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**REPORT**  
**Evaluation of Magnetic Field Attraction for the**  
**3G Transducer and Transducer Mount**

***Project Conducted by:***  
**Frank G. Shellock, Ph.D.**

A handwritten signature in black ink, appearing to read "Frank G. Shellock".

**01/14/18**

***Presented to:***  
**Spencer Howe**  
**MRIAUDIO, Inc.**  
**2720 Loker Avenue West, Suite N**  
**Carlsbad, CA 92010**

**Product:** 3G Transducer and Transducer Mount (combined), MRIAudio, Inc. (**Figure 1**)

**Tests:** Magnetic field attraction at 3-Tesla

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

**IMPORTANT NOTE:** The 3G Transducer and Transducer Mount are intended for use inside of the MRI environment (e.g., in the MR system room, close to the scanner). However, these parts are not intended for use directly inside of the MR system (e.g., inside of the bore of the scanner), itself. During the intended use, the 3G Transducer and Transducer Mount (combined) are securely mounted to the floor close to the front of the MR system. Therefore, testing was performed with that information taken into consideration. Thus, The 3G Transducer and Transducer Mount were assessed for attraction to a 3-Tesla MR system at the distances of 2-, 3-, 4-, and 5-feet from the front of the bore and on the floor 1-foot (on the side) relative to the MR system, representing

worst-case positioning scenarios where these parts may be utilized according to their intended use.

*MR system:* A 3-Tesla (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) active-shielded, scanner was used for the assessments of magnetic field interactions (**Figure 2**).

### **MAGNETIC FIELD ATTRACTION**

Testing for magnetic field attraction for the 3G Transducer and Transducer Mount (combined) was conducted with regard to exposure to a 3-Tesla MR system.

Prior to exposure to the MRI environment, the 3G Transducer and Transducer Mount (combined) were thoroughly evaluated using a powerful hand-held magnet to determine the presence of ferromagnetism for any metallic component or part.

For the formal assessment of magnetic field interaction, the 3G Transducer and Transducer Mount (combined) were assessed by applying a rope securely around the devices. The end of the rope was tethered a suitable distance from the 3-Tesla MR system to prevent the 3G Transducer and Transducer Mount from becoming projectiles in the event that substantial magnetic field interaction was present.

The 3G Transducer and Transducer Mount (combined) were slowly moved towards the MR system in a methodical, incremental manner with an emphasis on positions of the 3-Tesla scanner. A small amount of “slack” was intentionally allowed in the rope so that any magnetic field attraction could be readily detected. Photographs were obtained to document this procedure and are included in this report.

Next, the 3G Transducer and Transducer Mount were then rotated 180 degrees (i.e., perpendicular to the direction of the horizontal static magnetic field) relative to the bore of the MR system at those same positions relative to the 3-Tesla MR system. This was done to qualitatively determine if there was any influence of the static magnetic field on the position of the 3G Transducer and Transducer Mount (combined), or if they attempted to “align” to the magnetic field (i.e., another indication that “positive” magnetic field interactions were present). Photographs were taken to illustrate the tests that were performed on the product.

The following qualitative scale was applied to the results:

0, no magnetic field interaction

+1, mild magnetic field interaction, the device slowly changed orientation or moved relative to the static magnetic field

+2, moderate magnetic field interaction, the device moved gradually relative to the static magnetic field and moved into the bore of the MR system

+3, strong magnetic field interaction, the device showed rapid and forceful movement towards the static magnetic field and moved into the bore of the MR system

+4, very strong magnetic field interaction, the device showed very rapid and very forceful movement relative to the static magnetic field and moved into the bore of the MR system

## **RESULTS AND DISCUSSION**

The results of the tests performed to determine magnetic field attractions for the 3G Transducer and Transducer Mount at the distances of 2- 3-, 4-, and 5-feet from the front of the bore of the scanner and on the floor 1-foot (on the side) relative to the 3-Tesla MR system, indicated that the qualitative assessment of magnetic attraction was 0, no magnetic field interaction in each case. Furthermore, at the distances of 2- 3-, 4-, and 5-feet from the front of the bore and on the floor 1-foot (on the side) relative to the MR system, there was no evidence of rotation or alignment.

