

# CURRICULUM VITAE



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## Summary

Forward-thinking computational modeling and simulation engineer with 25+ years of experience in Magnetic Resonance Imaging (MRI) safety. Expertise in computational and experimental methods for MRI safety of active and passive implantable medical devices (AIMDs & PIMDs). Reviewed over 1000 MRI safety-related submissions during 20 years at the U.S. FDA, including the world's first MR Conditional pacemaker. Proficient in assessing medical devices utilizing electromagnetic, electric, magnetic, or thermal energy for tissue ablation and other applications. Skilled in leading large governmental research projects and acquiring grants. Possesses in-depth knowledge of scientific and regulatory requirements for AIMD, PIMD, and partially internal/external medical devices. Committed to accelerating the development of safe and effective medical devices in the MRI environment, as well as ensuring the most effective MR Conditional labeling for all medical devices.

## Expertise Keywords

electrical engineering; electronics; electromagnetics; radio-frequency (RF) engineering; electromagnetic compatibility; medical devices; safety and efficacy of medical devices; regulatory aspects of medical devices; Instructions For Use (IFU) for medical devices; labeling of medical devices; international standards development; Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES); Magnetic Resonance Imaging (MRI) safety and efficacy; passive implantable medical devices; active implantable medical devices; safety of medical devices in the MRI environment; Magnetic Resonance (MR) Conditional labeling; safety of humans and medical devices in electromagnetic, electric, and magnetic fields; thermal safety of humans and medical devices; radiological health; mobile phone safety; experimental RF and thermal dosimetry; computational RF and thermal dosimetry; computational modeling and simulations; electromagnetic, electric, magnetic, and thermal measurements; safety and efficacy of electrical nerve stimulation; computational modeling of electrical nerve stimulation; anatomically correct computer models of the human anatomy, including computer models of pregnant women and their fetuses; dielectric and thermal tissue properties; verification & validation; uncertainty analysis; electrical safety of medical devices; governmental research projects; grants acquisition; peer reviewed publications.

## Education

2000	Technical University Vienna, Austria Degree: Doctorate (PhD) Major: Technical Science Dissertation: Interference of Electronic Implants by Mobile Phones
1997	Technical University Vienna, Austria Degree: Master of Science (MS) Major: Electrical Engineering Thesis: Modeling of Radiofrequency Fields in the Human Body
1989	Technologisches Gewerbemuseum Vienna, Austria Degree: High School Diploma with Honors Major: Biomedical Engineering

## Positions

02/22-Present	President and Chief Executive Officer High Performance Computing for MRI Safety, LLC Jasper, GA, USA & Bad Reichenhall, Germany
02/02-02/22	Senior Research Biomedical Engineer & CDRH's Subject Matter Expert (SME) in MRI Safety Food and Drug Administration Center for Devices and Radiological Health Office of Science and Engineering Laboratories Division of Biomedical Physics Silver Spring, MD 20993, USA
01/01-02/02	Associate Director Foundation for Research on Information Technologies in Society (IT'IS) 8004 Zurich, Switzerland
11/99-01/01	Research Associate Austrian Research Centers (ARC) Seibersdorf Research, GmbH Department of Mobile Communications Safety 1220 Vienna, Austria
01/98-11/99	PhD Student Austrian Research Centers (ARC) Seibersdorf Research, GmbH Department of Mobile Communications Safety 1220 Vienna, Austria

## Professional Societies

- [1] Full SigmaXi, Member, Elected
- [2] Institute of Electrical and Electronics Engineers (IEEE) Standards Association, Member, Elected
- [3] IEEE International Committee on Electromagnetic Safety, Administrative Committee, Member, Elected

- [4] American Society for Testing and Materials (ASTM) International, Committee Member
- [5] International Standards Organization (ISO), Committee Member
- [6] IEEE Standards, Committee Member
- [7] International Electrotechnical Committee (IEC), Committee Member

## Publications: Articles

- [1] Yang L, Yang X, Ye H, Kaula N, Jin Y, Zheng J, [Kainz W](#), Chen J. Computational study of the effects of orthopedic plates on gradient-induced peripheral nerve stimulation under MRI using electromagnetic and neurophysiological modeling. *Magn Reson Med*; 93(5):2108-22. 2025.
- [2] Islam MZ, Guo R, Akter MK, Zheng J, [Kainz W](#), et al. RF-induced heating reduction by minimizing the external portion of the partially in and partially out medical devices under MRI at 1.5T. *Magn Reson Med*; 93(5):2108-22, 2025.
- [3] Akter MK, Guo R, Zheng J, [Kainz W](#), et al. Effect of Strain Relief Loop Position on the RF-Induced Heating of Active Implantable Medical Devices at 1.5-T MRI, *IEEE Trans Electromagn Compat*; 66(4):1041-56. 2024.
- [4] Yang X, Zheng J, [Kainz W](#), Chen X, Chen J. Impact of Patient Body Posture on RF-Induced Energy Absorption by Orthopedic Plates. *Conc Magn Reson*; 2024(7418643):10, 2024.
- [5] Chang J, Lan Q, Guo R, Zheng J, Romero R, Long S, [Kainz W](#), Chen J. MRI RF-induced heating prediction of complex-shaped passive implantable medical devices using mesh-based convolutional neural network. *IEEE Trans Microw Theory Techn*; 71(5):2207-14. 2023.
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- [7] Yang X, Zheng J, Wang Y, Long SA, [Kainz W](#), Ji Chen. Body-loop related MRI RF-induced heating hazards: Observations, characterizations, and guidelines. *Magn Reson Med*; 87:337-48. 2022.
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- [15] Xia M, Zheng J, Yang R, Song S, Xu J, Liu Q, [Kainz W](#), Long SA, Chen J. Effects of patient orientations, landmark positions, and device positions on the MRI RF-induced heating for modular external fixation devices. *Magn Reson Med*; 85(3):1669-80. 2021.
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## Guidances for Industry and Food and Drug Administration Staff

- [1] Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, 2021.
- [2] Reporting of Computational Modeling Studies in Medical Device Submissions, 2016.
- [3] Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, 2016.
- [4] Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices, 2016
- [5] Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices, 2016.
- [6] Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2014.
- [7] Radio Frequency Wireless Technology in Medical Devices, 2013.
- [8] Coronary Drug-Eluting Stents - Nonclinical and Clinical Studies, 2008.
- [9] Criteria for Significant Risk Investigations of Magnetic Resonance Diagnostic Devices, 2003.

## Contributions to International Standards

- [1] IEC 62570:2014, International Electrotechnical Commission (IEC), Technical Committee (TC) 62 Electrical equipment in medical practice, Subcommittee (SC) 62B Diagnostic imaging equipment, Working Group (WG) 45 Items within the controlled access area of magnetic resonance equipment for human application, "Standard practice for marking medical devices and other items for safety in the magnetic resonance environment", 2014.
- [2] IEC 60601-2-33:2010+AMD1:2013+AMD2:2015, International Electrotechnical Commission (IEC), Technical Committee (TC) 62 Electrical equipment in medical practice, Subcommittee (SC) 62B Diagnostic imaging equipment, Maintenance Team (MT) 40 Magnetic resonance equipment for medical diagnosis "Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis", 2015.
- [3] IEC 62232:2017 ED 2, International Electrotechnical Commission (IEC), Technical Commission (TC) 106, Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure, "Determination of RF field strength, power density and SAR in the vicinity of radiocommunication base stations for the purpose of evaluating human exposure", 2017.
- [4] IEC 62209-1 ED 2.0 B, International Electrotechnical Commission (IEC), Technical Commission (TC) 106, Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure, "Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Part 1: Devices used next to the ear (Frequency range of 300 MHz to 6 GHz)", 2016.
- [5] IEC 62209-2 AMD1 ED1, International Electrotechnical Commission (IEC), Technical Commission (TC) 106, Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure, IEC 62209-2/AMD1 ED1, "Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)", 2010.

