ICS 11.040.55, 17.140.50 SLOVENSKÁ TECHNICKÁ NORMA Marec 2016

STN	**Zdravotnícke elektrické prístroje. Časť 2-37: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti ultrazvukových zdravotníckych diagnostických a monitorovacích prístrojov. Zmena A1**	**STN EN 60601-2-37/A1** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/16

STN EN 60601-2-37 z júla 2009 sa bez zmeny A1 môže používať do 13. 07. 2018.

Obsahuje: EN 60601-2-37:2008/A1:2015, IEC 60601-2-37:2007/AMD1:2015

122367

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

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

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

IEC 60601-2-37:2007-08/AMD1:2015-06(en-fr)

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

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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.

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*

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).