BS EN 62570:2015

BSI Standards Publication

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

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National foreword

This British Standard is the UK implementation of EN 62570:2015. It is identical to IEC 62570:2014.

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 committee 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.

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Date	Text affected

EUROPEAN STANDARD

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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.

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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

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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.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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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.

3. Terminology

3.1 *Definitions:*

3.1.1 *harmful interaction*— unintended direct or indirect interaction of items with MR equipment, especially with the static magnetic field, the gradient fields and the RF fields of the MR equipment, that can pose hazards to patients or other persons.

NOTE 1- In this context, the affected image quality or image artifacts are not considered to be a harmful interaction.

3.1.2 *hazard*—potential source of harm. [ISO/IEC Guide 51]

3.1.3 *item*—object that might be brought into the MR environment.

3.1.4 *magnetically induced displacement force*—force produced when a magnetic object is exposed to the spatial gradient of a static magnetic field. This force will tend to cause the object to translate in the spatial gradient of the static magnetic field.

3.1.5 *magnetically induced torque*—torque produced when a magnetic object is exposed to a magnetic field. This torque will tend to cause the object to align itself along the magnetic field in an equilibrium direction that induces no torque.

3.1.6 *magnetic induction or magnetic flux density (B in T)*—that magnetic vector quantity which at any point in a magnetic field is measured either by the mechanical force experienced by an element of electric current at the point, or by the electromotive force induced in an elementary loop during any change in flux linkages with the loop at the point. The magnetic induction is frequently referred to as the magnetic field. B_0 is the static field in an MR equipment and accessories. Plain type indicates a scalar (for example, B) and bold type indicates a vector (for example, $\boldsymbol{B}$).

3.1.7 *magnetic resonance (MR)*—resonant absorption of electromagnetic energy by an ensemble of atomic nuclei situated in a magnetic field. IEC 60601-2-33, definition 201.3.217

3.1.8 *magnetic resonance (MR) equipment*—medical electrical equipment which is intended for *in vivo* magnetic resonance examination of a patient comprising all parts in hardware and software from the supply mains to the display monitor.

NOTE 2- The MR equipment is a programmable electrical medical system (PEMS) IEC 60601-2-33, definition 201.3.218

3.1.9 *magnetic resonance (MR) examination*—process of acquiring data by magnetic resonance from a patient IEC 60601-2-33, definition 201.3.219

3.1.10 *magnetic resonance (MR) environment*—the three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.

3.1.11 *MR Conditional*–an item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.

3.1.12 *Supplementary Marking*—additional information that, in association with a marking as "MR Conditional," states via additional language the conditions in which an item can be used safely within the MR environment.

3.1.13 *MR Safe*—an item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic

Note 3- An item composed entirely of electrically nonconductive, nonmetallic and nonmagnetic materials may be determined to be MR Safe by providing a scientifically based rationale rather than test data. Examples of MR Safe items are a cotton blanket or a silicone catheter.

3.1.14 *MR Unsafe*—an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.

NOTE 4— ISO 14971 Medical devices - Application of risk management to medical devices, includes a process for evaluating risks, including identifying unacceptable risks. MR Unsafe items include items such as a pair of ferromagnetic scissors.

3.1.15 *medical device*—any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

(1) diagnosis, prevention, monitoring, treatment, or alleviation of disease;

(2) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury;

(3) investigation, replacement, modification, or support of the anatomy or of a physiological process;

(4) supporting or sustaining life;
(5) control of conception;
(6) disinfection of medical devices;
(7) providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means. [ISO 13485]

3.1.16 *radio frequency (RF) magnetic field*—the magnetic field in MRI that is used to flip the magnetic moments. The frequency of the RF field is γB_0 where γ is the gyromagnetic constant, 42.56 MHz/T for protons, and B_0 is the static magnetic field in Tesla.

3.1.17 *safety*—freedom from unacceptable risk.

3.1.18 *specific absorption rate (SAR)*—radio frequency power absorbed per unit of mass (W/kg). [IEC 60601-2-33]

3.1.19 *tesla, (T)*—the SI unit of magnetic induction equal to 10^4 gauss (G).

