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REPORT
Evaluation of Magnetic Field Interactions, Heating, and Artifacts at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33

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Presented to:
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EXECUTIVE SUMMARY

Based on the MRI testing information, the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 will not present an additional hazard or risk to a patient undergoing an MRI procedure using a scanner operating with a static magnetic field of 3-Tesla or less and under the MRI-related heating conditions (MRI for 15-min. at an MR system reported whole body averaged specific absorption rate, SAR, value of 2.9-W/kg) used for this evaluation. The artifacts for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 may present problems if the MR imaging area of interest is in or near the area of where this device is located. The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 is considered “MR-conditional” according to the specific conditions used for this assessment (see attached recommended labeling incorporating the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International).

For medical implants and devices, the objectives of magnetic resonance imaging (MRI) testing are to determine the presence of magnetic field interactions, heating, and artifacts in association with the use of an MR system. Accordingly, assessments of magnetic field interactions (deflection angle and torque), MRI-related heating, and artifacts were conducted at 3-Tesla on the following:

Product Name: On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33, On-X Life Technologies, Inc., Austin, TX **(Figure 1)**

Materials:
-unalloyed pyrolytic carbon (outer coating on valve orifice substrate and leaflet substrates of graphite carbon)
-10 weight Tungsten particles in a graphite substrate (for radio-opacity in the valve leaflets)
-TI-6-4 ELI titanium (6% vanadium 4 % aluminum) meets specification ASTM F136 for bands to attach valve sewing ring to valve orifice
-woven PTFE (Teflon) for sewing ring
-braided polyester suture sizes 2-0 and 5-0 in the sewing ring

Intended use: Heart valve replacement in the mitral position

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

MAGNETIC FIELD INTERACTIONS

Testing for magnetic field interactions involved evaluations of translational attraction and torque for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 using a 3-Tesla MR system.

Translational Attraction

For the assessment of translational attraction, a test was conducted known as the “deflection angle test”, which is described in the following publications:

(1) American Society for Testing and Materials (ASTM) Designation: F 2052-06e1. 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.
(8) Shellock FG, Gounis M, Wakhloo A. Detachable coil for cerebral aneurysms: *In vitro* evaluation of magnet field interactions, heating, and artifacts at 3-Tesla. American Journal of Neuroradiology 2005;26:363-366.
(9) Shellock FG, Valencerina S. In vitro evaluation of MR imaging issues at 3-T for aneurysm clips made from MP35N: Findings and information applied to 155 additional aneurysm clips. AJNR Am J Neuroradiology 2009 Dec 24. [Epub ahead of print]

The American Society for Testing and Materials (ASTM) International Designation: F2052-06e1, Standard test method for measurement of magnetically induced displacement force on passive implants in the magnetic resonance environment was carefully followed for this test.

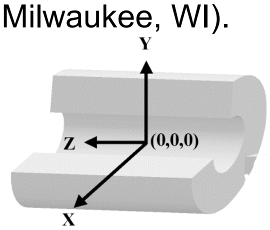
MR system: 3-Tesla, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner (**Figure 2**).

The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 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 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 MR system bore were turned off during the measurements.

The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 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 (**Figure 3**). Motion of the string with the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was not constrained by the support structure of the protractor.

Measurements of deflection angles for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 were obtained at the position in the 3-Tesla MR system that produced the greatest magnetically induced deflection. This point was determined for the MR system using gauss line plots, measurements, and visual inspection to identify the location where the spatial magnetic field gradient was the greatest. The location was marked by tape to facilitate measurements of the deflection angles for this device.

The direction of the magnetic field for the 3-Tesla scanner is horizontal. The highest spatial gradient for the 3-Tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI) occurs at an off-axis position that is 74-cm from isocenter of the scanner. The magnetic spatial gradient at this position is 720 gauss/cm (Personal Communication, Dewain Purgill and Daniel J. Schaefer, General Electric Healthcare, Milwaukee, WI).



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 positions, or “isocenter” is at the center of the MR system’s magnet. At this location, the magnetic field is homogeneous and the static spatial magnetic gradients are effectively zero (0).

The test fixture was positioned to record the highest deflection angle for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. The device was held on the test fixture so that the string was vertical and then released. The deflection angle for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve

Prosthesis; Size 25-33 from the vertical direction to the nearest 1-degree was measured three times and a mean value was calculated.

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 On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. This procedure involved the use of a flat plastic material with a grid on the bottom.

The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was placed on the test apparatus in an orientation that was 45-degrees relative to the static magnetic field of the 3-Tesla MR system **(Figure 4)**. The use of 45-degree increments is deemed appropriate for a qualitative assessment of torque for an implant or device, based on reports published in the peer-reviewed literature (see reference list below).

The test apparatus with the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was positioned in the center of the MR system, where the effect of torque from the static magnetic field was determined to be the greatest (i.e., based on a previous magnetic field survey and the well-known characteristics of the 3-Tesla MR system with a horizontal magnetic field used for this evaluation).

The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was directly observed for possible movement with respect to alignment or rotation relative to the static magnetic field of the 3-Tesla MR system. Having the investigator inside the bore of the MR system during the test procedure facilitated the observation process. The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was then moved 45 degrees relative to its previous position and again observed for alignment or rotation. This process was repeated to encompass a full 360 degrees rotation of positions for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 in the 3-Tesla MR system. The entire procedure was conducted three times and a mean value was calculated for the device with it orientated along its long axis and short axis.

The following qualitative scale of torque was applied to the results: 0, no torque; +1, mild or low torque, the device slightly changed orientation but did not align to the magnetic field; +2, moderate torque, the device aligned gradually to the magnetic field; +3, strong torque, the device showed rapid and forceful alignment to the magnetic field; +4, very strong torque, the device showed very rapid and very forceful alignment to the magnetic field.

Peer-reviewed, scientific publications that support performance of the test to qualitatively assess magnetic-field related torque for a metallic implant or device in association with an MR system are, as follows:
(1) Shellock FG, Detrick MS, Brant-Zawadzki MN. MR compatibility of Guglielmi detachable coils. Radiology 203:568-570, 1997.

(2) Shellock FG, Shellock VJ. MR-compatibility evaluation of the Spetzler titanium aneurysm clip. Radiology. 206:838-841, 1998.
(3) Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. Radiology. 207:822-825, 1998.
(4) Shellock FG, Kanal E. Yasargil aneurysm clips: evaluation of interactions with a 1.5 Tesla MR system. Radiology. 207:587-591, 1998.
(5) Kanal E, Shellock FG. Aneurysm clips: effects of long-term and multiple exposures to a 1.5 Tesla MR system. Radiology. 210:563-565, 1999.
(6) Shellock FG, Shellock VJ. Stents: Evaluation of MRI safety. American Journal of Roentgenology. 173:543-547, 1999.
(7) 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.
(8) Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.
(9) 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.
(10) Shellock FG, Gounis M, Wakhloo A. Detachable coil for cerebral aneurysms: *In vitro* evaluation of magnet field interactions, heating, and artifacts at 3-Tesla. American Journal of Neuroradiology 2005;26:363-366.