Thus, this evaluation demonstrated that the 3G Transducer and Transducer Mount are considered to be MR Conditional according to their intended use.

## RECOMMENDED MRI LABELING BASED ON THE TEST RESULTS

### *MRI Safety Information*



### **MR Conditional**

Non-clinical testing demonstrated that the 3G Transducer and Transducer Mount (combined) are MR Conditional under the following conditions:

- Static magnetic field of 3-Tesla or less.

**IMPORTANT NOTE:** The 3G Transducer and Transducer Mount (combined) are intended for use inside of the MRI environment (e.g., in the MR system room, close to the scanner). However, these parts are not intended for use directly inside of the MR system (e.g., inside of the bore of the scanner), itself. During the intended use, the 3G Transducer and Transducer Mount must be securely mounted to the floor close to the front of the MR system according to the instructions in the Installation Manual.

### **Disclaimer**

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 Sherlock R & D Services, Inc. shall not be held liable for the product labeling or damages related to the use of this labeling.

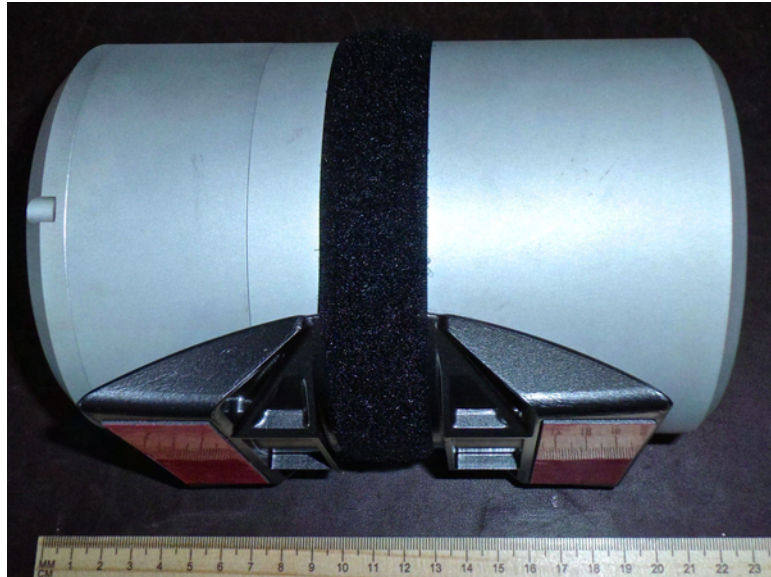
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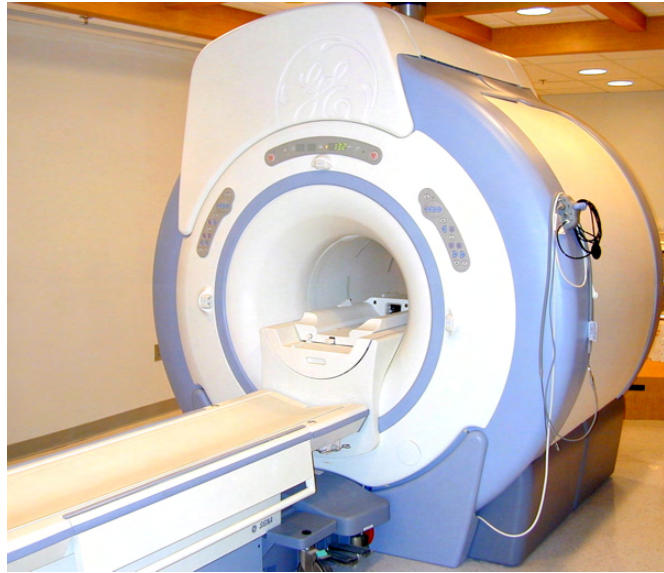
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**FIGURE 1. The 3G Transducer and Transducer Mount (combined) that underwent testing for magnetic field attraction at 3-Tesla.**

