tissue i.e. liver, spleen In cardiac scanning In vascular scanning

CC.2 Prudent use

It is conventional to consider all biological effects of ultrasound as deterministic effects, in contrast to the assumption for ionizing radiation, for which it is known that some effects are stochastic and act without threshold. For some effects, e.g., those due to inertial cavitation, this reflects the fact that the responsible physical mechanism does not occur below a particular exposure level. For other effects, e.g., those due to increased temperature, this can reflect the difficulty of observing a small increase in the rate of occurrence of rare events. In order for an apparent threshold of this type to be exceeded, a biological effect shall occur frequently enough for an observer to be aware of having "observed" an effect. A temperature rise from 37 °C to 40 °C for quite a long time may be deemed sub-threshold because it produces too low an increased incidence to be observed, whereas a temperature rise to 42 ºC for any duration may not be acceptable, i.e., it may produce an observable effect. An appropriate guide to the user would be that although there may be a biological effect, not all biological effects result in a hazard. Healthy human cells are obviously able to survive small temperature rises. Apart from the fact that the science evaluating the hazard is incomplete at the moment, there is enough evidence about thermal teratology, exposure levels, and temperature rise to carry out a basic risk analysis.

A prudent starting-point for each examination would be first to set the machine for the lowest index setting and then modify from this level until a satisfactory image or Doppler signal is obtained, keeping track of the *TI* and *MI*; and second, the exposure time, during one examination, should be kept as short as possible. A safety guideline on this should be included [19].

Annex DD
(informative)

Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES

DD.1 General

The test object set-up described below is a result of measurements presented in the report [32]. For at least 10 different transducers, the surface temperatures of the transducers as measured when radiating into human under-arms were compared with the set-up described.

Basically, the set-up consists of a piece of soft tissue mimicking material (TMM) covered by a slab of silicone rubber on which a (thin film) thermocouple is placed (see Figure DD.1). The TMM is placed on a piece of material that absorbs all acoustic energy.

The properties of the materials used will be those of silicon and TMM as listed in Table DD.1:

Table DD.1 – Acoustic and thermal properties of tissues and materials

Tissue/ material	Velocity c m/s	Density ρ kg/m³	Attenuation coefficient α dB/cm-MHz	Acoustic impedance Z 10^6 kg/m²-s	Spec. Heat capacity C J/kg-K	Thermal Conductivity κ W/ kg-K	Thermal Diffusivity D 10^{-6} m²/s	Source
Skin	1 615	1 090	2,3 to 4,7 3,5	1,76	3 430	0,335	0,09	ICRU rep. 61, 1998 [1] Chivers 1978 [33]
Soft tissue	1 575	1 055	0,6 to 2,24 [a]	1,66	3 550	0,525	0,150	ICRU rep. 61. 1998 [1]
Soft tissue fatty	1 465	985	0,4	1,44	3 000	0,350	0,135	ICRU rep. 61, 1998 [1]
Cortical bone[b]	3 635	1 920	14 to 22	6,98	1 300	0,3 to 0,79	0,32	ICRU rep. 61, 1998 [1]
Silicone	1 021	1 243	1,8[c]	1,3		0,25		TNO / Dow Corning[32]
TMM	1 540	1 050	0,5[c]	1,6	3 800	0,58	0,15	TNO (Soft Tissue Model)

[a] Frequency dependence: $f^{1,2}$.

[b] Wide uncertainty has been reported in bone properties [34].

[c] Determined at 3 MHz.

DD.2 Preparation of the soft tissue mimicking material (TMM)

A mixture is made from the materials provided in Table DD.2 (weight % pure components).

Table DD.2 – Weight % pure components

Component	Weight %
Glycerol	11,21
Water	82,95
Benzalkonium chloride	0,47
Silicon Carbide (SiC (-400 mesh))	0,53
Aluminium Oxide (Al_2O_3 (0,3 µm))	0,88
Aluminium Oxide (Al_2O_3 (3 µm))	0,94
Agar	3,02
Sum	100,00

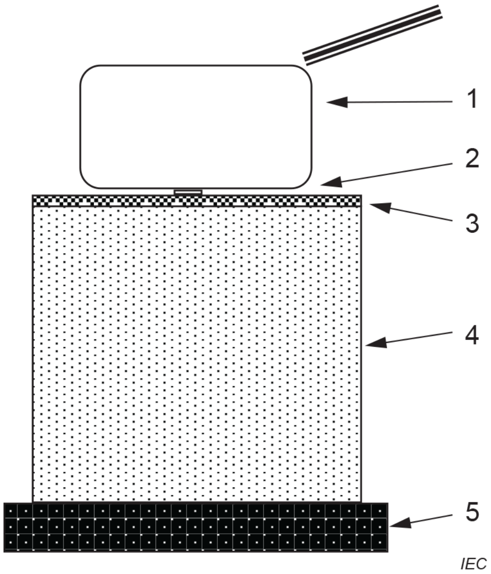
- Recipe to prepare the soft tissue mimicking material and the set-up
  1) Mix all components listed in the table and degas at laboratory temperature.
  2) Heat, while stirring, until 90 °C

     To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
  3) Cool the substance, while stirring as long as the viscosity allows, until about 47 °C,

     To avoid evaporation and hence a change in components ratio, the substance should be covered during this process.
  4) Pour the substance quickly in a mould and let it further cool down while the mould is covered.
  5) The TMM is now ready for use. To prepare the total measurements set-up, the TMM should be covered with a slab of silicone rubber with a thickness of 1,5 mm. Take care that there is no air between the TMM and the silicon rubber. (This will result in about equal measurement results as when using human under-arms). Although Figure DD.1 shows a set-up for a flat transducer surface, a curved surface is easily obtained by cutting the curvature in the TMM.
  6) A (thin film) thermocouple shall be placed on top of the silicone rubber layer.
  7) Finally the transducer under test shall be placed, coupled with acoustic coupling gel.
- Maintenance

The material should be stored in a closed container under normal laboratory conditions (18 °C to 25 °C). While stored, keep the material in a water/glycerol mixture to prevent it from drying out and to avoid air contact. This mixture contains 88,1 % (weight) demineralised water and 11,9 % (weight) glycerol (purity >99 %).

The shelf life of the material if it is preserved without air contact is at least one year. The addition of a 0,5 % (weight) solution of benzalkonium chloride acts as an antifungal agent extending the life of the phantom. With produced samples shelf lives over 2 years were found.



Key

1 ULTRASONIC TRANSDUCER under test, coupled to the test object using acoustic coupling gel

2 Thermal sensor, e.g. thin film thermocouple

3 Silicone rubber, thickness: 1,5 mm

4 Soft tissue mimicking material (TMM)

5 Acoustic absorber

Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers

Annex EE
(informative)

Acoustic output table intended for third parties

Table EE.1 provides an example acoustic output table to allow 3rd parties to recalculate the *TI* and *MI* values for each operating mode, including the contributions from each mode in COMBINED-OPERATING MODES.

The 'index component values' for *MI* and *TIC* are the index values for each DISCRETE-OPERATING MODE comprising the operating mode.

The 'index component values' for *TIS* and *TIB* are the values of the 'at-surface' and below-surface' *TI* formulations for each DISCRETE-OPERATING MODE comprising the operating mode. "✓" indicates cells where to enter one or more numerical values. The equipment setting related to the index is entered in the operating control section.

NOTE 1 See Annex AA for descriptions of "maximum index value' and 'index component values'.

NOTE 2 An operating mode can be interpreted to be any DISCRETE-OPERATING MODE (like B, M) as well as any COMBINED-OPERATING MODE (like B+D+CFM).

NOTE 3 According to 201.3.201, the bone tissue is located deeper position in the *TIB* model. Therefore "*TIB* at surface" is equal to "*TIS* at surface", not *TIC*.