Important Note: According to the American Society for Testing and Materials (ASTM) International, F2213-06, Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment,

> "There are other possible methods for evaluation of the magnetic torque on an implant in the magnetic resonance environment."

Therefore, the above-indicated procedure is considered to be one such method that is acceptable for the evaluation of torque for a metallic implant or device. Notably, there is substantial support in the peer-reviewed literature for the qualitative torque measurement method utilized in this report (see reference list indicated above).

RESULTS AND DISCUSSION

Table 1 summarizes the results of the tests performed to determine magnetic field interactions for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. The findings for translational attraction for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was 1-degree.

Please be advised that, for this device, the highest deflection angle occurred at the same point of the highest spatial magnetic gradient for the MR system used for this study.

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

"If the implant 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, the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 that underwent testing passed the ASTM acceptance criteria for deflection angle with respect to exposure to the 3-Tesla MR system used in this evaluation. The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment with regard to translational attraction or migration.

The qualitatively measured torque at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was 0, no torque. As such, this device will not present an additional risk or hazard to a patient in the 3-Tesla MRI environment or less with regard to torque.

Importantly, because of the minor amount of translational attraction (deflection angle, 1-degree) and no torque (qualitatively determined) at 3-Tesla, it is deemed unnecessary to conduct a quantitative evaluation of torque for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

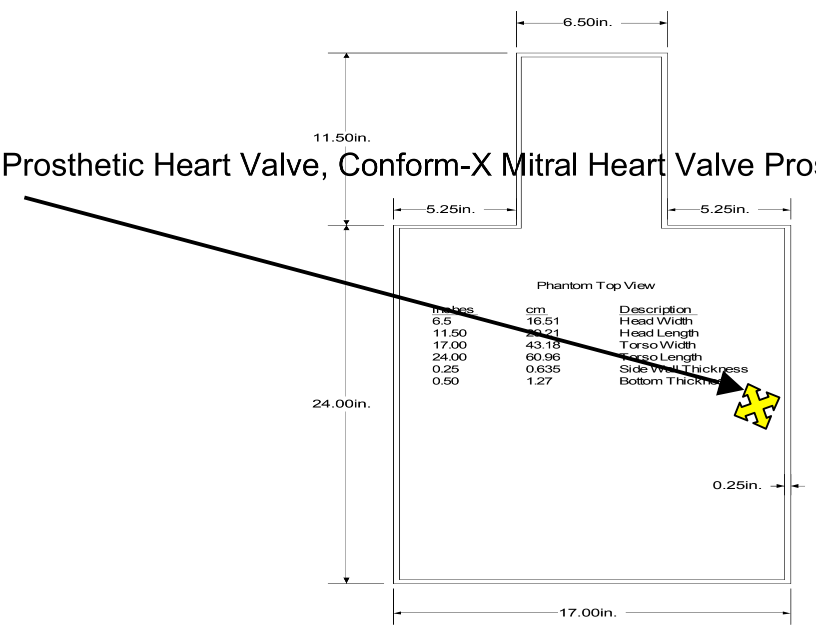
MRI-RELATED HEATING

This report pertains to the MRI-related heating test conducted at 3-Tesla on the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. MRI-related heating was assessed for this device according to recommendations in the following document:

American Society for Testing and Materials International, Designation F 2182–09 Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging, ASTM International, 2009.

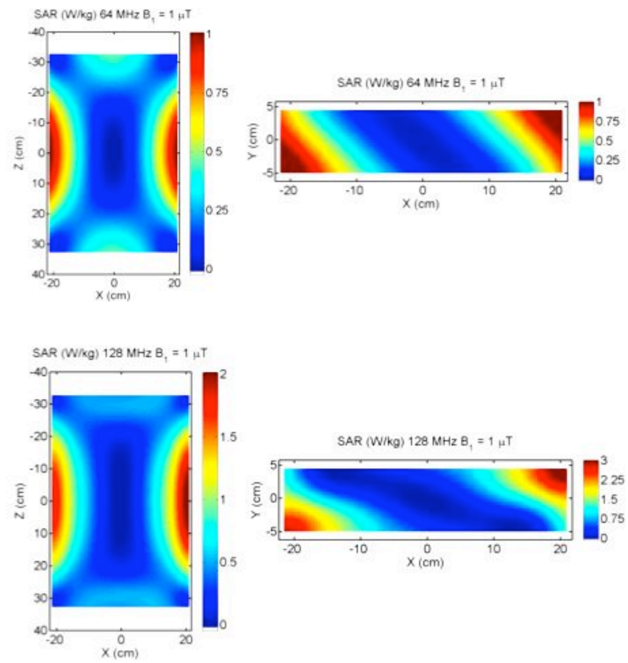
Preparation of the Phantom. A plastic phantom was filled with a semi-solid, gelled-saline (prepared according to ASTM F 2182-09) that was prepared to simulate human tissue.

The ASTM head/torso phantom has a configuration and dimensions to approximate the human head and torso, as follows (also, note, the position of the device marked by the "X" to create worst case placement based on an analysis of this ASTM head/torso phantom):



Comments on Positioning, 3-Tesla: The device was placed in the ASTM head/torso phantom at a position mid-line on the left side, slightly (5-mm) below the mid-depth (vertical orientation) of the gelled-saline. For this particular 3-Tesla/128-MHz MR system and experimental set up, the left side of the ASTM head/torso phantom was found to be associated with a greater temperature rise than the right side of the head/torso phantom for a given implant or device. Therefore, the device was placed on the left side of the ASTM head/torso phantom to yield the worst-case temperature rise for the described measurement conditions, based on prior analysis of device heating for this particular MR system (i.e., due to asymmetry in heating patterns for this phantom and MR system).

With further regard to this MRI-related heating assessment, supporting the SAR distribution in the ASTM head/torso phantom, this has been carefully analyzed by Professor John Nyenhuis, Purdue University, presenting the findings below showing to the SAR distribution in this phantom:



SAR distribution for the ASTM phantom in the coronal (left) and axial (right) mid-planes in circularly polarized birdcage coils. Top plots are for 64 MHz and lower plots are for 128 MHz. Phantom average SAR is 0.32 W/kg at 64 MHz and 0.63 W/kg at 128 MHz.

Please refer to the following publications that address the issue of implant placement as well as that related to asymmetry of implant heating during MRI:

Amjad A, Kildishev AV, Park SM and Nyenhuis JA. Power deposition inside of a phantom for testing MRI heating. IEEE Transactions on Magnetics 2005;41:4185-4187.

Nordbeck P, Fidler F, Weiss I, Warmuth M, et al. Spatial distribution of RF-induced E-fields and implant heating in MRI. Magn Reson Med. 2008;60:312-9.

Langman DA, et al. Asymmetric pacemaker lead tip heating along the x-axis in 1.5-T and 3-T MR systems. Proceedings of the International Society for Magnetic Resonance in Medicine 2007:15:1079.

