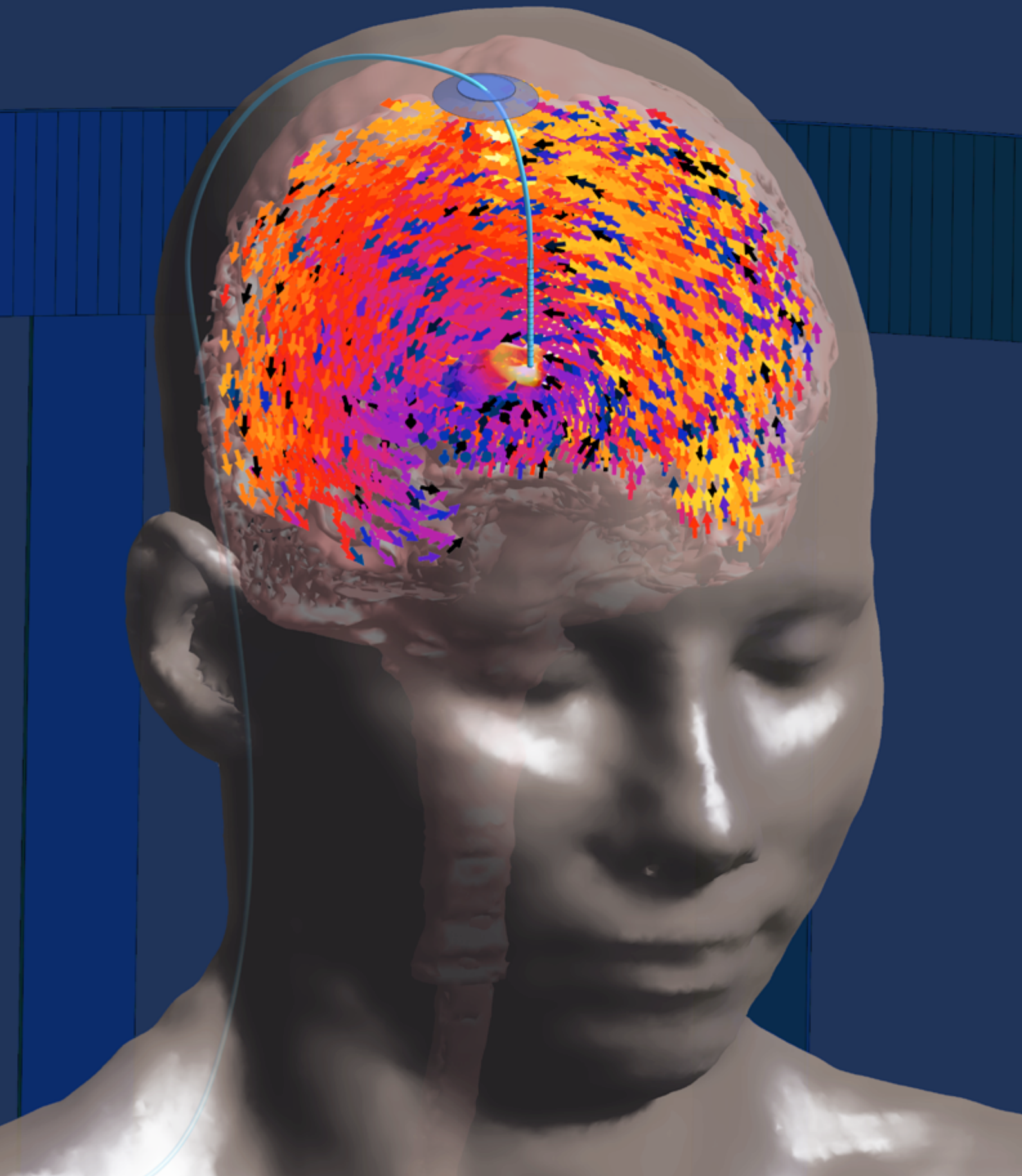


IT^{IS} FOUNDATION 2015



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Cover: MRI induced radiofrequency electric fields in the brain and the resulting SAR in the vicinity of electrodes of an active deep brain stimulator.

