Testing Services for Magnetic Resonance Safety & Compatibility

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MR Labeling - Marking Draft

Related to Report No.: TR0384-301

MR systems: 3 Tesla, Magnetom Verio, Siemens Healthcare

Test objects: “Titanium Tools”

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Content:

1. Information about used MR systems

MR scanner used for testing:

Displacement force and qualitative torque:

Magnetom Verio, Siemens AG, Erlangen, Germany

3 Tesla, horizontal static magnetic field, actively shielded
Static magnetic gradient field $|\nabla B| \leq 15$ Tesla/meter

Static magnetic gradient field product $|B| \cdot |\nabla B| \leq 27$ Tesla^2/meter.
Software: Numaris/4 MR B19 Latest_20121201:P5 (SP1)

2. Rationale for values reported in MR marking

The following sections provide a rationale for the values presented in the MR marking.

Considered is the following matrix: all Titanium tools of product catalog no. 080114 that consist of 100% titanium 6AL-4V.

FIG. 1: Matrix of titanium tools, e.g. “Titanium Tools. KIT-SMS-251”

In order to cover this product matrix the following worst-cases have been determined (nominal dimensions):

Displacement force and qualitative torque: combination wrench, metric size 19, CWT-M19, largest dimension and greatest metallic mass

2.1 Displacement force - static magnetic field induced

Values related to magnetically induced displacement force are reported in TR0384-301 and discussed here for use in the MR labeling below.

For generalizing the maximum static spatial field gradient, an extrapolation is used as follows (based on the assumption that most materials are magnetically saturated by their individual property of magnetic saturation, if exposed to static fields higher than 1 Tesla [1]):

In general for extrapolation of the spatial field gradient and force product:

Spatial field gradient parameter:

$$|\nabla B| \quad = \frac{\quad}{\quad}|\nabla B| \quad > |\nabla B| \qquad (1)$$

α_{limit}	=	45°
α_{max}	=	max. deflection from ASTM F2052 test result (°)
$\lvert\nabla B\rvert_{test}$	=	spatial field gradient of test location (T/m)
$\lvert\nabla B\rvert_{extrapolated}$	=	spatial field gradient extrapolated to 45° limit (T/m)
$\lvert\nabla B\rvert_{extrapolated\ rounded}$	=	spatial field gradient extrapolated and rounded for MR labeling (T/m)

Force product parameter (spatial gradient magnetic field product):

$$|\boldsymbol{B}||\boldsymbol{\nabla B}| \quad \text{eee eeeee eeee} = \frac{\text{uuu}_{e}\ \text{m}_{e}}{\text{uu}_{\alpha}} |\boldsymbol{B}||\boldsymbol{\nabla B}| \quad \text{e ete} > |\boldsymbol{B}||\boldsymbol{\nabla B}| \quad \text{e e} \tag{2}$$

α_{limit}	=	45°
α_{max}	=	max. deflection from ASTM F2052 test result (°)
$\lvert B\rvert\cdot\lvert\nabla B\rvert_{test}$	=	force product of test location (T^2/m)
$\lvert B\rvert\cdot\lvert\nabla B\rvert_{extrapolated}$	=	force product extrapolated to 45° limit (T^2/m)
$\lvert B\rvert\cdot\lvert\nabla B\rvert_{extrapolated\ rounded}$	=	force product extrapolated and rounded for MR labeling (T^2/m)

According to equation (1) the extrapolated maximum static spatial field gradient with device under test can be calculated as follows:

$$\frac{\tan 45°}{\tan 2°} \cdot 4.42 \frac{T}{m} = 126.6 \frac{T}{m} > 126 \frac{T}{m}$$

which is equal to

$$126 \frac{T}{m} \cdot 10^2 \frac{G \cdot m}{T \cdot cm} = 12{,}600 \ \frac{G}{cm}$$

Using equation (2) the maximum force product of the test location can be calculated with:

$$\frac{\tan 45°}{\tan 2°} \cdot 7.7 \frac{T^2}{m} = 220.5 \frac{T^2}{m} > 220 \frac{T^2}{m}$$

which is equal to

$$220 \frac{T^2}{m} \cdot 10^6 \frac{G^2 \cdot m}{T^2 \cdot cm} = 220{,}000{,}000 \ \frac{G^2}{cm}$$

The MR user can then compare maximum spatial field gradient parameter of the MR labeling with the technical specification data sheet of the MR system.

3. MR labeling - Marking examples

3.1 Marking example (long version) based on US FDA guidance, ASTM F2503, IEC 62570 and for CE marking

The following marking example can be used in the instructions for use:

Non-clinical testing has demonstrated that the Titanium-Tool (max. 217 x 31 x 17 mm) is MR conditional.

magnetically induced force of 2% (equal to ≈ 1°) of the limit and a
static magnetic field of 3 Tesla with a
static spatial field gradient $|\nabla B| \approx 4.4$ Tesla/meter and a
force product $|B| \cdot |\nabla B| \approx 7.7$ Tesla^2/meter.

According to these test results, entering the MR environment can be considered safe without safety discussion for

static magnetic fields of 3 Tesla and less only, with a
$|\nabla B| < 126$ Tesla/meter and a $|B| \cdot |\nabla B| < 220$ Tesla^2/meter (values extrapolated). The

Titanium-Tool has not been tested in simultaneous combination with other devices

3.2 Marking example (short version) based on suggestion of US FDA guidance, ASTM F2503, IEC 62570 and for CE marking

The following marking information (short version) is based on US FDA Guidance for Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, December 11, 2014 and can be used on the device and inside the instructions for use.

Internal remark: Bold labeling text below is a suggestion by MR:comp in addition to the pure FDA guidance standard text in order to increase safety and to provide additional important information to the MR user

<Begin of MR labeling draft>:

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated the Titanium-Tool (max. 217 x 31 x 17 mm) is MR conditional. This device can be safely moved to an MR system meeting the following conditions:

- Static magnetic field of 3 Tesla and less**, with**
- Maximum spatial field gradient of 12,600 G/cm (126 T/m)
- **Maximum force product of 220,000,000 G^2/cm (220 T^2/m)**

<End of MR labeling draft>

Alternative symbols can be used for MR labeling if needed or required by design of the device.

Alternative symbol for MR Conditional:

4. Disclaimer

The above marking information is an example only, which is based on a suggestion of the US FDA guidance and the current active standards ASTM F2503 and IEC 62570 for device marking. The issued marking examples are no direct demand for their usage on any device and can be used in these or modified forms by the device manufacturer. The manufacturer is responsible for its device marking and is liable for any damages involved in the device marking and its usage. The authors or MR:comp shall not be held liable for the marking or any damages, which can result from the marking usage of any kind.

5. References

[1] R. Luechinger et al, "Material- and B_0-dependent scaling of torque effects", Proc. Intl. Soc. Mag. Reson. Med. 16 (2008)

[2] C. J. Yeung, R. C. Susil, E. Atalar; RF Safety of Wires in Interventional MRI: Using a Safety Index; Magn Reson Med 47:187–193, (2002)

[3] ASTM F2503-13, "Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment"; 2013, www.astm.org

[4] IEC 62570:2014 Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

[5] 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" and Amendments 1 and Amendment 2