Park SM, Kamondetdacha R, Nyenhuis JA. Calculation of MRI-induced heating of an implanted medical lead wire with an electric field transfer function. J Magn Reson Imaging. 2007;26:1278-85.

Small plastic posts were placed in the plastic frame to guide and maintain the positions of the fluoroptic thermometry probes used to record temperatures (i.e., on the device).

This basic experimental set-up for the evaluation of MRI-related heating of an implant has been previously described in the peer-reviewed literature and used for many assessments of implant heating related to MRI procedures. For example, see:

Mattei E, Triventi M, Calcagnini G, Censi F, Kainz W, Bassen HI, Bartolini P. Temperature and SAR measurement errors in the evaluation of metallic linear structures heating during MRI using fluoroptic probes. Phys Med Biol. 2007 Mar 21;52(6):1633-46.

Triventi M, Mattei E, Calcagnini G, Censi F, Bartolini P, Kainz W, Bassen H. Magnetic-resonance-induced heating of implantable leads. Ann Ist Super Sanita. 2007;43:229-40.

Mattei E, Triventi M, Calcagnini G, Censi F, Kainz W, Mendoza G, Bassen HI, Bartolini P. Complexity of MRI induced heating on metallic leads: experimental measurements of 374 configurations. Biomed Eng Online. 2008 Mar 3;7(1):11

Rezai AR, Finelli D, Nyenhuis JA, Hrdlick G, Tkach J, Ruggieri P, Stypulkowski PH, Sharan A, Shellock FG. Neurostimulator for deep brain stimulation: Ex vivo evaluation of MRI-related heating at 1.5-Tesla. Journal of Magnetic Resonance Imaging, 15:241-250, 2002.

Finelli DA, Rezai AR, Ruggieri P, Tkach J, Nyenhuis J, et al. MR-related heating of deep brain stimulation electrodes: an *in vitro* study of clinical imaging sequences. American Journal of Neuroradiology, 23:1795-1802, 2002.

Sharan A, Rezai AR, Nyenhuis JA, et al. MR safety in patients with implanted deep brain stimulation systems (DBS). Acta Neurochir Suppl. 87:141–145, 2003.

Park SM, Nyenhuis JA, Smith CD, Lim EJ, Foster KS, et al. Gelled vs. nongelled phantom material for measurement of MRI-induced temperature increases with bioimplants. IEEE Transactions on Magnetics, 39:3367-3371, 2003.

Shellock FG, Cosendai G, Park S-M, Nyenhuis JA. Implantable microstimulator: magnetic resonance safety at 1.5-Tesla. Investigative Radiology, 39:591-599, 2004.

Bhidayasiri R, Bronstein JM, Sinha S, et al. Bilateral neurostimulation systems used for deep brain stimulation: In vitro study of MRI-related heating at 1.5-Tesla and implications for clinical imaging of the brain. Magnetic Resonance Imaging, 23:549-555, 2005.

Baker KB, Tkach J, Hall JD, Nyenhuis JA, Shellock FG, Rezai AR. Reduction of MRI-related heating in deep brain stimulation leads using a lead management system. Neurosurgery, 57:392-397, 2005.

Gray RW, Bibens WT, Shellock FG. Simple design changes to wires to substantially reduce MRI induced-heating at 1.5-Tesla: Implications for implanted leads. Magnetic Resonance Imaging, 23:887-891,2005.

Nyenhuis JA, Park SM, Kamondetdacha R, Amjad A, Shellock FG, Rezai A. MRI and implanted medical devices: basic interactions with an emphasis on heating. IEEE Transactions on Device and Materials Reliability 5:467-478, 2005.

Shellock FG, Fieno DS, Thomson TJ, Talavage TM, Berman DS. Cardiac pacemaker: in vitro assessment of MR safety at 1.5-Tesla. American Heart Journal, 151:436-443, 2006.

The phantom was filled with a gelling agent in an aqueous solution. That is, the formulation was 1.32 g/L NaCl and 10 g/L polyacrylic acid (PAA) in distilled water. Using this formulation, the room temperature (22˚C) conductivity was 0.47 S/m and viscosity was sufficient to prevent convective heat transport. The head/torso phantom was filled to a depth of 9-cm. The mass of the phantom filled with the gelled-saline was 50-kg. This gelled-saline simulates the electrical and thermal properties of human tissue (prepared according to ASTM 2182-09). Because this phantom and experimental set-up lacks “blood flow”, it further involves an extreme condition used to assess MRI-related heating for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

MR System. 3-Tesla, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner. The body radiofrequency (RF) coil was used to transmit and receive RF energy.

Pulse Sequence. MR imaging parameters were applied to generate a relatively high level of radiofrequency (RF) energy at 3-Tesla, as follows: fast spin echo pulse sequence; axial plane; repetition time, 425-msec; echo time, 14-msec; echo train length, 4; flip angle, 90 degrees; bandwidth, 16 kHz; field of view, 40-cm; imaging matrix, 256 x 256; section thickness, 10-mm; number of section locations, 20; phase direction, anterior to posterior; transmitter gain setting, 180; imaging time, 15-min. Patient body weight used, 50-kg.

The land-marking position (i.e., the center position or anatomic region for the MR imaging procedure) and section locations were selected to encompass the entire area of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 under evaluation.

Specific Absorption Rates: The imaging parameters produced an MR system reported, value for the whole body averaged specific absorption rate (SAR) of 2.9-W/kg.

Specific Absorption Rate (SAR) Measurement Using Calorimetry. Calorimetry was used to measure the whole body SAR associated with the 3-Tesla/128-MHz MR system reported values for this experimental set up. Calorimetry was performed following the details described in NEMA MS 8-1993, Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems, using Section 3, Calorimetry Method.

Calorimetry calculated whole body averaged SAR: 2.7-W/kg

Comments: Thus, the 3-Tesla/128-MHz MR system (Excite, Software HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) reported whole body averaged SAR value of 2.9-W/kg was associated with a calculated whole body averaged SAR value of 2.7-W/kg for this experimental set-up.