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- [8] IEC/IEEE 62704-2 ED1, International Electrotechnical Commission (IEC), Technical Commission (TC) 106, Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure, "Determining the peak spatial-average specific absorption rate (SAR) in the human body from wireless communications devices, 30 MHz to 6 GHz - Part 2: Specific requirements for finite difference time domain (FDTD) modelling of exposure from vehicle mounted antennas", 2017.
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- [16] IEEE C95.7-2014, Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES), Standard Coordinating Committee 39 (SCC39), Technical Committee 95 (TC95) Exposure Standards, Subcommittee 2 (SC2) Terminology, Units of Measurement and Hazard Communication, IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz, 2014.
- [17] IEEE C95.6-2002 (R2007), Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES), Standard Coordinating Committee 39 (SCC39), Technical Committee 95 (TC95) Exposure Standards, Subcommittee 3 (SC3) Safety Levels with Respect to Human Exposure, 0-3 kHz, IEEE Standard for Safety Levels With Respect to Human Exposure to Electromagnetic Fields, 0-3 kHz, 2007.
- [18] IEEE C95.1-2005, Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES), Standard Coordinating Committee 39 (SCC39), Technical Committee 95 (TC95) Exposure Standards, Subcommittee 4 (SC4) Safety Levels with Respect to Human Exposure, 3 kHz-300 GHz, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, 2005.
- [19] IEEE C95.1a-2010, Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES), Standard Coordinating Committee 39 (SCC39), Technical Committee 95 (TC95) Exposure Standards, Subcommittee 4 (SC4) Safety Levels with Respect to Human Exposure, 3 kHz-300 GHz, IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, Amendment 1: Specifies Ceiling Limits for Induced and Contact Current, Clarifies Distinctions between Localized Exposure and Spatial Peak Power Density, 2010.
- [20] IEEE C95.4-2002 (R2008), Institute of Electrical and Electronics Engineers (IEEE), International Committee on Electromagnetic Safety (ICES), Standard Coordinating Committee 39 (SCC39), Technical Committee 95 (TC95) Exposure Standards, Subcommittee 5 (SC5) Electro-Explosive Devices, IEEE Recommended Practice for Determining Safe Distances From Radio Frequency Transmitting Antennas When Using Electric Blasting Caps During Explosive Operations, 2008.
- [21] ASTM F2052-2015, American Society for Testing and Materials (ASTM), Subcommittee: F04.15, "Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment", West Conshohocken, PA, ASTM International, 2015.
- [22] ASTM F2119-2013, American Society for Testing and Materials (ASTM), Subcommittee: F04.15, "Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants", West Conshohocken, PA, ASTM International, 2013.
- [23] ASTM F2182-2011a, American Society for Testing and Materials (ASTM), Subcommittee: F04.15, "Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging", West Conshohocken, PA, ASTM International, 2011.
- [24] ASTM F2503-2013, American Society for Testing and Materials (ASTM), Subcommittee: F04.15, "Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment", West Conshohocken, PA, ASTM International, 2013.
- [25] ASTM F2213-17, American Society for Testing and Materials (ASTM), Subcommittee: F04.15, "Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment", West Conshohocken, PA, ASTM International, 2017.
- [26] SAE J2954-2016, Society of Automotive Engineers (SAE) International, "Wireless Power Transfer for Light-Duty Plug-In / Electric Vehicles and Alignment Methodology", 2016.

## Honors and Awards

- [1] 2018 Food and Drug Administration's Outstanding Service Award – Virtual Population Group
- [2] The citation reads: For outstanding service in the development of the Virtual Population computational models.
- [3] 2018 Food and Drug Administration's Excellence in Review Science Award – MRI Compatibility Review Group
- [4] The citation reads: To recognizes sustained efforts to improve MRI labeling for all medical devices and in particular for MR Conditional devices.
- [5] 2017 Food and Drug Administration's Group Recognition Award - BVS GT1 Fully Biodegradable Coronary Drug-Eluting Stent Team
- [6] The citation reads: For excellence in applying outstanding regulatory judgment and scientific expertise to the review and approval of the first fully biodegradable stent on the US market.
- [7] 2017 CDRH/OSEL Performance Management Appraisal Program (PMAP) Award
- [8] 2016 Magnetic Resonance in Medicine Highlights, Editor's Special Pick, "Virtual Population-Based Assessment of the Impact of 3 Tesla Radiofrequency Shimming and Thermoregulation on Safety and B1+ Uniformity"
- [9] 2016 Food and Drug Administration's Chief Scientist Publication Award for Basic Translational or Applied Science
- [10] The citation reads: For exceptional contribution to applied physics and regulatory science in generating a novel high resolution computational model of the human head and neck.
- [11] 2015 CDRH Excellence in Premarket Team Review Award - The Nucleus Hybrid L24 Original PMA Review Team
- [12] The citation reads: For excellence in reviewing a first-of-a-kind hearing implant system, Nucleus Hybrid L24, designed to provide electrical and acoustical stimulation simultaneously.
- [13] 2014 Citations Prize - The publication "The Virtual Family - Development of Anatomical CAD Models of two Adults and two Children for Dosimetric Simulations" (Physics in Medicine and Biology 55, N23–N38, 2009), won the Physics in Medicine and Biology 2014 Citations Prize: The Rotblat Medal. The Medal is awarded once a year to the authors of the research paper that has received the most citations in the preceding five years (according to the Institute for Scientific Information (ISI)). The Rotblat Medal is named in honor of Prof. Sir Joseph Rotblat who was the second — and longest serving — editor of PMB from 1961–1972. PMB has currently an impact factor of 2.9. Since its publication in 2009 the Virtual Family was cited 753 times in peer-reviewed literature.
- [14] 2010 Food and Drug Administration's Award of Merit. FDA's most prestigious Honor Award for exceptional performance and achievement that brought tribute to the FDA, HHS, or the Federal government.
- [15] The citation reads: 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.
- [16] 2009 Food and Drug Administration's Award for Distinguished Scientific Contribution
- [17] The citation reads: For exceptional leadership related to the safety of implantable medical devices in the magnetic resonance imaging (MRI).
- [18] 2008 Food and Drug Administration's Award for Distinguished Scientific Contribution

- [19] The citation reads: For distinguished scientific contributions related to the safety of implantable medical devices in the magnetic resonance imaging (MRI).
- [20] 2007 Food and Drug Administration's Group Recognition Award as member of the Magnetic Resonance Imaging Compatibility Working Group
- [21] The citation reads: For exceptional leadership in assuring the safety of implants and other devices that might be exposed to magnetic resonance imaging systems.
- [22] 2006 CDRH Group Recognition Award
- [23] Magnetic Resonance Imaging of Patients with Implanted Neurological Stimulators Postmarket Issue Action Team
- [24] The citation reads: For exceptional performance and dedication in addressing safety concerns related to the magnetic resonance imaging of patients with implanted neurological stimulators resulting in significant contribution to FDA's mission to protect the public health.
- [25] 2006 Food and Drug Administration's Award for Distinguished Scientific Contribution
- [26] The citation reads: For distinguished scientific contributions related to the safety of implantable medical devices in the magnetic resonance imaging (MRI) environment through the development of the SAR Intercomparison for MRI systems.
- [27] 2005 Food and Drug Administration's Award for Distinguished Scientific Contribution
- [28] The citation reads: For distinguished research related to electromagnetic compatibility of active implantable medical devices (AIMDs). This invention will directly contribute to ISO and AAMI standard development for implantable infusion pumps and neurostimulators. Dr. Kainz's research serves the public health need of helping to assure the safety of AIMD's in a daily growing environment of electromagnetic sources. Therefore, Dr. Kainz should be recognized for this set of significant and distinguished achievements by receiving a cash award.
- [29] 2005 CDRH Special Recognition Award
- [30] The citation reads: For outstanding scientific leadership in protecting the public health for medical devices and human exposure with metal detector security systems.
- [31] 2005 Best Student Paper Award, IEEE 2005 EMC Symposium
- [32] Wu D., Qiang R., Chen Ji, Kainz W, Seidman S. "Safety Evaluation of Walk-Through Metal Detectors"
- [33] 2004 Food and Drug Administration's Award for Outstanding Scientific Productivity
- [34] The citation reads: For outstanding productivity in modeling electromagnetic dosimetry in the human. This work serves the public health need of helping to assure the safety of cell phones. Therefore, Dr. Kainz should be recognized for this set of significant achievements by receiving a cash award.
- [35] 2003 Food and Drug Administration's Leveraging/Collaboration Award
- [36] The citation reads: For promoting public health through the establishment and implementation of an Interagency Agreement with the Federal Aviation Administration (FAA) to address electromagnetic compatibility of medical devices.
- [37] 2003 Food and Drug Administration's Award for Outstanding Efforts
- [38] The citation reads: For outstanding efforts involving risk assessment of radiofrequency emitting products. His work is from highest interest for the Center to guarantee CDRH's mission of protecting the health of the public by ensuring the safety of radiological products.
- [39] 2003 Bioelectromagnetics Society (BEMS) Student Award

- [40] The award was given for the best student presentation. I am co-author of the paper "Exposure setups for simultaneous exposure of 17 rats for risk assessment studies at 902 MHz and 1 747 MHz" and project leader for the exposure setup development.

