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REPORT
Evaluation of Magnetic Field Interactions at 7-Tesla for the MRI Non Magnetic Stethoscope

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Product: 03-E1004 MRI Non Magnetic Stethoscope (Indicated in this report as "MRI Non Magnetic Stethoscope"), Magmedix, www.magmedix.com (**Figure 1**)

Test: Magnetic field interactions at 7-Tesla

Test site*:* MRI Center, University of Southern California Hospital, 1500 San Pablo Street, Los Angeles, CA 90033

IMPORTANT NOTE: The 7-Tesla MR system (MAGNETOM, Terra, Siemens Healthineers) approved by the Food and Drug Administration currently has a transmit/receive RF head and a transmit/receive RF knee coil. There is no transmit/receive RF body coil. During the intended use of the MRI Non Magnetic Stethoscope, this product is not implanted in the anatomic regions of the head or the knee. Therefore, the MRI testing performed on this product was limited to an assessment of magnetic field interactions, only. *Once a transmit/receive RF body coil becomes commercially available for this clinical scanner, it will be necessary to conduct*

further MRI testing to evaluate MRI-related heating and artifacts for the MRI Non Magnetic Stethoscope.

MAGNETIC FIELD INTERACTIONS

Testing for magnetic field interactions involved evaluations of translational attraction and torque for the MRI Non Magnetic Stethoscope using a 7-Tesla MR system. The MRI Non Magnetic Stethoscope that was evaluated was representative of the manufactured or "finished" version of this device. A single sample of this device was tested and deemed appropriate since there are insignificant variations due to manufacturing differences.

Translational Attraction

For the assessment of translational attraction, a test was conducted known as the "deflection angle test", which is described in the following document:
American Society for Testing and Materials (ASTM) Designation: F2052-15. Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment. ASTM International, West Conshohocken, PA.

MR system: A 7-Tesla (Terra, Siemens) active-shielded, scanner (**Figure 2**).

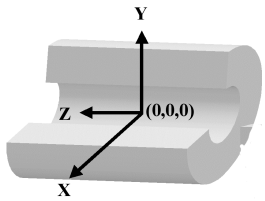
The MRI Non Magnetic Stethoscope was attached to a special non-metallic, test apparatus to measure the deflection angle in the MR system. The test fixture consisted of a sturdy structure capable of holding the device in position without movement and contained a protractor with 1˚-graduated markings, rigidly mounted to the structure. The 0˚ indicator on the protractor was oriented perpendicular. The test fixture also had a plastic bubble level attached to the top to ensure proper orientation in the MR system during the test procedure. Sources of forced air movement within the bore of the scanner were turned off during the measurements.

The MRI Non Magnetic Stethoscope was suspended from a thin, lightweight string (weight, less than 1% of the weight of the device) that was attached to the protractor (**Figure 3**). Motion of the string with the MRI Non Magnetic Stethoscope was not constrained by the support structure of the protractor.

Measurements of deflection angles for the MRI Non Magnetic Stethoscope were obtained in the 7-Tesla MR system. The test location was near the entrance of the MR system's bore, on the axis of the bore, which is within 20% of the maximum spatial gradient along the z-axis for this MR system. The value of the static magnetic field at the position where the translational attraction was determined for the MRI Non Magnetic Stethoscope was 5.0-Tesla and the spatial gradient magnetic field was 820-gauss/cm (personal communication, Bernd Stoeckel, Ph.D., Siemens Healthineers).

Note that the test apparatus was positioned so that the center of mass of the implant/device was at the test location. At this test location, the magnetically induced force, F_m, is horizontal and both B and ∇B act in the z-direction. At this position, the spatial gradients of the magnetic field have components in the z-direction, only.

The test fixture was positioned to record the deflection angle for the MRI Non Magnetic Stethoscope. The device was held on the test fixture so that the string was vertical and then released. The deflection angle for the MRI Non Magnetic Stethoscope from the vertical direction to the nearest 1-degree was measured three times and a mean value was calculated.



The coordinate system shown above references the MR system used for the tests in this report. The locations indicated in this report are referenced to this diagram. Note the orientations of the MR system with respect to the direction of the coordinates, X, Y, and Z. The X=0, Y=0, and Z=0 position, or "isocenter" is at the center of the MR system's magnet. At this isocenter location, the static magnetic field is homogeneous.

Qualitative Assessment of Torque

The next evaluation of magnetic field interaction was conducted to qualitatively determine the presence of magnetic field-induced torque for the MRI Non Magnetic Stethoscope, according to American Society for Testing and Materials (ASTM) International, F2213-17, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

The static magnetic field associated with an MR system produces a torque on a device that acts to align the long axis of the object with the direction of the magnetic field. Five methods for measurement or assessment of magnetically induced torque are given in the aforementioned standard: the Suspension Method, the Low Friction Surface Method, the Torsional Spring Method, the Pulley Method, and the Calculation Based on Measured Displacement Force Method.

In this assessment of torque for the MRI Non Magnetic Stethoscope, the Suspension Method was considered to be the most appropriate technique to use because the magnetically-induced torque was expected to be less than the torque due to gravity (i.e., based on the materials used to make the MRI Non Magnetic Stethoscope).

The Suspension Method is a qualitative technique that was performed by suspending the MRI Non Magnetic Stethoscope at its center of mass on a special apparatus by a lightweight string (i.e., the weight of the string was less than 1% of the weight of the MRI Non Magnetic Stethoscope and capable of holding it on the apparatus without breaking) while it was positioned at the isocenter of the 7-Tesla MR system. Importantly, the test apparatus with the MRI Non Magnetic Stethoscope was positioned in the center of the MR system, where the effect of torque from the static magnetic field of the scanner is known to be the greatest (i.e., based on a previous magnetic field survey and the well-known characteristics of the horizontal field 7-Tesla MR system that was used for this

evaluation).