FOCUSSING ON OUR STRENGTH



In 2015, to further accelerate the broadening of the boundaries of scientific knowledge and technology in a harshening research environment, we decided to first refocus and consolidate our collective strengths built up over more than 15 years at our premises in downtown Zurich, where we have continuously developed the laboratories of the IT'IS Foundation and the two commercial spin-off companies Schmid & Partner Engineering AG (SPEAG) and ZMT Zurich MedTech AG. Today, these three combine the expertise of more than 100 scientists, engineers, and specialists in production, export, sales, and marketing from over 10 scientific disciplines and more than 30 nations. We call it our Zurich43 Family.

The IT'IS Foundation is the core of the family, driven solely by its non-profit mission and ambition to make a tangible difference in people's lives. This is achieved by enhanced quality, user friendliness, and safety of emerging electromagnetic technologies and with contributions to advances in powerful *in silico* medicine ranging from computational functionalized human models, powerful solvers, tissue models to experimental validation systems. IT'IS electromagnetic research currently focuses on solutions for the emerging network of the 5th generation (5G) and wireless power transfer systems. In computational life sciences, we explore the *in silico* potential in personalized MRI optimization (see pages 14–15) and the development of novel solutions for neuronal and acoustic simulations (pages 12–13). Another cornerstone is the complementation of our segmentation tools with morphing tools to almost instantly create personalized patient models (page 16). To underline our priorities, we are co-organizing the three-day Latsis Symposium on "Personalized Medicine – Challenges and Opportunities" in June 2016 together with the Competence Center on Personalized Medicine of ETH Zurich and the University of Zurich. For the first time, this symposium brings together researchers from the entire multidisciplinary spectrum of research, technologies, and innovations in personalized medicine, ranging from genomics to simulations of virtual patient models, to discuss the visions and solutions for the future.

SPEAG and ZMT round out the Zurich43 Family. Founded in 1994, SPEAG (www.speag.com) is the dominant player and provider for compliance systems to the wireless

industry today. Key products are DASY6, cSAR3D, ICEy/TDS, DAK, EM Phantoms and SEMCAD X. To better serve its customers, a calibration laboratory certified by the Swiss Accreditation Service (SAS) for ISO/IEC 17025 Accreditation was established in 2001. The laboratory provides extensive calibration services for industry, regulators, and governments and to the entire Zurich43 Family.

ZMT (www.zurichmedtech.com), the youngest member of the family, was founded in 2006 to develop tools and best practices for targeted life sciences applications for simulation, analysis, and prediction of complex and dynamic biological processes and interactions. ZMT's flagship product is Sim4Life.

To bring services closer to Zurich43's global customer and partner base, a number of satellite facilities were co-founded: IT'IS USA in 2010, the SPEAG Calibration Laboratory Korea in 2011, and the BNNSPEAG Test & Calibration Laboratory India in 2012.

The sustainability of the achievements of IT'IS over more than fifteen years speaks to the remarkable commitment, intelligence, agility, and creativity of our staff (Page 5). Furthermore, our success would not be possible without our vast engagement in research activities across ETH Zurich, EPFL, the University of Zurich, and a wide network of other partner universities in Switzerland and abroad (Page 10). In particular, we would like to thank the members of our Board (Page 4) as well as Gábor Székely and Juan Mosig for sharing infrastructure and advising our jointly appointed PhD students and postdoctoral fellows.

We are also extremely grateful to our many sponsors and donors (Page 9), whose commitment to and trust in our vision has made it possible to pursue our goals year after year; especially, the generous support from CTI, the Swiss Federal Office of Public Health, the Swiss National Research Foundation, and the EU Commission is deeply appreciated.