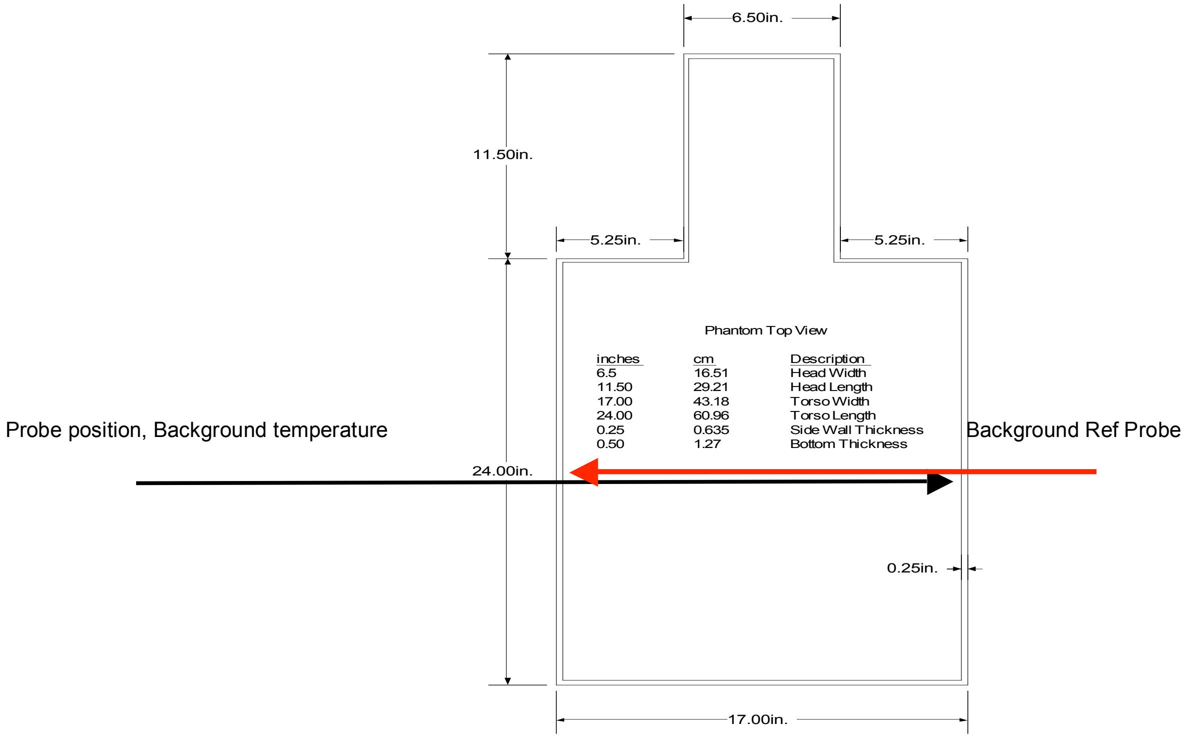
Thermometry System. Temperature recordings were obtained in this experiment using a Luxtron Model 3100 Fluoroptic Thermometry System (Luxtron, Santa Clara, CA) previously demonstrated to be MRI-compatible and unperturbed at static magnetic field strengths up to 9.0-Tesla (an MR spectrometer). This thermometry system has small fiber-optic probes (Model SFF-2; 0.5-mm diameter) that respond rapidly (response time, 0.25 seconds; sensitive volume radius, less than 1-mm), with an accuracy and resolution of $\pm$ 0.1˚C. The thermometry system was calibrated immediately before obtaining temperature measurements.

Thermometry Probe Placement. The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 had thermometry probes attached to record a representative temperature during the experiment, as follows (**Figure 5**):

Probe #1, sensor portion of the probe placed in contact on one end of the device
Probe #2, sensor portion of the probe placed in contact with the other end of the device
Probe #3, sensor portion of the probe placed in contact with middle portion of the device

In addition, a thermometry probe was placed in the phantom at a position removed (at least 30-cm away and 1-cm from the opposite edge of the phantom, away from the device) from the device but within the area of MR imaging, to record a reference temperature during the heating experiment (Probe #4).

Assessment of Temperature Without Device Present, Background Temperature: The “background” temperature was recorded in the ASTM head/torso phantom at a comparable position used for the evaluation of MRI-related heating for the device. Thus, the temperature change recorded at this position in the phantom in association with MRI-related heating of the gelled-saline-filled phantom *without* the device is reported, herein. To record the background temperature, a fluoroptic thermometry probe (Background temperature) was placed in the ASTM head/torso phantom at a position mid-line on the far left side at the same spot where the device was positioned and a reference probe was placed across from that position, as follows:



Verification of Positions for the Thermometry Probes. The thermometry probes were visually inspected immediately before and immediately after the MRI-heating experiment to ensure that they were properly positioned, as stated above.

Rationale for Placement of the Thermometry Probes. The fluoroptic thermometry probes were placed in direct contact with the ends and/or metal portions of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 since these positions are where the greatest amount of heating will occur based on prior work performed on similar implants and devices. See the following articles that support this statement:

Nyenhuis JA, Kildishev AV, Foster KS, Graber G, Athey W. Heating near implanted medical devices by the MRI RF-magnetic field. IEEE Trans Magn 1999;35:4133–4135

Smith CD, Nyenhuis JA, Kildishev AV. Chapter 16. Health effects of induced electrical currents: Implications for implants. In: Magnetic Resonance: Health Effects and Safety, FG Shellock, Editor, CRC Press, Boca Raton, FL, 2001; pp. 393-413.

Rezai AR, Finelli D, Nyenhuis JA, Hrdlicka G, Tkach J, Sharan A, Rugieri P, Stypulkowoski PH, Shellock FG. Neurostimulation systems for deep brain stimulation: In vitro evaluation of magnetic resonance imaging-related heating at 1.5-Tesla. J Magn Reson Imaging 2002;15;241-250.

Finelli DA, Rezai AR, Ruggieri P, Tkach J, Nyenhuis J, Hidlicka G, Sharan A, Gonzalez-Martinez J, Stypulkowski PH, Shellock FG. MR-related heating of deep brain stimulation electrodes: an *in vitro* study of clinical imaging sequences. AJNR American Journal of Neuroradiology 2002;23:1795-1802.

Shellock FG. Reference Manual for Magnetic Resonance Safety, Implants and Devices: 2010 Edition. Biomedical Reference Publishing Group, Los Angeles, CA, 2010.

Protocol: The gelled-saline-filled phantom was placed in the 3-Tesla MR system and allowed to equilibrate to the environmental conditions for more than twenty-four hours. The room temperature and temperature of the bore of the MR system were continuously monitored (measured every 5-min. throughout the experimental session to ensure that no change greater than 0.1˚C occurred).

The temperature in the MR system room was monitored and did not change by more than 1-degree C per one hour. MR system fan was not on during the experiment. There was sufficient thermal equilibrium between the phantom and surrounding temperature such that the temperature of the phantom did not change by more than 0.2°C during the pre-MRI observation time for a period of 15 minutes.

Baseline (Pre-MRI) temperatures were recorded at 4-sec. intervals for 5-minutes. MRI was then performed for 15 minutes with temperatures recorded at 4-sec. intervals. Post-MRI temperatures were recorded for 2-minutes with temperatures recorded at 4-sec. intervals **(Figure 6**). The highest temperature changes recorded for each thermometry probe is reported, herein, for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 during the MRI-related heating experiment as well as for the recording of the background temperature.