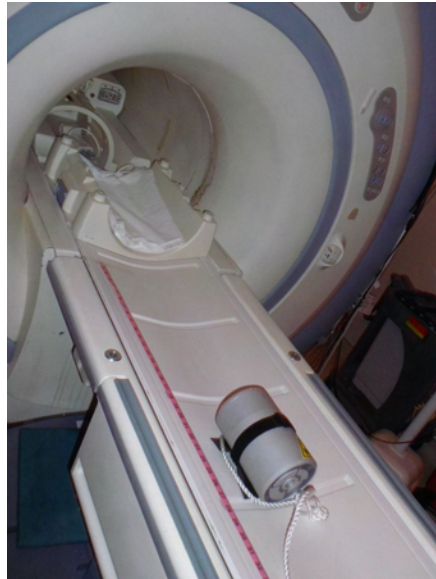


**FIGURE 2. The 3-Tesla MR system used for MRI testing.**



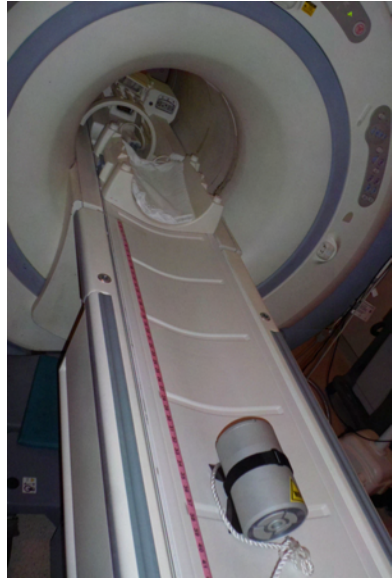
**FIGURE 3. Testing the 3G Transducer and Transducer Mount (combined) at distances of 2- 3-, 4-, and 5-feet from the front of the bore of the scanner and on the floor 1-foot (on the side) from the scanner. Note the lack of magnetic field translational attraction for 3G Transducer and Transducer Mount (combined) in each case, as evidenced by the slack in the rope that was attached to this device. This demonstrates that there was no magnetic field attraction at 3-Tesla for the 3G Transducer and Transducer Mount (combined) when in the positions indicated above.**

**2-feet**

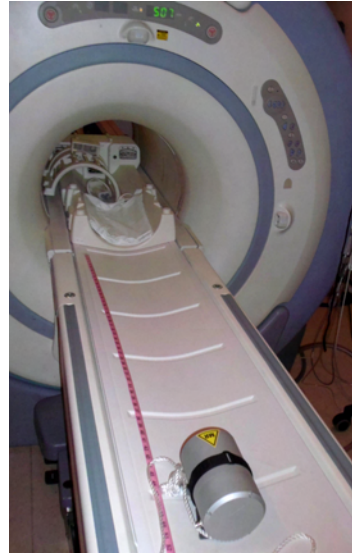




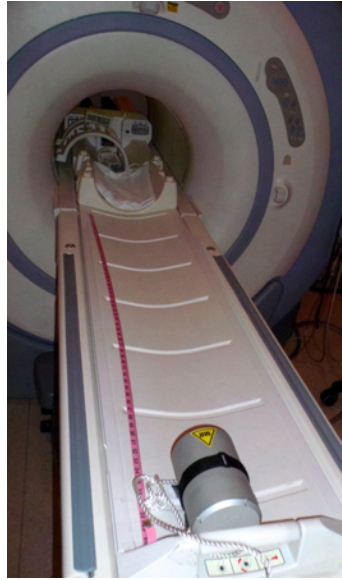
**3-feet**



**4-feet**



**5-feet**



**1-foot, floor**

