

Medical electrical equipment —

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

ICS 11.040.55; 17.140.50

National foreword

This British Standard is the UK implementation of EN 60601-2-37:2008+A1:2015. It is identical to IEC 60601-2-37:2007, incorporating amendment 1 2015. It supersedes BS EN 60601-2-37:2008+A11:2011 which will be withdrawn on 13 July 2018.

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

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical equipment in medical practice, to Subcommittee CH/62/2, Diagnostic imaging equipment.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments/corrigenda issued since publication

Date	Comments
30 April 2012	Implementation of CENELEC amendment A11:2011. Annex ZZ has been revised.
30 September 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015. Annex ZA amended

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**Medical electrical equipment -
Part 2-37: Particular requirements for the basic safety
and essential performance of ultrasonic medical diagnostic
and monitoring equipment
(IEC 60601-2-37:2007)**

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
(CEI 60601-2-37:2007)

Medizinische elektrische Geräte -
Teil 2-37: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von
Ultraschallgeräten für die medizinische
Diagnose und Überwachung
(IEC 60601-2-37:2007)

This European Standard was approved by CENELEC on 2007-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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

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

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

CENELEC

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

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

Foreword

The text of document 62B/624/CDV, future edition 2 of IEC 60601-2-37, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel Unique Acceptance Procedure and was approved by CENELEC as EN 60601-2-37 on 2007-10-01.

This European Standard supersedes EN 60601-2-37:2001 + A1:2005 + A2:2005.

EN 60601-2-37:2008 combines EN 60601-2-37:2001 + A1:2005 + A2:2005 into a form compatible with the parent EN 60601-1:2006.

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2008-08-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2010-10-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

In this standard, the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: IN SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, 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 standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “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.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-37:2007 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A11

This document (EN 60601-2-37:2008/A11:2011) has been prepared by CLC/TC 62 "Electrical equipment in medical practice".

The following dates are fixed:

- latest date by which this document has (dop) 2012-10-01
to be implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2014-10-01
standards conflicting with this
document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

European foreword to amendment A1

The text of document 62B/978/FDIS, future IEC 60601-2-37:2008/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-37:2008/A1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-04-13
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-07-13
standards conflicting with the
document have to be withdrawn

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-37:2008/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-37:2007/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-37:2008, the following note has to be **added** for the standard indicated:

IEC 61157:2007	NOTE	Harmonized as EN 61157:2007.
IEC 60601-1-11:2015	NOTE	Harmonized as EN 60601-1-11:2015.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Addition:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ A12	2014
IEC 60601-2-18	2009	Medical electrical equipment -- Part 2-18: Particular requirements for 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	EN 62127-1	2007
+ A1	2013		+ A1	2013
IEC 62359	2010	Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	EN 62359	2011

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

- Essential Requirement 6a
- Essential Requirement 7.4
- Essential Requirement 7.5 paragraph 2 & 3
- Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

INTRODUCTION.....	7
201.1 Scope, object and related standards	8
201.2 Normative references.....	9
201.3 Terminology and definitions	10
201.4 General requirements	15
201.5 General requirements for testing ME EQUIPMENT	16
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	16
201.7 ME EQUIPMENT identification, marking and documents	16
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	20
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	20
201.10 Protection against unwanted and excessive radiation HAZARDS	20
201.11 Protection against excessive temperatures and other HAZARDS	21
201.12 Accuracy of controls and instruments and protection against hazardous outputs	25
201.13 Hazardous situations and fault conditions	26
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	27
201.15 Construction of ME EQUIPMENT	27
201.16 ME SYSTEMS	27
201.17 *Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	27
202.6 ELECTROMAGNETIC COMPATIBILITY	27
Annex AA (informative) Guidance and rationale for particular subclauses	30
Annex BB (informative) Guidance in classification according to CISPR 11	35
Annex CC (informative) Guidance to the MANUFACTURER on the interpretation of <i>TI</i> and <i>MI</i> to be used to inform the OPERATOR.....	36
Annex DD (informative) Example set-up to measure surface temperature of externally applied TRANSDUCER ASSEMBLIES	39
Annex EE (informative) Acoustic output table intended for 3rd parties	42
Bibliography.....	44
Index of defined terms	47
Figure DD.1 – Set-up of an example test object to measure the surface temperature of externally applied transducers	41
Table 201.101 – List of symbols.....	14
Table 201.102 – Distributed essential performance requirements	15
Table 201.103 –Acoustic output reporting table	19
Table 201.104 – Overview of the tests noted under 201.11.1.3	24
Table CC.1 – Relative importance of maintaining low exposure indices in various scanning situations	38
Table DD.1 – Acoustic and thermal properties of tissues & materials	39
Table DD.2 – Weight % pure components.....	40

INTRODUCTION

In this particular standard, safety requirements additional to those in the general standard are specified for ULTRASONIC DIAGNOSTIC EQUIPMENT.

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

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

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

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

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 applies, except as follows:

201.1.1 *Scope

A1 Replacement: **A1**

This International Standard 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 standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of this standard.

NOTE See also subclause 4.2 of this standard.

This particular standard 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 particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ULTRASONIC DIAGNOSTIC EQUIPMENT as defined in 201.3.217.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard 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.

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 particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 6 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101, 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 standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

A1 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*

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). **A1**

A1 201.3 Terms and definitions A1

For the purposes of this document, the terms and definitions given in the general standard and in IEC 62359, as well as the following additions apply:

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

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

201.3.201

A1 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] **A1**

201.3.202

COMBINED-OPERATING MODE

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

201.3.203

A1 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.] **A1**

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

a 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

Symbol: *MI*

Unit: None

NOTE 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

- A1** 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.] **A1**

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

- A1** **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.] **A1**

201.3.214

- A1** **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.] **A1**

201.3.215

TRANSDUCER ASSEMBLY

- A1** 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.] **A1**

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] ⓘ

ⓘ 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

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

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). ⓘ

A1 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 **A1**

A1 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] **A1**

A1 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
$z_{pii,\alpha}$	= DEPTH FOR PEAK ATTENUATED PULSE INTENSITY INTEGRAL	
z_{sii}	= DEPTH FOR PEAK SUM OF PULSE INTENSITY INTEGRALS	
$z_{sii,\alpha}$	= DEPTH FOR PEAK SUM OF ATTENUATED PULSE INTENSITY INTEGRALS	
z_s	= DEPTH FOR TIS	IEC 62359 A1