Table EE.1 – Example of acoustic output table for third parties

MODE: ______________________

Index label			*MI*	*TIS*			*TIB*			*TIC*	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Maximum index value			✓	✓			✓			✓	
Index component value			✓	✓	✓	✓	✓	✓	✓	✓	✓
Associated acoustic parameters	$p_{r,\alpha}$ at z_{MI}	(MPa)	✓								
	P	(mW)		✓	✓		✓	✓		✓	✓
	P_{1x1}	(mW)		✓	✓		✓	✓			
	Min. of $[P_\alpha(z_s), I_{ta,\alpha}(z_s) \times 1\ cm^2]$(mW)					✓					
	z_s	(cm)				✓					
	z_{bp}	(cm)				✓			✓		
	z_b	(cm)							✓		
	z_{pii}	(cm)	✓			✓			✓		
	z_{MI}	(cm)	✓								
	d_{eq} at $_{zb}$	(cm)							✓		
	f_{awf}	(MHz)	✓	✓	✓		✓	✓		✓	✓
	Dim of A_{aprt}	X (cm)		✓	✓		✓	✓		✓	✓
		Y (cm)		✓	✓		✓	✓		✓	✓

Index label			*MI*	*TIS*			*TIB*			*TIC*	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At surface	At surface	Below surface	At surface	At surface	Below surface	At surface	At surface
Other information	Mode components		✓	✓	✓		✓	✓		✓	✓
	t_d	(µsec)	✓								
	prr	(Hz)	✓								
	srr	(Hz)	✓								
	p_r at z_{pii}	(MPa)	✓								
	d_{eq} at z_{pii}	(cm)							✓		
	$I_{pa,\alpha}$ at $z_{pii,\alpha}$	(W/cm²)	✓								
	Focal length	*FLx* (cm)	✓			✓			✓		
		FLy (cm)	✓			✓			✓		
Operating control conditions	Control 1										
	Control 2										
	Control 3										
	Control 4										
	Control 5										
	…										
	Control x										

NOTE 1 Only one operating condition per index.

NOTE 2 Data can be entered for each component transmit pattern active in COMBINED-OPERATING MODES.

NOTE 3 Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

NOTE 4 If the requirements of 201.12.4.2a) or b) are met, it is not required to enter any data in the columns related to *TIS*, *TIB* or *TIC*.

NOTE 5 If the requirements of 201.12.4.2c) are met, it is not required to enter any data in the column related to *MI*.

NOTE 6 Focal Length is a NOMINAL value.

NOTE 7 "Mode component" identifies the DISCRETE-OPERATING MODES in a COMBINED-OPERATING MODE. As an example of the labelling of mode components, see 4.1 of IEC 61157:2007.

NOTE 8 'Dim of A_{aprt}' is, for scanning modes, the dimensions of the SCANNED APERTURE AREA and, for non-scanning mode, the dimensions of the OUTPUT BEAM AREA, see definition section of IEC 62359.

Bibliography

[1] International Commission on Radiation Units and Measurements (ICRU), *Tissue substitutes, phantoms and computational modelling in medical ultrasound*, report 61, 1998, ISBN 0-913394-60-2

[2] HEKKENBERG, RT. and BEZEMER, RA. *Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers.* TNO report: PG/TG/2001.246, Leiden, 2002, ISBN 90-5412-078-9

[3] ISO/IEC Guide 98-1:2024, *Guide to the expression of uncertainty in measurement – Part 1: Introduction*

[4] DEWEY, WC. Arrhenius relationships from the molecule and cell to the clinic. *Intl J Hyperthermia*, 1994, 10(4): pp. 457-483

[5] World Federation for Ultrasound in Medicine and Biology (WFUMB), *Conclusions and Recommendations on Thermal and Non-thermal Mechanisms for Biological Effects of Ultrasound*. Report of the 1996 WFUMB Symposium on Safety of Ultrasound in Medicine. Barnett, S. B (ed). *Ultrasound in Medicine and Biology*, Vol 24, suppl 1, 1998

[6] ABBOTT, JG. Rational and Derivation of MT and TI – a Review. *Ultrasound in Med & Biol*, 1999, Vol. 25, No. 3, pp 431 – 441

[7] DUCK, FA. The meaning of Thermal Index (TI) and Mechanical Index (MI) values. *BMUS Bulletin*, Nov. 1997, pp. 36-40

[8] American Institute of Ultrasound in Medicine (AIUM). Bio-effects considerations for the safety of diagnostic ultrasound. *J Ultrasound Med 7*: supplement (1988)

[9] APFEL, RE. and HOLLAND, CK. Gauging the likelihood of cavitation from short-pulse low-duty cycle diagnostic ultrasound. *Ultrasound Med Biol*, 1991, 17: p.179-185

[10] American Institute of Ultrasound in Medicine (AIUM), Mechanical Bioeffects from Diagnostic Ultrasound: AIUM Consensus Statement. *J. Ultrasound Med*., 2000, Vol. 19, No. 2 or 3

[11] SALVESEN, KA. *Epidemiological studies of diagnostic ultrasound. Chapter 9, In: The safe use of ultrasound in medical diagnosis.* British Medical Ultrasound Society/British Institute of Radiology. Editors ter Haar, G.R. and Duck, F.A., 2000, pp. 86-93

[12] National Council on Radiation Protection and Measurements (NCRP), *Exposure criteria for medical diagnostic ultrasound: II. Criteria based on all known mechanisms*, NCRP Report No. 140, National Council on Radiation Protection and Measurements, Bethesda MD (2002)

[13] LUBBERS J., HEKKENBERG, RT., BEZEMER, RA. Time to Threshold (TT), a safety parameter for heating by diagnostic ultrasound. *Ultrasound in Med. & Biol.*, May 2003, Vol. 29, 5, pp.755-764

[14] CHURCH, CC. Spontaneous Homogeneous Nucleation, Inertial Cavitation and the Safety of Diagnostic Ultrasound. *Ultrasound Med. and Biol.*, 2001, 28(10), 1349-1364

[15] CHURCH, CC. Frequency, pulse length, and the mechanical index. *Acoust Res Lett Online,* 2005, 6(3):162-168

[16] ŠPONER, J. Dependence of the cavitation threshold on the ultrasonic frequency. *Czech. J. Phys.*, 1990, 40: pp. 1123–1132

[17] ŠPONER, J. Theoretical estimation of the cavitation threshold for very short pulses of ultrasound. *Ultrasonics,* 1991, 29: pp. 376–380

[18] CHURCH, CC., O'BRIEN, WC. Evaluation of the Threshold for Lung Hemorrhage by Diagnostic Ultrasound and a Proposed New Safety Index. *Ultrasound Med Biol,* 2007, 33

[19] BARNETT, SB, ter HAAR, GR., ZISKIN, MC., ROTT, H-D., DUCK, FA., MAEDA, K. International recommendations and guidelines for the safe use of diagnostic ultrasound in medicine. *Ultrasound in Medicine and Biology*, 2000, Vol. 26, No. 3

[20] Bioeffect and Safety Committee of ISUOG. ISUOG statement on the safe use of Doppler in the 11 to 13 + 6-week fetal ultrasound examination, *Ultrasound Obstet Gynecol*. 37:628 (2011)

[21] British Medical Ultrasound Society. Guidelines for the safe use of diagnostic ultrasound equipment. *Ultrasound 2010*; 18:52–59

[22] AIUM (American Institute of Ultrasound in Medicine). *Official Statement: Recommended Maximum Scanning Times for Displayed Thermal Index (TI) Values*. Approved: 10/30/2016; Reapproved: 09/26/2022

[23] HARRIS G.R., CHURCH C.C., DALECKI D., ZISKIN M.C., BAGLEY J.E. Comparison of Thermal Safety Practice Guidelines for Diagnostic Ultrasound Exposures. *Ultrasound in Med. Biol*. 42, No. 2, pp. 345–357 (2016)

[24] KOLLMANN, C., JENDERKA, K. V., MORAN, C. M., DRAGHI, F., JIMENEZ DIAZ, J. F., & SANDE, R. (2020). EFSUMB Clinical Safety Statement for Diagnostic Ultrasound – (2019 revision). *Ultraschall in der Medizin* (Stuttgart, Germany: 1980), 41(4), 387–389. https://doi.org/10.1055/a-1010-6018

[25] SHIINA, T. et al*,* WFUMB guidelines and recommendations for clinical use of ultrasound elastography: Part 1: basic principles and terminology*, Ultrasound Med Biol.* 2015; 41:1126-47

[26] B. A. HERMAN AND G. R. HARRIS*,* Models and regulatory considerations for transient temperature rise during diagnostic ultrasound pulses*, Ultrason. in Med. & Biol.*, vol. 28, pp. 1217-1224,2002

[27] N. NITTA, Y. ISHIGURO, H. SASANUMA, N.TANIGUCHI, I. AKIYAMA, In Vivo Measurement of Temperature Rise in Living Rabbit's Liver Exposed to Ultrasound with Acoustic Radiation Force*. Proceedings of the IEEE International Ultrasonics Symposium,* 2014, pp. 1175 – 1178

[28] KAZUMA RIFU, et.al, An acoustic radiation force impulse under clinical conditions with a single infusion of an ultrasound contrast agent evokes arrhythmias in the rabbit heart, *J. Med. Ultrasonics* (2021)

[29] DOUGLAS L. MILLER. et.al. Pulmonary Capillary Hemorrhage Induced by Super Sonic Shear Wave Elastography in Rats. *Ultrasound Med Biol,* 2019, 45: p.2993-3004

[30] N. TAKAYAMA, Y. ISHIGURO, et.al*,* The effect of ultrasound with acoustic radiation force on rabbit lung tissue: a preliminary study*, J. Med. Ultrasonics* (2016) 43:pp. 481 – 485