Zurich, May 2016

Prof. Niels Kuster

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Marie-Christine Gosselin, PhD Student (EEO)

Adamos Kyriakou, PhD Student
Kyle Loizos, Intern
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Lénárd Szolnoki, Intern
Frederico Teixeira, PhD Student
Philipp Wissmann, PhD Student
Aiping Yao, PhD Student

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Silvia Farcito, Scientific Assistant
Eveline Huber, Scientific Assistant
Dimce Illiev, RF Engineer
Roger Jacot, Scientific Assistant
Amie Rieseberg, Scientific Assistant

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Greg Melia, Academic Visitor

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Dr. Roger Yew-Siow Tay, SG

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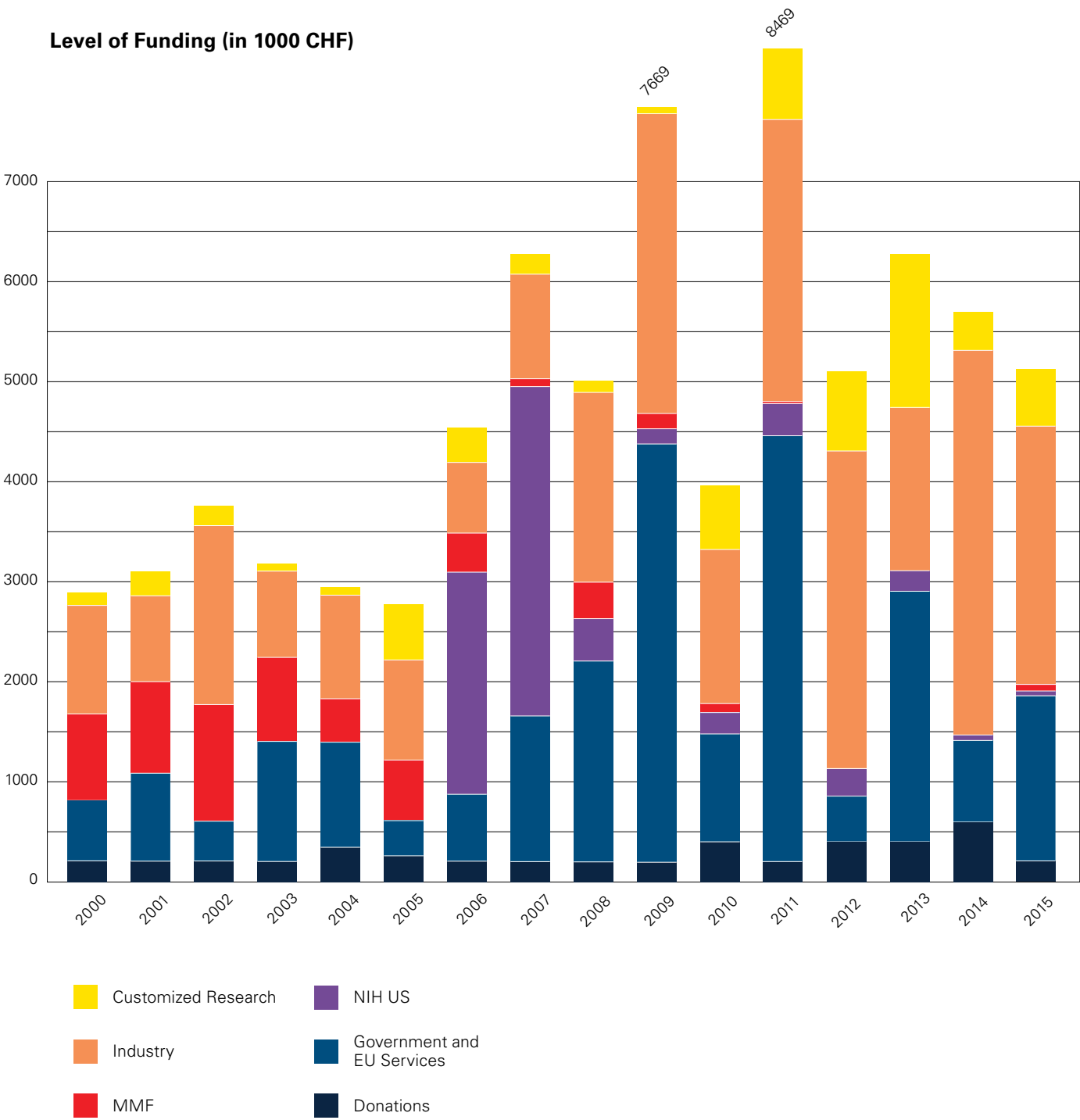
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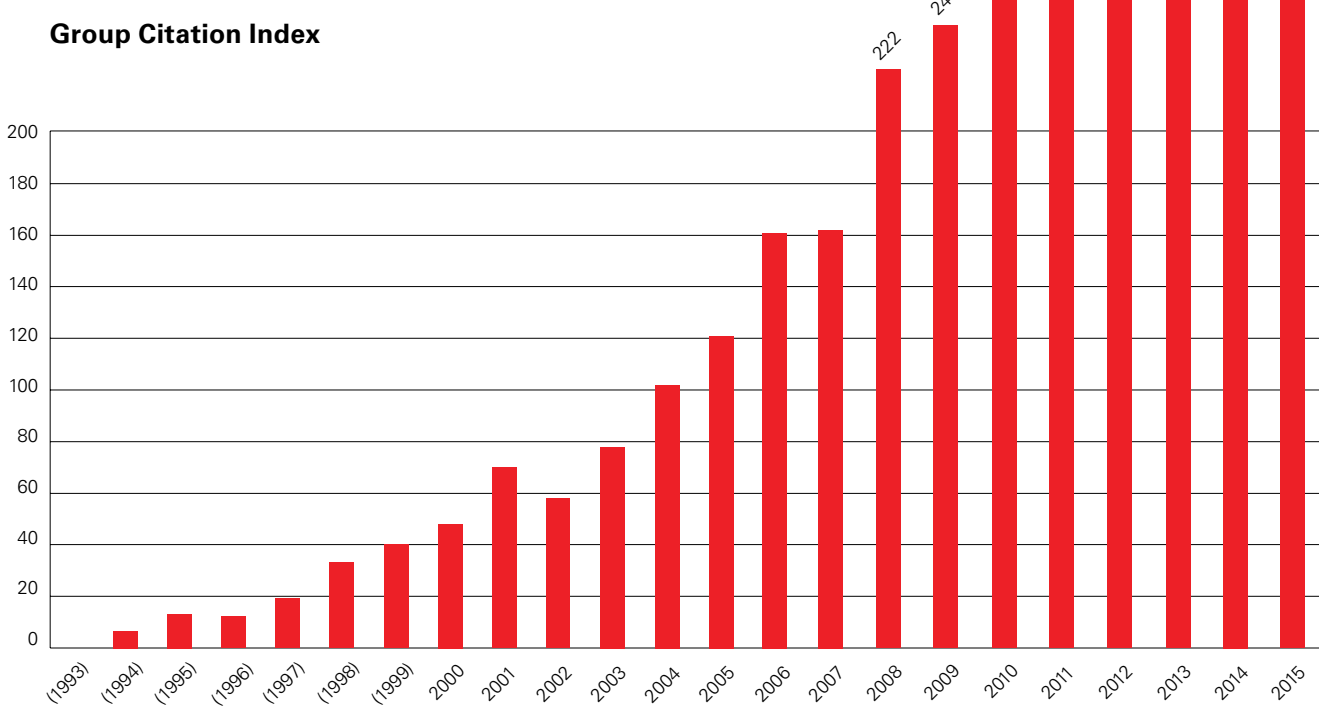
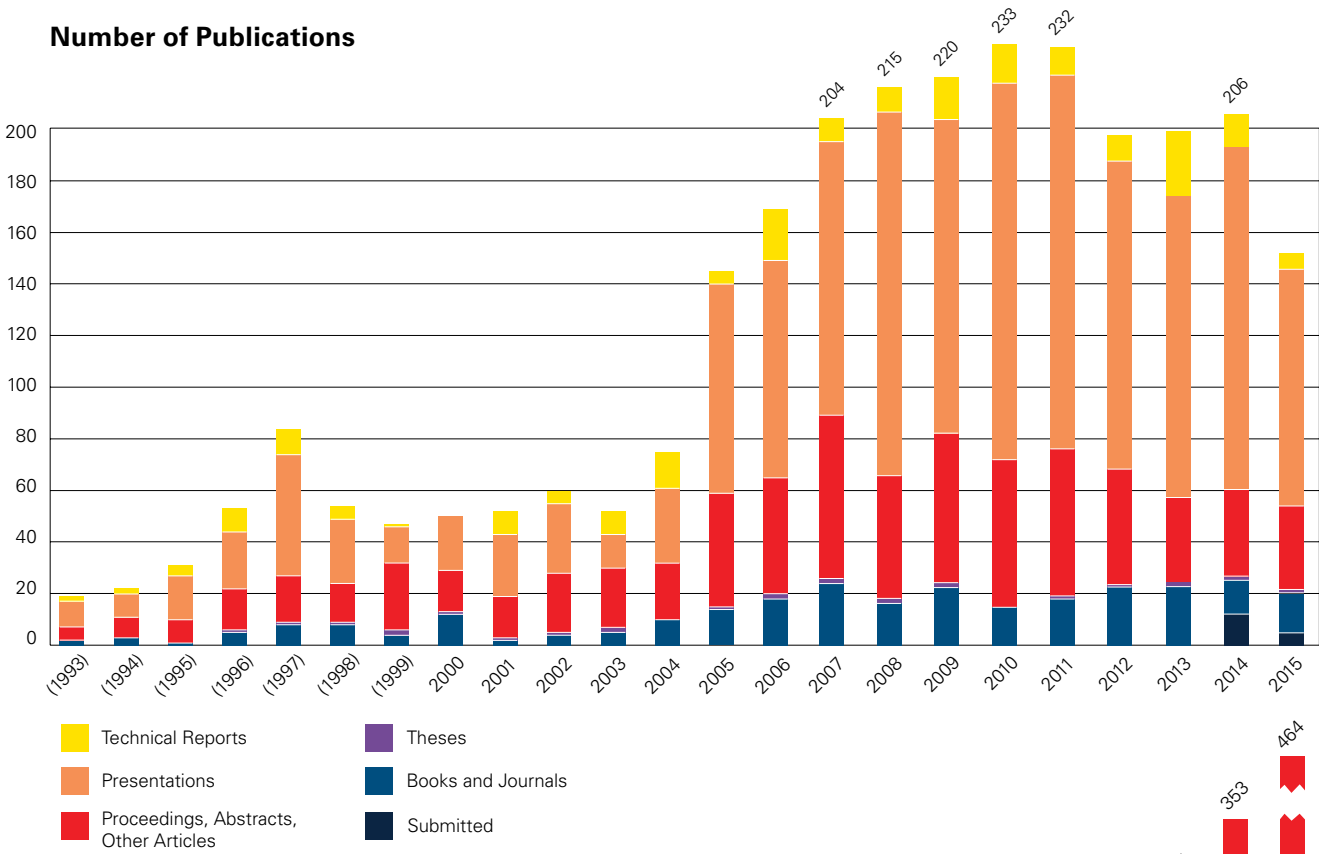
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KEY FIGURES



