PLATINUM SPONSOR GWT CORPORATION

SILVER SPONSOR ANSYS NORTHWEST EMC

IEEE Twin Cities Workshop

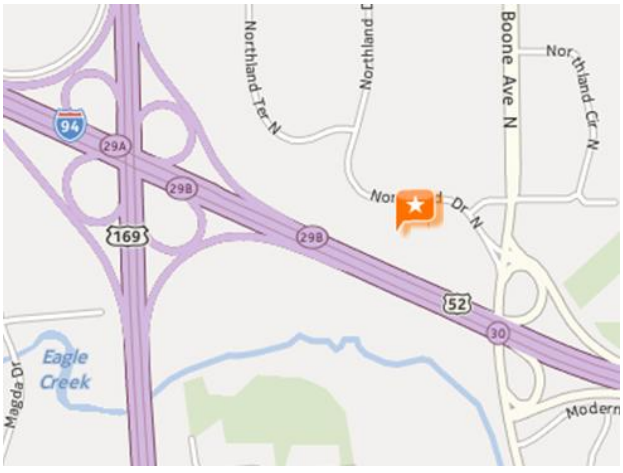
MRI Safety/Compatibility Considerations for Medical Devices

The workshop is an all-day event for engineers and managers interested in learning about MRI technology and safety/compatibility with medical devices. Attendees will learn practical approaches used to set requirements, design and test the MRI compatibility of medical devices, including associated regulatory standards and practical experience from the field. This workshop provides a unique opportunity to learn how to incorporate MRI safety/compatibility into medical devices and network with leaders in the field of medical devices and MRI safety.

Agenda:

7:00 A.M. - 8:00 A.M.	Social/Continental Breakfast
8:00 A.M. - 8:15 A.M.	Opening Remarks & An Overview of the Technical Program
8:15 A.M. - 9:00 A.M.	Dr. Thomas Vaughan, University of Minnesota: RF Heating for MRI: 1.5T, 3T, 7T, 9.4T & 10.5T
9:00 A.M. - 9:45 A.M.	Dr. David Nghiem, Global Wireless Technology: MRI Survivability for Wireless Bio-Sensors & Medical Devices
9:45 A.M. - 10:15 A.M.	Morning break, including snacks and beverages
10:15 A.M. - 11:00 A.M.	Dr. Wolfgang Kainz of the FDA and Dr. Ji Chen, University of Houston: Methodologies to Determine Worst-case Heating for MRI Conditional Devices
11:00 A.M. - 11:45 A.M.	Curt Sponberg, Medtronic: Overview of Passive and Active Implant-MRI Interaction Standards
11:45 A.M. - 1:00 P.M.	Lunch Buffet (provided)
1:00 P.M. - 1:45 P.M.	Dr. Michael Mollerus, MD, Essentia Health-St. Mary's Medical Center: Clinical Status of MRI Scanning of Patients with CIED Devices, and Musing about the Future
1:45 P.M. - 2:30 P.M.	Tom Lloyd, Imricor: Considerations for Interventional Medical Device and System Functionality in the MR Environment
2:30 P.M. - 3:00 P.M.	Afternoon break, including snacks and beverages
3:00 P.M. - 3:45 P.M.	Dr. Blaine Chronik, University of Western Ontario: Analysis of Gradient (dBg/dt) Environment in and around the MR Scanner: Extremes and Means
3:45 P.M. - 4:30 P.M.	John Tangren, Boston Scientific: Overview of MRI Induced IMD Vibration
4:30 P.M. - 4:45 P.M.	Closing Remarks

Time:	7 AM – 5:00 PM
Day:	Thursday
Date:	September 26th, 2013
Place:	Minneapolis Marriott Northwest 7025 Northland Drive North Brooklyn Park, MN 55428
Cost:	$80/$100 IEEE/Non-IEEE by Sept. 12 $100/$120 IEEE/Non-IEEE after Sept. 12
Questions:	TC-MTT@IEEE.ORG



Registration Website: http://www.eventbrite.com/event/7659715415

Attendees will receive CEUs/PDHs towards their PE certification.

SPOTLIGHT PRESENTATIONS

RF Heating MRI: 1.5T, 3T, 7T, 9.4T and 10.5T

8:15 A.M. – 9:00 A.M.