[31] Y. ISHIGURO, N. NITTA, N. TANIGUCHI, et.al. Ultrasound exposure (mechanical index 1.8) with acoustic radiation force impulse evokes extrasystolic waves in rabbit heart under concomitant administration of an ultrasound contrast agent. *J. Med. Ultrasonics* (2016) 43:pp. 3 – 7

[32] HEKKENBERG, RT., BEZEMER, RA. *Aspects concerning the measurement of surface temperature of ultrasonic diagnostic transducers, part 2: on a human and artificial tissue*, TNO report: PG/TG/2003.134, ISBN 90-5412-085-1, Leiden, 2003

[33] CHIVERS, RC., PARRY, RJ. Ultrasonic velocity and attenuation in mammalian tissues. *J. Acoust. Soc. Am.*, 1978, 63, pp. 940-953

[34] DUCK, FA. *Physical properties of tissue – a comprehensive reference book*. Academic Press, London. ISBN 0-12-222800-6, 1990

[35] O'BRIEN, WD. and ELLIS, DS. *IEEE Trans. Ultrasonics Freq. Control*, vol 46, no. 6 November 1999, pp. 1459-1476

[36] World Federation for Ultrasound in Medicine and Biology (WFUMB) Symposium on Safety and Standardisation in Medical Ultrasound, Synopsis. *Ultrasound in Med & Biol*, 1992, 18, 733-737

[37] American Institute of Ultrasound in Medicine (AIUM), *Bio-effects and safety of diagnostic ultrasound*, American Institute of Ultrasound in Medicine, 1470 Sweitzer Lane, suite 100, Laurel MD 20707-5906 (1993)

[38] CARSTENSEN, EL., CHILD, SZ., CRANE, C., PARKER, KJ. Lysis of cells in Elodea leaves by pulsed and continuous wave ultrasound. *Ultrasound Med Biol*, 1990a, 16:p.167-173

[39] CARSTENSEN, EL., CHILD, SZ., NORTON, S., NYBORG, WL. Ultrasonic heating of the skull. *J Acous Soc Am*, 1990b, 87: p.1310-1317

[40] CHILD, SZ., HARTMAN, CL. McHALE, LA. CARSTENSEN, EL. Lung damage from exposure to pulsed ultrasound. *Ultrasound Med Biol*, 1990, 16: p.817-825

[41] CURLEY, MG. Soft tissue temperature rise caused by scanned, diagnostic ultrasound. *IEEE Trans Ultrasonics, Ferroelectrics and Frequency Control*, 1993, 49:p.59-66

[42] HOLLAND, CK., APFEL, RE. Thresholds for transient cavitation produced by pulsed ultrasound in a controlled nuclei environment. *J Acoust Soc Am*, 1989, 88:p.2059-2069

[43] National Council on Radiation Protection and Measurements (NCRP), *Exposure criteria for medical diagnostic ultrasound: I. Criteria based on thermal mechanisms*, NCRP Report No. 113, National Council on Radiation Protection and Measurements, Bethesda MD (1992)

[44] SEKINS, KM., EMERY, AF. "Thermal science for physical medicine", chapter 3:70-132, in *Therapeutic Heat and Cold*, Lehmann JF editor. Williams & Wilkins, Baltimore, MD, 1982

[45] World Federation of Ultrasound in Medicine and Biology (WFUMB), Second world federation of ultrasound in medicine and biology symposium on safety and standardization in medical ultrasound. *Ultrasound Med Biol,* 1989, 15:supplement

[46] American Institute of Ultrasound in Medicine (AIUM), *Medical Ultrasound Safety,* AIUM, 14750 Sweitzer Lane, Suite 100, Laurel MD 20707 – 5906, USA, 1994

[47] American Institute of Ultrasound in Medicine (AIUM), National Electrical Manufacturers Association (NEMA), *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment,* Rev.1. American Institute of Ultrasound in Medicine & National Electrical Manufacturers Association, 2004

[48] CHRISTOPHER, T., CARSTENSEN, EL. Finite amplitude distortion and its relationship to linear derating formulae for diagnostic ultrasound systems. *Ultrasound in Med. and Biol.*, 1996, 22, pp.1103-1116

[49] SHAW, A., PAY, NM. and PRESTON, RC. *Assessment of the likely thermal index values for pulsed Doppler ultrasonic equipment – Stages II and III: experimental assessment of scanner/transducer combinations,* NPL Report CMAM 12, The National Physical Laboratory, Teddington, Middlesex TW11 OLW, UK, 1998

[50] IEC 61157:2007, *Standard means for the reporting of the acoustic output of medical diagnostic ultrasonic equipment*
IEC 61157:2007/AMD1:2013[2]

[51] IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*
IEC 60601-1-11:2015/AMD1:2020

[52] IEC TS 63070:2019, *Ultrasonics – Field characterization – Infrared imaging techniques for determining temperature elevation in tissue-mimicking material and at the radiation surface of a transducer in still air*

[53] IEC 60050-802:2011, *International Electrotechnical Vocabulary (IEV) – Part 802: Ultrasonics*

[54] ISO/IEC Guide 63:2019, *Guide to the development and inclusion of aspects of safety in International Standards for medical devices*

[2] There exists a consolidated edition (2.1) including IEC 61157:2007 and its Amendment 1 (2013).

Index of defined terms

____

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-37: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
5) L'IEC elle-même ne fournit aucune attestation de conformité. Des organismes de certification indépendants fournissent des services d'évaluation de conformité et, dans certains secteurs, accèdent aux marques de conformité de l'IEC. L'IEC n'est responsable d'aucun des services effectués par les organismes de certification indépendants.
6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
7) Aucune responsabilité ne doit être imputée à l'IEC, à ses administrateurs, employés, auxiliaires ou mandataires, y compris ses experts particuliers et les membres de ses comités d'études et des Comités nationaux de l'IEC, pour tout préjudice causé en cas de dommages corporels et matériels, ou de tout autre dommage de quelque nature que ce soit, directe ou indirecte, ou pour supporter les coûts (y compris les frais de justice) et les dépenses découlant de la publication ou de l'utilisation de cette Publication de l'IEC ou de toute autre Publication de l'IEC, ou au crédit qui lui est accordé.
8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments du présent document de l'IEC peuvent faire l'objet de droits de brevets. L'IEC ne prend pas position quant à la preuve, à la validité et à la portée de ces droits de propriété. À la date de publication du présent document, l'IEC n'a reçu aucune déclaration relative à des droits de brevets, qui pourraient être exigés pour la mise en œuvre du présent document. Toutefois, il est rappelé aux responsables de cette mise en œuvre qu'il ne s'agit peut-être pas des informations les plus récentes, qui peuvent être obtenues dans la base de données disponible à l'adresse https://patents.iec.ch. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-37 a été établie par le sous-comité 62B: Appareils d'imagerie médicale, logiciels et systèmes, du comité d'études 62: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette troisième édition annule et remplace la deuxième édition parue en 2007, et l'Amendement 1:2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) modifications techniques et rédactionnelles, qui résultent de la norme générale amendée IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 et IEC 60601-1:2005/AMD2:2020 et de ses normes collatérales IEC 60601-1-xx ;
b) modifications techniques et rédactionnelles qui résultent de la maintenance des références normatives ;
c) modifications techniques et rédactionnelles qui résultent des évolutions correspondantes des normes du CE 87 Ultrasons. En particulier, l'Article 201.11 concernant la protection contre les températures excessives et les autres dangers a été entièrement révisé.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62B/1318/CDV	62B/1348/RVC

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les directives ISO/IEC, Partie 2, il a été développé selon les directives ISO/IEC, Partie 1 et les directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains.
– *modalités d'essais: caractères italiques.*
– indications de nature informative qui figurent hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif figurant dans les tableaux est également en petits caractères.
– les TERMES DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Les références à des articles dans le présent document sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans le présent document sont conformes à l'usage donné à l'Article 7 des directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document;
– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou de justifications à consulter à l'Annexe AA.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général: *Appareils électromédicaux*, se trouve sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

IMPORTANT – Le logo "colour inside" qui se trouve sur la page de couverture de ce document indique qu'il contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer ce document en utilisant une imprimante couleur.

INTRODUCTION

Dans le présent document, les exigences de sécurité complémentaires à celles de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, et l'IEC 60601-1:2005/AMD2:2020 sont spécifiées pour les APPAREILS DE DIAGNOSTIC A ULTRASONS.

Des recommandations générales et des justifications relatives aux exigences du présent document sont données à l'Annexe AA.