KEY FIGURES



Years in parentheses (1993–1999) show citation development while at ETH, before IT²IS was established as an independent foundation.

The compiled index is based on data available from the Thomson Reuters Web of Science™ database; the number of citations reported are from peer-reviewed publications and excludes self-citations.

SELECTED SPONSORS SINCE 2000

Government Agencies

5th Framework Programme of the EU (FP5), BE
6th Framework Programme of the EU (FP6), BE
7th Framework Programme of the EU (FP7), BE
Centre for Technology Assessment, CH
Commission for Technology and Innovation, CH
EUREKA, CH
Federal Office for the Environment, CH
Federal Office of Communications, CH
Federal Office of Energy, CH
Federal Office of Public Health, CH
Federal Institute for Occupational Safety & Health, DE
Federal Office for Radiation Protection, DE
National Institute of Environmental Health Sciences, USA
National Institute of Standards and Technology, USA
State Secretariat for Education, Research and Innovation, CH
Swiss National Science Foundation, CH
ZonMW, Netherlands

Non-Profit Organizations

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Health Canada, CA
KFG - Contact Group for Research Matters, CH
Research Association for Radio Applications, DE
Research Foundation on Mobile Communication, CH
University of Zurich, CH

Multinational Corporations (MNC)

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ARIB - Association of Radio Industries and Businesses, JP
Arizona Chemical, US
Biotronik, DE
Boston Scientific Corporation, US
Cisco Systems, US
Clarins Laboratories, FR
CTIA, US
Disney Research, US
Ericsson, SE
GE Medical Systems, US

GSM Association, CH
Intel Corporation, US
International Business Machines Corp., US
Kaba, CH
LG Electronics, SK
Micro Systems Engineering, US
Mitsubishi Electric, JP
Mobile Manufacturer Forum, BE
Motorola, US
Nokia, FI
Nokia Solutions and Networks, FI
NTT DoCoMo, JP
Panasonic, JP
Philips, NL
Phonak Communications AG, CH
Qualcomm Inc., US
Ruag, CH
Sagem, FR
Samsung, SK
Sensirion AG, CH
Siemens AG, DE
Sony Ericsson, JP
Sorin S.A.S., FR
St. Jude Medical Inc., US
Toshiba Medical Research Institute, US
Vodafone, GB

Small and Medium Enterprises (SME)

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Cardiatis S.A., BE
Felsenmeer AG, CH
maxwave AG, CH
MED-EL, AT
Medico S.p.A., IT
Nevro Corporation, US
Schmid & Partner Engineering AG, CH
Sensimed AG, CH
VAT Vacuumvalves AG, CH
ZMT Zurich MedTech AG, CH