RESULTS AND DISCUSSION

The results of the MRI-related heating tests are shown in Table 2. The background temperature change was 1.5˚C. The calculated local SAR associated with these MRI-related heating conditions was 6.9-W/kg (that is, the local SAR at the location *without* the implant in the gelled-saline filled phantom was calculated based on the local temperature change, according to the following equation: local SAR = c $\Delta T/\Delta t$; with c = 4160 J/k/˚C, the specific heat of the gelled-saline phantom material, T = Temperature change in ˚C; /Δt = time in sec). The local SAR at the reference probe position *without* the implant present was 3.2-W/kg.

According to these data, the highest temperature change measured for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was 1.6˚C. The local SAR at the reference probe position *with* the implant present was 3.2-W/kg. Therefore, the MRI-related heating experiment for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 at 3-Tesla using a transmit/receive RF body coil at an MR system reported, whole body averaged SAR of 2.9-W/kg indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to 1.6˚C. Importantly, this change in temperature is not considered to be physiologically consequential for a human subject.

ARTIFACT TEST

MR imaging artifacts were assessed for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 in association with the use of a 3-Tesla MR system. This test was accomplished by performing MR imaging with the device placed inside of a gadolinium-doped, saline filled plastic phantom following aspects of the American Society for Testing and Materials (ASTM) International Designation: F2119-07, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants. ASTM International, West Conshohocken, PA.

Gadolinium-doped, saline fluid was used for this evaluation and deemed acceptable as it provides a high signal background for the assessment of a metallic object and has been used in many previous MRI artifact evaluations for implants and devices (see peer-reviewed literature that supports use of gadolinium-doped saline for artifact assessment, to follow).

MR imaging was conducted with the device placed inside of the gadolinium-doped, saline filled, plastic phantom (i.e., using an appropriate size relative to the size of the device that underwent testing; 25-cm length, 20-cm width, 18-cm depth). The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 was attached to a plastic frame to facilitate positioning and MR imaging within this phantom (**Figure 7**).

MR imaging was performed using a 3-Tesla MR system (3-Tesla MR system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI), a send-receive RF coil, and the following pulse sequences:

(1) T1-weighted, spin echo pulse sequence; repetition time, 500 msec; echo time, 20 msec; matrix size, 256 X 256; section thickness, 10-mm; field of view, 24-cm; number of excitations, 2; bandwidth; 16 kHz
(2) Gradient echo (GRE) pulse sequence; repetition time, 100 msec; echo time, 15 msec; flip angle, 30 degrees; matrix size, 256 X 256; section thickness, 10-mm; field of view, 24-cm; number of excitations, 2; bandwidth, 16 kHz

These are commonly used pulse sequences for MR imaging. In addition, the GRE pulse sequence is a gradient echo or partial flip angle technique that typically has a great degree of artifact associated with it when MR imaging is performed on a metallic implant or device. Thus, the use of the GRE pulse sequence represents a type of extreme MR imaging condition.

The imaging planes were oriented to encompass the long axis and short axis of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. The frequency encoding direction was parallel to the plane of imaging. Notably, image locations obtained through the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 were selected from multiple “scout” MR images to represent the largest or worst-case artifacts for this device.

Artifact is defined as a 30% difference in signal intensity between a baseline image acquired without the test object present and the image acquired when the device was present, according to ASTM International, F2119-07. The location of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 within the signal void artifact was marked on the images using the annotation software on the scanner, and the annotated images were saved as new images. The baseline images without the device was subtracted from the annotated images so that the relative locations of the device and the artifacts were known.

Artifacts that result from other positions of the imaging plane relative to the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 or with regard to the particular orientation of this device to the main magnetic field of the MR system may be slightly more or less to that observed under the experimental conditions used in the test for artifact assessment. Nevertheless, the MR imaging technique used to assess artifacts is the same as that published in the peer-reviewed literature (see partial list below). For this reason, this procedure was selected to assess the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33, since it is considered appropriate and facilitates comparison to previously evaluated metallic implants and devices.

Artifacts were characterized using a previously-published methodology described in the following publications:

(1) Shellock FG, Shellock VJ. MR-compatibility evaluation of the Spetzler titanium aneurysm clip. Radiology. 206:838-841, 1998.
(2) Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. Radiology. 207:822-825, 1998.
(3) 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.
(4) Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.
(5) Shellock FG. Forder J. Drug eluting coronary stent: *In vitro* evaluation of magnet resonance safety at 3-Tesla. Journal of Cardiovascular Magnetic Resonance 2005;7:415-419.
(6) Shellock FG, Gounis M, Wakhloo A. Detachable coil for cerebral aneurysms: *In vitro* evaluation of magnet field interactions, heating, and artifacts at 3-Tesla. American Journal of Neuroradiology 2005;26:363-366.
(7) Shellock FG, Valencerina S. Septal repair implants: evaluation of MRI safety at 3-Tesla. Magnetic Resonance Imaging, 23:1021-1025, 2005.
(8) Shellock FG, Habibi R, Knebel J. Programmable CSF shunt valve: *In vitro* assessment of MRI safety at 3-Tesla. American Journal of Neuroradiology, 27:661-665, 2006.
(9) Shellock FG, Wilson SF, Mauge CP. Magnetically programmable shunt valve: MRI at 3-Tesla. Magnetic Resonance Imaging, 25:1116-21, 2007.
(10) Shellock FG, Valencerina S. Ventricular assist implant (AB5000): *In Vitro* assessment of MRI issues at 3-Tesla. Journal of Cardiovascular Magnetic

Resonance. 10:23, 2008.
(11) Shellock FG, Valencerina S. In vitro evaluation of MR imaging issues at 3-T for aneurysm clips made from MP35N: Findings and information applied to 155 additional aneurysm clips. AJNR Am J Neuroradiology 2009 Dec 24. [Epub ahead of print]

The planimetry software provided with the MR system was used to measure the cross-sectional areas for the artifacts associated with the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. The accuracy of this measurement method is ± 10%. Measurements were obtained to determine the maximum or worst-case artifact area related to the presence of this device for each MR imaging condition. This ensured that the sizes of the artifacts for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 were not underestimated. MR images are provided showing the artifacts associated with the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

Important Note: There are numerous articles in the peer-reviewed literature that substantiate the fact that the method stated in this report is a valid and useful technique for characterizing MRI artifacts for metallic implants and devices. These articles include, the following:

Shellock FG, Shellock VJ. Evaluation of cranial flap fixation clamps for compatibility with MR imaging. Radiology. 207:822-825, 1998.

Shellock FG, Shellock VJ. Cardiovascular catheters and accessories: Ex vivo testing of ferromagnetism, heating, and artifacts associated with MRI. Journal of Magnetic Resonance Imaging. 8:1338-1342, 1998.

Shellock FG, Shellock VJ. Metallic marking clips used after stereotactic breast biopsy: ex vivo testing of ferromagnetism, heating, and artifacts associated with MRI. American Journal of Roentgenology. 172:1417-1419, 1999.

Shellock FG, Shellock VJ. Metallic stents: Evaluation of MRI safety. American Journal of Roentgenology. 173:543-546, 1999.

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.

Shellock FG. Surgical instruments for interventional MRI procedures: assessment of MR safety. Journal of Magnetic Resonance Imaging, 13:152-157, 2001.