## Special Invitations

- [1] Invitation by William R. Geisler, M.S., DABR, Community Health East to lecture at the American Association of Physicists in Medicine (AAPM) Summer School on EM dosimetry, medical device testing, and FDA MR regulations, guidelines, and recommendations, Summer 2018.
- [2] Invitation by Benjamin M.W. Tsui, Ph.D., Professor, Johns Hopkins Medicine Division of Medical Imaging Physics, Department of Radiology and Radiological Science, John Hopkins University to take the lead on the review article "Advances in Computational Human Phantoms and Their Applications in Biomedical Engineering – A Topical Review" to be published as an invited review article in the Journal IEEE Transactions on Radiation and Plasma Medical Sciences, to be published end of 2018.
- [3] Invitation by Devashish Shrivastava, PhD, Senior Staff Fellow/Mechanical Engineer, General Surgical Devices Branch, Division of Surgical Devices, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration to participate in a new textbook related to MR Imaging and MR Safety, to be published 2019.
- [4] Invitation by Prof. Dr. Niels Kuster, Director Foundation for Research on Information Technologies in Society (IT'IS), to participate in the Sim4Life Workshop "In Silico Solutions for Advanced Electroceuticals" during the 47<sup>th</sup> Annual Meeting of the Society for Neuroscience (SfN) and present FDA's view on "Verification, Validation, and Uncertainty Assessment for
- [5] EM & Neuro Modeling", Washington DC, USA, 14 Nov. 2017.
- [6] Invitation by Devashish Shrivastava, PhD, Senior Staff Fellow/Mechanical Engineer, General Surgical Devices Branch, Division of Surgical Devices, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration to participate in the International Society for Magnetic Resonance in Medicine (ISMRM) Workshop "Ensuring RF Safety in MRI: Current Practices & Future Directions" and present FDA's view on "Assessing the Radiofrequency (RF) Induced Heating of Simple & Multi-Component Passive Devices", McLean Tysons Corner, McLean, VA, USA, 28 Sep. – 1 Oct. 2017.
- [7] Invitation by Julia Brimacombe, Organizer Oxford Global's Inaugural Precision Medicine Congress to speak at the Precision Medicine Congress regarding FDA's view on regulating personalized and precision medicine, London, UK, 25-26 April 2017.
- [8] Invitation by Benjamin M.W. Tsui, Ph.D., Professor, Johns Hopkins Medicine Division of Medical Imaging Physics, Department of Radiology and Radiological Science, John Hopkins University, to participate in the Steering Committee organizing the 7<sup>th</sup> International Workshop on Computational Human Phantoms (CP2017), Annapolis, MD, 27-30 Aug. 2017.
- [9] Invitation by Michael Oberle, Ph.D., Chief Executive Officer, Zurich Med Tech to participate in GE's (General Electric) Computational Simulation Workshop in the Special Session "Major challenges and current use of Electronic Design Automation (EDA) tools, numerical phantoms, and validation methodologies, FDA's view on verification, validation, and uncertainty assessment, Aurora, OH, 12-13 Sep. 2016.
- [10] Invitation by Jorge A. Ochoa, Ph.D., Principal Engineer for biomedical engineering, Exponent to participate in the Medical Device Workshop's panel discussion and present FDA's view on MRI safety of active and passive implants in a Special Seminar on MRI Safety of Medical Devices, San Francisco, CA, USA, 25 April 2016.

- [11] Invitation by Prof. Dr. Niels Kuster, Director Foundation for Research on Information Technologies in Society (IT'IS), Competence Center for Personalized Medicine of the Swiss Federal Institute of Technology (ETH) Zurich, the University Zurich, the University Hospital of Zurich, and the Latsis Foundation, Zurich, Switzerland to participate in the Latsis Symposium 2016 on "Personalized Medicine – Challenges and Opportunities" in the session "Models, technologies & validation – towards the in silico patient" and present in a keynote speech on FDA's view and vision for the regulatory pathway of personalized medicine, ETH, Zurich, Switzerland, 27-29 Jun. 2016.
- [12] Invitation by Prof. Dr. Antonio Šarolić, Chair of EU COST Action BM1309 "EMF-MED", Chair of Applied Electromagnetics, University of Split, Croatia to participate in the COST Action BM1309 European network for innovative uses of EMFs in biomedical applications (EMF-MED), Workshop on Verification, Validation, and Uncertainty Assessment in Medical EMF Applications and present FDA's view on "Verification and Validation Requirements in the Regulatory Context", Prague, Czech Republic, 18 Nov. 2015.
- [13] Invitation by Teruo Onishi, Senior Research Engineer, RF Technology Research Group, Research Laboratories, NTT DOCOMO, INC., Kanagawa, Japan to participate in the 9<sup>th</sup> International Symposium on Medical Information and Communication Technology (ISMICT) Special Session on "EMC issues related with healthcare and medical information and communication technology (ICT)" and present FDA's view on EMC of medical devices and ICT, Kamakura, Japan, 24-26 March 2015.
- [14] Invitation by Prof. Jorge R Costa, Ph.D., Instituto de Telecomunicações, Associate Professor, Instituto Universitário de Lisboa to participate in the 9<sup>th</sup> European Conference on Antennas and Propagation, Special Session "Towards standardized methods for computational electromagnetics in biomedical technology" about standardized methods for the application of the Finite Difference Time Domain (FDTD) method in numerical dosimetry, Lisbon, Portugal, 12-17 April 2015.
- [15] Invitation by Prof. Dr. Niels Kuster, Director Foundation for Research on Information Technologies in Society (IT'IS), Zurich, Switzerland to participate in the 2015 Asia-Pacific International Electromagnetic Compatibility (EMC) Symposium and Exhibition (APEMC 2015) Special Session "Electromagnetic Interference & Compatibility Assessment within Anatomical/Physiological Environments" and present FDA's view on the "Compliance of Active Implants in Strong EM Environments such as MR, Wireless Power Transfer, Welding", Taipei, Taiwan, 26–29 May 2015.
- [16] Invitation by Chan Hyeong Kim, Ph.D., Professor, Department of Nuclear Engineering, Hanyang University, Seoul, Korea to participate in the Steering Committee for the 5<sup>th</sup> International Workshop on Computational Human Phantoms (CP2015) in Seoul, Korea, 20-22 Jul. 2015.
- [17] Invitation by Dipl.-Ing. (FH), Gregor Schaeffers, Managing Director, MR:comp GmbH, Testing Services for MR Safety & Compatibility, Gelsenkirchen, Germany to lecture at the MRI Safety Seminar on MR safety and compatibility of medical devices and current standards, FDA guidances, and MR testing methods, San Francisco, CA, USA, 3-5 Dec. 2014.
- [18] Invitation by J. Thomas Vaughan, Ph.D., Professor of Biomedical Engineering in the Mortimer B. Zuckerman Mind Brain Behavior Institute to participate in the International Society for Magnetic Resonance in Medicine (ISMRM) MR Safety Study Group Meeting and present FDA's view on current of future RF related standards and practices for MRI, Milan, Italy, 10-16 May 2014.
- [19] Invitation by Frank G. Shellock, Ph.D., FISMRM, FACC, FACSM, Adjunct Clinical Professor of Radiology and Medicine, Keck School of Medicine, University of Southern California to participate in the writing of the Textbook "MRI Bioeffects, Safety, and Patient Management" with two chapters: 1. "Using MRI Simulations and Measurements to Evaluate Passive Metallic Implants" and 2. "MRI Standards and Guidance Documents from the United States, Food and Drug Administration", Biomedical Research Publishing Group, 2013.

