SIST

SLOVENSKI STANDARD

SIST EN 60601-2-37:2008/A1:2015

01-december-2015

Medicinska električna oprema - 2-37. del: Posebne zahteve za osnovno varnost in bistvene lastnosti ultrazvočne medicinske diagnostične in nadzorovalne opreme - Dopolnilo A1

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

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-37:2008/A1:2015**

ICS:

11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 60601-2-37:2008/A1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-37:2008/A1

August 2015

ICS 11.040.55; 17.140.50

English Version

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/A1:2015)

Appareils électromédicaux - Partie 2-37: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons
(IEC 60601-2-37:2007/A1:2015)

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/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-37:2008; it was approved by CENELEC on 2015-07-13. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

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

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:

Publication	Year	Title	EN/HD	Year
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

IEC 60601-2-37

Edition 2.0 2015-06

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 essentielles des appareils de diagnostic et de surveillance médicaux à ultrasons

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.55; 17.140.50 ISBN 978-2-8322-2699-5

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.

INTRODUCTION TO AMENDMENT 1

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

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

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/AMD1:2012[1]

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/AMD1:2013[2]

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:

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]

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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

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

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

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).