

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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
essentiels des appareils de diagnostic et de surveillance médicaux à ultrasons





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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

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INTERNATIONAL
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ICS 11.040.55; 17.140.50

ISBN 978-2-8322-2699-5

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FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62B/978/FDIS	62B/988/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

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INTRODUCTION TO AMENDMENT 3.1

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.

201.1.1 *Scope

Replace “Addition:” with “Replacement:”

201.2 Normative references

Replace the existing text of this subclause by the following:

Clause 2 of the general standard 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/AMD1:2012¹

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, *Ultrasonics – Hydrophones – Part 1: Measurement and characterization of medical ultrasonic fields up to 40 MHz*
IEC 62127-1:2007/AMD1:2013²

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

201.3 Terminology and definitions

Replace the existing title of this clause with the following:
<https://standards.iteh.ai/catalog/standards/sist/4b2a7f49-6cb1-4375-86fe-3c94c15ad964/iec-60601-2-37-2007-amd1-2015>

201.3 Terms and definitions

201.3.201

Replace the existing text of the term and definition by the following:

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, 3.17, modified – The definition no longer refers to neonatal cephalic applications, and the original notes have been deleted]

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).

201.3.203

Replace the existing text of the term and definition by the following:

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, 3.21, modified – The definition now includes a reference to neonatal cephalic applications, and the original notes have been deleted.]

201.3.211

PRUDENT USE STATEMENT

Replace the existing text of the definition by the following:

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, 3.40, modified – The definition has been reworded.]

201.3.213

Replace the existing text of the term and definition by the following:

SOFT TISSUE THERMAL INDEX

TIS

THERMAL INDEX related to soft tissues <https://standards.iteh.ai/catalog/standards/sist/4b2a7f49-6cb1-4375-86fe-3c94c15ad964/iec-60601-2-37-2007-amd1-2015>

Unit: None.

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

201.3.214

Replace the existing text of the term and definition by the following:

THERMAL INDEX

TI

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, 3.56, modified – The term "ATTENUATED ACOUSTIC POWER" has been replaced twice by the term "ATTENUATED OUTPUT POWER", and the original note has been deleted.]

201.3.215

TRANSDUCER ASSEMBLY

Replace the existing text of the definition by the following:

those parts of ULTRASONIC DIAGNOSTIC EQUIPMENT comprising the ULTRASONIC TRANSDUCER and/or ULTRASONIC TRANSDUCER ELEMENT GROUP, 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, modified – the original term "medical diagnostic ultrasound equipment" has been replaced by "ULTRASONIC DIAGNOSTIC EQUIPMENT" in the definition.]

201.3.216
TRANSMIT PATTERN

Add, at the end of the term and definition, the following source reference:

[SOURCE: IEC 62359:2010, 3.58]

201.3.218
ULTRASONIC TRANSDUCER

Replace the existing text of the term and definition by the following:

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]

Add the following new definitions:

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

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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, 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.

Unit: $W\ m^{-2}$

201.3.220
NUMBER OF PULSES PER ULTRASONIC SCAN LINE

the 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

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

Unit: m

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

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

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.

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

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.

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 ($p_{ii,\alpha}$)

Unit: m

[SOURCE: IEC 62359:2010, 3.23]

Replace the existing table by the following:

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	
p_{ii}	= PULSE-INTENSITY INTEGRAL	IEC 62359
$p_{ii,\alpha}$	= ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359
$I_{\text{sppa},\alpha}$	= ATTENUATED SPATIAL-PEAK PULSE-AVERAGE INTENSITY	
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
P	= OUTPUT POWER	IEC 62359
P_{α}	= ATTENUATED OUTPUT POWER	IEC 62359
$p_{r,\alpha}$	= ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
p_r	= PEAK-RAREFACTIONAL ACOUSTIC PRESSURE	IEC 62359
n_{pps}	= NUMBER OF PULSES PER ULTRASONIC SCAN LINE	IEC 61157
prr	= PULSE REPETITION RATE	IEC 62359
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 TIB	IEC 62359
z_{bp}	= BREAK-POINT DEPTH	IEC 62359
z_{pii}	= DEPTH FOR PEAK PULSE-INTENSITY INTEGRAL	
Z_{MI}	= DEPTH FOR MECHANICAL INDEX	IEC 62359
$z_{\text{pii},\alpha}$	= DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL	
z_{sii}	= DEPTH FOR PEAK SUM OF PULSE INTENSITY INTEGRALS	
$z_{\text{sii},\alpha}$	= DEPTH FOR PEAK SUM OF ATTENUATED PULSE INTENSITY INTEGRALS	
z_s	= DEPTH FOR TIS	IEC 62359

201.4 General requirements

Add the following new subclause:

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 particular standard.

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

201.7 ME EQUIPMENT identification, marking and documents

201.7.9.2.2 *Warning and safety notices

Add, at the end of this subclause, the following new text:

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 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.

201.7.9.2.12 Cleaning, disinfection and sterilization

Delete the instruction concerning the addition of the note and the text of the added note.

Add, after the additional third dashed item, the following new note:

NOTE This list of parameters is neither exhaustive nor mandatory.

201.7.9.3 Technical description

201.7.9.3.101 Technical data regarding acoustic output levels (see also Table 201.103)

Replace the existing title and text of this subclause by the following:

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.

For a TRANSDUCER ASSEMBLY and ultrasound instrument console that satisfies all of the exemption conditions cited in 201.12.4.2 a) and b), information declared in the ACCOMPANYING DOCUMENTS shall state that the THERMAL INDICES and the MECHANICAL INDEX are 1,0 or less for all device settings.

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, the z_s and z_b values are entered for non-scanned (component) modes.

NOTE 4 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

Replace the existing table with the following:

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Table 201.103 – Acoustic output reporting table

MODE _____

Index label		MI	TIS		TIB		TIC
			At surface	Below surface	At surface	Below surface	
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	p_{rr} (Hz)	✓					
	s_{rr} (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” both in 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) 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) 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 7 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.