- [20] Invitation by Ji Chen, Ph.D., Professor, Department of Electrical & Computer Engineering, University of Houston to participate in the second meeting of the Industrial Advisory Board (IAB) for the Center for Electromagnetic Compatibility, University of Houston Hilton Hotel, Houston, TX, USA, 19-20 Nov. 2013.
- [21] Invitation by Dr. David Nghiem, Institute of Electrical and Electronics Engineers (IEEE) Region 4 Conferences Administrator & Vice Chair of IEEE Microwave Theory and Techniques Society to present "FDA's Perspective on MRI Compatibility of Medical Devices" as Keynote speaker at the 2013 IEEE Twin-Cities Workshop on MRI Safety/Compatibility Technologies for Biosensors & Medical Devices, Minneapolis, MN, Aug. 2013.
- [22] Invitation by Prof. Dr. Niels Kuster, Director Foundation for Research on Information Technologies in Society (IT'IS), Zurich, Switzerland on behalf of the Consortium of Computational Human Phantoms (CCHP) to present "Regulatory Aspects & Applications of the Virtual Family" at the 4<sup>th</sup> International Workshop on Computational Phantoms for Radiation Protection, Imaging and Radiotherapy, Zurich, Switzerland, 20-22 May 2013.
- [23] Invitation by Jose L. Contreras-Vidal, Ph.D., Director, Laboratory for Noninvasive Brain-Machine Interface Systems, Professor, Department of Electrical & Computer Engineering, University of Houston to participate in the 2013 International Workshop on Brain-Neural Machine Interface Systems, and present FDA's view on neurotechnology and medical device safety, The Methodist Hospital Research Institute, Houston, TX, USA, 24-27 Feb 2013.
- [24] Invitation by Benoît Derat, PhD, President, ART-Fi SAS, Paris, France to participate in the Special Session "New challenges and innovative approaches in Specific Absorption Rate (SAR) assessment within a broad variety of applications" at the European Conference on Antennas and Propagation (EuCAP 2013) and speak about the SAR assessment in patients with implanted devices under MRI exposure, Gothenburg, Sweden), 8-12 April 2013-
- [25] Invitation by Dipl.-Ing. (FH), Gregor Schaefers, Managing Director, MR:comp GmbH, Testing Services for MR Safety & Compatibility, Gelsenkirchen, Germany to lecture at the Hands-on MR Seminar "Medical Device Magnetic Resonance (MR) Safety Specialist for MR Imaging Safety and Compatibility of Medical Devices on MR safety and compatibility of medical devices and current standards, FDA guidances, and MR testing methods, Minneapolis, MN, USA, 14-16 June 2012.
- [26] Invitation by Dr. Gunde Ziegelberger, International Commission on Non-Ionizing Radiation Protection (ICNIRP), Federal Office for Radiation Protection to participate in the ICNIRP/WHO (World Health Organization) jointly organized Workshop on Non-Ionizing Radiation Protection in Medicine and speak about high intensity non-ionizing radiation applications and adverse events, Bonn, Germany, 2 Dec. 2012.
- [27] Invitation by Dr. Gunde Ziegelberger, International Commission on Non-Ionizing Radiation Protection (ICNIRP), Federal Office for Radiation Protection, to speak about medical and cosmetic aspects of Non-Ionizing Radiation at the 7<sup>th</sup> International Non-Ionizing Radiation Workshop, Edinburgh, United Kingdom, 9-11 May 2012.
- [28] Invitation by Nathalie Mariano, Program and Events Manager, SV Forum Health Tech Conference "New Technologies and Business Models - Regulation and the Role of Standards: Ensuring Safety, Quality, Scalability" to participate in the Panel Discussion, Redwood City, CA 16<sup>th</sup> May 2012.
- [29] Invitation by Dr. Regula Storrlein-Gasser, Managing Director Centro Stefano Franscini to attend the Workshop "EMF Health Risk Research: Lessons Learned and Recommendations for the Future" and participate in the Podiums Discussion as Invited Speaker, Monte Verita, Switzerland, 21-26 Oct. 2012.
- [30] Invitation by Jean-Frederic Gerbeau, INRIA Paris-Rocquencourt to participate, and present Division of Biomedical Physics' (DBP) Magneto Hydro Dynamic Project at the Symposium "Magneto Hydro Dynamic Effect in the MRI" held in conjunction with the 18<sup>th</sup> international conference on Biomagnetism, Paris, France, 26-30 August 2012.



- [31] Invitation by J. Thomas Vaughan, Ph.D., Professor of Biomedical Engineering in the Mortimer B. Zuckerman Mind Brain Behavior Institute to present FDA's perspective on MRI RF safety at the 8<sup>th</sup> Biennial Minnesota Workshop on High and Ultra-High Field Imaging at the Center for Magnetic Resonance Research (CMRR), University of Minnesota, Minneapolis, MN, 14-16 Oct. 2011.
- [32] Invitation by Yao Lu, MD, PhD, Executive Chair of EPS Montreal Occupational Safety & Health Forum & President of EPS Global Medical Development Inc. to present my work on exposure safety of pregnant women "Calculation of induced current densities and specific absorption rates (SAR) for pregnant women exposed to hand-held metal detectors", Montreal, Quebec, Canada, 15-16 Aug., 2011.
- [33] Invitation by Prof. Andreas Melzer, MD, DDS, Director Institute for Medical Science and Technology, University of Dundee, UK, Leader of MRI-guided Intervention and Surgery to present an update on FDA's view on MR safety and compatibility at the German Technical Committee "MR Technology in Medicine" Annual Meeting held in conjunction with the German Biomedical Congress, Freiburg, Germany, 27-30 Sep. 2011.
- [34] Invitation by Prof. George Xu from the Nuclear Engineering and Engineering Physics Department at the Rensselaer Polytechnic Institute to write a Chapter about "Applications to Nonionizing Radiation Protection" for the Handbook of Anatomical Models for Radiation Dosimetry, Editors Xie George Xu and Keith F. Eckerman, CRC Press, Taylor & Francis Group, 2009.
- [35] Invitation by Prof. James Weaver from the Bioelectromagnetics Society: "The opportunity for in-silico bioelectromagnetics, BEMS 2006, 28th Annual Meeting, Cancun, Mexico, 11-15 June 2006.
- [36] Invitation by Dr. Mays Swicord, Chairman IEEE International Committee on Electromagnetic Safety (ICES) Technical Committee (TC) 95 to lead a workshop on Dosimetry Research Needs, Session "EM Modeling from 0.1 MHz to 300 GHz" at the Mobile Manufacturers Forum (MMF) Meeting, Rockville, MD, 11 May 2004.
- [37] Invitation by the 21<sup>st</sup> International Congress on Biomedical Engineering to chair the Session "Medical Devices II", Bethesda MD, 28-29 Sep. 2002.
- [38] Invitation by Ferdinand Kaser from the European Commission (EU) to review EU funded projects for the International Science and Technology Center (ISTC) and the Science and Technology Centre in Ukraine (STCU).

## Offices, Committee Assignments, or Special Assignments Held in Professional and Honorary Societies

- [1] 2013 – Member of IEEE/ICES International Committee on Electromagnetic Safety (ICES) Technical Committee 95, Sub-Committee 6 (SC6), EMF Dosimetry Modeling with Application to Human Exposure Standards.
- [2] 2012 – Member of the SAE J2954 Taskforce: Wireless Power Transfer for Light-Duty Plug-In Electric Vehicles and Positioning Communication.
- [3] 2007 – Member International Standards organization (ISO) – International Electrotechnical Commission (IEC) Joint Working Group (JWG) Subgroup on Active Implantable Medical Devices (AIMD) Mode for MRI: To develop the rationale behind the creation of these standardized exposure levels and their unique advantages and limitations, and further define their specifications and methodologies via which they may be implemented throughout the MR community and industry today.
- [4] 2006-2009 – Chairman of the IEEE SCC34/SC2/WG2 SAM (Specific Anthropomorphic Phantom) Intercomparison Study including 12 international recognized expert groups on FDTD (Finite Difference Time Domain) Modeling.
- [5] 2006-2010 – Secretary of ICES (International Committee on Electromagnetic Safety) Standard Coordination Committee, Sub-Committee 1 (ICES/SC1). ICES/SC1 is developing the standard titled "Recommended Practice for Measurements and Computation of Electric, Magnetic and Electromagnetic Fields With Respect to Human Exposure to Such Fields, 0 - 100 kHz", since 2010 Member of ICES/SC1.
- [6] 2006 – Member IEEE ICES (International Committee on Electromagnetic Safety) Administrative Committee (AdCom): The ICES AdCom has been established to oversee the operation of ICES, including fundraising and liaison with IEEE and non-IEEE national and international organizations of similar scope, including the International Commission on Non-Ionizing Radiation Protection (ICNIRP), WHO, IEC, NATO, national groups, such as the National Council on Radiation Protection and Measurements (NCRP), the American Conference of Government Industrial Hygienists (ACGIH), and the relevant federal agencies of the US, e.g., FDA, FCC, OSHA, NIOSH, as well as corresponding national agencies of other countries, since 2013 Member at Large.
- [7] 2006 – Member – CDRH Liaison as Technical Expert to ISO-IEC JWG: Developing a Technical Specification as a “prospective standard for provisional application” in the field of active implantable medical device (AIMD) and Magnetic Resonance (MR) compatibility. The MR compatibility of AIMDs is expressed in defined terms as MR Safe, MR Conditional, and MR Unsafe.
- [8] 2006 – Member - IEC - TC62B - WG45: This standard specifies a uniform marking practice, which indicates possible hazards in the environment of MR Equipment (Standard for Marking). The standard provides simple visual symbols and terms that are intended to avoid injuries and other accidents. For marking items it is recommended to use the presented symbols.
- [9] 2006 – Member – CDRH Primary Liaison - IEC - TC62B – Maintenance Team (MT) 40: Develops 60601-2-33 “Medical electrical equipment. Particular requirements for safety. Particular requirements for the safety of magnetic resonance equipment for medical diagnosis”.
- [10] 2005-2014 – Chairman of IEEE TC34 / SC1: IEEE P1528-2003 - IEEE Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head from Wireless Communications Devices: Measurement Techniques, since 2014 Member of IEEE TC34/SC1.