PARTNERS SINCE 2000

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Automatic Control Laboratory, ETHZ, CH
Biomedical Optics Research Laboratory, ETHZ, CH
Computer Vision Laboratory, ETHZ, CH
Institute of Biomedical Engineering, ETHZ, CH
Institute of Robotics and Intelligent Systems, ETHZ, CH
Integrated Systems Laboratory, ETHZ, CH
Interactive Geometry Lab, ETHZ, CH
Laboratory of Thermodynamics in Emerging Technologies, ETHZ, CH
Neuroscience Center Zurich, ETHZ, CH
Center for Applied Biotechnology and Molecular Medicine, UZH, CH
Department of Neurology, UZH, CH
Institute of Pharmacology and Toxicology, UZH, CH
Vetsuisse Faculty, UZH, CH
University Children's Hospital Zurich, CH
University Hospital Zurich, CH
University of Zurich, CH
Cantonal Hospital Aarau (KSA), CH
Hirslanden Clinic, Zurich, CH
University of Applied Sciences, Zurich, CH
Center for Neuroprosthetics, EPFL, CH
Laboratory of Electromagnetics & Acoustics, EPFL, CH
Powder Technology Laboratory, EPFL, CH
Clinical Morphology & Biomedical Engineering, UNIBAS, CH
Computer Science Department, UNIBAS, CH
Department of Biomedicine, UNIBAS, CH
Laboratory of Biomechanics & Biocalorimetry, UNIBAS, CH
Medical Image Analysis Center, UNIBAS, CH
Orthopedic Section, Basel University Hospital, CH
Swiss Tropical and Public Health Institute, CH
University Children's Hospital Basel, CH
ARTORG Center for Biomedical Engineering Research, UNIBE, CH
Division Veterinary Pharmacology & Toxicology, Vetsuisse Facility, UNIBE, CH
Institute for Social & Preventive Medicine, UNIBE, CH
Inselspital Academic Health Center, CH
University Hospital, Bern, CH
Laboratory of Pharmaceutics & Biopharmaceutics, UNIGE, CH
Children's Hospital Geneva, CH
Geneva University Hospital, CH
Geneva University, CH
Hospital of La-Chaux-de-Fonds, CH
Institute of Computational Science, USI, CH
University of Applied Sciences of Southern Switzerland, CH
Centre Hospitalier Universitaire Vaudois, CH
University of Wollongong, AU
Austrian Institute of Technology, AT
Medical University of Vienna, AT
Tissue Dynamics Laboratory, Paracelsus Private Medical University, AT
University of Vienna, AT
INTEC, University of Ghent, BE
Interdisciplinary Institute for BroadBand Technology, BE
McGill University, CA
University of Toronto, CA
Beijing University of Technology, CN
Third Military Medical University, CN
Zhejiang University, CN
Danish Cancer Society, DK
Department of Electronic Systems, Aalborg University, DK
University of Aarhus, DK
Finnish Institute of Occupational Health, FI
Helsinki University of Technology, FI
STUK – Finnish Center for Radiation and Nuclear Safety, FI
University of Eastern Finland, FI
University of Kuopio, FI
Association pour la Recherche Epidémiologique dans les Cancers de l'Enfant et de l'Adolescent, FR
Epidemiological Research and Surveillance Unit in Transport, Occupation and Environment, FR
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University of Bordeaux, FR
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Fraunhofer Institute of Toxicology and Experimental Medicine, DE
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IMTEK, Department of Microsystems Engineering, University of Freiburg, DE
Institute for Mobile and Satellite Technology, University of Duisburg-Essen, DE
Institute of Biophysics, Leibniz University Hannover, DE
IPK Gatersleben, DE

Ludwig Maximilians University of Munich, DE
Max Planck Institute for Human Cognitive and Brain Sciences, DE
Max Planck Institute for Neurological Research, DE
University Hospital Benjamin Franklin, Free University Berlin, DE
University Hospital Erlangen, Friedrich-Alexander-University, DE
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University of Ulm, DE
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Aristotle University of Thessaloniki, GR
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Budapest University of Technology and Economics, HU
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The Gertner Institute for Epidemiology and Health Policy Research, IL
Schneider Children's Medical Center, IL
Weizmann Institute of Science, IL
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Institute of Biomedical Engineering, Politecnico di Milano, IT
University of Bologna, IT
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Fukushima Medical University Hospital, JP
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Tokyo Metropolitan University, JP
University of Tokyo, JP
Erasmus MC–Daniel den Hoed Cancer Center, NL
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Utrecht University, NL
Wageningen University, NL
Haukeland University Hospital, NO
University of Bergen, NO
King Saud University, SA
Institute of Nonionizing Radiation, SI
Centre for Research in Environmental Epidemiology, ES
Universidad Autónoma de Madrid, ES
Instituto de Biología Molecular y Celular del Cancer (CSIC/USAL), ES
Institute of Applied Physics, ES
Department of Signals and Systems, Chalmers University of Technology, SE
Karolinska Institute, SE
Stress Research Institute, University of Stockholm, SE
Hospital of Uppsala, SE
Beatson Institute for Cancer Research, GB
Hammersmith Hospital, GB
Imperial College, GB
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Oxford University, GB
University of Cambridge, GB
University of Leicester, GB
University of York, GB
Center for Magnetic Resonance Research, University of Minnesota, US
Illinois Institute of Technology Research Institute, US
Johns Hopkins Bayview Medical Center, US
Massachusetts Institute of Technology, US
University of Alabama at Birmingham, US
University of Buffalo, US
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University of Colorado at Boulder, US
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University of Houston, US
University of Maryland, US
University of Miami, US
University of Minnesota, US
University of Pennsylvania, US
Temple University, US
University of Wisconsin, US
Washington University, US

