

Workshop website was designed by Jodie R. Nghiem, Mounds View High School Honors Student

A Report on 2012 IEEE Twin-Cities Workshop: Wireless Bio-Sensors & Medical Devices

Chris Fuller
Chairman of IEEE TC-MTT-S
November 15th, 2012

The Twin Cities Microwave Theory and Techniques Society (TC-MTT-S) organized the workshop “Wireless Bio-Sensors and Medical Devices: A Practical Development Approach” on November 7th, 2012 at the Elm Creek Auditorium of the Minneapolis Marriott Northwest in Brooklyn Park, Minnesota.

The workshop was a unique opportunity for attendees to learn how to apply wireless technology to a bio-sensor or medical device and to network with leaders in the field of bio-sensors and medical devices. World class experts spoke at the workshop, including Mr. Kevin Bennet of the Mayo Clinic, Dr. Don Witters of the FDA, Dr. Rashmi Doshi of the FCC, Dr. David Nghiem of Global Wireless Technology, Mr. Robert Gaskill Director Medtronic-Neuro and many others.

The workshop was an all-day event for engineers and managers interested in learning how to implement wireless technology into bio-sensors and medical devices. Attendees were taught processes and an approach to setting requirements, designing, testing, and manufacturing wireless bio-sensors and medical devices, including regulatory approval processes.

The full-day workshop received significant sponsorship from our many sponsors. Our gold sponsor (i.e. \$5000 or more) was Global Wireless Technology Corporation (GWT, Inc). The five silver sponsors (i.e. \$1000 or more) included Analog Devices Corporation, Ansys Corporation, Northwest EMC Corporation, the IEEE MTT national and the IEEE Region 4. Three bronze sponsors (i.e. \$500) included TRS-RenTelco Corporation, Rohde & Schwarz Corporation, and the University of Minnesota-Institute for Engineering in Medicine.

The workshop had many volunteers, including Honors students from the University of Minnesota and Mounds View High School. The advice and insight of several members of the IEEE Twin Cities section was also invaluable to making the workshop a success.



University of Minnesota Honors Students Volunteering at the Registration Booth



Honors Students from Mounds View High School Helped Set Up the Workshop

Prior to the workshop, the IEEE Twin Cities Engineering in Medicine and Biology Society (TC-EMB-S) was defunct. An effort to renew interest in the TC-EMB-S was included in the effort to organize the workshop. Before the workshop event on November 7th, the TC-EMB-S was restarted by a terrific core of engineering leaders! The TC-EMB-S was provided a table during the workshop to help promote their organization and received significant interest from the attendees.



IEEE TC-EMB-S Table

Many other tables were located in the back of the workshop room for attendees to be able to find out more about the Twin Cities Microwave Theory and Techniques Society (TC-MTT-S), and our silver and gold sponsors.



TC-MTT-S Table

The IEEE national provided much of the membership development information that was on the MTT table, including enough free pens with an IEEE logo to be able to provide each attendee with a pen.



Global Wireless Technology Corporation Table



Analog Devices Corporation Table

The workshop was sold out with attendance at 140, the maximum capacity of the room. The workshop kicked off at 7:45 A.M. with a brief description of the events and many thanks to volunteers and sponsors.



Kick Off!

The first speaker of the workshop was Mr. Kevin Bennet of The Mayo Clinic on “Remote Monitoring - Medical Imperative and Engineering Advances for Health Care Delivery”

The abstract for Mr. Bennet’s talk was:

In order to improve the quality of medical care, reduce cost and assist more people in leading healthier lives, Cardiologists and Engineers have collaborated at Mayo Clinic to create a wireless device to measure and report a variety of physiological parameters in almost real time. The presentation will provide insights into the medical rationale and development path for this device which culminated in FDA approval last month. Additional thoughts concerning further infrastructure development will be provided.

Mr. Bennet’s biography:

Mr. Kevin E. Bennet is the Chairman of the Division of Engineering of the Mayo Clinic of Rochester, Minnesota, Assistant Professor of Neurosurgery and co-Director of the Neural Engineering Laboratory. His division, comprised of 67 technical staff, is responsible for the development and application of new technology for clinical practice and research. Major development efforts include deep brain stimulation, wireless physiological monitoring and minimally invasive surgery.