La connaissance des raisons qui ont conduit à ces exigences facilitera non seulement l'application correcte du présent document, mais accélérera, en temps voulu, toute révision rendue nécessaire par des modifications dans la pratique clinique ou par suite des développements technologiques.

L'approche et la philosophie de rédaction du présent document relatif à la sécurité pour les APPAREILS DE DIAGNOSTIC A ULTRASONS sont cohérentes avec celles des normes de la série IEC 60601-2, qui s'appliquent à d'autres modalités de diagnostic, telles que les appareils à rayonnement X et les systèmes à résonance magnétique.

Dans chacun des cas, il est prévu que la norme de sécurité exige une complexité croissante de l'affichage des indicateurs de sortie ou des commandes, en fonction de l'augmentation des niveaux d'énergie dans le domaine de l'exploration diagnostique. Ainsi, pour toutes ces modalités de diagnostic, il est de la responsabilité de l'OPERATEUR de comprendre les risques présentés par les émissions de l'APPAREIL DE DIAGNOSTIC A ULTRASONS et d'agir de manière appropriée, de façon à obtenir l'information diagnostique nécessaire avec un minimum de risques pour le PATIENT.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-37: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 *Domaine d'application

Remplacement:

Le présent document s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS DE DIAGNOSTIC A ULTRASONS comme cela est défini en 201.3.217, désignés ci-après sous le terme APPAREILS EM.

Si un article ou un paragraphe est destiné spécifiquement à être applicable uniquement aux APPAREILS EM, ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue de l'APPAREIL EM ou du SYSTEME EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception du 201.7.2.13.

Le présent document ne couvre pas les appareils thérapeutiques à ultrasons. Les appareils utilisés pour réaliser l'imagerie ou le diagnostic de structures du corps par ultrasons, en association avec une autre procédure médicale, sont couverts.

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir les exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS DE DIAGNOSTIC A ULTRASONS comme définies en 201.3.217.

201.1.3 Normes collatérales

Addition:

Le présent document se réfère aux normes collatérales applicables qui sont énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et à l'Article 201.2 du présent document.

L'IEC 60601-1-2:2014, l'IEC 60601-1-2:2014/AMD1:2020, l'IEC 60601-1-12:2014 et l'IEC 60601-1-12:2014/AMD1:2020 s'appliquent telles qu'elles sont modifiées à l'Article 202 et à l'Article 212 respectivement. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles qu'elles sont publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 en fonction de ce qui est approprié à l'APPAREIL EM à l'étude et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La numérotation des sections, articles et paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, 201.1 dans le présent document traite du contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou de la norme collatérale applicable avec le préfixe "20x" où x est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.6 dans le présent document traite du contenu de l'Article 6 de la norme collatérale IEC 60601-1-2 et 203.4 dans le présent document traite du contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte du présent document.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué dans le présent document.

Les paragraphes, les figures ou les tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées 3.1 à 3.154, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes supplémentaires sont notées AA, BB, etc., et les alinéas supplémentaires aa), bb), etc.

Les paragraphes ou figures qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le numéro de la norme collatérale, par exemple, 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, à toutes les normes collatérales applicables et au présent document, examinés ensemble.

Lorsque le présent document ne comprend pas de section, d'article ou de paragraphe correspondant, la section, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

201.2 Références normatives

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-12:2014, *Appareils électromédicaux – Partie 1-12: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence*
IEC 60601-1-12:2014/AMD1:2020

IEC 60601-2-18:2009, *Appareils électromédicaux – Partie 2-18: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'endoscopie*

IEC 62127-1:2022, *Ultrasons – Hydrophones – Partie 1: Mesurage et caractérisation des champs ultrasoniques médicaux*

IEC 62359:2010, *Ultrasons – Caractérisation du champ – Méthodes d'essai pour la détermination d'indices thermique et mécanique des champs d'ultrasons utilisés pour le diagnostic médical*
IEC 62359:2010/AMD1:2017

CISPR 11:2024, *Appareils industriels, scientifiques et médicaux – Caractéristiques de perturbations radioélectriques – Limites et méthodes de mesure*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et de l'IEC 62359 ainsi que les suivants s'appliquent:

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse https://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse https://www.iso.org/obp

NOTE 1 Un index des termes définis est donné après la Bibliographie.

NOTE 2 Une liste des symboles utilisés dans le présent document est donnée dans le Tableau 201.101.

Addition:

201.3.201
INDICE THERMIQUE OSSEUX
TIB
INDICE THERMIQUE pour des applications dans lesquelles le faisceau ultrasonore traverse des tissus mous et où une région focale se trouve à proximité d'un os, telles que les applications fœtales (second et troisième trimestres)

Unité: Aucune

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.17, modifié – Les notes d'origine ont été supprimées.]

201.3.202
MODE DE FONCTIONNEMENT COMBINE
mode de fonctionnement d'un APPAREIL DE DIAGNOSTIC A ULTRASONS qui combine plusieurs MODES DE FONCTIONNEMENT DISCRETS

201.3.203
INDICE THERMIQUE CRANIEN
TIC
INDICE THERMIQUE pour des applications au cours desquelles le faisceau d'ultrasons traverse l'os situé à proximité de l'entrée du faisceau dans le corps, telles que des examens crâniens pédiatriques et chez l'adulte ou des applications céphaliques néonatales

Unité: Aucune

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.21, modifié – Les notes d'origine ont été supprimées.]

201.3.204
CONFIGURATION PAR DEFAUT
état de contrôle spécifique dans lequel se trouve un APPAREIL DE DIAGNOSTIC A ULTRASONS lors de sa mise en marche, de la sélection d'un nouveau PATIENT ou du passage d'applications non fœtales à des applications fœtales

201.3.205
MODE DE FONCTIONNEMENT DISCRET
mode de fonctionnement d'un APPAREIL DE DIAGNOSTIC A ULTRASONS dont l'excitation du TRANSDUCTEUR ULTRASONIQUE ou du groupe d'éléments TRANSDUCTEURS ULTRASONIQUES a pour but d'utiliser une seule méthodologie de diagnostic

201.3.206
COMMANDE TOTALE PAR LOGICIEL DE L'EMISSION ACOUSTIQUE
moyens par lesquels l'APPAREIL DE DIAGNOSTIC A ULTRASONS gère l'émission acoustique indépendamment de la commande directe de l'OPERATEUR

201.3.207
ENSEMBLE TRANSDUCTEUR INVASIF
transducteur qui, en totalité ou en partie, pénètre à l'intérieur du corps, à travers un orifice corporel ou à travers la surface du corps

201.3.208
INDICE MECANIQUE
indicateur du risque d'effets biologiques dus à des mécanismes mécaniques ou non thermiques, comme la cavitation

Symbole: *MI*

Unité: Aucune

Note 1 à l'article: Voir l'IEC 62359 pour les méthodes de détermination de l'INDICE MECANIQUE.

201.3.209
APPAREIL DE DIAGNOSTIC A ULTRASONS D'USAGE GENERAL
APPAREIL DE DIAGNOSTIC A ULTRASONS prévu pour plusieurs applications cliniques

201.3.210
MODE NON EXPLORATEUR
mode de fonctionnement d'un APPAREIL DE DIAGNOSTIC A ULTRASONS qui implique une séquence d'impulsions ultrasoniques donnant lieu à des lignes d'exploration ultrasonique qui suivent le même parcours acoustique

201.3.211
DECLARATION D'UTILISATION PRUDENTE
affirmation du principe selon lequel il convient d'acquérir uniquement les données cliniques nécessaires et il convient d'éviter les niveaux élevés d'exposition et les expositions prolongées

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.40]

201.3.212
MODE EXPLORATEUR
mode de fonctionnement d'un APPAREIL DE DIAGNOSTIC A ULTRASONS qui implique une séquence d'impulsions ultrasoniques donnant lieu à des lignes d'exploration qui ne suivent pas le même parcours acoustique

201.3.213
INDICE THERMIQUE DES TISSUS MOUS
TIS
INDICE THERMIQUE relatif aux tissus mous

Unité: Aucune

[SOURCE: IEC 62359:2010, 3.52, modifié – Les notes d'origine ont été supprimées.]

201.3.214
INDICE THERMIQUE
TI
indicateur du risque d'effet biologique dû à des mécanismes thermiques, exprimé comme le rapport de la PUISSANCE D'EMISSION ATTENUEE en un point spécifié et de la PUISSANCE D'EMISSION ATTENUEE exigée pour élever la température de 1 °C en ce point dans un modèle de tissu spécifique

Unité: Aucune

Note 1 à l'article: L'abréviation "TI" est dérivée du terme anglais développé correspondant "*thermal index*".

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.56, modifié – Addition de « indicateur du risque d'effet biologique dû à des mécanismes thermiques, exprimé comme le », et la note d'origine a été supprimée.]

