SHELLOCK
R & D SERVICES, INC.

7511 McConnell Avenue
Los Angeles, CA 90045
(310) 670-7095 voice (310) 417-8639 fax
www.MagneticResonanceSafetyTesting.com

REPORT
Magnetic Field Interaction Testing Conducted at 7-Tesla on Products from Amerex

Project Conducted by:
Frank G. Shellock, Ph.D.
Shellock R & D Services, Inc.
7511 McConnell Ave.
Los Angeles, CA 90045

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Presented to:
Marc Stewart
Amerex Corporation
P.O. Box 81, 7595 Gadsden Highway
Trussville, AL 35173-0081

This report pertains to magnetic field interaction testing conducted at 7-Tesla on the following products from Amerex Corporation:

1. Model B270NM 6-Liter Water Mist Extinguisher

2. Model B272NM 2.5-Gallon Water Mist Extinguisher

3. Model 322NM 5.0-LB CO_2 Extinguisher

4. Model 801 NM 17737 Bracket

5. Model 810 NM 06572 Bracket

6. Model 816 NM 14315 Bracket

According to information form the Amerex Corporation, these products are made from non-magnetic or weakly magnetic materials and are intended for use in a high magnetic

field environment such as that associated with a magnetic resonance (MR) system.

NOTE: These products are intended for use inside of the MRI environment (e.g., in the MR system room, close to the scanner). However, they will not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), itself. As such, the assessment of magnetic field interactions for these fire extinguishers specifically involved a qualitative evaluation of translational attraction to the powerful magnetic field of a 7-Tesla MR system, *only.*

A limited, qualitative assessment of the functional aspects of the fire extinguishers was also conducted. That is, each fire extinguisher was "activated" for approximately 5-seconds while in close proximity (within 2 feet) to the 7-Tesla MR system.

MAGNETIC FIELD INTERACTIONS

The tests for magnetic field interactions for the products were conducted with regard to exposure to a shielded, 7-Tesla MR system (General Electric Medical Systems, Milwaukee, WI). The highest spatial gradient for this 7-Tesla MR system is approximately 1,500 gauss/cm.

For the assessment of magnetic field interactions, each item was first tested using a powerful hand-held magnet to determine the possible presence of magnetic field interactions. This testing yielded negative results in each case.

For the fire extinguishers, each fire extinguisher was first assessed by applying a nylon rope securely around the device. The end of the rope was tethered a suitable distance from the 7-Tesla MR system to prevent the fire extinguisher from becoming a projectile in the event that substantial magnetic field interactions were present.

Each fire extinguisher was slowly moved towards the 7-Tesla MR system in a methodical, incremental manner. Accordingly, each product was placed as close as possible relative to the opening of the bore of the 7-Tesla MR system.

A small amount of "slack" was intentionally allowed in the rope so that any magnetic field interactions could be readily detected (i.e., as the slack would be quickly taken up if the fire extinguisher was attracted by the 7-Tesla MR system).

Accordingly, each fire extinguisher was brought up to the entrance of the bore of the 7-Tesla MR system, which is essentially considered to be a "worst-case" position for a device used externally to the MR system. Photographs were taken in order to illustrate the tests performed on these devices (see attached).

The above testing was also performed on the following bracket: Model 810 NM 06572 Bracket. The other wall brackets underwent testing using the deflection angle measurement technique described later in this report.

The presence of eddy currents was assessed for these relatively large products by moving it around the entrance of the bore of the 7-Tesla MR system. The following qualitative scale was applied to the eddy current assessment:

0, No eddy currents
+1, Mild eddy currents, slight sensation of resistance during product movement
+2, Moderate eddy currents, moderate sensation of resistance during product movement
+3, High eddy currents, high sensation of resistance during product movement
+4, Very high eddy currents, very high sensation of resistance during product movement

Finally, each fire extinguisher was "activated" for a period of approximately 5-seconds to qualitatively assess its function.