Shellock FG. Prosthetic heart valves and annuloplasty rings: assessment of magnetic field interactions, heating, and artifacts at 1.5-Tesla. Journal of Cardiovascular Magnetic Resonance. 3:159-169, 2001.

Shellock FG. Metallic neurosurgical implants: evaluation of magnetic field interactions, heating, and artifacts at 1.5 Tesla. Journal of Magnetic Resonance Imaging. 14:295-299, 2001.

Shellock FG. New metallic implant used for permanent female contraception: evaluation of MR safety. American Journal of Roentgenology. 178:1513-1516, 2002.

Shellock FG, Cosendai G, Park S-M, Nyenhuis JA. Implantable microstimulator: magnetic resonance safety at 1.5-Tesla. Investigative Radiology, 39:591-599, 2004.

Shellock FG, Gounis M, Wakhloo A. Detachable coil for cerebral aneurysms: *In vitro* evaluation of magnet field interactions, heating, and artifacts at 3-Tesla. American Journal of Neuroradiology, 26:363-366, 2005.

Shellock FG. Forder J. Drug eluting coronary stent: *In vitro* evaluation of magnet resonance safety at 3-Tesla. Journal of Cardiovascular Magnetic Resonance 2005;7:415-419.

Shellock FG, Valencerina S. Septal repair implants: evaluation of MRI safety at 3-Tesla. Magnetic Resonance Imaging, 23:1021-1025, 2005.

Shellock FG, Habibi R, Knebel J. Programmable CSF shunt valve: *In vitro* assessment of MRI safety at 3-Tesla. American Journal of Neuroradiology, 27:661-665, 2006.

Shellock FG, Wilson SF, Mauge CP. Magnetically programmable shunt valve: MRI at 3-Tesla. Magnetic Resonance Imaging, 25:1116-21, 2007.

Shellock FG, Valencerina S. Ventricular assist implant (AB5000): *In Vitro* assessment of MRI issues at 3-Tesla. Journal of Cardiovascular Magnetic Resonance. 10:23, 2008.

Shellock FG, Valencerina S. In vitro evaluation of MR imaging issues at 3-T for aneurysm clips made from MP35N: Findings and information applied to 155 additional aneurysm clips. AJNR Am J Neuroradiology 2009 Dec 24. [Epub ahead of print]

RESULTS AND DISCUSSION

Artifact test results are indicated in Table 3 of this report and shown on the figures displaying the MR images (**Figures 8 to 11**; corresponding to each orientation, parallel and perpendicular and each pulse sequence – T1-weighted spin echo and gradient echo). For the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33, the artifacts that appeared on the MR images were shown as localized signal voids (i.e., signal loss) that were “small” (based on a scale of small, moderate, and large) in size in relation to the size and shape of this device. The gradient echo pulse sequence produced larger artifacts than the T1-weighted, spin echo pulse sequence for this device. Overall, the artifacts for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 may present problems if the MR imaging area of interest is in or near the area where this device is located.

MRI LABELING BASED ON THE TEST RESULTS (Note: use verbatim)

MRI Information

MR Conditional

The **On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33** was determined to be MR-conditional according to the terminology specified in the American Society for Testing and Materials (ASTM) International, Designation: F2503-08. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania.

Non-clinical testing demonstrated that the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field

-Static magnetic field of 3-Tesla or less
-Maximum spatial gradient magnetic field of 720-Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in the 3-Tesla (3-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MR system:

Highest temperature change +1.6˚C

Therefore, the MRI-related heating experiments for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 at 3-Tesla using a transmit/receive RF body coil at an MR system reported whole body averaged SAR of 2.9 -W/kg (i.e., associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated that the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6˚C.

Artifact Information

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

Pulse Sequence	T1-SE	T1-SE	GRE	GRE
Signal Void Size	1,090-mm^2	686-mm^2	1,478-mm^2	1,014-mm^2
Plane Orientation	Parallel	Perpendicular	Parallel	Perpendicular

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Table 1. Evaluation of magnetic field interactions at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

	Deflection Angle (degrees)	Torque long axis	Torque short axis
Measurement #1	1	0	0
Measurement #2	1	0	0
Measurement #3	1	0	0

Deflection Angle (degrees, m ± SD)	Torque (m ± SD) long axis	Torque (m ± SD) short axis
1 ± 0	0 ± 0	0 ± 0

Table 2. Summary of MRI-related heating at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

Thermometry Probe	Highest Temperature Change (˚C)
Probe #1	+1.5˚C
Probe #2	+1.6˚C
Probe #3	+1.5˚C
Probe #4	+0.7˚C
Background Probe (without implant/device)	+1.5˚C
Background Reference Probe (without implant/device)	+0.7˚C

Table 3. Summary of MRI artifacts at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

Signal Void Size	1,090-mm^2	686-mm^2	1,478-mm^2	1,014-mm^2
Static Magnetic Field (T)	3	3	3	3
Pulse Sequence	T1-SE	T1-SE	GRE	GRE
TR (msec.)	500	500	100	100
TE (msec.)	20	20	15	15
Flip Angle	N/A	N/A	30˚	30˚
Bandwidth	16 kHz	16 kHz	16 kHz	16 kHz
Field of View	24 cm	24 cm	24 cm	24 cm
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256
Section Thickness	10 mm	10 mm	10 mm	10 mm
Imaging Plane	parallel (long axis)	perpendicular (short axis)	parallel (long axis)	perpendicular (short axis)

(T1-SE, T1-weighted spin echo; GRE, gradient echo; N/A, not applicable)

FIGURE 1. The On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 that underwent testing at 3-Tesla.

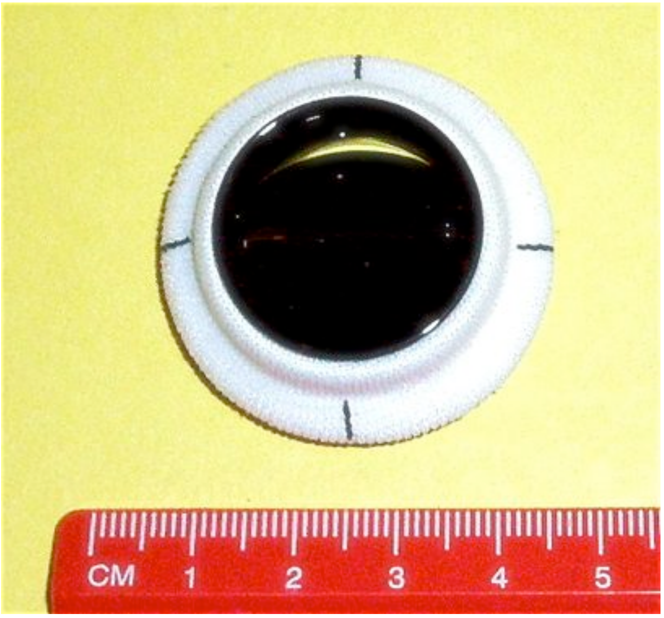


FIGURE 2. The 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI) used for MRI testing of the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