4. Significance and Use

4.1 Interactions of medical devices and other items with the MR environment has resulted in serious injuries and death of patients and other individuals. Additionally, hazards stemming from equipment malfunction are of concern. Section 4.2 lists possible direct and indirect causes of hazards in the MR environment.

4.2 Potential direct and indirect causes of hazards

4.2.1 Direct causes:

4.2.1.1 mechanical causes, including magnetically induced displacement force, torque, and vibration

4.2.1.2 electromagnetic causes, including induction (heating, stimulation) and discharge (spark gap)

4.2.1.3 acoustic causes

4.2.2 Indirect causes:

4.2.2 malfunction of items, for example of vital components such as valves, monitors and pumps

4.3 This practice provides a uniform system for marking to indicate the conditions for which it has been determined that a medical device or other item may be safely placed and used in the MR environment. It provides simple visual icons and terms which are intended to reduce injuries and other mishaps that occur when items that pose hazards in the MR environment are brought into the MR environment.

5. Requirements for assessment of potential hazards caused by interactions of an item and the MR Environment

5.1 Perform testing sufficient to characterize the behavior of the item in the MR environment.

5.1.1 In particular, testing for items that may be placed in the MR environment should address magnetically induced displacement force (Test Method F2052), magnetically induced torque (Test Method F2213), and RF heating (Test Method F2182 for passive implants and ISO TS 10974 for active implants). Additionally, electronic components shall be evaluated for malfunction.

5.1.2 Other possible safety issues to consider for the hazard assessment include, but are not limited to, thermal injury, induced currents/voltages, interaction with the switched gradient field, dB/dt, for all items that may go inside the magnet bore, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and the malfunction of the item and the malfunction of the MR equipment and accessories. See Table X.1.1 for some hazards and associated test methods. Also see Section X1.2.1.4.

5.2 List any parameter that affects the safety of the item. Describe any condition that is known to produce an unsafe condition.

NOTE 5 - These remarks do not claim to be complete. Therefore it is recommended that the user of this standard consider specific questions and topics that may be applicable to the specific item being evaluated. Some potential hazards to patients and others in the MR environment are given in X1.2.1 and Table X1.1.

6. Methods of Marking

6.1 The marking method shall not compromise performance or function of the marked item and should provide legibility over the anticipated service life of the item. For all items external to the body of a person for which it is technically feasible, labeling for MR Conditional items shall appear on the item and include the conditions for safety in the MR environment.

7. Information Included in MR Marking

7.1 Medical devices and other items vary widely in size, and the amount of information that practically can be included in marking varies accordingly. For implants, the MR marking shall be included in the labeling (including the instructions for use, package inserts, patient and physician manuals) and on the patient information card. Non-implanted items, where feasible, shall have MR marking on the item as well as in the labeling. Some items (for example, small or very thin ones) do not provide any surfaces which can be marked practically. For items for which direct marking is not practical, the MR marking shall be included in the labeling. For both implants and non-implanted items, the MR marking may be placed on the product packaging label (e.g. on the box), however the package label should clearly indicate the item(s) inside the packaging to which the MR marking applies (e.g., implant only or implant and delivery system).

7.2 The marking method shall not compromise performance or function of the marked item and should remain readable over the anticipated service life of the item.

7.3 *Minimum Information*—As a result of the testing described in Section 5, mark the item as MR Safe, MR Conditional, or MR Unsafe using the icons as shown in Tables 1 and 2.

7.3.1 The MR Safe icon consists of the letters "MR" surrounded by a green square (Table 1 and Figures 1 and 2). Two options are given. When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Figures 3 and 4). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color. For both color and black and white options in Tables 1 and 2, the option that is most visible for the individual application should be chosen.