Results and Discussion

The following results were noted:

Product	**Results**
Model B270NM 6-Liter Water Mist Extinguisher	No magnetic field interactions
Model B272NM 2.5-Gallon Water Mist Extinguisher	No magnetic field interactions
Model 322NM 5.0-LB CO_2 Extinguisher	No magnetic field interactions
Model 810 NM 06572 Bracket	No magnetic field interactions

Accordingly, there were no "free movements" (i.e., no evidence of translational attraction, rotation, or alignment) seen for these fire extinguishers and the bracket that underwent testing with respect to exposure to the 7.0-Tesla MR system.

Each product indicated above exhibited eddy currents at the +4 level (i.e., Very high eddy currents, very high sensation of resistance during product movement).

Each fire extinguisher was successfully activated for 5-seconds during exposure to the 7-Tesla MR system. There was no evidence of problems with this procedure.

Recommendations

During exposure to the 7-Tesla MR system, there were no qualitative signs of magnetic field interactions for the following:

Model B270NM 6-Liter Water Mist Extinguisher
Model B272NM 2.5-Gallon Water Mist Extinguisher
Model 322NM 5.0-LB CO_2 Extinguisher
Model 810 NM 06572 Bracket

Therefore, given the "intended use" of these specific types of fire extinguishers and the bracket (i.e., to be positioned outside of the MR system, but brought into the 7-

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Tesla MR system room to extinguish a fire), they should be considered MR conditional for use in an MRI environment associated with MR systems operating at 7-Tesla or less. It should be noted that the test results are specific to the 7-Tesla MR system utilized in this assessment of magnetic field interactions.

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MRI Information

MR Conditional

The following products were determined to be MR conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment:

Model B270NM 6-Liter Water Mist Extinguisher
Model B272NM 2.5-Gallon Water Mist Extinguisher
Model 322NM 5.0-LB CO_2 Extinguisher
Model 810 NM 06572 Bracket

Non-clinical testing demonstrated that each product is MR Conditional and can be used in the MRI environment according to the following conditions:

-Static magnetic field of 7-Tesla or less

-Spatial gradient magnetic field of 1,500-Gauss/cm or less

NOTE: These products are intended for use inside of the MRI environment (e.g., in the MR system room, close to the scanner). However, they will not be utilized directly inside of the MR system (e.g., inside of the bore of the scanner), itself. As such, the assessment of magnetic field interactions for these fire extinguishers specifically involved a qualitative evaluation of translational attraction to the powerful magnetic field of a 7-Tesla MR system, *only*.

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IMPORTANT NOTE: If you plan to use this information for labeling or promotion of these fire extinguishers as being "non-magnetic" or for use in the MRI environment, please provide me with the content to review in order to ensure proper presentation of the information.

DISCLAIMER

The information in this report is provided without warranty of any kind, either expressed or implied including without the limitation of implied warranties of merchantability and fitness for a particular purpose. The author of this report, Magnetic Resonance Safety Testing Services, and Shellock R & D Services, Inc. shall not be held liable for any direct, indirect, consequential, special or other damages suffered by the manufacturer of the device or product or by other parties, as a result of the use of the report results, data, or other deliverables.

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Figure 1. The products that underwent MRI testing in the 7-Tesla MRI environment.

Model B270NM 6-Liter Water Mist Extinguisher

Model B272NM 2.5-Gallon Water Mist Extinguisher

Model 322NM 5.0-LB CO_2 Extinguisher

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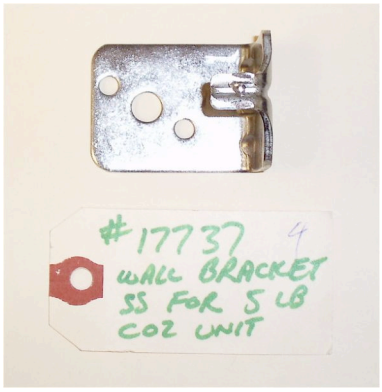
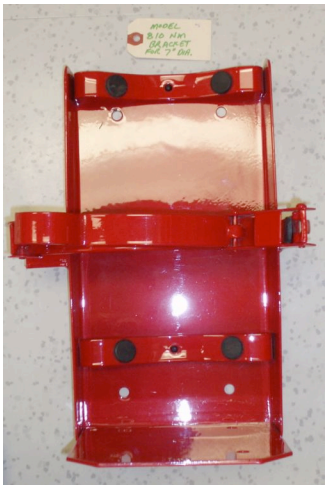
Figure 1. Continued