Mr. Bennet joined the Mayo Clinic in 1990 with current and past appointments as Chair of Strategic Alliances, Vice Chair of Information Technology Standards & Architecture Subcommittee, Clinical Practice Committee Equipment Subcommittee, Information Technology Coordinating Executive Committee, Pharmacy and Therapeutics Committee, Medical/Industry Relations Committee as well as chair and membership in various workgroups and taskforces. He has also served as a reviewer of Mayo Clinic Proceedings and the NIH Small Business Innovation Research program.

He has over 30 years of experience in technology development with organizations including W.R. Grace & Co., Exxon International and Amoco Chemicals. He has been a consultant to the National Institutes of Health and served on NIH site visit teams. He holds patents concerning semiconductor and optical technology has founded several technology-based companies.

Mr. Bennet received a Bachelor of Science degree in Chemical Engineering from the Massachusetts Institute of Technology and a Masters of Business Administration from Harvard Business School.



Mr. Kevin Bennet of the Mayo Clinic



Dr. Donald Witters of the U.S. Food and Drug Administration (FDA) spoke via Webex on the topic “Considerations for Wireless Technology in Healthcare.” Which described many of the topics which should be considered by a designer and manufacturer of medical devices, including Electro-Magnetic Compatibility (EMC) considerations.



Webex Being Set-up for Dr. Donald Witters of the FDA

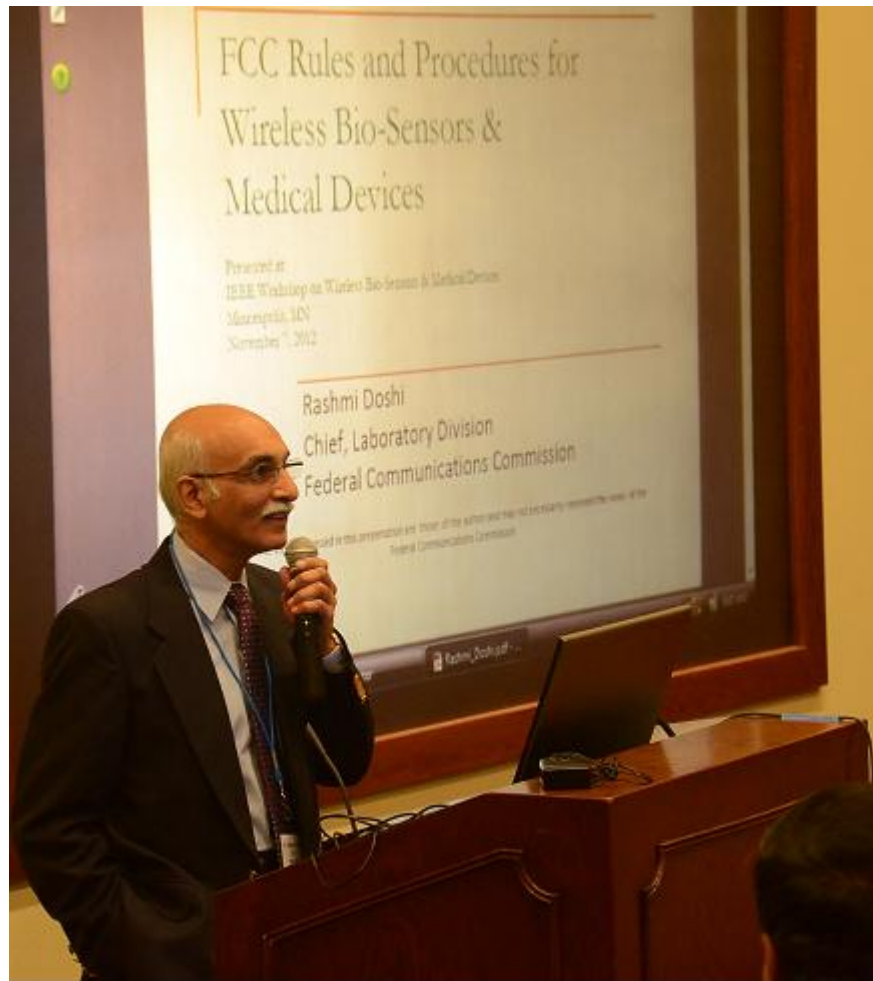
Dr. Rashmi Doshi was the third speaker of the morning on the topic of “An Overview of FCC Rules and Procedures for Wireless Bio-sensors and Medical Devices”