201.3.215
ENSEMBLE TRANSDUCTEUR
parties de l'APPAREIL DE DIAGNOSTIC A ULTRASONS comprenant le TRANSDUCTEUR ULTRASONIQUE et le GROUPE D'ELEMENTS TRANSDUCTEURS ULTRASONIQUES, ou les deux, associés aux composants intégrés tels que la lentille acoustique ou l'isolant intégré

Note 1 à l'article: L'ENSEMBLE TRANSDUCTEUR est généralement séparé de la console de l'appareil à ultrasons.

[SOURCE: IEC 62359:2010 et IEC 62359:2010AMD1:2017, 3.57, modifié – "appareil de diagnostic médical à ultrasons", "transducteur à ultrasons" et "groupe d'éléments transducteurs à ultrasons" ont été remplacés par "APPAREIL DE DIAGNOSTIC A ULTRASONS", "TRANSDUCTEUR ULTRASONIQUE" et "GROUPE D'ELEMENTS TRANSDUCTEURS ULTRASONIQUES" dans la définition.]

201.3.216
PROFIL DE TRANSMISSION
combinaison d'un ensemble spécifique de caractéristiques du transducteur ayant trait à la formation du faisceau (déterminée par la taille d'ouverture de transmission, la forme d'apodisation et le profil relatif de synchronisation/déphasage sur la zone d'ouverture, produisant une longueur et un sens focaux spécifiques) avec un type d'onde d'entraînement électrique présentant une forme fixe spécifique mais une amplitude variable

[SOURCE: IEC 62359:2010, 3.58]

201.3.217
APPAREIL DE DIAGNOSTIC A ULTRASONS
APPAREIL ELECTROMEDICAL destiné à des examens ultrasoniques médicaux

201.3.218
TRANSDUCTEUR ULTRASONIQUE
appareil qui permet de convertir l'énergie électrique en énergie mécanique dans la plage de fréquences ultrasonores et, réciproquement, l'énergie mécanique en énergie électrique

[SOURCE: IEC 62127-1:2022, 3.88]

201.3.219
INTENSITE ATTENUEE MOYENNE DE L'IMPULSION
$I_{pa,\alpha}$
valeur de l'INTENSITE ACOUSTIQUE MOYENNE DE L'IMPULSION après atténuation et à un point spécifique, et donnée par

$$I_{pa,\alpha}(z) = I_{pa}(z)10^{(-\alpha z f_{awf}/10\,dB)} \quad (1)$$

où

α est le COEFFICIENT D'ATTENUATION ACOUSTIQUE tel qu'il est défini dans l'IEC 62359:2010, définition 3.1;

z est la distance entre l'OUVERTURE DU TRANSDUCTEUR EXTERNE et le point concerné;

f_{awf} est la FREQUENCE DE FONCTIONNEMENT ACOUSTIQUE telle qu'elle est définie dans l'IEC 62359:2010 et l'IEC 62359:2010/AMD1:2017, définition 3.4;

$I_{pa}(z)$ est l'INTENSITE MOYENNE DE L'IMPULSION mesurée dans l'eau telle qu'elle est définie dans l'IEC 62127-1:2022, 3.53.

Unité: W m^{-2}

201.3.220
NOMBRE D'IMPULSIONS PAR LIGNE D'EXPLORATION ULTRASONIQUE
n_{pps}
nombre d'impulsions acoustiques se propageant le long d'une LIGNE D'EXPLORATION ULTRASONIQUE particulière

Note 1 à l'article: Ici la LIGNE D'EXPLORATION ULTRASONIQUE se réfère au parcours des impulsions acoustiques sur un AXE D'ALIGNEMENT DU FAISCEAU particulier en modes EXPLORATEURS et NON EXPLORATEURS.

Note 2 à l'article: Ce nombre peut être utilisé dans le calcul de toute valeur moyenne temporelle des ultrasons par des mesures de l'HYDROPHONE.

Note 3 à l'article: L'exemple suivant représente le NOMBRE D'IMPULSIONS PAR LIGNE D'EXPLORATION ULTRASONIQUE et le NOMBRE DE LIGNES D'EXPLORATION ULTRASONIQUES (";" représente la fin de la salve):

1 2 3 4; 1 2 3 4; 1 2 3 4... n_{pps} = 1; n_{sl} = 4

1 1 2 2 3 3 4 4; 1 1 2 2 3 3 4 4; ... n_{pps} = 2; n_{sl} = 4

1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; 1 1 1 1 2 2 2 2 3 3 3 3 4 4 4 4; ... n_{pps} = 4; n_{sl} = 4

1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; 1 1 2 2 3 3 4 4 1 1 1 2 2 2 3 3 3 4 4 4; ... n_{pps} = 5; n_{sl} = 4 (dans une salve, les impulsions descendent à chaque ligne sans être contiguës).

Dans une salve, toutes les lignes d'exploration peuvent ne pas avoir la même valeur n_{pps}. Par exemple: 1 2 2 3 3 4; 1 2 2 3 3 4; ... avg n_{pps} =1,5; max n_{pps} = 2; n_{sl} = 4

[SOURCE: IEC 61157:2007/AMD1:2013, 3.45, modifié – Le quatrième exemple dans la Note 3 à l'article a été corrigé.]

201.3.221
ENDOSCOPE A ULTRASONS
ENDOSCOPE comprenant des TRANSDUCTEURS ULTRASONORES intégrés

201.3.222
ENDOSCOPE
instrument médical comportant un dispositif de visualisation, avec ou sans optique, introduit dans une cavité du corps par une ouverture naturelle ou créée par voie chirurgicale à des fins d'examen, de diagnostic ou de thérapie

Note 1 à l'article: Les ENDOSCOPES peuvent être de type rigide, flexible ou à capsule, chaque type pouvant comporter des systèmes de prise de vues différents (par exemple au moyen de lentilles ou de capteurs électroniques/à ultrasons) ainsi que des systèmes de transmission d'images différents (par exemple optiques (au moyen de lentilles ou de faisceaux de fibres,) ou électriques/électroniques).

Note 2 à l'article: La Note 1 à l'article diffère de la NOTE 1 de la définition 3.1 figurant dans l'ISO 8600-1 afin d'inclure les endoscopes à "capsule".

[SOURCE: IEC 60601-2-18:2009, 201.3.203]

201.3.223
PROFONDEUR POUR L'INTEGRALE CRETE SUR L'IMPULSION DE L'INTENSITE
z_{pii}
profondeur z de l'AXE DU FAISCEAU et au-delà de la PROFONDEUR DU POINT DE RUPTURE z_{bp} entre l'ouverture du transducteur externe et le plan de l'INTEGRALE D'INTENSITE D'IMPULSION MAXIMALE (pii) sous forme approximative à l'aide de l'INTEGRALE DE PRESSION D'IMPULSION AU CARRE ($ppsi$)

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.24, modifié — Notes à l'article 1, 2 et 3 supprimées.]

201.3.224
PROFONDEUR POUR L'INTEGRALE CRETE SUR L'IMPULSION DE L'INTENSITE ATTENUEE
$z_{pii,\ \alpha}$
profondeur z de l'AXE DU FAISCEAU et au-delà de la PROFONDEUR DU POINT DE RUPTURE z_{bp} de l'intégrale crête sur l'IMPULSION DE L'INTENSITE ATTENUEE

Unité: m

Note 1 à l'article: Les termes AXE DU FAISCEAU et PROFONDEUR DU POINT DE RUPTURE sont définis dans l'IEC 62359.

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.71, modifié — Terme principal « profondeur pour $_{pii,\ \alpha}$ maximale » remplacé par « profondeur pour l'intégrale crête sur l'impulsion de l'intensité atténuée », Notes 1, 2 et 3 à l'article supprimée et addition d'une nouvelle Note 1 à l'article.]

201.3.225
PROFONDEUR POUR LA SOMME CRETE DES INTEGRALES SUR L'IMPULSION DE L'INTENSITE
z_{sii}
profondeur z de l'AXE DU FAISCEAU et au-delà de la PROFONDEUR DU POINT DE RUPTURE z_{bp} de l'INTEGRALE CRETE D'INTENSITE D'EXPLORATION

Unité: m

Note 1 à l'article: Les termes AXE DU FAISCEAU et PROFONDEUR DU POINT DE RUPTURE sont définis dans l'IEC 62359.

Note 2 à l'article: L'indice "*sii*" indique l'intégrale d'intensité d'exploration (sii). L'indice *sii* des composants en MODE EXPLORATEUR un point particulier est déterminé à partir de la somme sur une trame d'exploration complète des INTEGRALES SUR L'IMPULSION DE L'INTENSITE des LIGNES D'EXPLORATION ULTRASONIQUE constituant les composants d'exploration d'un mode combiné. Les composants en mode non explorateur sont exclus de cette somme. Voir l'IEC 62359 et l'IEC 62127-1 pour des informations plus détaillées.

