SLOVENSKI STANDARD
SIST EN 62570:2015

01-september-2015

Oprema z magnetno resonanco za medicinsko slikanje - Navodila za označevanje predmetov znotraj nadzorovanega območja

Magnetic resonance equipment for medical imaging - Instructions for marking items within the controlled access area

Standardverfahren für die Kennzeichnung medizinischer Geräte und anderer Gegenstände zur Sicherheit in der Umgebung von Magnetresonanzeinrichtungen

Appareils à résonance magnétique utilisés pour l'imagerie médicale - Instructions pour le marquage des éléments à l'intérieur de la zone à accès contrôlé

Ta slovenski standard je istoveten z: **EN 62570:2015**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
11.040.55	Diagnostična oprema	Diagnostic equipment

SIST EN 62570:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62570

May 2015

ICS 11.040.50; 11.040.55

English Version

Standard practice for marking medical devices and other items for safety in the magnetic resonance environment (IEC 62570:2014)

Pratiques normalisées relatives au marquage des appareils médicaux et des éléments de sûreté divers dédiés aux environnements de résonance magnétique (IEC 62570:2014)

Standardverfahren für die Kennzeichnung medizinischer Geräte und anderer Gegenstände zur Sicherheit in der Umgebung von Magnetresonanzeinrichtungen (IEC 62570:2014)

This European Standard was approved by CENELEC on 2015-04-14. 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 CEN-CENELEC Management Centre 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 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

Ref. No. EN 62570:2015 E

Foreword

The text of document 62B/933/FDIS, future edition 1 of IEC 62570, 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 62570:2015.

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)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

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(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 62570:2014 was approved by CENELEC as a European Standard without any modification.

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.

Publication	Year	Title	EN/HD	Year
ASTM F2052	-	Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	-	-
ASTM F2119	-	Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	-	-
ASTM F2182	-	Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	-	-
ASTM F2213	-	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	-	-
IEC 60601-2-33	2010	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	EN 60601-2-33	2010
-	-		+ corrigendum Oct.	2010
-	-		+ A11	2011
ISO 14971	-	Medical devices - Application of risk management to medical devices	EN ISO 14971	-
ISO/IEC Guide 51	-	Safety aspects - Guidelines for their inclusion in standards	-	-
ISO/TS 10974	-	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EU 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 given in Annex I of EU Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

WARNING: Other requirements and other EU Directives can be applied to the products falling within the scope of this standard.

IEC 62570

Edition 1.0 2014-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

Pratiques normalisées relatives au marquage des appareils médicaux et des éléments de sûreté divers dédiés aux environnements de résonance magnétique

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

PRICE CODE
CODE PRIX

Q

ICS 11.040.50; 11.040.55

ISBN 978-2-8322-1443-5

CONTENTS

FOREWORD 3
1 Scope 5
2 Referenced Documents 5
3 Terminology 6
4 Significance and Use 7
5 Requirements for assessment of potential hazards caused by interactions of an item and the MR Environment 7
6 Methods of Marking 7
7 Information Included in MR Marking 8
8 Keywords 10
APPENDIX 13
X1. RATIONALE 13

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

STANDARD PRACTICE FOR MARKING MEDICAL DEVICES AND OTHER ITEMS FOR SAFETY IN THE MAGNETIC RESONANCE ENVIRONMENT

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 62570, integrating the unmodified text of ASTM F2503 - 13, has been developed by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Medical equipment in medical practice, in collaboration with ASTM.

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

FDIS	Report on voting
62B/933/FDIS	62B/934/RVD

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

The committee has decided that the contents of this 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.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

F2503 - 13

Standard Practice for
Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment[1]

This standard is issued under the fixed designation F2503 - 13; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This international standard applies to the practice of marking of items that might be used in the magnetic resonance (MR) environment.

1.2 The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking.

1.3 The standard specifies the permanent marking of items, which are used in an MR environment, by means of terms and icons.

1.4 MR image artifacts are not considered to be a performance issue and so are not addressed in this international standard practice (see X1.5).

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of his standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.2 *ASTM Standards:*[2]

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

2.3 *Other Standards:*

IEC 60601-2-33 Medical Electrical Equipment—Part 2-33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis[4]

ISO 14971 *Medical Devices — Application of Risk Management to Medical Devices*

ISO/IEC Guide 51 *Safety Aspects — Guidelines for their Inclusion in Standards*

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device

[1]This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved Oct. 1, 2008. Published November 2008. Originally approved in 2005. Last previous edition approved in 2005 as F2503 – 05. DOI: 10.1520/F2503 - 08.

[2]For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.