7.3.2 The MR Conditional icon consists of the letters "MR" within a yellow equilateral triangle with a thick black band around the perimeter (Table 1 and Figure 5). The triangle is oriented with its horizontal side below the letters "MR." When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Figure 6). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

7.3.2.1 For MR Conditional items, the item labeling (instructions for use, package inserts, operator manual, patient information card, patient and physician information pamphlets, as appropriate) shall include appropriate information from Section 5. *(1)* The MR Conditional icon may be supplemented by supplementary marking which includes the appropriate information from Section 5 and describes the conditions for which the item has been demonstrated to be MR Conditional. The supplementary marking consists of text surrounded by a rectangular frame (Figure 7).

7.3.2.2 For all items external to the body of a person for which it is technically feasible, labeling for MR Conditional items shall appear on the item and include conditions for safety in the MR environment from Section 5.

NOTE 6— This marking may be particularly useful for inclusion on nonimplanted items that are used in the MR environment, for instance on electronic equipment, room furnishings, or item packaging and labeling.

Note 7– This marking may also be used if one portion of a kit or device with accessories is MR Conditional. For example, indicate "stent only" for a system that consists of stent plus delivery catheter.

7.3.3 The MR Unsafe marking consists of the letters "MR" surrounded by a red circle with a diagonal red bar across the letters extending from the upper left quadrant to the lower right quadrant of the circle and oriented at 45° from the horizontal (Table 1 and Figure 8). When color reproduction is not practical, the icon may be printed in black and white (Table 2 and Figure 9). The use of the colored icon is strongly encouraged for the added visibility and information provided by the color.

7.4 The icons shall comply with the layout requirements given below. The colors are given in Table 3. Note that the colors represented in an electronic or paper copy of this document may not match the colors as defined in Table 3.

7.4.1 MR Safe icon, *Color Option 1 (Figure 1)*:

7.4.1.1 The colors of the MR Safe icon shall be as follows for option 1:

(1) Background color: green

(2) Letters 'MR': white

(3) The letters 'MR' shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible to be contained within the green square, but not touching the border of the square.

7.4.2 MR Safe icon, *Color Option 2 (Figure 2)*:

7.4.2.1 The colors of the MR Safe icon shall be as follows for option 2:

(1) Background color: white
(2) Letters ‘MR’: green
(3) Frame: green. The width of the frame shall be approximately 10% of the length of a side of the square.
(4) The letters ‘MR’ shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the border of the frame.

7.4.3 MR Safe icon, *Black and White Option 1(Figure 3)*:
7.4.3.1 For option 1 of the black and white version of the MR Safe icon, the colors shall be as follows:
(1) Background color: black
(2) Letters ‘MR’: white
(3) The letters ‘MR’ shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the border of the square.

7.4.4 MR Safe icon, *Black and White Option 2(Figure 4)*:
7.4.4.1 For option 2 of the black and white version of the MR Safe icon, the colors shall be as follows:
(1) Background color: white
(2) Letters ‘MR’: black
(3) Frame: black. The width of the border shall be approximately 10% of the side length of the square.
(4) The letters ‘MR’ shall be capitalized, in Arial font and centered in the square. The letters shall be sized as large as possible, but not touching the frame.

7.4.5 *MR Conditional Icon, Color Option (Figure 5)*:
7.4.5.1 The colors of the MR Conditional icon shall be as follows:
(1) Background color: yellow
(2) Triangular frame: black
(3) Letters ‘MR’: black
(4) The letters ‘MR’ shall be capitalized, in Arial font and sized as large as possible within the black frame, but not touching the frame.

7.4.6 MR Conditional Icon, Black and White Option (Figure 6)
7.4.6.1 For the black and white version of the MR Conditional icon, the colors of the icon shall be as follows:
(1) Background color: white
(2) Triangular frame: black
(3) Letters ‘MR’: black
(4) The letters ‘MR’ shall be capitalized, in Arial font and sized as large as possible within the black frame, but not touching the frame.

7.4.7 *Supplementary marking for MR Conditional Items, Color Option (Figure 7)*:
7.4.7.1 For the color option of the MR Conditional Supplementary marking, colors shall be as follows:
(1) Background color: yellow
(2) Rectangular Frame: black
(3) Text: black
(4) The safety color yellow shall cover at least 50 % of the total area of the icon.
(5) The text shall be in Arial font.

