

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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



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COMMISSION

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CONTENTS

FOREWORD.....	4
INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	10
201.3 Terms and definitions.....	10
201.4 General requirements	17
201.5 General requirements for testing ME EQUIPMENT	18
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	18
201.7 ME EQUIPMENT identification, marking and documents	18
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	23
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	23
201.10 Protection against unwanted and excessive radiation HAZARDS	23
201.11 Protection against excessive temperatures and other HAZARDS	24
201.12 Accuracy of controls and instruments and protection against hazardous outputs	29
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	31
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	31
201.15 Construction of ME EQUIPMENT	31
201.16 ME SYSTEMS	31
201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	31
202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests.....	31
212 Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (EMS)	33
Annexes	34
Annex AA (informative) Particular guidance and rationale	35
Annex BB (informative) Guidance in classification according to CISPR 11	43
Annex CC (informative) Guidance to the MANUFACTURER on the interpretation of <i>Tl</i> and <i>MI</i> to be used to inform the OPERATOR.....	44
Annex DD (informative) Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES	48
Annex EE (informative) Acoustic output table intended for third parties.....	51
Bibliography.....	54
Index of defined terms	58
Figure AA.1 – Method a) for an external probe.....	38
Figure AA.2 – Method b) for an external probe.....	39
Figure AA.3 – Method b) for an external probe.....	39
Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers	50
Table 201.101 – List of symbols.....	16
Table 201.102 – Distributed essential performance requirements	18

Table 201.103 – Acoustic output reporting table	22
Table 201.104 – Overview of the tests noted under 201.11.1.3	28
Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations	46
Table DD.1 – Acoustic and thermal properties of tissues and materials.....	48
Table DD.2 – Weight % pure components	49
Table EE.1 – Example of acoustic output table for third parties	52

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

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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.

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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

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

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
$P_{1\times 1}$	= 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 62359-1

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
$z_{pii,a}$	= DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL	IEC 62359
z_{sii}	= DEPTH FOR PEAK SUM OF PULSE INTENSITY INTEGRALS	IEC 62359
$z_{sii,a}$	= 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		<i>MI</i>	<i>TIS</i>		<i>TIB</i>		<i>TIC</i>
			At surface	Below surface	At surface	Below surface	
Maximum index value		✓	✓		✓		✓
Index component value			✓	✓	✓	✓	
Acoustic Parameters	$p_{r,a}$ at z_{MI} (MPa)	✓					
	P (mW)		✓		✓		✓
	$P_{1 \times 1}$ (mW)		✓		✓		
	z_s (cm)			✓			
	z_b (cm)					✓	
	z_{MI} (cm)	✓					
	$z_{pii,a}$ (cm)	✓					
	f_{awf} (MHz)	✓	✓		✓		✓
Other Information	p_{rr} (Hz)	✓					
	s_{rr} (Hz)	✓					
	n_{pps}	✓					
	$I_{pa,a}$ at $z_{pii,a}$ (W/cm ²)	✓					
	$I_{spta,a}$ at $z_{pii,a}$ or $z_{sii,a}$ (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 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 $z_{pii,a}$ apply to NON-SCANNING MODES, while the depths z_{sii} and $z_{sii,a}$ 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:* $(3\,500 \pm 500) \text{ J/(kg}\cdot\text{K)}$;
- *thermal conductivity:* $(0,5 \pm 0,1) \text{ W/(m}\cdot\text{K)}$;
- *attenuation at 5 MHz:* $(2,5 \pm 1,0) \text{ dB/cm}$.

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 $23\text{ °C} \pm 3\text{ °C}$.

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 $23\text{ °C} \pm 3\text{ °C}$. 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,

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

For invasive transducer assemblies,

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

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.

201.11.1.3.101.2 * 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.

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

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 $< 0,12\text{ }^{\circ}\text{C}$ 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	<i>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.</i> The temperature shall not exceed 43 °C	<i>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.</i> The temperature shall not exceed 43 °C.
	b) Temperature rise	<i>Initially the temperature at the object-transducer interface shall be between 20 °C and 33 °C and shall be in thermal steady state.</i> <i>The ambient temperature shall be 23 °C ± 3 °C.</i> The temperature rise plus the THERMAL OFFSET shall not exceed 10 °C.	<i>Initially the temperature at the object-transducer interface shall be between 20 °C and 37 °C and shall be in thermal steady state.</i> <i>The ambient temperature shall be 23 °C ± 3 °C.</i> 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	<i>The ambient temperature shall be 23 ± 3 °C and shall be in thermal steady state.</i> <i>Initially the temperature at the surface of the TRANSDUCER ASSEMBLY shall be the ambient temperature.</i> 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:

- 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).
- 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/cm² and the SPATIAL-PEAK TEMPORAL-AVERAGE INTENSITY (I_{spta}) is less than 100 mW/cm² (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 $f_{\text{awf}} < 10,5$ MHz, and $A_{\text{aprt}} < 1,25$ cm². 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.