Dr. Thomas Vaughan – Professor in the Departments of Radiology, Electrical Engineering and Biomedical Engineering at the University of Minnesota – Administrator of the Engineering Core of the Center for Magnetic Resonance Research

Abstract: While industry safety standards and metrics continue to emphasize the specific absorption rate (SAR) of MRI procedures, and continue to rely upon "cartoon" models of standardized human anatomy to predict SAR magnitudes and distributions in the body, temperature continues to be overlooked as the most important parameter of concern for MRI with and without biomedical devices introduced. Knowing SAR by itself, outside of the context of an accurate bio-heat equation, is not sufficient to knowing either the magnitude or the location of thermal "hot spots". SAR level or location do not adequately predict safety risk. Temperature is the causative parameter of tissue thermogenic damage, pain, and systemic stress. SAR is but one parameter in a bio-heat transfer equation including electromagnetic, thermodynamic, and physiodynamic terms, all of which are equated to temperature. To consider MRI safety therefore, all terms must be considered to account for temperature. Biomedical research at the Center for Magnetic Resonance Research at the University of Minnesota makes use of many research-grade MRI systems, often at field strengths beyond 8T considered by the FDA to be the "non-significant risk" limit. We are constantly developing new technologies and methods to support our cutting-edge research. These new techniques and technologies and unprecedented field strengths must be used safely. To comply with FDA, IRB, IACUC guidelines and regulations, to be safe, and to be successful in our research we must understand SAR and thermal safety very well. RF safety in the MRI environment especially therefore is a major area of research for us. Toward understanding and conducting safe and successful research, we have developed a new more accurate and precise bio-heat equation for predicting and explaining heating and temperature in the anatomy. We have developed new means of implementing this theory through numeric modeling and measurement. Our theory and models have been validated and applied through extensive animal modeling using the WHO porcine model. And we have reaped the benefits. By predicting and tracking MR safety based on temperature, we can be more versatile with our SAR management while being safer with our In-vivo studies. Our theory, models, methods, technologies, and results will be shared in this talk.

Biography: Dr. Thomas Vaughan is a professor with tenure in the Departments of Radiology, Electrical Engineering and Biomedical Engineering at the University of Minnesota. Dr. Vaughan administers the Engineering Core of the Center for Magnetic Resonance Research. After receiving two B.S. degrees in electrical engineering and biology at Auburn University, Dr. Vaughan went to work for NASA at Kennedy Space Center. Following the first Space Shuttle launch, Dr. Vaughan was recruited for a DOD project at Texas Instruments in Dallas before continuing his graduate education and employment at the University of Texas Southwestern. Here he worked as the RF Engineer on a project to construct the first 2T human NMR system begun in 1984. In 1989 Dr. Vaughan took the post of Chief Engineer for a University of Alabama – Philips Research Labs consortium to build the first 4T system sited in the U.S. Dr Vaughan received his doctoral degree in Biomedical Engineering from the UAB in 1993, after which he accepted the positions of Assistant Professor at Harvard University and Assistant in Physics and Director of Engineering at the Massachusetts General Hospital NMR Center. Following a four year term at the MGH to help commission a 3T system and launch a 7T program, Dr. Vaughan accepted tenure at the University of Minnesota in 1999 where he continues his work at 4T, 7T, 9.4T and beyond.

MRI Survivability for Wireless Bio-sensors and Medical Devices

9:00 A.M. – 9:45 A.M.

Dr. David Nghiem – President & CEO of Global Wireless Technology (GWT), Inc.

Abstract: The popularity of wireless bio-sensors and medical devices is understandable; however, convenience and popularity should not get in the way of safety and efficiency. The antenna of the devices provides a good mean to trap more unwanted electromagnetic fields. The devices might not survive undergoing MRI scans. For MRI safety and compatibility considerations, a practical approach for designing and testing wireless bio-sensors and medical devices will be presented.

Biography: Dr. David Nghiem is the Founder, President and CEO of Global Wireless Technology (GWT), Inc. David has invented many practical antenna technologies for state-of-the-art wireless-communication systems, including medical applications. In addition, Dr. Nghiem has been developing innovative electromagnetic technologies, including technologies for MRI safety/compatibility for medical devices and bio-sensor applications, and explosives detection for home-land security and anti-terrorism applications. Dr. Nghiem was an Assistant Dean of the Cullen College of Engineering, and a Director of the Telecommunication Center at the University of Houston. Dr. Nghiem has also spent many years in the telecommunication and medical industries, including Harris Corporation, Qualcomm, USA Wireless and Medtronic. David is a Senior Member of IEEE. He is an avid researcher. His work has been published in leading academic and scientific journals. David has also been providing the industry with fast-turn-around, cost-effective, compact and more efficient antenna technologies.