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.74, modifié — Terme principal « profondeur pour maximale sii » remplacé par « profondeur pour la somme crête des intégrales sur l'impulsion de l'intensité », Notes 1, 2 et 3 à l'article supprimée et addition de nouvelles Notes 1 et 2 à l'article.]

201.3.226
PROFONDEUR POUR LA SOMME CRETE DES INTEGRALES SUR L'IMPULSION DE L'INTENSITE ATTENUEE
$z_{sii,\alpha}$
profondeur z de l'AXE DU FAISCEAU et au-delà de la PROFONDEUR DU POINT DE RUPTURE z_{bp} de l'INTEGRALE CRETE D'INTENSITE D'EXPLORATION ATTENUEE

Unité: m

Note 1 à l'article: Les termes AXE DU FAISCEAU et PROFONDEUR DU POINT DE RUPTURE sont définis dans l'IEC 62359.

Note 2 à l'article: L'indice "sii" indique l'"intégrale d'intensité d'exploration" qui désigne la somme à un point particulier des INTEGRALES SUR L'IMPULSION DE L'INTENSITE des LIGNES D'EXPLORATION ULTRASONIQUE constituant un composant en MODE EXPLORATEUR Voir l'IEC 62359 et l'IEC 62127-1 pour plus de renseignements.

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.75, modifié — Terme principal « profondeur pour maximale sii_{α}» remplacé par « profondeur pour la somme crête des intégrales sur l'impulsion de l'intensité atténuée», addition de « crête » dans la définition, Notes 1, 2 et 3 à l'article supprimée et addition de nouvelles Notes 1 et 2 à l'article.]

201.3.227
PROFONDEUR POUR L'INDICE MECANIQUE
z_{MI}
profondeur de l'AXE DU FAISCEAU entre l'OUVERTURE DU TRANSDUCTEUR EXTERNE et le plan de l'intégrale de PRESSION D'IMPULSION AU CARRE ATTENUEE maximale ($ppsi_{\alpha}$)

Unité: m

[SOURCE: IEC 62359:2010 et IEC 62359:2010/AMD1:2017, 3.23]

201.3.228
DECALAGE THERMIQUE
ΔT_{offset}
différence entre a) la température de la PARTIE APPLIQUEE de l'ENSEMBLE TRANSDUCTEUR à l'état stable dans la configuration de mesure avant le début de la transmission et b) la température en régime permanent au même emplacement dans la configuration de mesure en l'absence de l'ENSEMBLE TRANSDUCTEUR

Note 1 à l'article: La valeur du DECALAGE THERMIQUE peut être positive, négative ou nulle.

201.3.229
ULTRASON
vibration acoustique dont la fréquence est supérieure à la limite supérieure des fréquences des sons audibles (environ 20 kHz)

[SOURCE: IEC 60050-802:2011, 802-01-01]

Tableau 201.101 – Liste de symboles

Symbole	Terme	Référence
A_{aprt}	= SURFACE DU FAISCEAU D'EMISSION −12 dB	IEC 62359
d_{eq}	= DIAMÈTRE DE FAISCEAU ÉQUIVALENT	IEC 62359
f_{awf}	= FRÉQUENCE DE FONCTIONNEMENT ACOUSTIQUE	IEC 62359
$I_{\text{pa},\alpha}$	= INTENSITE ATTENUEE MOYENNE DE L'IMPULSION	
pii	= INTEGRALE SUR L'IMPULSION DE L'INTENSITE	IEC 62359
pii_{α}	= INTEGRALE SUR L'IMPULSION DE L'INTENSITE ATTENUEE	IEC 62359
$I_{\text{sppa},\alpha}$	= INTENSITE ATTENUEE MOYENNE DE L'IMPULSION DE CRETE SPATIALE	IEC 62359
I_{spta}	= INTENSITE MOYENNE TEMPORELLE DE CRETE SPATIALE	IEC 62359
$I_{\text{spta},\alpha}$	= INTENSITE ATTENUEE MOYENNE TEMPORELLE DE CRETE SPATIALE	IEC 62359
$I_{\text{ta},\alpha}(z)$	= INTENSITÉ ATTÉNUÉE MOYENNE TEMPORELLE	IEC 62359
MI	= INDICE MÉCANIQUE	IEC 62359
n_{pps}	= NOMBRE D'IMPULSIONS PAR LIGNE D'EXPLORATION ULTRASONIQUE	IEC 61157
P	= PUISSANCE D'ÉMISSION	IEC 62359
$P_{1\text{x}1}$	= PUISSANCE D'EMISSION RESTREINTE AU CARRE	IEC 62359
P_{α}	= PUISSANCE D'ÉMISSION ATTÉNUÉE	IEC 62359
$p_{\text{r},\alpha}$	= PRESSION ACOUSTIQUE DE CRETE ATTENUEE	IEC 62359
p_{r}	= PRESSION ACOUSTIQUE DE CRÊTE	IEC 62359
prr	= TAUX DE REPETITION DES IMPULSIONS	IEC 62359
srr	= REGIME DE REPETITION DES EXPLORATIONS	IEC 62127-1

Symbole	Terme	Référence
TI	= INDICE THERMIQUE	IEC 62359
TIB	= INDICE THERMIQUE OSSEUX	IEC 62359
TIC	= INDICE THERMIQUE CRÂNIEN	IEC 62359
TIS	= INDICE THERMIQUE DES TISSUS MOUS	IEC 62359
t_d	= DURÉE D'IMPULSION	IEC 62359
X, *Y*	= DIMENSIONS DU FAISCEAU D'EMISSION –12 dB	IEC 62359
z_b	= PROFONDEUR POUR L'INDICE THERMIQUE OSSEUX	IEC 62359
z_{bp}	= PROFONDEUR DU POINT DE RUPTURE	IEC 62359
z_{pii}	= PROFONDEUR POUR L'INTEGRALE CRETE SUR L'IMPULSION DE L'INTENSITE	IEC 62359
z_{MI}	= PROFONDEUR POUR L'INDICE MÉCANIQUE	IEC 62359
$z_{pii,\alpha}$	= PROFONDEUR POUR L'INTEGRALE CRETE SUR L'IMPULSION DE L'INTENSITE ATTENUEE	IEC 62359
z_{sii}	= PROFONDEUR POUR LA SOMME CRETE DES INTEGRALES SUR L'IMPULSION DE L'INTENSITE	IEC 62359
$z_{sii,\alpha}$	= PROFONDEUR POUR LA SOMME CRETE DES INTEGRALES SUR L'IMPULSION DE L'INTENSITE ATTENUEE	IEC 62359
z_s	= PROFONDEUR POUR LE TIS	IEC 62359
ΔT_{offset}	= DÉCALAGE THERMIQUE	
ΔT_{tx}	= échauffement provoqué par la transmission de l'ENSEMBLE TRANSDUCTEUR	

201.4 Exigences générales

L'Article 4 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.4.1 Conditions d'application aux APPAREILS EM ou SYSTEMES EM

Addition:

Un ENDOSCOPE A ULTRASONS dans lequel les moyens d'imagerie sont limités aux ultrasons doit être considéré comme un TRANSDUCTEUR ULTRASONORE et doit satisfaire aux exigences du présent document.

NOTE 1 Ces TRANSDUCTEURS ULTRASONORES comprennent par exemple les sondes transvaginales, transœsophagiennes (TEE), rectales, laparoscopiques et autres sondes endocavitaires analogues.

Un ENDOSCOPE A ULTRASONS équipé de moyens d'imagerie en plus des ultrasons doit également satisfaire aux exigences du 201.11.6.5 de l'IEC 60601-2-18:2009.

NOTE 2 Ces moyens d'imagerie additionnels incluent par exemple des moyens optiques et des dispositifs à couplage de charge (CDD – *charge-coupled device*).

201.4.3 PERFORMANCE ESSENTIELLE

Paragraphe complémentaire:

201.4.3.101 Exigences complémentaires de PERFORMANCE ESSENTIELLE

Le Tableau 201.102 dresse la liste des sources potentielles de risque inacceptable identifiées pour caractériser les PERFORMANCES ESSENTIELLES des APPAREILS DE DIAGNOSTIC A ULTRASONS et des paragraphes qui contiennent les exigences.