- [11] 2005-2014 – Chairman of IEEE Standard Coordination Committee 34, Sub-Committee 2, Working Group 2, SCC34/SC2/WG2, Development of Standard titled IEEE Recommended Practice for Determining the Spatial-Peak Specific Absorption Rate (SAR) in the Human Body Due to Wireless Communications Devices: Computational Techniques, Invited by Howard Bassen - Chairman of SCC34/SC, since 2014 Member of IEEE TC34/SC2.
- [12] 2004 – Member American Society for Testing and Materials (ASTM) F2182–02a Committee F04: Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging.
- [13] 2005 – IEEE ICES TC34 SC2 – Member Standard Committee P1528.1: “IEEE P1528.1™/D1.0 Draft Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Body from Wireless Communications Devices, 30 MHz - 6 GHz: General Requirements for using the Finite Difference Time Domain (FDTD) Method for SAR Calculations”.
- [14] 2005 – IEEE ICES TC34 SC2 – Member Standard Committee P1528.2: “IEEE P1528.2™/D1.0 Draft Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Body from Wireless Communications Devices, 30 MHz - 6 GHz: Specific Requirements for Finite Difference Time Domain (FDTD) Modeling of Vehicle Mounted Antennas”.
- [15] 2005 – IEEE ICES TC34 SC2 – Member Standard Committee P1528.3: “IEEE P1528.3™/D1.0 Draft Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Body from Wireless Communications Devices, 30 MHz - 6 GHz: Specific Requirements for Finite Difference Time Domain (FDTD) Modeling of Mobile Phones/Personal Wireless Devices”.
- [16] 2005 – IEEE ICES TC34 SC2 – Member Standard Committee P1528.4: “IEEE P1528.4™/D1.0 Recommended Practice for Determining the Peak Spatial Average Specific Absorption Rate (SAR) in the Human Body from Wireless Communications Devices, 30 MHz - 6 GHz: Requirements for Using the Finite-Element Method for SAR Calculations, specifically involving Vehicle Mounted Antennas and Personal Wireless Devices”.

## Participation in National Scientific Meetings, Technical Conferences, Workshops, Seminars, etc.

- [1] IEEE EMBS Conference on Neural Engineering, Boston, USA, 25-27 Apr. 2023.
- [2] ISMRM (The International Society for Magnetic Resonance in Medicine) & ISMRT (The International Society for MR Radiographers & Technologists) Annual Meeting & Exhibition, annually since 2002.
- [3] ISMRM Workshop on MR Safety: From Physics & Physiology to Policies & Practice, 21-23 October 2022, NYU Langone Health, New York City, NY, US
- [4] Lectured in the „Medical Device MR Safety Specialist“ & „MR Safety Expert“ Seminar in Mar. 2022, Jun. 2022, Oct. 2022, Dec. 2022, Feb. 2023, and Jun. 2023.
- [5] Participation in the Seminar “Longitudinal examinations of deep brain stimulation: Can reverse translation help?”, 15 Sep. 2017.
- [6] Modeling and Simulation Session at the 2017 FDA Science Forum: “The Virtual Family”
- [7] Participation in the FDA sponsored Workshop on Verification, Validation and Uncertainty Quantification, 15-16 Aug. 2017.
- [8] Participation in the seminar “Assessing the Credibility of Complex Computational Models, such as Cardiac Models”, 9 June 2017.
- [9] Participation in the Neuroscience 2017 Conference, Washington DC, 11-15 Nov. 2017.
- [10] Participation in the seminar “Living Heart Project: Applicability Analysis of Complex Biomedical Models”, 4 May 2017.
- [11] Participation in the Medical Device Innovation Consortium (MDIC) Annual Public Forum, 21 Sep. 2016.
- [12] Participation in the seminar “Bayesian Statistics: What the Non-Statistician Needs to Know”, 25 Oct. 2016.
- [13] CDRH Science Sharing Seminar: “Techniques to Assess MRI RF Induced Heating for Medical Devices”, 1 Feb. 2016.
- [14] Participation in the seminar OpenSim “Locus of Control: Are You in Control of Your Simulations?”, 28 Oct. 2015.
- [15] CDRH Science Sharing Seminar: “A virtual high-definition model of the human head for regulatory science”, 5 May 2014.
- [16] Participate in the Interagency Modeling and Analysis Group (IMAG) Multiscale Modeling Consortium Meeting, 3-4 Sep. 2014.
- [17] Participation in FDA’s public workshop on Computer Models and Validation, 11-12 Jun. 2013.
- [18] Biomedical Engineering Society (BMES)/FDA Frontiers in Medical Devices Conference, participation annually since the first conference in 2012.
- [19] Participation in the Computer Modeling Workshop, 6-8 Sep. 2012.
- [20] “MR Critical Implants, MR Critical Medical Devices and ASTM MR Safety Standards”, The International Society for Magnetic Resonance in Medicine, Seventeenth Scientific Meeting and Exhibition, Honolulu, Hawai’i, USA, 18-24 April 2009.
- [21] “Magneto-hydrodynamic simulations for non-invasive cardiac blood flow measurement”, BioEM2009, Joint Meeting of the Bioelectromagnetics Society (BEMS) and the European BioElectromagnetics Association (EBEA), Davos, Switzerland, June 14-19, 2009.

- [22] Invited presentation at the “Technical Committee Meeting MR Technology in Medicine” 10th of September 2009, Munich, Germany to present “FDA Guidance (2008) on MR Safety and Compatibility of Passive Implants”, 10 Sep. 2009.
- [23] Contributions Towards the Rigorous RF Safety Testing of Medical Implants and MR Critical Medical Devices During MR Exams”, BioEM2009, Joint Meeting of the Bioelectromagnetics Society (BEMS) and the European BioElectromagnetics Association (EBEA), Davos, Switzerland, 14-19 June 2009.
- [24] Electromagnetic Compatibility Issues between Vehicular Mounted Antennas and Implantable Medical Devices”, BioEM2009, Joint Meeting of the Bioelectromagnetics Society (BEMS) and the European BioElectromagnetics Association (EBEA), Davos, Switzerland, 14-19 June 2009.
- [25] “Variation of whole body averaged phantom specific absorption rate (SAR)”, ASIA-Pacific EMC Week, Topical Meeting on Biomedical Electromagnetics, Singapore, 19-23 May 2008.
- [26] “Safety Considerations for Radio Frequency Induced Heating of Implants”, ISMRM Safety Workshop, Lisbon, Portugal, 13-14 Jul. 2008.
- [27] “CAD-Phone SAR Computational Inter-Laboratory Study IEEE TC34, SC2-WG2 1528.3”, 2<sup>nd</sup> International Conference on Bioinformatics and Biomedical Engineering, Shanghai, China, 16-18 May 2008.
- [28] “Numerical and Experimental Evaluation of RF Induced Heating of a Generic Medical Implant During MRI Exams”, BEMS 2008, 30th Annual Meeting, 8-12 June 2008.
- [29] Performance of the Exposure Systems Developed for the PERFORM A Studies”, EBEA 2007, 8<sup>th</sup> International Congress of the European Bio-Electromagnetics Association (EBEA), Bordeaux, France, 10-13 Apr. 2007.
- [30] The “Virtual Family” – Novel CAD based anatomical models of two adults and two children for dosimetry and implant evaluations”, BEMS 2007, 29<sup>th</sup> Annual Meeting, Kanazawa, Japan, 10-15 June 2007.
- [31] “The opportunity for in-silico bioelectromagnetics, BEMS 2006, 28<sup>th</sup> Annual Meeting, Cancun, Mexico, 11-15 June 2006.
- [32] “Possible non-compliance of one walk through metal detector for pregnant women models as compared to ICNIRP Guidelines”, BEMS 2006, 28<sup>th</sup> Annual Meeting, Cancun, Mexico, 11-15 June 2006.
- [33] “Sound procedures for compliance testing of active implantable medical devices with safety limits for RF exposure”, BEMS 2006, 28<sup>th</sup> Annual Meeting June 11-15, Cancun, Mexico, 2006, “Macro-Dosimetry and the Virtual Family”, Aegis Mini-Symposium on Scientific Issues in Non-Lethal Interventions at BEMS 2006, 28<sup>th</sup> Annual Meeting, Abstract, Cancun, Mexico, 11-15 June 2006.
- [34] “An efficient two-dimensional FDTD method for bio-electromagnetic applications”, IEEE Transaction on Magnetics (Compumag 2005), 15<sup>th</sup> Conference on the Computation of Electromagnetic Fields, Shenyang, Liaoning, China, 26-30 June 2005.
- [35] "Development of pregnant woman models for nine gestational ages and calculation of fetus heating during magnetic resonance imaging (MRI)", The Bioelectromagnetics Society (BEMS), BioEM 2005, University College of Dublin, Ireland, 19-24 June 2005.
- [36] "The specific anthropomorphic mannequin (SAM) compared to 14 anatomical head models using a novel definition for the mobile phone positioning", The Bioelectromagnetics Society (BEMS), BioEM 2005, University College of Dublin, Ireland, 19-24 June 2005.
- [37] "The future of anatomical models - Anatomical CAD models for numerical dosimetry and implant evaluations", The Bioelectromagnetics Society (BEMS), BioEM 2005, University College of Dublin, Ireland, 19-24 June 2005.
- [38] “Calculation of induced current densities and specific absorption rates (SAR) for pregnant women exposed to handheld metal detectors”, Bioelectromagnetics Society - BEMS 25<sup>th</sup> annual meeting, 2004.

