

STN	Normalizovaný postup na označovanie zdravotníckych pomôcok a iných predmetov na účely bezpečnosti v prostredí magnetickej rezonancie	STN EN IEC 62570 36 4801
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Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

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. 03/26

Obsahuje: EN IEC 62570:2025, IEC 62570:2025

Oznámením tejto normy sa od 30.11.2028 ruší
STN EN 62570 (36 4801) z decembra 2015

EUROPEAN STANDARD

EN IEC 62570

NORME EUROPÉENNE

EUROPÄISCHE NORM

November 2025

ICS 11.040.50; 11.040.55

Supersedes EN 62570:2015

English Version

**Standard practice for marking medical devices and other items
for safety in the magnetic resonance environment
(IEC 62570:2025)**

Pratiques normalisées relatives au marquage des appareils
médicaux et des éléments de sûreté divers dédiés aux
environnements de résonance magnétique
(IEC 62570:2025)

Standardverfahren für die Kennzeichnung medizinischer
Geräte und anderer Gegenstände zur Sicherheit in der
Umgebung von Magnetresonanzeleinrichtungen
(IEC 62570:2025)

This European Standard was approved by CENELEC on 2025-10-23. 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.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 62570:2025 (E)

European foreword

The text of document 62B/1381/CDV, future edition 2 of IEC 62570, prepared by SC 62B "Medical imaging equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 62570:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-11-30 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-11-30 document have to be withdrawn

This document supersedes EN 62570:2015 and all of its amendments and corrigenda (if any).

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Endorsement notice

The text of the International Standard IEC 62570:2025 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 are referred to in the text in such a way that some or all of their content constitutes requirements 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.

NOTE 1 Where 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.cencenelec.eu.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 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	-	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	EN IEC 60601-2-33	-
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	-	-



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INTERNATIONAL STANDARD

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

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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.
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IEC 62570 has been prepared by subcommittee 62B: Medical imaging equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

It is based on ASTM F2503-23 and was submitted as a Fast-Track document.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62B/1381/CDV	62B/1388/RVC

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

The language used for the development of this International Standard is English.

The structure and editorial rules used in this publication reflect the practice of the organization which submitted it.

This document was developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.
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Designation: F2503 – 23^{ε1}

Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment¹

This standard is issued under the fixed designation F2503; 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 reappraisal. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reappraisal.

^{ε1} NOTE—References in 6.3.3 were editorially corrected in October 2023.

1. Scope

1.1 This practice applies to medical devices and other items that are anticipated to enter the magnetic resonance (MR) environment.

NOTE 1—“Medical devices and other items” will be referred to as “items” for the remainder of this practice.

1.2 The practice specifies the marking of items anticipated to enter the MR environment by means of terms and icons, and recommends information that should be included in the labeling.

1.3 MR image artifacts are not in the scope of the mandatory portions of this practice because they do not present a direct safety issue resulting from specific characteristics of the MR examination (see X1.12).

1.4 The values stated in SI units are to be regarded as standard.

1.5 *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 this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 The following referenced documents are indispensable for the application of this practice. For dated references, only

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 April 1, 2023. Published May 2023. Originally approved in 2005. Last previous edition approved in 2020 as F2503 – 20. DOI: 10.1520/F2503-23E01.

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 (Withdrawn 2022)³

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 and Documents:

IEC 60601-2-33 Medical Electrical Equipment—Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis⁴

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices⁵

ISO/IEC Guide 51 Safety Aspects—Guidelines for their Inclusion in Standards⁵

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device⁵

koniec náhľadu – text ďalej pokračuje v platenej verzii STN

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.

³ The last approved version of this historical standard is referenced on www.astm.org.

⁴ Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, P.O. Box 131, CH-1211 Geneva 20, Switzerland, <http://www.iec.ch>.

⁵ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.