The abstract for Dr. Doshi’s talk:

The FCC permits wireless devices to operate under different rule parts and procedures. These rules are based on a variety of factors like power levels, frequency, potential for sharing the spectrum, etc. This talk will provide an overview of the rules relevant for medical devices and bio-sensors including some recent developments in the “medical radio (MedRadio)” rules. This will be followed by a discussion of procedures and requirements for authorization of equipment to comply with the rules. The review will conclude by presenting some of the factors to consider for co-existence of devices with other wireless devices.

Dr. Doshi’s Biography:

Rashmi Doshi is currently the Chief of FCC Laboratory Division in the Office of Engineering and Technology. He is responsible for managing the FCC’s laboratory staff in leading the evaluation of new technologies and the development of measurement procedures for RF compliance in support of the major policy initiatives at the FCC. He also manages the FCC’s Equipment Authorization program including the oversight of the Telecommunications Certification Bodies in the US and related conformity assessment programs. Rashmi has been involved in the communications industry for over 35 years and has worked as Executive Director for Verizon (Bell Atlantic, NYNEX) and held engineering positions at Bell-Northern Research and British Telecom Research Center. He has been involved in the development of network technologies for voice, data and multi-media services.



Dr. Rashmi Doshi of the U.S. Federal Communications Commission (FCC)



Coffee Break!

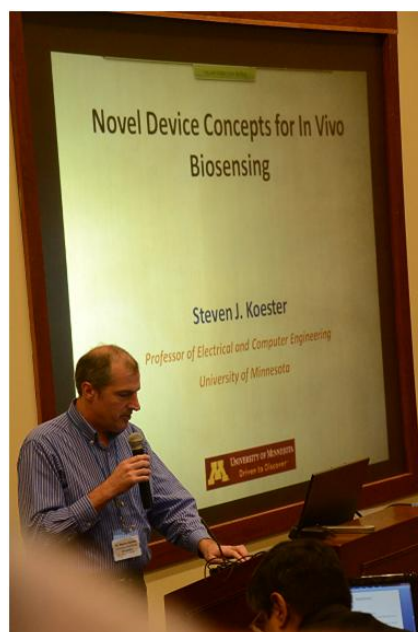
Dr. Steven Koester of the University of Minnesota Electrical and Computer Engineering Department spoke on the topic of “Novel Concepts for Passive Wireless Bio-Sensors”

The abstract for Dr. Koester’s talk:

In this talk, he described two novel concepts for realizing passive wireless biosensors. The first involves the use of fully-depleted silicon-on insulator (FDSOI) technology to realize ultrasmall, passive wireless dosimeters for radiation cancer therapy. Experimental results showing the response of the devices under a variety of medically-relevant irradiation conditions will be described and the design and fabrication challenges to realizing practical sensors will be discussed. In the second part of the talk, he described a novel wireless sensor concept based upon graphene. Graphene is a recently isolated two-dimensional material that has many unique and remarkable properties that make it interesting for use in a wide variety of electronic device applications. The particular property that will be exploited for wireless sensor applications is the low density of states, which leads to a strong quantum capacitance effect, an effect whereby the electrostatic potential changes as electrons are added or removed from the graphene. In this talk, he explained how the quantum capacitance effect can be utilized to realize passive wireless sensors for biological applications, and he showed recent simulation and experimental results on these devices, as well as provide an assessment for how these sensors can provide an advantage over MEMS-based passive wireless sensors.

Dr. Koester’s Biography:

Dr. Koester received his Ph.D. in 1995 from the University of California, Santa Barbara. From 1997 to 2010 he was a research staff member at the IBM T. J. Watson Research Center and performed research on a wide variety of electronic and optoelectronic devices, with an emphasis on those utilizing the Si/SiGe material system. From 2006-2010 he served as manager of Exploratory Technology at IBM Research where his team investigated advanced devices for use in advanced microprocessor technology. Since 2010, he has been a Professor of ECE at the University of Minnesota where his research focuses in part on novel electronic and photonic device concepts. Dr. Koester has authored or co-authored over 150 technical publications and conference presentations, 6 volumes, 3 book chapters, and holds 36 United States patents. He is a senior member of IEEE and is an associate editor for IEEE Electron Device Letters.



