

# **Biophan Technologies CRADA Workshop on the Safe Use of Implantable Medical Devices in Magnetic Resonance (MR) Systems – Summary from Initial Workshop**

**Editors:** Howard Bassen, Jeffrey Helfer, Andreas Melzer.\*

## **Introduction**

Biophan Technologies, Inc. and the United States Food and Drug Administration (FDA) co-hosted a Workshop on October 9, 2006. The purpose of the workshop was to assemble a team of experts to outline necessary research and improvements in testing methods for measuring certain aspects of MRI safety of medical implants. The future work would involve leads of cardiac rhythm management (implanted pacemaker and defibrillator) and neurostimulation devices, and evaluation of electromagnetic interference (EMI) of active implanted medical devices. FDA's Office of Science and Engineering Laboratories (OSEL) and Biophan Technologies, Inc. are collaborating in a Cooperative Research and Development Agreement (CRADA) to perform research and define methods for measuring Magnetic Resonance Imaging (MRI) safety of medical implants by examining the leads of cardiac rhythm management and neurostimulation devices. The CRADA is titled: *Measurements and Computer Modeling to Evaluate the Safety of Medical Implants by Examining Leads of Cardiac Rhythm Management and Neurostimulation Devices in the Presence of Electromagnetic Fields from Magnetic Resonance Imaging*.

Representatives from a variety of specialties, including cardiac pacing and neurostimulator manufacturers, the MRI safety industry, MRI systems manufacturers, academia and clinical practice participated in small group discussions focusing on factors which they perceive as the most relevant to specific aspects of MRI safety. The factors involved implanted device lead heating, induced voltages on leads, and device performance during MR imaging procedures of a patient with an implanted medical device.

## **Discussion**

In addition to identifying important parameters that influence the safety of a medical implants' leads and a device's performance under MR imaging procedures, there were suggestions that several crucial terms related to safety were in need of definitions that would be universally accepted and recognized. It was determined that differences of interpretation or calculation exist for such terms as *whole body SAR*, *local SAR (without implant)*, *local SAR (with implant)*, *worst case condition to determine and evaluate test conditions*, *locally induced temperature* and *the root mean square (RMS) magnitude of RF fields*.

Key factors affecting heating and gradient-field induced voltage were determined to belong to seven general categories. These categories were:

- Magnetic resonance system scanner variables and scan parameters

- Lead/pulse generator system design
- Physiological (patient) issues
- Phantom (patient model) issues
- Temperature measurements
- Gradient-field induced voltage measurements
- “MRI-safe” acceptance criteria

Regarding RF fields, all groups listed the variation between MR systems’ field strengths (which dictates the RF frequency of the system) as a significant factor that would influence RF induced heating in an implanted lead. Other MR system factors identified that influence heating are: the RF field orientation and distribution; the MR scanning parameters, local and whole body average SAR calculated and reported by the system; the MR scanner software associated with the above, the variability of RF coil design between various systems and the magnitude and the orientation of the RF electric and magnetic fields with respect to the patient. For gradient fields the peak dB/dt and fields’ spatial distribution as well as the maximum allowable pulsed energy, the effective “loop area” formed by the lead and pulse generator case. The orientation of device loop relative to the E and B fields is an issue with respect to both the RF and gradient coils. Lead length, impedance (real and imaginary components), and design, as well as the placement position in the body and the total geometry (post-implantation) influence heating. The pacing system’s “condition” with respect to the presence of abandoned leads (intact or broken) and the pulse generator with batteries at different stages of their life cycle can affect heating and stimulation to various degrees.

All workgroups expressed concern over the accuracy and uncertainty of the MRI scanners’ system-reported specific absorption rate (SAR) and its use as the qualifying parameter on which lead heating test results are defined. One workgroup suggested that the B1 RMS (root mean squared B1 field) is a more relevant parameter to reference or that the B1 field itself could be used as an alternative for whole body SAR. Another workgroup suggested that calorimetry be used to determine whole body SAR rather than MRI scanner reported SAR.

It was also acknowledged that the patient’s body influences the reaction of the device implanted within them to the MR fields. The patient’s body size, shape and composition (e.g. body fat percentage) as well as the tissue type and morphology at or near the electrode can influence the implanted device. In addition, the electrical and thermal conductivity of different tissues and fluid perfusion at the site of the implanted electrode are generally agreed by all workgroups to affect lead heating.

With so many possible influences on induced heating and voltages in implanted leads, there is a very real need to develop and validate test methodologies. One such effort is under way in the form of an RF heating intercomparison sponsored by an ASTM working group and coordinated by FDA. Workgroups also discussed requirements needed in test methodologies to yield relevant and reliable testing results. It was strongly suggested that a device’s intended use should be considered when evaluating its safety during MRI procedures, as this is a factor in determination of “worst case” conditions. Implanted

leads used for cardiac, and various neurological and other stimulation therapies are all very different in not only their physical structure, but their implant location and purpose. All of these factors should be considered when determining both testing methods and acceptance criteria.