- [39] “Metal detector simulator for medical device EMI test”, 21<sup>st</sup> International Congress on Biomedical Engineering, Biomedical Engineering: Recent Developments, J Vossoughi (Editor), ISBN: 1-930636-01-6, 2003.
- [40] “Exposure setups for simultaneous exposure of a large number of rats for risk assessment studies at the mobile communication frequencies 902 MHz and 1747 MHz”, EBEA 2001, 5<sup>th</sup> International Congress of the European Bio-Electromagnetics Association (EBEA), 6-8 September, Marina Congress Center, Helsinki, Finland, 2001.
- [41] “Interference of electronic article surveillance systems and metal detector gates with implantable neurological pulse generators”, EBEA 2001, 5<sup>th</sup> International Congress of the European Bio-Electromagnetics Association (EBEA), Marina Congress Center, Helsinki, Finland, 6-8 Sep. 2001.
- [42] “High resolution animal models for numerical dosimetry”, EBEA 2001, 5<sup>th</sup> International Congress of the European Bio-Electromagnetics Association (EBEA), Marina Congress Center, Helsinki, Finland, 6-8 Sep. 2001.
- [43] “Electromagnetic interference of GSM mobile phones with implantable neurological pulse generators”, Bioelectromagnetics Society 22<sup>nd</sup> Annual Meeting Abstract Book, Technical University Munich, Germany, pp. 19 – 20, 11-16 June 2000.

## Food and Drug Administration Special Assignments and Advisory Committees

- [1] 2021 – Work with Biniyam Tesfaye Taddese, Howard Bassen, and Anne Hammer (Network of Experts Coordinator) to find experts helping with the physiological responses from induced voltages in neurostimulators when patients get exposed to Electronic Article Surveillance Systems.
- [2] 2020 – Work with Howard Bassen and Joseph D. Bowman, PhD, Research Industrial Hygienist, Engineering and Physical Hazards Branch, Center for Disease Control (CDC) / NIOSH (National Institute for Occupational Safety and Health) to answer questions about acceptable level of Wi-Fi radiation exposure in the office environment.
- [3] 2018 – Work with DBP’s MR team on Dr. Lisa Gilotty’s, Chief, Research Program on Autism Spectrum Disorders, Division of Translational Research, National Institute of Mental Health, request about the use of MRI/fMRI for brain scans in fetuses for research purposes.
- [4] 2017 – Associate Editor for a Special Issue in IEEE Transactions on Radiation and Plasma Medical Sciences (TRPMS) related to Computational Human Phantoms (CHP) for computational modeling and simulations (CM&S) for biomedical imaging, radiation dosimetry, treatment planning, and regulatory submissions.
- [5] 2016 – Draft CDRH response to media request on wireless charging safety.
- [6] 2016 – Participate in CDRH’s Ad-hoc team to assist the Medical Imaging and Technology Alliance (MITA) with MRI Multi-Channel RF Transmit Coils (Tx) Definitions and Normal Operating Mode Clause exception.
- [7] 2015 – Draft (as single author) of a New Level I CDRH Guidance “Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices Guidance for Industry and Food and Drug Administration Staff”, published within 13 months in final version on 22 Mar. 2016.
- [8] 2015 – Scientific review of the DOE (Department of Energy) project proposal “Electromagnetic Modeling of Human Body Using High Performance Computing”.
- [9] 2015 – Drafting for the FDA Link employee newsletter: “Regulatory Applications of the Virtual Family”.

- [10] 2015 – CDRH RF Health Effects Working Group: Co-author of two official FCC (Federal Communication Commission) requests: 1. Letter from FCC on Notice of Inquiry, and 2. FCC Letter on Wireless Power Transfer (WPT).
- [11] 2014 – Working with FDA’s Office of Media Affairs on a press release for the Virtual Family.
- [12] 2014 – Participation in the Office of the Center Director’s team developing performance metrics for CDRH’s research programs: providing the details of using the Virtual Family in CDRH medical device submissions. The Virtual Family is frequently used in regulatory submissions; on average in ~30 medical device submissions per year and was cited more than 750 times in peer-reviewed literature (Feb. 2018).
- [13] 2013 – Participation in CDRH’s MR Working Group sub-team to develop guidance on labeling accessories in the MRI environment.
- [14] 2013 – Co-authoring together with Dr. Terry Woods (OSEL) and Dr. Jana Delfino (OIR) a MRI Safety Seminar Series for ODE.
- [15] 2013 – Participation in CDRH’s Working Group and American Society of Mechanical Engineers (ASME) Verification & validation (V&V) 40 Subcommittee developing a RAM (Risk Assessment Matrix) & CAM (Credibility Assessment Matrix).
- [16] 2013 – Participation in the OIR/ODE Working Group to develop guidance for MR Conditional Devices in Multi-Transmit MR Systems.
- [17] 2013 – Participation in the CDRH MR WG team for developing recommendations for labeling accessories in the MRI environment.
- [18] 2012 – Contributions to the CDRH Science Report “Regulatory Science in FDA’s Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health”.
- [19] 2012 – Advising the National Center for Toxicological Research (NCTR) on their exposure system for in-vitro cell exposure to cell phone radiation.
- [20] 2012 – Advising the National Institute for Occupational Safety and Health in the development for guidance on Wi-Fi safety.
- [21] 2012 – Tasked by Bryan H. Benesch, Special Assistant to the Director and CDRH Device Determination Expert, to be part of CDRH’s new Standards Priority Criteria scoring system.
- [22] 2012 – Initiation, together with Jim Olsen, MR Research Manager, Medtronic Inc., to develop a new MRI scan mode overcoming the limitations of the current scan modes: the Fixed Parameter Option:B (FPO:B). This proposal was eventually incorporated 2015 in the MR safety Standards IEC 60601-2-33.
- [23] 2012 – Invited by Dr. Gunde Ziegelberger, International Commission on Non-Ionizing Radiation Protection (ICNIRP), Federal Office for Radiation Protection, to participate in the review of the "Draft Guidelines for Limiting Exposure to Electric Fields Induced by Movement of the Human Body in a Static Magnetic Field and by Time-Varying Magnetic Fields Below 1 Hz".
- [24] 2012 – Invited by Prof. Dr. Niels Kuster, Director Foundation for Research on Information Technologies in Society (IT’IS) to be member of the Advisory Committee for the two, industry funded, MR safety projects MRI+ and MRI#.
- [25] 2012 – Tasked by Dr. Steve Pollack, Director OSEL to develop a DBP research program related to Metal-on Metal (MoM) implant safety.
- [26] 2012 – Tasked by Dr. Jeff Shuren, Director CDRH, to draft a reply letter to Zimmer Biomet regarding computational modeling requirements for MR Conditional implants.
- [27] 2012 – Member of CDRH/OSEL Working Group to develop a CDRH Library of Models.