Dr. Steven Koester of the EECSCI Dept./U of MN

Jeff Solum, Starkey: Advanced Wireless Hearing-Aid System

Jeff Solem of Starkey Labs Corporation spoke on the topic of “Next Generation Wireless Connectivity for Hearing Aids”

The abstract for Mr. Solem’s talk:

Modern hearing instruments now have wireless connectivity for transporting digital data and digital audio to and from hearing instruments and accessory devices and between hearing instruments. This has enabled features like remote programming, remote control, audio streaming for phone calls, audio entertainment, assistive listening, ear to ear synchronization, and binaural signal processing. These systems have limited size and power budgets while having to maintain connectivity in an indoor and outdoor wireless setting. Challenges facing designers include small aperture antennas, antenna detuning due to proximity to the human body, multipath propagation, limited power budget, limited resources such as memory, processor instruction cycles, etc. Topics to be discussed in this presentation include:

- Propagation on the head
- Antenna considerations
- Binaural signal processing
- Power management
- Protocols
- New developments in Made for iPhone Hearing Instruments

Mr. Solem’s Biography:

Jeff Solum received his undergraduate degree in electrical engineering from North Dakota State University in Fargo, ND and his MSEE from Iowa State University in Ames, IA while working on wireless systems at Rockwell Collins in Cedar Rapids, IA. He has been the wireless system architect at Starkey Labs Inc. in Eden Prairie, Minnesota for the past 9 years, before that he was system architect at ADC telecommunications for both cable and wireless communications.



Mr. Jeff Solum of Starkey Labs Corporation

The all-you-can-eat lunch buffet was held in a room near the restaurant to ease food service. During the lunch, the silver sponsors (The IEEE Region 4/Jim Riess, Analog Devices, Ansys, Northwest EMC) spoke. Jim Riess also promoted IEEE membership development.



John Kruse of Analog Devices Corporation

After lunch, an industry panel presented on “Design Considerations and Implementation Options for Wireless Communication in Medical Device Systems”

The overall abstract for the talks was:

The prevalence of wireless communication is expanding rapidly in the medical device space. In general, wireless systems result in a more effective patient and user experience. While the convenience factor for clinicians and patients is very high with wireless communication, security and privacy must be paramount in the architecture design. These are among the significant system design and business considerations that need to be evaluated in the architecture of wireless applications for medical devices. Design and architecture trade-offs will be reviewed in the areas of safety risk management, security, privacy, standards, quality and business considerations. Development process will be compared around total custom solutions versus various levels of integrating off-the-shelf solutions. These considerations will be summarized to define priorities in total ownership costs, competitive advantage, and product application.

Antenna System Design Approach:

- a. Specification
- b. Antenna design for implant device
- c. Antenna design for external device
- d. Testing

RF Circuit Design Approach:

- a. Planning and Requirements definition
- b. Component survey
- c. Design
- d. Verification calculations/simulations
- e. Layout considerations
- f. Build and Test
- g. Verification testing/analyses/simulations

Development of software and firmware for medical systems is similar yet different from other systems. This discussion will recap the technical and management challenges posed by microelectronics, resource-constrained embedded platforms and regulatory requirements that affect medical devices.

Design Verification Testing & Production Testing

Biographies:

The speakers included Dr. David Nghiem, President & CEO of GWT Corporation; Robert Gaskill, Director of Medtronic Neurological Division; Chris Fuller of ATK Corporation and David Tran of Starkey Labs Corporation.

Dr. David Nghiem is the Founder, President and CEO of Global Wireless Technology (GWT), Inc. Dr. Nghiem has many years experience in the telecommunication and medical industries, including Harris Corporation, Qualcomm, USA Wireless and Medtronic. Dr. Nghiem is a former Assistant Dean of the Cullen College of Engineering, and former Director of the Telecommunication Center at the University of Houston.

David has invented a variety of practical antenna technologies for wireless-communication systems, including bio-sensor applications, MRI safety/compatibility for medical devices, and explosive detection for home-land

security and anti-terrorism applications. David has also been providing industry with fast-turn-around, cost-effective, compact and efficient antenna technologies. Dr. David Nghiem is Founder and Chairman of Global Environment Center (GEC) and Global Learning Center (GLC).