Model 801 NM 17737 Bracket



Model 810 NM 06572 Bracket

Model 816 NM 14315 Bracket

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Figure 2. Testing the products for magnetic field interactions during exposure to a 7-Tesla MR system. Note the lack of magnetic field translational attraction for these products as illustrated by the slack in the rope used to tether each item in the 7-Tesla MRI environment.

Model B270NM 6-Liter Water Mist Extinguisher

Model B272NM 2.5-Gallon Water Mist Extinguisher

Model 322NM 5.0-LB CO_2 Extinguisher

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Figure 2. Continued

Model 810 NM 06572 Bracket

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Tests for magnetic field interactions for each product were conducted with regard to exposure to a 7-Tesla MR system as previously described.

For the formal assessment of magnetic field interactions, each product was evaluated using the deflection angle test to determine magnetic qualities.

The deflection angle test was conducted using the procedure described in the following publications:
(1) American Society for Testing and Materials (ASTM) Designation: F 2052. Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment. In: Annual Book of ASTM Standards, Section 13, Medical Devices and Services, Volume 13.01 Medical Devices; Emergency Medical Services. West Conshohocken, PA, pp; 1576-1580.
(2) Shellock FG, Morisoli SM. Ex vivo evaluation of ferromagnetism, heating, and artifacts for heart valve prostheses exposed to a 1.5 Tesla MR system. Journal of Magnetic Resonance Imaging. 4:756-758, 1994.
(3) Shellock FG, Detrick MS, Brant-Zawadski M. MR-compatibility of Guglielmi detachable coils. Radiology. 203: 568-570, 1997
(4) Edwards, M-B, Taylor KM, Shellock FG. Prosthetic heart valves: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. Journal of Magnetic Resonance Imaging. 12:363-369, 2000.
(5) Shellock FG, Shellock VJ. Stents: Evaluation of MRI safety. American Journal of Roentgenology 173:543-546, 1999.
(6) Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.
(7) Shellock FG. Biomedical implants and devices: assessment of magnetic field interactions with a 3.0-Tesla MR system. Journal of Magnetic Resonance Imaging. 16:721-732, 2002.

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Each item was attached to a special test fixture 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 vertically. The test fixture had a plastic bubble level attached to the top to ensure proper orientation in the MR system. Sources of forced air movement within the MR system bore were turned off during the measurements.

Each item was suspended from a thin, lightweight string (weight, less than 1% of the weight of the device) that was attached at the 0˚ indicator position on the protractor. The length of the string was 20-cm, which was long enough so that the device could be suspended from the test fixture and hang freely in space.

Measurements of deflection angles were obtained at the position in the 7-Tesla MR system that produced the greatest magnetically induced deflection.

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

RESULTS AND DISCUSSION

The findings for translational attraction for the brackets were as follows:

Model 801 NM 17737 Bracket 67-degrees

Model 816 NM 14315 Bracket 78-degrees

This information should be considered in view of the deflection angle measurement recommendation provided by the ASTM, which states:

If the implant (device) deflects less than 45˚, then the magnetically induced deflection force is less than the force on the implant 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, these products that underwent testing ***failed*** the ASTM acceptance criteria for deflection angle with respect to exposure to the 7-Tesla MR system used in this evaluation.

However, what must also be taken into consideration is the intended use of these products, which will be retained in position using some form fixation means, such as screws and bolts. As such, these retention mechanisms are likely to prevent these products from posing issues in a 7-Tesla or less environment. *Proper labeling to ensure that these brackets do not become a projectile in a 7-Tesla environment is required.*

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