- [28] 2011 – Member of the Working Group drafting the Office of Science and Technology Policy (OSTP), The White House, White Paper “Cheaper, Faster, Safer: The Case for Investing in Medical Device Computer Modeling and Simulation and Ushering in the Next Medical Age”.
- [29] 2011 – Member of the Working Group for the Guidance Document on “Reporting of Computational Modeling Studies in Medical Device Submissions”.
- [30] 2011 – Member of the Working Group for the Office of Science and Engineering Laboratories (OSEL) Knowledge Management Team for OSEL’s IT needs.
- [31] 2011 – U.S. Marshals Service - John Shell Judicial Security Inspector requested FDA’s assistance in assessing the exposure of pregnant woman to metal detectors.
- [32] 2011 – Member of the CDRH MRI Safety Initiative Working Group which organized the FDA sponsored MRI Safety Workshop held on 25-26 Oct. 2011.
- [33] 2011 – Advisor to the National Institute for Occupational Safety and Health, CDC, regarding the safety of Wi-Fi systems.
- [34] 2011 – Invitation by the National Institute of Standards and Technology to participate at the “Electroshock Weapons Test and Measurement Workshop”, 21 Jan. 2011.
- [35] 2010 – Leading the OSEL Team to develop a MRI Labeling library together with Brian Fitzgerald from OSEL/DESE.
- [36] 2010 – Member of the CDRH MR Club to review and discuss important MR related publications on a monthly basis.
- [37] 2009 – Member of the CDRH Task Force to work with CMS (Centers for Medicare & Medicaid Services) improving MRI Safety. Members of this Task Force include CDRH personnel from OCER, OCD, ODE, OIVD, OSB and OSEL and is led by Commander Sean Boyd.
- [38] 2007 – Participation in the MMF-GSMA (Groupe Spéciale Mobile Association) Dosimetry Program Phase 2: Scientific Basis for Base Station Exposure Compliance Standards.
- [39] 2005 – since 2005 Member of the CDRH RF Health Effects Working Group.
- [40] 2005 – Member of the Working Group for the Guidance Document on “Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment”.
- [41] 2006 – since 2006 Member of the MRI+ research consortium; the MRI+ develops a new scientific basis for controlling the maximum temperature increase during MR scanning, and to make its work available for the applicable international standard, IEC 60601-2-33. MRI+ was finalized in November 2011; and 1 year extension is planned.
- [42] 2004 – Member of the Working Group for the Guidance Document on “Radio-Frequency Wireless Technology in Medical Devices”.
- [43] 2003 – since 2003 Member of the CDRH MRI Safety Working Group.
- [44] 2003 – U.S. Department of State - Pregnant woman security workers exposed to metal detectors. David Needham, Director U.S. Department of State, Division of Safety, Health and Environmental Management request through Dr. Larry Kessler with an official request from the U.S. State Department for my involvement in this issue of pregnant woman security workers exposed to metal detectors.
- [45] 2003 – Dr. Rashmi Doshi, Chief FCC (Federal Communications Commission) Laboratories, Federal Communications Commission (FCC) request a review of the dipole validation calculations for the IEC (International Electrotechnical Commission) Standard "Procedure to measure the Specific Absorption Rate (SAR) in the frequency range of 300 MHz to 3 GHz, Part 1: hand-held mobile wireless communication devices. FCC also requested my advice on whole body modeling methods for human exposure evaluations.



- [46] 2002 – U.S. Department of Transportations, Transportation Security Administration - Pregnant women exposed to handheld metal detectors. Walter Wall, Manager Systems Integration Branch, U.S. Department of Transportations, Transportation Security Administration (TSA) from Sep. 25<sup>th</sup>, 2002, to request a formal FDA opinion based on the publication "Calculation of induced current densities and specific absorption rates (SAR) for pregnant women exposed to hand-held metal detectors".

## Successful External Funding & Research Collaborations

- [1] 2017 – Collaboration with the Foundation for Research on Information Technologies in Society (IT'IS) on the NIH (National Institute of Health) Grant entitled "o2S2PARC – Open Online Simulations for Stimulating Peripheral Activity to Relieve Conditions". The 5-year project got funded with \$1.5Mio per year, co-author of grant application.
- [2] 2017 – Based on the successful funding of the o2S2PARC NIH Grant initiation of a new 5-year CRADA (Cooperative Research and Development Agreement) with the Foundation for Research on Information Technologies in Society (IT'IS). The CRADA is titled "Verification and Validation of the Computational Platform "Open Online Simulations for Stimulating Peripheral Activity to Relieve Conditions". A total funding of \$150k will be provided to FDA, concept of CRADA research plan and FDA PI.
- [3] 2017 – Established Research Collaboration (RCA) with Univ. Houston (Prof. Ji Chen). The RCA is titled "MRI Safety Assessment of Medical Devices"; concept of RCA research plan and FDA PI.
- [4] 2016 – Collaboration with Univ. Houston (UH, Prof. Chen) and the Medical University Vienna (Prof. Alesch) on "Development of an Absorbing Radio Frequency Shield for Safe Magnetic Resonance Imaging at 3 Tesla (128MHz) of Deep Brain Stimulation Patients", funded \$100k by BCS (Boston Scientific Cooperation), concept of project and grant application, FDA PI.
- [5] 2016 – Collaboration with the Foundation for Research on Information Technologies in Society (IT'IS) on the MWF (Mobile & Wireless Forum) funded project "EMF Exposure Limits and Compliance Assessment for Wireless Devices Operating at Frequencies above 6 GHz", \$120k, co-author of grant application.
- [6] 2016 – Collaboration with the Foundation for Research on Information Technologies in Society (IT'IS) on the GE (General Electric) funded project "MRInext: Personalized RF Exposure Assessment via Patient Mapping Approaches". The objective is to increase the confidence of in-silico MR safety evaluations, \$350k, co-author of grant application and Co-PI.
- [7] 2014 – Collaboration with the Foundation for Research on Information Technologies in Society (IT'IS) on the project "Capitalis – A Novel Computational Platform for Analysis and Optimization of the Neurovascular and Neurological Devices and Treatments in the Head", funded \$790k by CTI (Commission for Technology and Innovation), Switzerland, co-author of grant application and Co-PI.
- [8] 2013 – Collaboration with the Foundation for Research on Information Technologies in Society (IT'IS) on the GE (General Electric), Siemens, and Philips funded project "MRI# - MRI radiofrequency exposure risk assessment based on transient- and perfusion-dependent local temperature doses (CEM43) for improved standards", \$280k, co-author of grant application and Co-PI.
- [9] 2010 – 5-year CRADA with IMRICOR Inc. The CRADA is titled "Radiofrequency Safety Assessment Method for Medical Devices in MRI". A total funding of \$250k will be provided to FDA, concept of CRADA research plan and FDA PI.
- [10] 2009 – 2-year CRADA Extension "The Virtual Family – Development of Computational Anatomical Models". A total funding of \$42k was provided to FDA, concept of CRADA research plan and FDA PI.

- [11] 2007 – 2-year CRADA Extension “The Virtual Family – Development of Computational Anatomical Models”. A total funding of \$52k was provided to FDA, concept of CRADA research plan and FDA PI.2007 – Collaboration with J. Thomas Vaughan, Ph.D., Professor of Biomedical Engineering in the Mortimer B. Zuckerman Mind Brain Behavior Institute on the NIH Grant R01 EB007327-01A1 titled “RF Safety for Ultra-High Field MRI”; \$2.1Mio, co-author of grant application and Co-PI.
- [12] 2005 – 3-year CRADA with the Foundation for Research on Information Technologies in Society (IT’IS). The CRADA is titled “The Virtual Family – Development of Computational Anatomical Models”. A total funding of \$95k was provided to FDA, concept of CRADA research plan and FDA PI.

## Successful Internal FDA Funding

- [1] 2014 – Office of Women’s Health (OWH) funded project “Assessing the exposure of pregnant women in multi-channel transmit coils”; \$100k, co-author of concept of research project and Co-PI.
- [2] 2014 – CDRH CP (Critical Path) funded project “Development of a Passive Implant Test Exemption Criteria (PITEC) for RF Induced Heating”, 2-year CP funded, total funding of \$185k, co-author of concept of research project and Co-PI.
- [3] 2012 – CDRH CP (Critical Path) funded project “Functionalized anatomical models for EM-Neuron interaction modeling”. The objective is to develop functionalized anatomical models allowing coupled EM-neuron modeling to computationally predict nerve stimulation. 2-year CP funded, total funding of \$475k, concept of research project, grant application, and PI.

