SHELLOCK
R & D SERVICES, INC.

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

REPORT

Evaluation of the Arctic Sun, Energy Transfer Pad Using an MR System Operating at 3-Tesla

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

01/15/06

Presented to:

Gary Carson
Medivance, Inc.
1172 Century Drive Suite 240
Louisville, Colorado 80027

For medical implants and devices, the objectives of magnetic resonance imaging (MRI) testing are to determine the presence of magnetic field interactions and heating in association with the use of an MR system. Artifacts, while not an MRI safety issue, should also be evaluated for a given device to determine the impact, if any, on image quality.

Because the Arctic Sun, Energy Transfer Pad does not have metallic components or conducting materials, it is not necessary to perform tests for magnetic field interactions and MRI related heating. Therefore, artifact testing, *only*, was performed on the Arctic Sun, Energy Transfer Pad.

MR system: 3-Tesla, Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI; active-shielded, horizontal field scanner

Test site: University of Southern California Hospital, Los Angeles, CA

ARTIFACT TEST

MR imaging artifacts were assessed for one sample of the Arctic Sun, Energy Transfer Pad in association with the use of a 3-Tesla MR system. This test was accomplished by performing MR imaging with the Arctic Sun, Energy Transfer Pad attached to the outside of a copper sulfate phantom (see figures) to simulate the intended *in vivo* use of this device.

MR imaging was conducted using a 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI), a send-receive body 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, 48-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, 48-cm; number of excitations, 2; bandwidth, 16 kHz
(3) T2-weighted, fast spin echo pulse sequence; repetition time, 3,000 msec; effective cho time, 116 msec; 256 X 256; section thickness, 10-mm; field of view, 48-cm; number of excitations, 2; bandwidth, 16 kHz

For each pulse sequence, the imaging plane was oriented to encompass the short axis the Arctic Sun, Energy Transfer Pad (i.e., transverse section location, mid-slice obtained through the middle of the pad and copper sulfate phantom).

The MR images were visually inspected using qualitative criteria (i.e., no effect, mild effect, moderate effect, large effect) to determine if the presence of the Arctic Sun, Energy Transfer Pad significantly impacted the image quality for a given pulse sequence.

RESULTS AND DISCUSSION

Artifact test results are shown on the enclosed figures displaying the MR images. Subtle signal in association with the presence of the Arctic Sun, Energy Transfer Pad was seen on the T1-weighed and T2-weighed, fast spin echo pulse sequences. It was not possible to observe signal from the Arctic Sun, Energy Transfer Pad on the gradient echo pulse sequence. Overall, the signal seen in association with the Arctic Sun, Energy Transfer Pad using T1-weighted, gradient echo, and T2-weighted, fast spin echo pulse sequences at 3-Tesla demonstrated that image quality will not be significantly affected or compromised by the presence of the Arctic Sun, Energy Transfer Pad. Notably, the findings stated above are highly specific to imaging parameters used for this evaluation.

EXECUTIVE SUMMARY

Based on the MRI testing information, the Arctic Sun, Energy Transfer Pad does not alter image quality using T1-weighted, gradient echo, or T2-weighed, fast spin echo pulse sequences at 3-Tesla under the conditions used for this evaluation.

RECOMMENDED MRI LABELING

MRI Information. The Arctic Sun, Energy Transfer Pad was determined to be MR-safe (i.e., according to information provided in the following document: 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. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005) based on the fact that there are no metallic components or conducting materials used to make this device.

MR imaging assessed at 3-Tesla using T1-weighted, gradient echo, and T2-weighted, fast spin echo pulse sequences demonstrated that image quality will not be significantly affected or compromised by the presence of the Arctic Sun, Energy Transfer Pad.

IMPORTANT NOTE: If you plan to submit this information to the United States Food and Drug Administration or other regulatory agency to obtain a labeling claim relative to this MRI testing information, please provide me with the content to review to ensure proper presentation of the labeling 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. The author of this work disclaim any liability for the acts of any physician, individual, group, or entity acting independently or on behalf of any organization who utilizes this information for any medical procedure, activity, service, or other situation.

FIGURE 1. The Arctic Sun, Energy Transfer Pad samples that underwent MRI testing at 3-Tesla. Note: this device has no metallic components.