Methodologies to Determine Worst-case Heating for MRI Conditional Devices

10:15 A.M. – 11:00 A.M.

Dr. Wolfgang Kainz - Senior Principal Scientist at the U.S. Food and Drug Administration in the Center for Devices and Radiological Health.
Dr. Ji Chen – Professor in the Department of Electrical Engineering at the University of Houston

Abstract: In this talk, the methodologies to determine worst-case heating for MRI conditional implantable and external fixation devices are discussed. The discussion includes factors related to the worst-case heating for 1) external fixation devices, 2) multi-component orthopedic devices, and 3) pacemaker or ICD leads. Modeling and experimental methods will be presented for efficient evaluation of MRI induced heating for these devices.

Biographies:

Dr. Ji Chen is a Professor in the Department of Electrical Engineering at the University of Houston. Dr. Chen's research interests include Microprocessor full chip-level interconnect extraction, wireless communication system on chip (SOC) interconnect characterization, computer system EMC/EMI modeling, signal integrity analysis, and bioelectromagnetics with applications to MRI systems Computational electromagnetic. Dr. Chen is the recipient of the ORISE Fellowship in 2006 and Motorola Engineering Award in 2000.

Dr. Wolfgang Kainz is a Senior Principal Scientist at the U.S. Food and Drug Administration in the Center for Devices and Radiological Health. Dr. Kainz received an MS degree in electrical engineering

from the Technical University of Vienna, Austria, in 1997 and a PhD degree in technical science from the same university in 2000. He is Chairman of the IEEE, International Committee on Electromagnetic Safety (ICES), Technical Committee 34, which develops compliance techniques for wireless devices, and he is a member of the Administrative Committee of ICES. After working for the Austrian Research Center Seibersdorf (ARCS), he joined the Foundation for Research on Information Technologies in Society - IT'IS in Zurich, Switzerland - as Associate Director. At IT'IS, Dr. Kainz worked on the development of in-vivo and in-vitro exposure setups for bio-experiments. His research interest is currently focused on the safety and effectiveness of medical devices and safety of humans in electromagnetic fields. This includes computational electrodynamics for safety and effectiveness evaluations using anatomical models of the human anatomy; magnetic resonance imaging (MRI) safety; performance and safety of wireless technology used in medical devices; electromagnetic compatibility of medical devices; and dosimetric exposure assessments. In 2004, Dr. Kainz initiated the Virtual Family Project in co-operation with IT'IS and the University of Houston. In 2010, Dr. Kainz received the Food and Drug Administration's Award of Merit for exceptional leadership in performance in addressing issues of compatibility of medical devices during magnetic resonance imaging by applying transparently scientific research to device regulation. FDA's Award of Merit is the most prestigious Honor Award for exceptional performance and achievement that brought tribute to the FDA, HHS, or the Federal government.

Clinical Status of MRI Scanning of Patients with CIED Devices, and Musing about the Future

1:00 P.M. – 1:45 P.M.

Dr. Michael Mollerus, MD – Essentia Health-St. Mary's Medical Center

Abstract: MRI is the diagnostic imaging modality of choice for a number of significant medical conditions. As the population ages, more people with implanted cardiac rhythm management devices will be referred for MRI scans. A body of literature now exists describing the clinical experience of patients with pacemakers and implantable cardioverter-defibrillators who have undergone MRI scans in a controlled environment. A review of that clinical experience as well as a description of scan protocols will be reviewed. Finally, reflections on requirements for future device capabilities to make them more MRI compatible will be provided.

Biography: Dr. Mike Mollerus is currently co-chair of the Essentia Heart and Vascular Medical Group of Essentia Health Systems as well as a practicing clinical cardiac electro-physiologist. A graduate of the University of San Francisco with a degree in Philosophy, he received his M.D. from the University of California, San Francisco in 1990, and completed his residency and fellowships at the Naval Medical Center, San Diego and at the University of California, San Diego. His research includes the behavior of pacemakers and implantable cardioverter-defibrillations in extreme EMI environments such as MRI scanners as well as rhythm discrimination using signal processing and other techniques.