The phantoms used in testing to assess heating in implanted devices were discussed. There have been papers published on the influence of the shape of the phantom tank on the energy that is delivered. (Amjad et al.) The workshop participants also listed the materials inside the phantom tank as variables in need of refinement. The thermal and dielectric properties of a typical phantom gel (ASTM F2182-02a) need to be better defined and measured. However, it is recognized that even if these parameters are controlled, the actual positioning of the lead and pulse generator, inside the phantom tank will influence the experimental results obtained and thereby affect the reproducibility of test methods. One group proposed that consideration be given to alternative phantoms and suggested that finite difference time domain (FDTD) modeling be used to determine the E fields tangential to the leads in computer models of phantoms and humans. This tangential E field could be used to calculate the power and temperature at the lead tip, or to set up a test with a phantom that duplicates the tangential field along the lead. With these concerns about phantoms expressly stated, the larger question was then: what is the correlation between lead heating in a phantom versus lead heating in a patient?

Temperature probe design and probe placement were factors of concern to all workshop groups since these factors greatly influence measured localized RF heating. Heating is so localized (e.g. one cubic millimeter) that it is difficult to locate the region of greatest heating with the accepted standard technology, fiber optic temperature probes. Alternative methods for two or three dimensional thermal mapping were discussed, including phase shift thermometry using the MRI scanner itself (Bassen 2005).

Thermal injury of different types of tissue due to RF heating was discussed by some workgroups. It was agreed that to address this, computations be performed to include RF heating, cooling via blood flow, and temperature versus time.

Electromagnetic interference (EMI) as it affects active implanted medical device performance was discussed by some workgroups but was not addressed by all due to the time limits of this workshop. The performance of a device during MR imaging can be influenced by the pulse generator design, the MR scanner design and sequences, the effective loop area of leads, and the implanted devices' characteristics and settings.

The workgroups were in general agreement that future test methods for measurement of radiofrequency induced heating and gradient field induced currents near an implant during MR imaging need to incorporate a *clinically relevant worst-case scenario* and an *active implant scenario*. The test method should also address calorimetry methods, electromagnetic interference, and accurate temperature measurements. It was also suggested that different testing and test acceptance criteria may be needed for devices with different configurations and purposes.

## **Conclusion**

There were several common factors identified by all of the workgroups associated with measuring MRI safety of medical implants, with some variability in the priority of these factors. These factors included Magnetic resonance (MR) system scanner variables and scan parameters, Lead/pulse generator system design, Physiological (patient) issues, Phantom issues, Temperature measurements, Gradient-field induced voltage measurements, and “MRI-safe” acceptance criteria. The common awareness of these factors by MR safety experts provides a high degree of validity for selecting the factors.

It is important to note there were some concerns generated by only one or two of the workgroups, and that some concerns involved lesser known or acknowledged factors.

The next phase of the CRADA will involve identifying worst-case conditions for testing MRI safety and defining standardized, repeatable, and accurate measurement methods. It should be evident that before it is possible to fulfill the mandate of the CRADA, there are several areas that need to be addressed with well designed experimental protocols. The next action will be to prioritize quickly the needs identified from this collaborative workshop. FDA and Biophan Technology researchers will then begin designing and conducting studies to address the needs identified. Other participants in the workshop may be invited to take part in this experimental work if interest and resources permit. Findings will be disseminated through conferences and technical papers and used to develop guidelines which will then be submitted for consideration to various standards setting organizations. The proposed test methods may also be considered by the FDA when evaluating MR safety of selected devices.

\* For correspondence or reprints contact: Susan Stalls, Biophan Technologies, Inc., 150 Lucius Gordon Dr., West Henrietta, NY 14586 or email at: [sstalls@biophan.com](mailto:ssalls@biophan.com).

### **Disclosures:**

Jeffrey Helfer is employed by Biophan Technologies, Inc.

Dr. Melzer is employed, in part, by Biophan Europe.

Howard Bassen is employed by the Food and Drug Administration.

### **Disclaimer:**

The opinions expressed in this article are not necessarily those of the authors or participants.

The views and opinions in this article do not necessarily reflect those of the United States Food and Drug Administration, Biophan Technologies, Inc. or Biophan Europe.

**Participants:**

Armstrong, S., Baker, K., Bassen, H., Bobgan, J., Boskamp, E., Chang, I., Chen, J., Christ, A., Cox, T., Dabney, W., Faris, O., Gray, R., Groff, P., Grossman, L., Hague, S., Hakim, B., Helfer, J., Kainz, W., Kanal, E., Lloyd, T., Melzer, A., Mendoza, G., Min, S., Mindrebo, S., Morich, M., Nynehuis, J., Oberle, M., Olsen, J., Parnis, S., Purdy, D., Schaefers, G., Shein, M., Smith, L., Stevenson, R., Witters, D., Wixon, S., Woods, T., Zaremba, L.

**References**

A. Amjad, et al., “Power Deposition Inside a Phantom for Testing of MRI Heating,” *IEEE Trans. On Magnetics*, vol. 41, No. 10, pp. 4185-4187, Oct. 2005.

ASTM F2182–02a – “Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging”, ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA

Bassen et al., “Real Time Measurement of Heating Near Metallic Implants Throughout a Phantom Using Phase-Shift MR Thermometry”, ISMRM 14th Scientific Meeting and Exhibition, Seattle, Washington, USA, 6-12 May 2006