7.4.8 *Supplementary marking for MR Conditional Items, Black and White Option (Figure 7)*:
7.4.8.1 For the black and white option of the MR Conditional Supplementary marking, the colors shall be as follows:
(1) Background color: white
(2) Rectangular Frame: black
(3) Text: black
(4) The text shall be in Arial font.

7.4.9 *MR Unsafe Icon, Color option (Figure 8)*:
7.4.9.1 The colors of the MR Unsafe icon shall be as follows:
(1) Background color: white
(2) Circular frame and diagonal bar: red

(3) Letters ‘MR’: black
(4) The letters ‘MR’ shall be capitalized, in Arial font, and sized as large as possible within the circular frame, but not touching the frame.

7.4.10 MR Unsafe Icon, black and white option (Figure 9):
7.4.10.1 For the black and white version of the MR Unsafe icon, the colors of the icon shall be as follows:
(1) Background color: white
(2) Circular frame and diagonal bar: black
(3) Letters ‘MR’: black
(4) The letters ‘MR’ shall be capitalized, in Arial font and sized as large as possible within the circular frame, but not touching the frame.

8. Keywords

8.1 magnet; magnetic; medical devices; metals (for surgical implants); MRI (magnetic resonance imaging); MR safety

TABLE 1 Requirements for Colored MR Icons

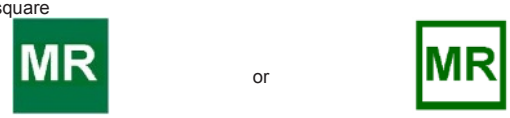
Icon Geometric Shape and Appearance	Meaning
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

TABLE 2 Requirements for Black and White MR Icons

Icon Geometric Shape and Appearance	Meaning
A square  or 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

TABLE 3 Examples from Color Order Systems for the Icon Colors (DIN, RAL, Munsell, AFNOR, and NCS examples from ISO 3864–1:2) [A]

Color	DIN 5381 DIN 6164	RAL	Munsell	AFNOR NF X08-002 and X08-010	NCS	Pantone
Red	7,5 : 8,5 :3	RAL 3001	7,5R 4/14	N°2805	S 2080-R	Pantone 1807 C
Yellow	2,5 : 6,5 : 1	RAL 1003	10YR 7/14	N°1330	S 1070-Y10R	Pantone 1235 C
Green	21,7 : 6,5 : 4	RAL 6032	5G 4/9	N°2455	S 3060-G	Pantone 3415 C
White	N : 0 : 0,5	RAL 9003	N 9,5	N°3665	S 0500-N	Pantone White
Black	N : 0 :9	RAL 9004	N 1	N°2603	S 9000-N	Pantone 6 C

[A]

FIG. 1 Color Option 1

FIG. 2 Color Option 2

FIG. 3 Black and White Option 1

FIG. 4 Black and White Option 2

FIG. 5 MR Conditional Icon Geometry, Color Option

FIG. 6 MR Conditional Icon Geometry, Black and White Option

FIG. 7 Supplementary Marking for MR Conditional Items

FIG. 8 MR Unsafe, Color Option

FIG. 9 MR Unsafe, Black and White Option

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 The intent of this practice is to provide needed information about the safety of items in and near MR scanners using a compact and easily recognized set of icons and terms. The terms MR safe and MR compatible as first defined in 1997 in the FDA draft guidance document, "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems," were used to describe the safety of devices in and near MR equipment and accessories. The *historical definitions* are:

MR Safe **(outdated definition)**	The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.
MR Compatible **(obsolete definition)**	The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device. The MR conditions in which the device was tested should be specified in conjunction with the terms MR safe and MR compatible since a device that is safe or compatible under one set of conditions may not be found to be so under more extreme MR conditions.