Tableau 201.102 – Exigences de performance essentielle inventoriées

Exigence	Paragraphe
Absence de bruit sur une forme d'onde ou artefacts ou déformation dans une image ou erreur d'une valeur numérique affichée qui ne peut pas être attribuée à un effet physiologique et qui peut altérer le diagnostic.	202.8.1
Absence d'affichage de valeurs numériques incorrectes associées au diagnostic à effectuer [a].	202.8.1
Absence d'affichage d'indications incorrectes liées à la sécurité.[a]	201.12.4.2 202.8.1
Absence de production d'une sortie non intentionnelle ou excessive d'ultrasons.	201.10.101 202.8.1
Absence de production d'une température de surface de l'ENSEMBLE TRANSDUCTEUR non intentionnelle ou excessive.	202.8.1
Absence de production d'un mouvement non intentionnel ou non contrôlé des ENSEMBLES TRANSDUCTEURS prévus pour une utilisation intracorporelle.	202.8.1
[a] "Incorrect" en ce sens que la valeur d'affichage est différente de ce qui est calculé (par suite d'une altération durant le transfert des données), ou le calcul lui-même n'est pas correct.	

Dans certaines circonstances, il convient d'évaluer la nécessité de répétition d'un examen ultrasonore comme une SITUATION DANGEREUSE, par exemple, dans les cas d'investigation intracorporelle et d'épreuve à l'effort pour des PATIENTS souffrant de maladies cardiaques.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.7.2.9 Classification IP

Addition:

Si la classification IPX spécifiée est applicable pour une partie seulement de l'ENSEMBLE TRANSDUCTEUR, le marquage du code IPX sur l'ENSEMBLE TRANSDUCTEUR n'est pas exigé.

201.7.2.13 *Effets physiologiques (SIGNAUX DE SECURITE et avertissements)

Addition:

Une description des moyens utilisés pour limiter à 43 °C au plus l'échauffement de surface des ENSEMBLES TRANSDUCTEURS INVASIFS en CONDITION DE PREMIER DEFAUT doit être fournie conformément aux exigences de l'Article 12.

Paragraphe complémentaire:

201.7.2.101 *Émission acoustique

Pour les APPAREILS DE DIAGNOSTIC A ULTRASONS pouvant générer des niveaux de sortie auxquels s'applique 201.12.4.2, et qui permettent à l'OPERATEUR de modifier directement les niveaux de sortie, l'effet du réglage de la commande qui fait varier le niveau de sortie doit être clair. Le marquage doit être sous la forme d'un affichage actif.

Un affichage de l'INDICE THERMIQUE et de l'INDICE MECANIQUE doit être fourni conformément aux exigences de l'Article 201.12, ainsi que la déclaration de précision décrite à l'Article 201.12.

Un affichage relatif aux niveaux de sortie ultrasonore (Article 201.12) doit être clairement visible à partir de la position de l'OPERATEUR, avec le ou les noms entiers ou l'abréviation ou les abréviations de l'indice ou des indices affichés.

201.7.9.2.2 *Avertissement et consignes de sécurité

Addition:

Pour les APPAREILS DE DIAGNOSTIC A ULTRASONS pouvant générer des niveaux de sortie auxquels s'applique l'Article 201.12, des informations doivent être fournies à l'OPERATEUR sur la méthode d'interprétation des paramètres d'exposition ultrasonore affichés, de l'INDICE THERMIQUE (*TI*) et de l'INDICE MECANIQUE (*MI*), selon les recommandations données à l'Annexe CC.

Les procédures nécessaires à un fonctionnement en toute sécurité doivent être fournies, tout en attirant l'attention sur les dangers mettant en jeu la sécurité qui peuvent survenir du fait d'une installation électrique inadéquate lorsque la PARTIE APPLIQUEE de l'APPAREIL DE DIAGNOSTIC A ULTRASONS est une PARTIE APPLIQUEE DE TYPE B.

Des instructions sur l'utilisation sûre des ENSEMBLES TRANSDUCTEURS doivent être fournies et, en particulier, les instructions pour vérifier que l'APPAREIL DE DIAGNOSTIC A ULTRASONS est du type adapté pour l'application prévue. En ce qui concerne les ENSEMBLES TRANSDUCTEURS destinés à une utilisation intracorporelle, les instructions doivent comporter un avertissement qui indique de ne pas activer l'ENSEMBLE TRANSDUCTEUR en dehors du corps du PATIENT si l'ENSEMBLE TRANSDUCTEUR ainsi activé n'est pas conforme aux exigences de conformité électromagnétique, et peut ainsi provoquer des interférences nuisibles avec d'autres équipements environnants. L'identification des interférences avec d'autres équipements ainsi que des techniques de réduction doivent être incluses dans les DOCUMENTS D'ACCOMPAGNEMENT si une réduction des niveaux d'essai est revendiquée par le FABRICANT.

Une notification doit être fournie si l'APPAREIL DE DIAGNOSTIC A ULTRASONS ou si des parties de celui-ci sont équipés de moyens de protection contre les brûlures du PATIENT, lorsqu'ils sont utilisés avec des appareils chirurgicaux à haute fréquence. Si aucun moyen de ce type n'est intégré, la notification doit figurer dans les DOCUMENTS D'ACCOMPAGNEMENT et des conseils doivent être fournis en ce qui concerne l'emplacement et l'utilisation de l'ENSEMBLE TRANSDUCTEUR, pour réduire le danger de brûlures en cas de défaillance de raccordement de l'électrode neutre chirurgicale à haute fréquence.

Une DECLARATION D'UTILISATION PRUDENTE doit être fournie pour les APPAREILS DE DIAGNOSTIC A ULTRASONS pouvant générer des niveaux de sortie auxquels s'applique 201.12.4.2.

Les descriptions de tout affichage ou de tous moyens par lesquels l'OPERATEUR peut modifier le fonctionnement de l'APPAREIL DE DIAGNOSTIC A ULTRASONS concernant la sortie ultrasonore doivent être fournies. Ces descriptions doivent être données dans une section distincte.

Une description de tout affichage ou de tous moyens par lesquels l'OPERATEUR peut modifier le fonctionnement de l'APPAREIL DE DIAGNOSTIC A ULTRASONS concernant la température de surface des ENSEMBLES TRANSDUCTEURS INVASIFS destinés à une utilisation transœsophagienne doit être fournie.

Une description des parties de l'ENSEMBLE TRANSDUCTEUR qu'il est admis d'immerger dans l'eau ou dans d'autres liquides, soit en UTILISATION NORMALE, soit dans un but d'évaluation de performances, doit être fournie.

Une recommandation qui attire l'attention de l'OPERATEUR sur la nécessité d'effectuer des essais réguliers et une maintenance périodique, dont un examen de l'ENSEMBLE TRANSDUCTEUR en vue de déceler les fissures qui laissent pénétrer du fluide conducteur, doit être fournie.

Des instructions destinées à éviter des réglages de commande et des niveaux d'émission acoustique non intentionnels doivent être fournies.

Les limites d'émission sélectionnées selon 201.12.4.5.1 doivent être déclarées dans les DOCUMENTS D'ACCOMPAGNEMENT. Pour les APPAREILS DE DIAGNOSTIC A ULTRASONS D'USAGE GENERAL, les limites d'émission doivent être déclarées pour chaque application.

Les sondes pour échographie transœsophagienne doivent être retirées du corps du PATIENT *avant* l'utilisation d'un défibrillateur.

Il convient de vérifier la surface extérieure des parties de l'ENSEMBLE TRANSDUCTEUR destinées à être insérées dans un PATIENT afin de vérifier l'absence de surfaces rugueuses, d'arêtes vives ou de protubérances non intentionnelles qui peuvent être préjudiciables.

Étant donné que l'utilisation des APPAREILS DE DIAGNOSTIC A ULTRASONS augmente dans le secteur des soins à domicile, il convient d'accorder une attention particulière à la transmission d'informations à ce type d'utilisateur. Il convient que le mode de transmission soit documenté dans le DOSSIER DE GESTION DES RISQUES. Voir l'IEC 60601-1-11.

201.7.9.2.10 Messages

Remplacement du premier alinéa:

Les instructions d'utilisation doivent énumérer tous les messages système, messages d'erreur et messages de défaut qui sont générés et sont visibles par l'OPERATEUR, sauf si ces messages sont compréhensibles par eux-mêmes.

201.7.9.2.12 Nettoyage, désinfection et stérilisation

Addition:

Après le deuxième tiret, ajouter:

– une liste des parties, des composants et/ou des fonctions correspondants qu'il convient de vérifier après chaque cycle de nettoyage, de désinfection ou de stérilisation, ainsi que de la ou des méthodes d'examen.

NOTE Cette liste de paramètres n'est ni exhaustive ni obligatoire.

201.7.9.3 Description technique

Paragraphe complémentaire:

201.7.9.3.101 *Données techniques concernant les niveaux d'émission acoustique

Pour chaque mode, fournir la valeur maximale de chaque INDICE THERMIQUE et MECANIQUE. Ces données doivent être fournies suivant le Tableau 201.103 et énumérées dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les valeurs numériques doivent être indiquées dans les cellules portant le symbole "✓".