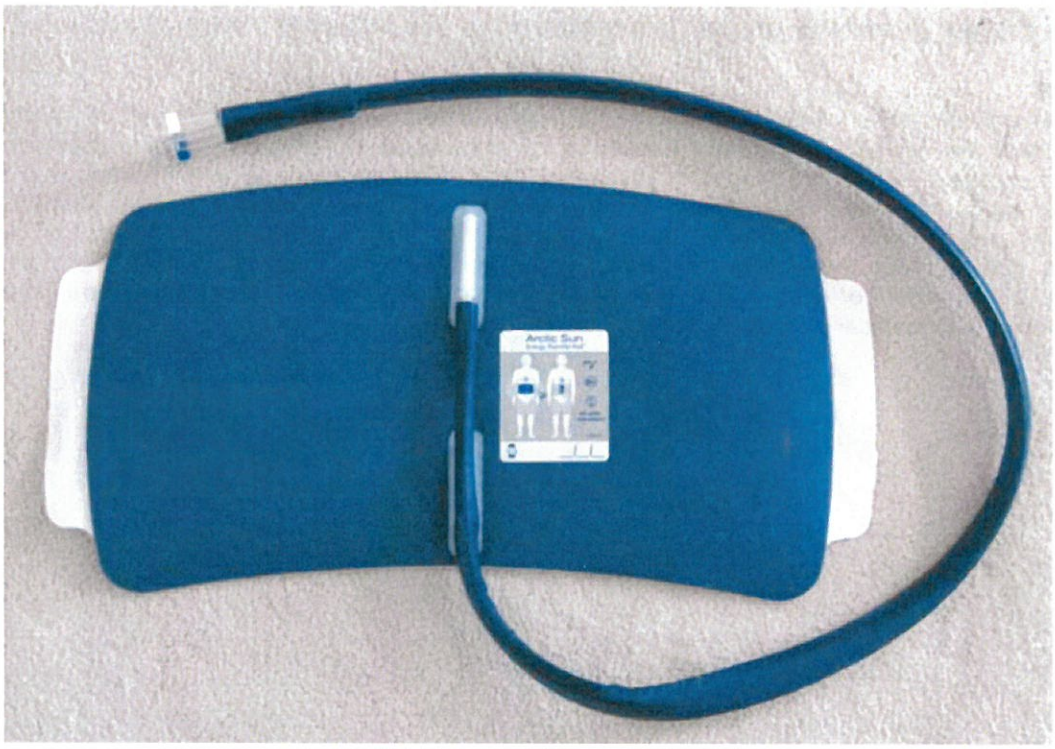

FIGURE 2. The 3-Tesla MR system (General Electric Healthcare, Milwaukee, WI) used for MRI testing of the Arctic Sun, Energy Transfer Pad.

FIGURE 3. Experimental set-up used to evaluate artifacts for the Arctic Sun, Energy Transfer Pad. The Arctic Sun, Energy Transfer Pad was placed on the outside of a copper sulfate phantom to simulate its intended *in vivo* use. The phantom with the Arctic Sun, Energy Transfer Pad was the subjected to MRI at 3-Tesla using three different pulse sequences.

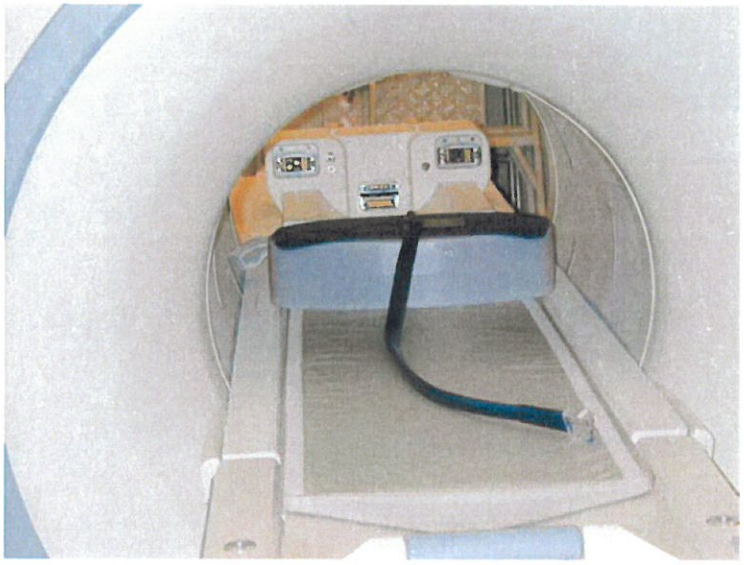

FIGURE 4. T1-weighted, spin echo pulse sequence used to assess artifacts for the Arctic Sun, Energy Transfer Pad (green arrow).