There was a great deal of confusion surrounding this terminology. An incorrect assumption was often made. Users often *incorrectly* assumed that items labeled MR safe or MR compatible were safe or compatible for *any* MR environment. MR environments vary in terms of magnetic field strength and RF conditions. Therefore, an item tested under one set of conditions may be affected differently by the conditions in another MR environment. In addition, some devices labeled MR safe and MR compatible using the historical definitions in X1.1 have gauss line restrictions or RF pulse sequence limitations that must be adhered to in order to safely use the device in the MR environment. In short, using the historical definitions it was impossible to definitively establish a device as MR safe or MR compatible without also specifying the conditions under which the device was tested. The current terms in this practice (MR Safe, MR Unsafe, and MR Conditional, Section 3) assist in clearing up this confusion.

NOTE X1.1—This revised terminology has not yet been applied to all medical devices tested before the approval of Practice F2503. Therefore, there are items that still contain the prior terminology (that is, use the old terms MR safe and MR compatible) in their labeling.

Note X1.2 IEC 60601-2-33 ed.3 201.7.9.3.101b provides a compatibility technical specification sheet containing parameters that describe the MR equipment. The specification sheet is part of the MR equipment user manual and can be used to assess MR Conditional requirements.

X1.2 Although a commercial 1.5 T MR system currently produces the conditions that are most commonly encountered, 3 T and higher strength MR systems are becoming more common in clinical situations. It is important to note that an item that can be marked MR Conditional in a 1.5 T scanner may not be safe in systems with higher or lower field strength. Also, there can be major differences in the characteristics of open and cylindrical MR systems. For instance, the spatial gradient of the static magnetic fields may be significantly higher in open systems. Depending on the design of the magnet, the direction and magnitude of the static magnetic field and the spatial gradient of the static magnetic field can vary significantly from system to system.

X1.2.1 A brief list of potential risks and hazards that have been observed include:

X1.2.1.1 Magnetically induced displacement force, both static and dynamic, that acts to pull magnetic items into the bore of the MR equipment.

(1) This force is applicable to all ferromagnetic, paramagnetic, and diamagnetic materials (including all metals).

(2) Magnetically induced displacement force depends on

(a) the static magnetic field B_0,

(b) the spatial gradient of the static magnetic field, and

(c) the magnetic saturation of the device material.

Dynamic magnetically induced force depends on the speed of the movement, the magnitude of the spatial gradient of the static magnetic field, the effective area of introduction, and the conductivity of the device material. Also see ASTM F2052 for more information on static magnetically induced force.

X1.2.1.2 Magnetically induced torque, both static and dynamic, that rotates magnetic objects to align them with the MR system magnetic field (as a compass needle is aligned with the Earth's magnetic field).

(1) This torque is applicable to all ferromagnetic, paramagnetic, and diamagnetic materials (including all metals).

(2) Magnetically induced torque depends on

(a) the static magnetic field B_0 ,

(b) the device dimensions and geometry, and

(c) the magnetic saturation of the device material.

Dynamic magnetically induced torque depends on the speed of the movement, the magnitude of the spatial gradient magnetic field, the effective area of introduction, and the conductivity of the device material. Also see ASTM F2213 for more information on static magnetically induced torque.

X1.2.1.3 Radiofrequency (RF) induced heating of objects inside the MRI bore.

(1) RF induced heating may occur with any electrically conductive item.

(2) RF induced heating depends on

(a) the electrical conductivity and permittivity of the device (impedance of electronic device parts),

(b) the geometric dimension of the device and configuration,

(c) the surrounding tissue conductivity and permittivity,

(d) the energy of the RF pulses (SAR), induced E field, B1 field,

(e) the geometric arrangement relative to RF transmit coil,

(f) the patient body relative to RF transmit coil,

(g) the specific MR coil electromagnetic field characteristics, and

(h) the center frequency of the specific MR system.

Also see ASTM F2182 for passive implants and ISO TS 10974 for active implants for more information.

X1.2.1.4 Gradient induced voltages resulting in patient stimulation, or item activation, deactivation, or damage, heating, and vibration.