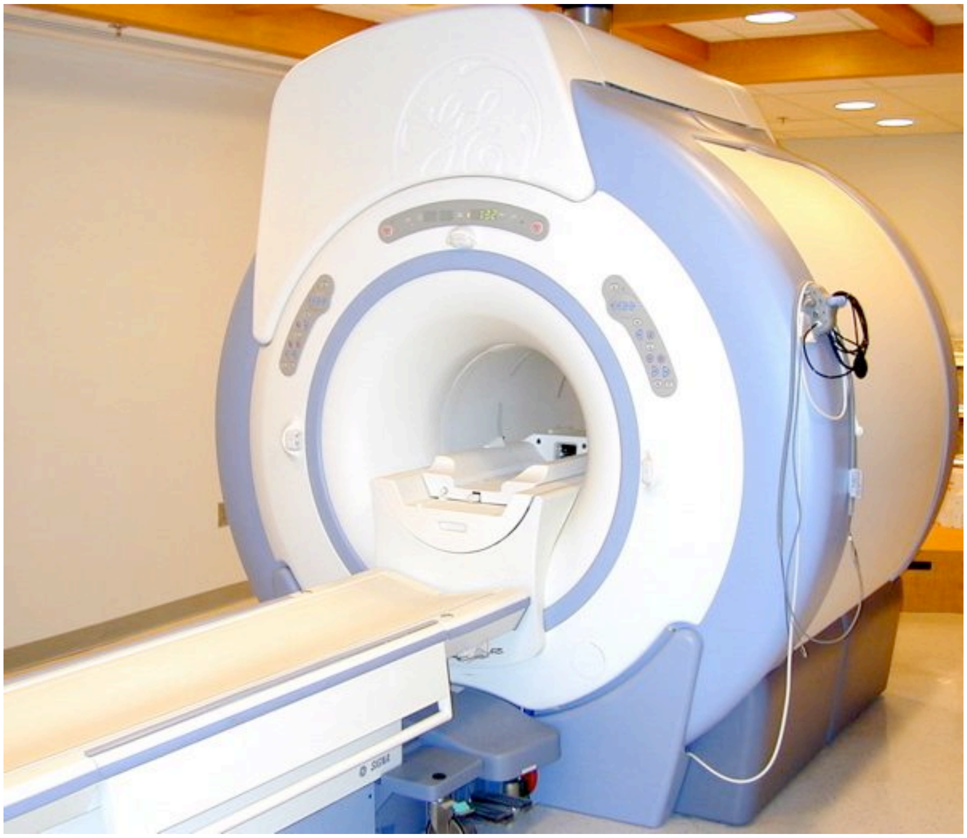


FIGURE 3. The deflection angle test conducted at 3-Tesla on the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. Note the deflection angle of 1-degree measured in the 3-Tesla MR system.

FIGURE 4. The experimental set-up used for the qualitative assessment of torque for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. This procedure involved the use of a flat plastic material with a grid on the bottom. The device was placed on the test apparatus in an orientation that was 45-degrees relative to the static magnetic field of the 3-Tesla MR system. The test apparatus with the device was then positioned in the center of the MR system, where the effect of torque is known to be the greatest and observed for possible alignment or rotation. (Figure shows the device outside of the scanner before it was moved into the center of the MR system).

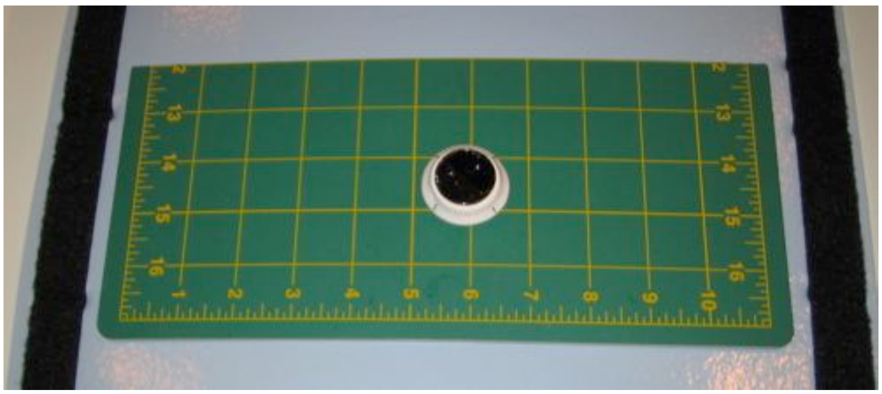
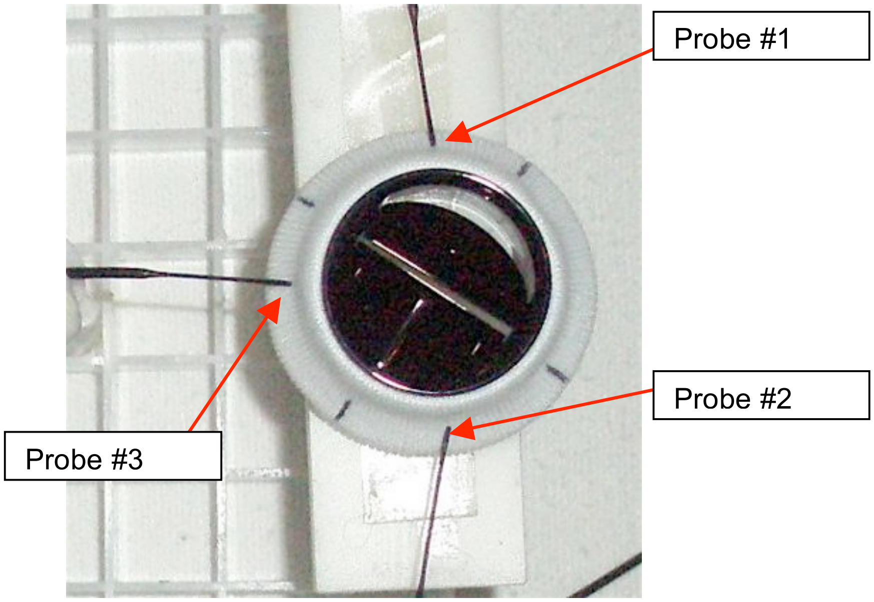


FIGURE 5. Positions for the fluoroptic thermometry probes relative to the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33 for the MRI-related heating experiment performed at 3-Tesla (close up and standard view). Note the plastic frame, which fits inside of the ASTM head/torso phantom.