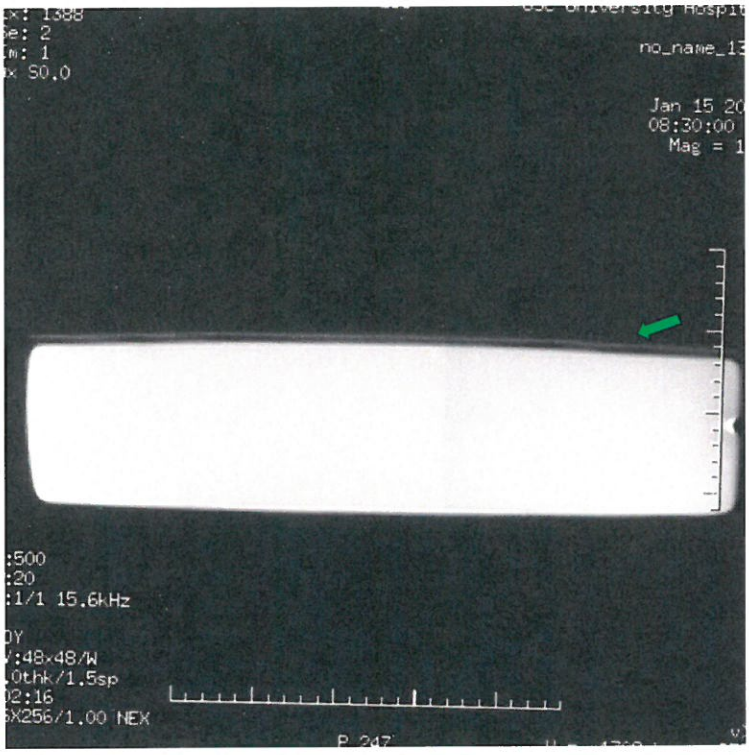

FIGURE 5. Gradient pulse sequence used to assess artifacts for the Arctic Sun, Energy Transfer Pad (not seen using this pulse sequence).

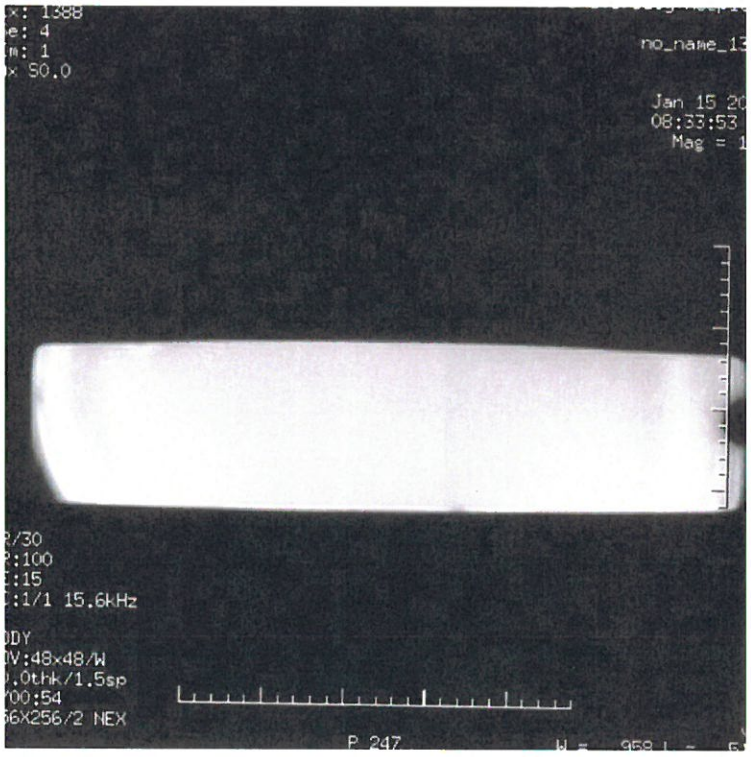

FIGURE 6. T2-weighted, fast spin echo pulse sequence used to assess artifacts for the Arctic Sun, Energy Transfer Pad (green arrow)