(1) Gradient induced interactions depend on

(a) the gradient amplitude (x,y,z) expressed in mT/m (milliTesla/meter)

(b) the effective stimulation time of the gradient pulse, the combination of these two parameters resulting in the gradient slew rate expressed in T/m/s

(c) the device position within the gradient coil, and

(d) the device orientation within the gradient coil, the effective areas of induction, the conductivity of the device materials, and the static magnetic field B. Also see ISO TS 10974 for more information.

X1.2.1.5 Item malfunction.

(1) Item malfunction depends on

(a) the static magnetic field,

(b) the switched gradient magnetic field,

(c) the RF electromagnetic field, and

(d) parameters such as the device configuration, orientation, and operational status (on, off, standby, or other).

Item malfunction will be highly dependent on the item. Malfunctions may cause false information to be presented on or to an electrically active item or an electromechanical item caused by the MR equipment's magnetic or radiofrequency fields. Also see ISO TS 10974, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device, for more information.

X1.2.1.6 Other risks exist.

(1) Other risks exist and a review of the available clinical literature is recommended to determine the appropriate MR safety marking for the device or item. Evaluation of medical devices for these risks and hazards generally involves a combination of testing and modeling. IEC 62464-1 "Magnetic Resonance Equipment for Medical Imaging - Part 1: Determination of essential image quality parameters" contains test methods to determine the signal noise ratio, image uniformity, image slice thickness, two dimensional geometrical distortion, spatial resolution, and ghosting artifacts.

(2) Examples of risk identification based on item components follows. These are not considered to be comprehensive, but may help the new user in identifying specific risks for given items.

(a) If an item contains magnetic materials, there is a potential risk from displacement forces and torques induced by the static magnetic field.

(b) If an item contains electrically conductive material, including electric wire or any metal, there is a potential risk of heating from the electric currents produced by induction in the conducting loops or the linear conductors. This heating may produce burns on a patient and/or result in thermal damage or ignition of material contacting the item. There is also a potential risk of item eddy current induced vibration resulting from the RF field as well as the switched gradient field.

(c) If an item contains electrically conductive material that is in contact with body tissue, there is a potential risk of nerve stimulation from electric currents in electrically conductive materials induced by switched gradient fields and RF pulses.

(d) If an item or item component interacts with RF energy, there is a potential risk that the item will not function properly.

(e) If an item emits RF energy, there is a potential risk that the MR equipment will not function properly.

(f) If an item responds to high sound pressure levels, there is a potential risk that the item will not function properly.

X1.2.2 Some of the hazards with associated test methods that can be used to address them are included in Table X.1.1 below, modified and extended from ISO/TS 10974, "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device"

Main issues	**General hazard to the patient or other individual in the MR environment**	**Risk analysis and/or testing related to interaction:**	**Test method or other standard**
MR safety	Force	Static magnetic field-induced displacement force	ASTM F2052
	Torque	Static magnetic field-induced torque	ASTM F2213
	Heat	RF field-induced heating	ASTM F2182, ISO TS 10974
		Gradient field-induced heating	ISO TS 10974
	Vibration	Gradient field-induced vibration	ISO TS 10974
	Extrinsic electric potential	Gradient field-induced (lead) voltage	ISO TS 10974
	Rectification	RF field-induced rectified (lead) voltage	ISO TS 10974
	Malfunction (of a device)	Static magnetic field-induced malfunction	ISO TS 10974
		RF field-induced device malfunction	ISO TS 10974
		Gradient field-induced malfunction	ISO TS 10974
MR compatibility	Misinterpretation of image (Image quality issues)	Susceptibility and RF artifact size of geometric distortion	ASTM F2119
		Influences on the MR image produced by various factors such as, but not limited to: – geometric distortion – eddy currents – RF noise signals – interference to the RF signal properties – interference by proton signals of plastics	individual per MR system manufacturer

Table X1.1 Potential Hazards, risk analysis and/or testing related to the MR interaction, and existing test methods or other standards

X1.3 Recommendations for items that can be marked for use in the MR environment:

X1.3.1 In general practice, all items that are placed within the MR environment should be carefully evaluated and marked when practical prior to permitting them in the MR environment. The American College of Radiology recommends in its Guidance Document for MR Safe Practices (Kanal, e. et al, ACR Guidance Document on Safe MR Practices: 2013, JMRI 2013; 37:501-530) that all portable metallic or partially metallic devices that are on or external to the patient are to be positively identified in writing as non-magnetic or magnetic prior to permitting them into the MR environment. Examples of such items include fire extinguishers, oxygen tanks, intravascular guide

wires, wrenches and other tools. Many items that might be purposefully or inadvertently brought into the MR Environment are not MR Safe and need special attention. Such items include emergency equipment, equipment for initiating anaesthesia, and small pieces of furniture in rooms for patient preparation and/or control rooms.

X1.3.1.1 The following items have known hazards that may not be immediately apparent. This list is NOT all inclusive.

(1) Any electrically operated (either AC powered or battery operated) items placed within the MR environment. These types of items generally contain magnetic materials and should be evaluated and marked accordingly.

(2) Any item or device that is known to contain metallic, magnetic, or electrically conductive components or sub-components. Be aware that some items may contain metallic, magnetic, or electrically conductive components that are not obvious. For example some sandbags, pillows, batteries, and certain items of clothing have been found to contain metallic, magnetic, or electrically conductive components. Also be aware that some non-metallic materials, for example, some polymers and carbon fiber composites, are conductive and could pose an RF heating hazard.

(3) Some non-metallic materials, for example, ceramic magnets, are magnetic and could pose force and torque projectile hazards.

X1.3.2 Some items present no additional risk within the MR environment. These items include most glass items, most plastics, and most wooden items (without any metallic fasteners like nails or screws). However, critical judgment should be used before permitting any uncertain items into the MR environment. These items should be as carefully screened for non-compatible materials as are the patients.

X1.3.3 In general, if potential injury or even delay in scanning can be avoided by having a particular device or item marked as described in this practice, marking is advisable.

X1.4 Information that may be included in MR Conditional labeling include:

X1.4.1 *Item information*, including name, model number, and/or lot number, and serial number, as appropriate.

X1.4.2 *MR equipment information*, including whole body SAR (W/kg), $B1_{rms}$ (μT), static magnetic field strength(s) (T), the spatial gradient of the static magnetic field (G/cm and T/m), force product (the product of the spatial gradient of the static magnetic field and the static magnetic field strength) (G^2/cm and T^2/m), RF transmit and receive coil type, time rate of change of the switched gradient magnetic field (T/m), and/or switched gradient magnetic field slew rate (T/m/s), standard spin echo sequence parameters, and standard gradient echo sequence parameters, normal operating mode or first level controlled mode, as appropriate.

X1.4.3 *Nonclinical phantom testing information*, including maximum temperature rise of the tested item (ºC), minimum background temperature rise (ºC), maximum temperature rise difference between the test item and the background (ºC), maximum duration of continuous MR scanning (min.), calorimetry assessed phantom SAR (W/kg), software displayed SAR (W/kg), and image artifact size beyond the test item for a given scan sequence (mm), as appropriate.

X1.5 Image artifact is not considered to be a performance issue and so it is excluded from the scope of this practice. Image artifacts depend on the magnitude of the static magnetic field B_0, the alignment of the item relative to B_0, and the MR pulse sequence parameter adjustments. In order to provide additional information to clinicians to help them make a decision about the appropriateness of a given MR scan for a patient with an implant or other item that is placed in the bore of the scanner during the scan, a statement about the image artifact produced by the item should be included in the product labeling. For devices that require patient information cards, the statement about image artifact should also be included on the patient information card. Test Method F2119 provides a method for evaluating image artifact for passive medical implants. Other methods may be needed to assess the image artifact from other devices or items.

X1.6 The standard was revised in 2008 to include the supplementary marking for MR Conditional items.

X1.7 The standard was revised in 2013 to create ASTM International and IEC standards with identical content.

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