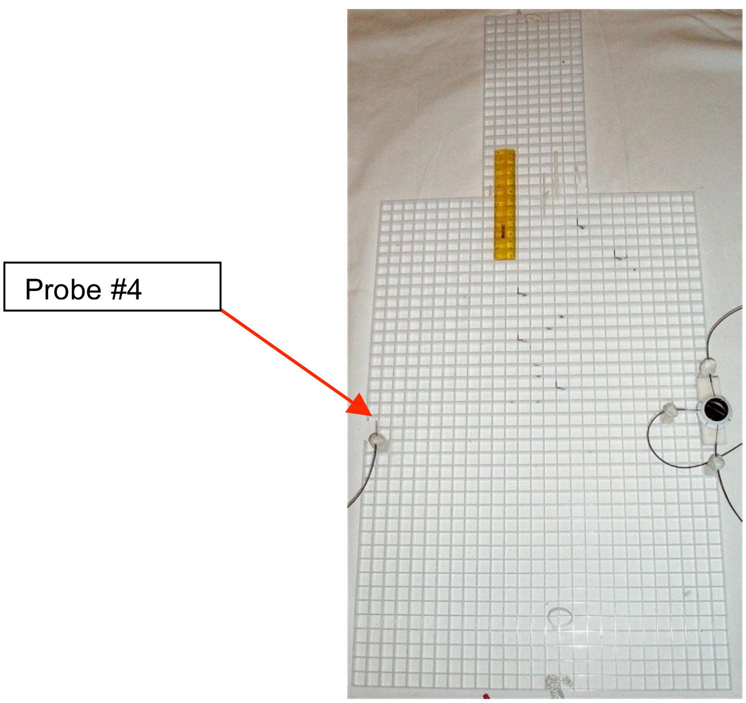


FIGURE 6. Experimental set up showing the 3-Tesla MR system and head/torso phantom used for the evaluation of MRI-related heating for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33. Note the cables going to the fluoroptic thermometry probes of the Luxtron Thermometry System.

FIGURE 7. Experimental set-up used to evaluate artifacts at 3-Tesla for the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

Plastic frame with the On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33.

Fluid-filled phantom with the device and the 3-Tesla MR system.

FIGURE 8. T1-weighted, spin echo pulse sequence; long axis imaging plane

On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33

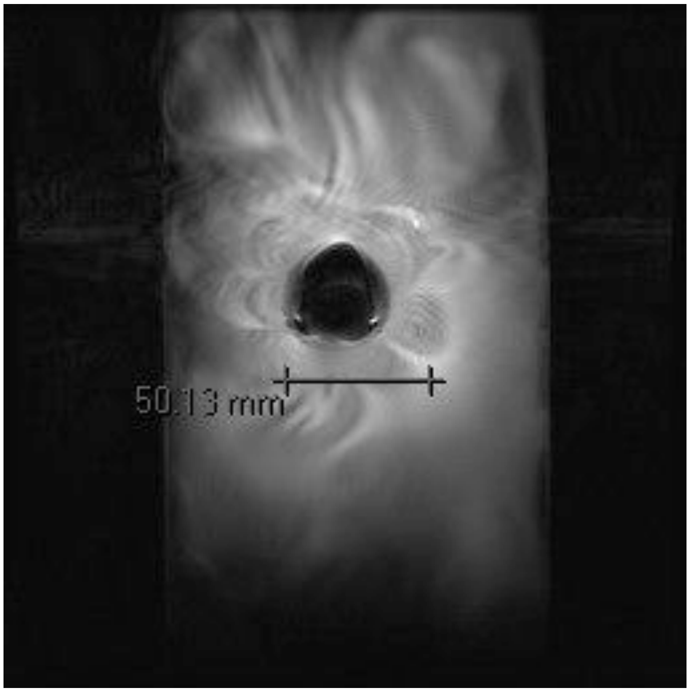


FIGURE 9. T1-weighted, spin echo pulse sequence; short axis imaging plane

On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33

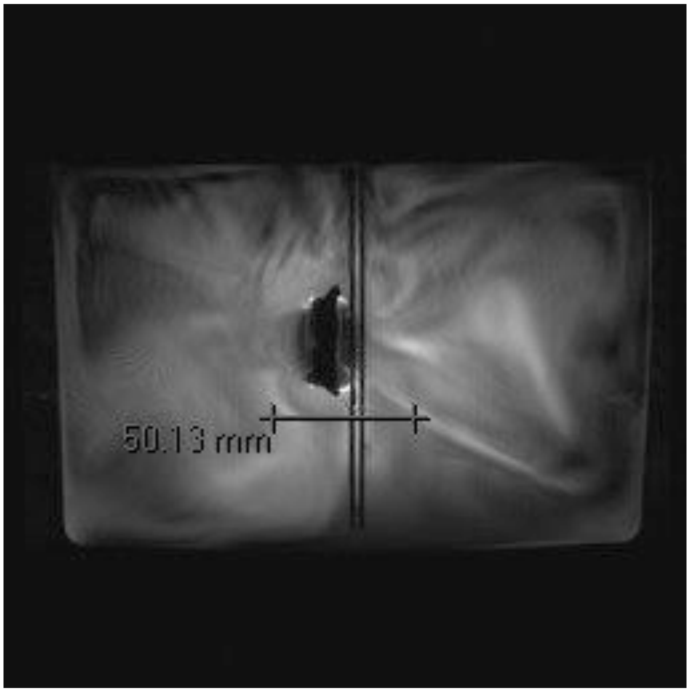


FIGURE 10. Gradient echo pulse sequence; long axis imaging plane

On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33

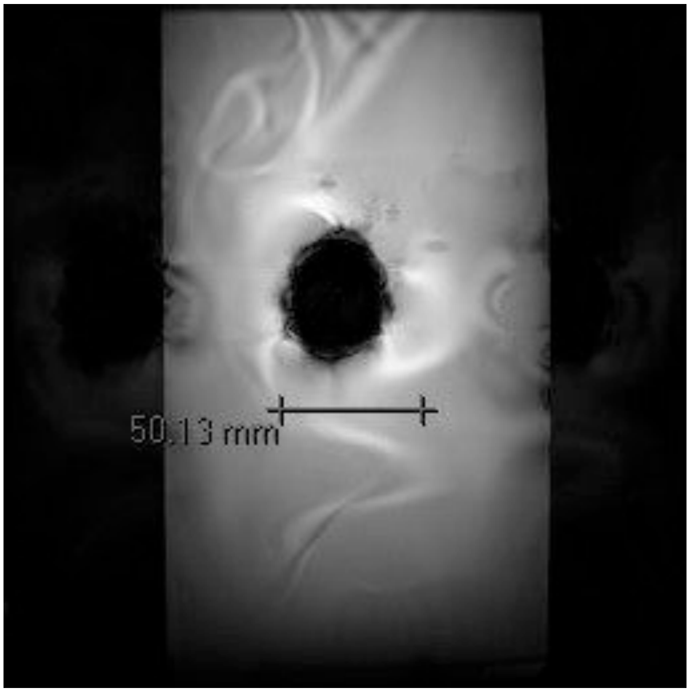


FIGURE 11. Gradient echo pulse sequence; short axis imaging plane

On-X Prosthetic Heart Valve, Conform-X Mitral Heart Valve Prosthesis; Size 25-33