The MRI Non Magnetic Stethoscope was rotated in defined angular increments (i.e., at 45 degrees increments for a total of 360 degrees) while possible movement or rotation of the MRI Non Magnetic Stethoscope to align with the direction of the static magnetic field was observed. Importantly, if rotation of the MRI Non Magnetic Stethoscope was not observed, the magnetically induced torque is considered to be relatively small and no further evaluation would be required.

Thus, the MRI Non Magnetic Stethoscope was attached to the test apparatus that permitted it to freely rotate or move relative to the direction static magnetic field of the 7-Tesla MR system. Notably, the investigator was slightly inside the bore of the MR system in order to carefully observe this test procedure as it was applied to the MRI Non Magnetic Stethoscope. The entire procedure was conducted three times for the MRI Non Magnetic Stethoscope. The results were determined to be either Negative or Positive. A negative result indicated that no additional characterization of torque was required for the MRI Non Magnetic Stethoscope.

RESULTS AND DISCUSSION

Table 1 summarizes the results of the tests performed to determine magnetic field interactions for the MRI Non Magnetic Stethoscope. The findings for translational attraction for the MRI Non Magnetic Stethoscope was 4-degrees.

This information should be considered in view of the deflection angle measurement recommendation provided by the ASTM, which states: "If the device deflects less than 45˚, then the magnetically induced deflection force is less than the force on the device due to gravity (its weight). For this condition, it is assumed that any risk imposed by the application of the magnetically induced force is no greater than any risk imposed by normal daily activity in the Earth's gravitational field."

Therefore, the MRI Non Magnetic Stethoscope that underwent testing passed the ASTM acceptance criteria for deflection angle with respect to exposure to the 7-Tesla MR system used in this evaluation. The MRI Non Magnetic Stethoscope will not present an additional risk or hazard to a patient in the 7-Tesla MRI environment with regard to translational attraction or migration.

Using the Suspension Method relative to exposure to the 7-Tesla MR system, there was no movement or alignment detected for the MRI Non Magnetic Stethoscope. Therefore, the magnetically induced torque is not substantial and no further evaluation of the MRI Non Magnetic Stethoscope is necessary. Notably, the MRI Non Magnetic Stethoscope will not present an additional risk or hazard to a patient in the 7-Tesla MRI environment or less with regard to torque.

Extrapolation of Higher Spatial Gradient Magnetic Field Value

Because the value of the deflection angle was relatively low (i.e., 4-degrees), it is possible and acceptable to extrapolate to a higher spatial gradient magnetic field value

for the MRI labeling of the MRI Non Magnetic Stethoscope according to the following calculation:

Delta Bc = 820-gauss/cm (spatial gradient magnetic field value used for the deflection angle test) (5.0-Tesla (value of the static magnetic field at the point of the positioning of the protractor for the deflection angle test)/7.0-Tesla (value of the static magnetic field of the MR system)* [Tan 45-degrees (1) / Tan 4-degrees 0.0699]= 8,372-gauss/cm. With a margin of safety included, the value would be 8,000-gauss/cm (55-T/m.

Recommended MRI labeling based on the document, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, Guidance for Industry and Food and Drug Administration Staff, Document issued on May 20, 2021.

MRI Safety Information

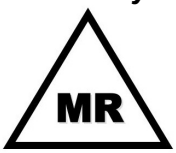
MR Conditional

The **MRI Non Magnetic Stethoscope** is MR Conditional. The MRI Non Magnetic Stethoscope may be safely scanned under the following conditions.

Name of the Device	MRI Non Magnetic Stethoscope
Static Magnetic Field (T)	7-T or less
Maximum Spatial Field Gradient (T/m and gauss/cm)	80-T/m (8,000-gauss/cm)

Recommended MRI labeling based on the document, American Society of Testing and Materials, International, ASTM F2503-20. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

MRI Safety Information



MR Conditional

Non-clinical testing demonstrated that the MRI Non Magnetic Stethoscope is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 7-Tesla, or less
- Maximum spatial gradient magnetic field of 8,000-Gauss/cm (80-T/m)

The recommended labeling information is provided as an example of proper labeling for this product based on the latest information from the Food and Drug Administration and the American Society for Testing and Materials (ASTM) International, Designation: F2503-13. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. The issued labeling may be modified by the manufacturer, as needed. The manufacturer of this product is ultimately responsible and liable for damages involved in the use of the MRI-related labeling. The author or Shellock R & D Services, Inc. shall not be held liable for the product labeling or damages related to the use of this labeling.

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Table 1. Evaluation of magnetic field interactions at 7-Tesla for the MRI Non Magnetic Stethoscope.

Deflection Angle (degrees)

Measurement #1	4
Measurement #2	4
Measurement #3	4

Deflection Angle (degrees, m ± SD)

4 ± 0

Torque

Device angle to field	Measurement 1	Measurement 2	Measurement 3
45	Negative	Negative	Negative
90	Negative	Negative	Negative
135	Negative	Negative	Negative
180	Negative	Negative	Negative
225	Negative	Negative	Negative
270	Negative	Negative	Negative
315	Negative	Negative	Negative
360	Negative	Negative	Negative

FIGURE 1. The sample of the MRI Non Magnetic Stethoscope that underwent MRI testing.

FIGURE 2. The 7-Tesla MR system used for MRI testing.

FIGURE 3. The deflection angle test conducted at 7-Tesla on the MRI Non Magnetic Stethoscope. Note the deflection angle of 4-degrees.