Chris Fuller has 24 years of experience in high-reliability design, including spacecraft components, science instruments, cell phone base station radios, medical implants, radar and near-field lenses. Mr. Fuller has an undergraduate degree in Electrical Engineering from the University of Minnesota - Minneapolis and a master degree with honors in Electrical Engineering from Johns Hopkins University. Mr. Fuller is the current chairman of the IEEE Twin Cities Microwave Theory and Techniques Society and is an adjunct faculty member at ITT-Tech.

Robert Gaskill has been involved in medical device product development since his first college internship in cochlear ear implants. He joined Cardiac Pacemakers, Inc., in 1987. Over 24 years, CPI became Guidant and later Boston Scientific. During this time, Bob was an engineer on teams and later led teams in the development of multiple platform products across multiple therapies. Over his last nine years at Boston Scientific, Bob led teams in the development and market release of programmers and remote patient management systems. Bob joined Medtronic Neuromodulation in 2011 and is leading product development projects in implantable infusion systems. Over the last ten years, the projects that Bob has led have included the implementation of single and multiple wireless communication systems. Bob has a BSEE from the University of Iowa and an MBA from the University of St. Thomas.

David Tran has worked at Medtronic and Starkey developing medical instruments and systems. David has also developed and supported systems for the telecommunications, transportation and retail industries. His experience includes systems engineering, software engineering and various management roles. The systems David has developed have ranged from real-time embedded hand-held systems to large-scale communications networks.



Mr. Gaskill of Medtronic Corporation



Dr. David Nghiem of Global Wireless Technology Corporation



Mr. Fuller of ATK Corporation



Mr. Tran of Starkey Labs Corporation





Coffee Break with TC-MTT-S Chairman Emeritus, Mike Gawronski

Following the afternoon coffee break, Dr. Nghiem, with the assistance of Rohde & Schwarz Corporation employees John Shasky and Alyssa Harder demonstrated antenna design techniques and discussed electromagnetic exposure risks.



The last formal speaker of the workshop was Dr. Rakesh Verma from the University of Houston who spoke on the topic of “Security of Implantable Devices, Sensors and Networks”

The abstract for Dr. Verma’s talk was:

Wireless Sensors are increasingly being deployed in hazardous, sensitive, or hostile environments for numerous civil, medical and military applications such as sensing the environment, biosensors, etc. They pose unique security challenges because of their inherent limitations in processing power and memory. This talk covers key concepts, features, applications, and security challenges of wireless sensor networks. Modern algorithms and techniques of authenticating the source of data to prevent malicious injection of bogus data into sensor networks will be explained. The talk will also include a discussion of efficient and secure key management, routing, and data aggregation protocols that are lightweight and can be implemented on resource-limited sensor nodes, and the adaptation of existing public key infrastructure for wireless sensor networks. Security challenges unique to medical applications will be discussed.

Dr. Verma’s biography:

Rakesh Verma is a Professor of Computer Science at the University of Houston (UH) and Director of the Secure Protocols and Systems Laboratory and the NSM Center for Information Assurance Research and Education at UH. He was the co-lead in the National Security Agency designation of UH as a Center of Academic Excellence in Information Assurance Education in 2009. His research interests are on formal methods with applications to protocol verification, automated reasoning and equational programming, on text and data mining, and on computer security. He has over seventy five peer-reviewed publications in leading journals and conferences. Rakesh was a visiting professor at the Centre for Informatics Research (CRIN) in Nancy, France, in 1995, 1996-97 and 2001. He received the PhD and MS degrees in Computer Science from the State University of New York at Stony Brook, where he was a Catacosinos Fellow, and his bachelor degree in Electronics Engineering from the Indian Institute of Technology (Varanasi), where he received the Prince of Wales Gold Medal. Rakesh is a member of ACM and co-organized the Second ACM SIGPLAN International Workshop on Rule-based programming (RULE 2001) workshop. He was a panel moderator at the ACM SIGCSE Symposium on Computer Science Education in 2006. He is a distinguished speaker of the ACM since 2011.



Dr. Rakesh Verma from the University of Houston