Le réglage de l'appareil lié à chaque indice doit être indiqué dans la section "conditions de commande de fonctionnement" du Tableau 201.103.

Pour un ENSEMBLE TRANSDUCTEUR et un pupitre d'appareil à ultrasons qui satisfont à toutes les conditions d'exemption citées au 201.12.4.2 a) et c), les informations déclarées dans les DOCUMENTS D'ACCOMPAGNEMENT doivent indiquer que les INDICES THERMIQUES sont inférieurs ou égaux à 0,7 et que l'INDICE MECANIQUE est inférieur ou égal à 1,0 pour tous les réglages de dispositif. Si 201.12.4.2 b) et c) sont satisfaits en lieu et place des points a) et c), la valeur de 0,7 pour les INDICES THERMIQUES dans cet énoncé doit être remplacée par 1,0.

NOTE 1 Pour le Tableau 201.103, voir l'Annexe AA pour une description de la "Valeur maximale d'indice" et (pour *TIS* et *TIB*) des "Valeurs des composants d'indice".

NOTE 2 Un mode de fonctionnement peut être considéré comme MODE DE FONCTIONNEMENT DISCRET (tel que B, M), ainsi que comme MODE DE FONCTIONNEMENT COMBINE (tel que B+D+CFM).

NOTE 3 Conformément à l'IEC 62359:2010 et à l'IEC 62359:2010/AMD1:2017, les valeurs z_s et z_b sont saisies pour les modes (composant) non explorateurs.

NOTE 4 Selon 201.3.201, dans le modèle *TIB*, le tissu osseux est situé sous un tissu mou. Par conséquent, le composant "*TIB* en surface" est égal au composant "*TIS* en surface", et non *TIC*.

NOTE 5 L'Annexe EE fournit un exemple de tableau qui permet aux parties tierces de recalculer les valeurs de *TI* et de *MI* pour chaque mode de fonctionnement, y compris les contributions de chaque mode dans les MODES DE FONCTIONNEMENT COMBINES.

Tableau 201.103 – Tableau des relevés d'émission acoustique

MODE ______________

Étiquette d'indice		*MI*	*TIS* En surface	*TIS* Sous la surface	*TIB* En surface	*TIB* Sous la surface	*TIC*
Valeur maximale d'indice		✓	✓		✓		✓
Valeur des composants d'indice			✓	✓	✓	✓	
Paramètres acoustiques	$p_{r,\alpha}$ à z_{MI} (MPa)	✓					
	P (mW)		✓		✓		✓
	P_{1x1} (mW)		✓		✓		
	z_s (cm)			✓			
	z_b (cm)					✓	
	z_{MI} (cm)	✓					
	$z_{pii,\alpha}$ (cm)	✓					
	f_{awf} (MHz)	✓	✓		✓		✓
Autres informations	*prr* (Hz)	✓					
	srr (Hz)	✓					
	n_{pps}	✓					
	$I_{pa,\alpha}$ à $z_{pii,\alpha}$ (W/cm^2)	✓					
	$I_{spta,\alpha}$ à $z_{pii,\alpha}$ ou $z_{sii,\alpha}$ (mW/cm^2)	✓					
	I_{spta} à z_{pii} ou z_{sii} (mW/cm^2)	✓					
	p_r à z_{pii} (MPa)	✓					
Conditions de commande de fonctionnement	Commande 1						
	Commande 2						
	Commande 3						
	Commande 4						
	Commande 5						
	…						
	Commande x						

NOTE 1 Uniquement une condition de fonctionnement par indice.

NOTE 2 Les données pour "en surface" et "sous la surface" sont entrées à la fois dans les colonnes relatives au *TIS* ou au *TIB*.

NOTE 3 Il n'est pas nécessaire de fournir les informations concernant le *TIC* pour tout ENSEMBLE TRANSDUCTEUR non prévu pour des utilisations transcrâniennes ou céphaliques néonatales.

NOTE 4 Si les exigences du 201.12.4.2 a) ou b) sont satisfaites, la saisie de données n'est pas exigée dans les colonnes relatives au *TIS*, au *TIB* ou au *TIC*.

NOTE 5 Si les exigences du 201.12.4.2 c) sont satisfaites, la saisie de données n'est pas exigée dans la colonne relative au *MI*.

NOTE 6 Les profondeurs z_{pii} et $z_{pii,\alpha}$ s'appliquent aux MODES NON EXPLORATEURS, tandis que les profondeurs z_{sii} et $z_{sii,\alpha}$ s'appliquent aux MODES EXPLORATEURS.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'Article 8 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.8.7.4.7 Mesure du COURANT DE FUITE PATIENT

Addition:

aa) Pour les essais des ENSEMBLES TRANSDUCTEURS, la PARTIE APPLIQUEE doit être immergée dans une solution saline à 0,9 %.

201.8.7.4.8 Mesure du COURANT AUXILIAIRE PATIENT

Addition:

Pour les essais des ENSEMBLES TRANSDUCTEURS, la PARTIE APPLIQUEE doit être immergée dans une solution saline à 0,9 %.

201.8.8.3 Tension de tenue

Addition:

aa) Pour les essais des ENSEMBLES TRANSDUCTEURS, la PARTIE APPLIQUEE doit être immergée dans une solution saline à 0,9 %.

201.8.9.3.4 Cycle thermique

Ajout, à la fin du premier alinéa:

et, pour les ensembles transducteurs à ultrasons seulement, où T_1 est

– *10 °C au-dessus de la température maximale admissible spécifiée dans les DOCUMENTS D'ACCOMPAGNEMENT pour le nettoyage, la désinfection, la stérilisation, l'utilisation normale ou le stockage.*

201.8.10.4 Dispositifs de commande TENUS A LA MAIN et pédales de commande

Addition:

Ce paragraphe ne s'applique pas aux ENSEMBLES TRANSDUCTEURS A ULTRASONS.

201.9 Protection contre les DANGERS MECANIQUES des APPAREILS EM et des SYSTEMES EM

L'Article 9 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique.

201.10 Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

L'Article 10 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

Paragraphe complémentaire:

201.10.101 *Énergie ultrasonique

Le FABRICANT doit traiter des RISQUES associés à l'énergie ultrasonique dans le PROCESSUS DE GESTION DES RISQUES tel qu'il est décrit dans le texte du présent document.

La vérification est effectuée par examen du DOSSIER DE GESTION DES RISQUES.

L'émission acoustique doit être interrompue lorsque l'acquisition du signal est arrêtée (c'est-à-dire lorsque la caractéristique "gel" est activée).

201.11 Protection contre les températures excessives et les autres DANGERS

L'Article 11 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012, et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.11.1.2.2 *PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT

Addition:

Les ENSEMBLES TRANSDUCTEURS appliqués au PATIENT doivent avoir une température de surface au contact du PATIENT qui ne dépasse pas 43 °C dans des CONDITIONS NORMALES, lorsqu'elle est mesurée dans les conditions d'essai du 201.11.1.3.101.1.

Les ENSEMBLES TRANSDUCTEURS appliqués au PATIENT doivent avoir une température de surface au contact du PATIENT qui ne dépasse pas 50 °C, lorsqu'elle est mesurée dans les conditions d'essai du 201.11.1.3.101.2.

La vérification est effectuée par le fonctionnement de l'APPAREIL DE DIAGNOSTIC A ULTRASONS et par des essais de température, comme cela est décrit au 201.11.1.3.

NOTE La surface au contact du PATIENT comprend tout élément de la PARTIE APPLIQUEE, et pas seulement la surface de rayonnement, à l'exception toutefois du câble.

201.11.1.3 *Mesures

Addition:

Pour la partie appliquée de l'ENSEMBLE TRANSDUCTEUR, remplacer le troisième alinéa et le reste du texte du paragraphe par ce qui suit:

La conformité aux exigences du 11.1.1 et du 11.1.2 est vérifiée par examen du DOSSIER DE GESTION DES RISQUES.

201.11.1.3.101 Conditions d'essai

Pour les besoins de cet essai, un régime thermique permanent est considéré comme atteint lorsque la vitesse de variation de la température est < 0,12 °C par minute pendant trois minutes consécutives.

L'ENSEMBLE TRANSDUCTEUR doit être soumis aux essais dans les conditions suivantes:

201.11.1.3.101.1 * Utilisation simulée

La PARTIE APPLIQUEE de l'ENSEMBLE TRANSDUCTEUR doit être couplée de façon acoustique – et être initialement en équilibre thermique – avec un objet d'essai, de manière que les ultrasons émis à partir de la surface active de l'ENSEMBLE TRANSDUCTEUR entrent dans cet objet d'essai.