## Noteworthy FDA Announcements

- [1] 20 Jun. 2017 - The **International Electrotechnical Commission (IEC)** and the **Institute of Electrical and Electronics Engineers (IEEE)** publishes the first **dual-logo standard** to computationally determine the spatial-peak specific absorption rate (SAR) for wireless communication devices. As chairman of IEEE ICES (International Committee on Electromagnetic Safety), Technical Committee 34 (TC34), Sub-Committee 2 (SC2) Dr. Kainz initiated in 2009 the development of dual-logo standards to computationally determine the spatial-peak specific absorption rate (SAR) for wireless communication devices. The first standard published in this series was IEEE/IEC 62704-1 which defines the general requirements for using the Finite Difference Time Domain (FDTD) method for computationally determining the SAR in the human body from wireless communications devices operating in the frequency range from 30 MHz - 6 GHz. Now IEEE/ICES/TC34/SC2 finalized 62704-2, a new IEC/IEEE dual logo standard, which describes the concepts, techniques, vehicle models, validation procedures, uncertainties, and limitations of the FDTD method, when used for determining the SAR in standardized human anatomical models exposed to vehicle mounted antennas. Intended users of this practice are wireless communication devices manufacturers and service providers for wireless communication that are required to certify that their products comply with the applicable SAR limits established by the Federal Communication Commission (FCC). This new standard opens now the possibility using fast and inexpensive computational methods, instead of costly and time-consuming measurement methods, to determine the SAR from vehicle mounted antennas. With this project Dr. Kainz contributed to CDRH’s 2017 regulatory science priorities to develop computational modeling technologies supporting regulatory decision making for safe, effective, and high-quality radiation-emitting products.
- [2] Aug. 2016 - **CDRH Develops a Novel Method to Quantitatively Validate Computational Results**: Complex multi-physics computational modeling is increasingly used in medical device pre-marked submissions. However, to achieve “regulatory grade” results and determine the associated uncertainty and validity range of these results, verification and validation are required. Wolfgang Kainz with his collaborators at

IT'IS (Foundation for Research on Information Technologies in Society, Zurich, Switzerland) developed a novel method for simulation validation by combining systematic NIST guideline-based uncertainty assessment with the gamma dose distribution comparison method. The method provides a scalar agreement metric and a natural means of visualizing areas of disagreement between the computed results and the comparator, typically measured results, for 2-, 3-, and 4-dimensional data. The authors apply the method to simulated and measured complicated 2-dimensional pressure distributions in the field of focused ultrasound. However, the generality of this validation approach makes it applicable to a wide range of computational results, beyond acoustic simulations. The article is entitled, "Approach to Validate Simulation-Based Distribution Predictions Combining the Gamma-Method and Uncertainty Assessment: Application to Focused Ultrasound", by Esra Neufeld, Adamos Kyriacou, Wolfgang Kainz, Niels Kuster, published in The American Society of Mechanical Engineers' Journal of Verification, Validation, and Uncertainty Quantification, Aug. 2016.

- [3] Sep. 2016 - **CDRH Publication Chosen as ISMRM Editor's Pick** for Sep. 2016 Magnetic Resonance in Medicine Highlights: Manuel Murbach, Esra Neufeld, Eugenia Cabot, Earl Zastrow, Niels Kuster (all IT'IS Foundation, Zurich, Switzerland), Juan Corcoles (Escuela Politecnica Superior, Madrid, Spain) and Wolfgang Kainz (CDRH/OSEL/DBP) published on Sep. 24<sup>th</sup> 2015 a paper in Magnetic Resonance in Medicine about safety and image quality in 3T MRI RF shimming. The paper concludes that the image quality in 3T body coils can be significantly increased by RF shimming. However, worst-case induced peak temperatures reach 42.5°C and 45.6°C in patients with normal and impaired thermoregulation, respectively. Therefore, the authors recommend that patients with impaired thermoregulation should not be scanned outside of the normal operating mode. In Sep. 2016, the ISMRM (International Society for Magnetic Resonance in Medicine) Editor for the online portal "Magnetic Resonance in Medicine Highlights" picked this paper, titled "Virtual Population-Based Assessment of the Impact of 3 Tesla Radiofrequency Shimming and Thermoregulation on Safety and B1+ Uniformity", as the highlight of the month.
- [4] Apr. 2015 – **CDRH Releases a Novel High-Resolution Computational Model of the Human Head and Neck –The MIDA Model:** Drs. Maria Ida Iacono, Ethan Cohen, Wolfgang Kainz, and Leonardo Angelone (OSEL/DBP) published a paper in PLoS One titled "MIDA: A Multimodal Imaging-based Detailed model of the Anatomy of the human head and neck". The study was performed in collaboration with the Foundation for Research on Information Technologies in Society (IT'IS, Zurich, Switzerland), the ETH (Swiss Federal Institute of Technology, Zurich, Switzerland), and Harvard Medical School, Massachusetts General Hospital, Boston, USA. The authors developed a multimodal imaging-based detailed anatomical model of the human head and neck to be used for computational modeling studies, including electromagnetic simulations. The model integrated several different structural and functional magnetic resonance imaging (MRI) modes and offers a detailed representation of brain surfaces, meninges, cerebrospinal fluid distribution, eyes, ears, and several deep brain structures, as well as several distinct muscles, bones and skull layers, blood vessels, cranial nerves, dental structures, and glands. The MIDA model has double the resolution (0.5 mm isotropic resolution) and more than three times the number of segmented anatomical structures of the head (153) as previously reported models. In the paper, the authors describe the application of the model to transcranial alternating current stimulation (tACS), which tested suitability to simulations involving different numerical methods and discretization approaches, as well as the impact of diffusion tensor imaging-based tensorial electrical conductivity information on electromagnetic analysis. The model can be used by industry, regulators, and academics to investigate the safety and effectiveness of medical devices used in or near the head. The voxel and the surface-based versions of the MIDA model are freely available to the scientific community. For inquiries, please email: MIDAmode@fda.hhs.gov.

- [5] Mar. 2015 - **CDRH Releases the Virtual Family 2.0:** The Virtual Family, initiated 10 years ago by Dr. Wolfgang Kainz from the OSEL Division of Biomedical Physics, has been widely and freely shared with the public. It is used by academia and regulated industry for basic research and virtual testing of new magnetic resonance and X-ray imaging devices. As of now (Mar. 2015) the VF was used in more than 120 regulatory submissions and was cited more than 250 times in peer-reviewed literature. The Virtual Family now includes version 2.0, which is freely available to all researchers: academia, government, and industry for any computational purposes. Furthermore, VF2.0 is a true CAD (Computer Aided Design) model, without gaps or overlaps between individual tissue surfaces. It is fully compatible with other types of computational methods, e.g., FDTD (Finite Difference Time Domain), FEM (Finite Element Method), FIT (Finite Integration Technique), etc. To reflect the release of VF 2.0 Dr. Wolfgang Kainz updated FDA's Virtual Family website.
- [6] Dec. 2014 - **The Virtual Family Citation Prize:** The Dr. Wolfgang Kainz, who initiated the development of the Virtual Family back in 2005 and co-authored with Dr. Andreas Christ the paper "The Virtual Family - Development of Anatomical CAD Models of two Adults and two Children for Dosimetric Simulations" (Physics in Medicine and Biology (PMB), 55, N23–N38, 2009), won the PMB 2014 Citations Prize: The Rotblat Medal. The Medal is awarded once a year to the authors of the research paper that has received the most citations in the preceding five years (according to the Institute for Scientific Information (ISI)). The Rotblat Medal is named in honor of Prof. Sir Joseph Rotblat who was the second — and longest serving — editor of PMB from 1961–1972. PMB has currently an impact factor of 2.9. Since its publication in 2009 the Virtual Family was cited 763 times (Feb. 2018). The latest development in the area of anatomically correct computational models of the human anatomy is the release of the Virtual Family Version 2.0 (VF 2.0) and the release of the MIDA (Multimodal Imaging-based Detailed Anatomical) Model of the Human Head and Neck (MIDA 1.0) on the FDA Website. The VF 2.0 and MIDA 1.0 will be freely available to all researchers — academia, government, and industry — and will be fully compatible with all computational methods, e.g., FDTD (Finite Difference Time Domain), FEM (Finite Element Method), FIT (Finite Integration Technique), etc. Furthermore, the VF 2.0 and MIDA 1.0 will available as true CAD (Computer Aided Design) models without gaps or overlaps between individual tissue surfaces.
- [7] May 2017 - **The Virtual Family in the CDRH Science Data Catalog and Usage in Medical Device Submissions:** The Virtual Family, initiated in 2005 by Dr. Wolfgang Kainz from the FDA, CDRH, Office of Science and Engineering Laboratories, Division of Biomedical Physics, has been widely and freely shared with the public. It is used by academia and regulated industry for basic research and virtual testing of medical devices, e.g., active and passive implants exposed to magnetic resonance imaging (MRI) and for testing of new MRI and X-ray imaging devices. The Virtual Family is frequently used in regulatory submissions (on average in ~30 medical device submissions per year) and was cited more than 750 times in the peer-reviewed literature (Feb. 2018). The Virtual Family now includes version 2.0, which is freely available to all researchers: academia, government, and industry for any computational purposes. Furthermore, the Virtual Family 2.0 models are true CAD (Computer Aided Design) data, without gaps or overlaps between individual tissue surfaces. The Virtual Family models are fully compatible with many types of computational methods, e.g., FDTD (Finite Difference Time Domain), FEM (Finite Element Method), FIT (Finite Integration Technique), etc.