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China Academy of Telecommunication Research, CN
Communications Research Center, Industry Canada, CA
Danish Council for Strategic Research, DK
Electronics and Telecommunication Research Institute, KR
Federal Communications Commission, US
Federal Office for Radiation Protection, DE
Federal Office for the Environment, CH
Federal Office of Communications, CH
Federal Office of Energy, CH
Federal Office of Public Health, CH
Food and Drug Administration, US
Health Council of The Netherlands, NL
Health Protection Agency, GB
International Agency for Research on Cancer, FR
National Institute of Environmental Health Sciences, US

National Institute of Information & Communications Technologies, JP
National Institute of Standards and Technology, US
National Research Council, IT
Norwegian Institute of Public Health, NO
Public Health England, GB
Radio Research Agency, KR
Russian Academy of Medical Science, RU
SITT, Industry Canada, CA
South African Bureau of Standards, ZA
Spanish National Research Council, ES
State Radio Monitoring Center, Ministry of Information Industry, CN
State Secretariat for Economic Affairs, CH
Telecommunication Metrology Center, CN
World Health Organization, CH

Private Industry

AGC Automotive, US
Alnair, JP
Antia Therapeutics, CH
ARIB, JP
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Biotronik, DE
Boston Scientific Corporation, US
Cardiatix, BE
CTIA, US
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Ericsson Radio Systems AB, SE
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Huber + Suhner AG, CH
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Image Guided Therapy, FR
Imricor Medical Systems, US
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LiveNova, FR
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Medico S.p.A., IT
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Vodafone, GB
Volvo Car Corporation, SE
Vratis, PL
York EMC Services, GB
ZMT Zurich MedTech AG, CH

PROJECTS

EM Technology

TD SENSOR	Development of time-domain near-field field sensor technology
OH4VNA	Development of a miniature optically-fed electrical measurement head for a vector network analyzer

EM Exposure & Risk Assessment

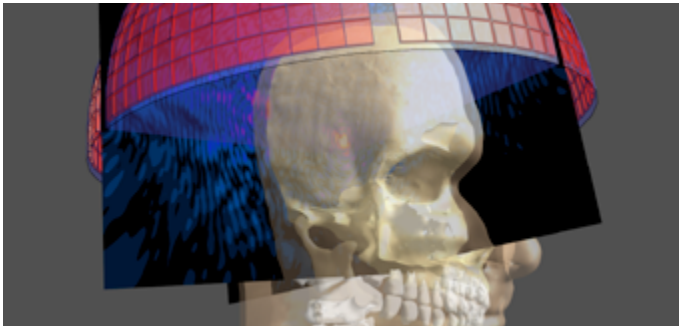
sXc, sXv, sXh	Development of optimized exposure systems for bio-experiments from static to GHz
sXv – NTP/NIEHS	Development, manufacturing, installation, and detailed dosimetry of the reverberation chamber-based exposure system for the NIEHS <i>in vivo</i> studies
FP7 ARIMMORA	Identification of possible causal relationships between EMF exposure and cancer, with a special focus on childhood leukemia
FP7 GERONIMO	Generalized EMF Research using novel methods
ANIMEX	Development, manufacturing, installation, and detailed dosimetry of a reverberation chamber-based exposure system for INERIS
CREST	Characterization of the RF exposure due to novel usage scenarios or new technologies for mobile communications devices
EPIRADIOMEM	Investigations of the effect of LTE 4G signals on cognitive functions, such as memory and its underlying epigenetic regulation

IT'IS for Health

AneuX	Development of a predictive tool to use shape as biomarker for aneurysm disease
CTI S4L-CAPITALIS	Extension of the Sim4Life platform (S4L) for analysis and optimization of neurovascular and neurological devices and treatments in the head
ViP 2.0 / 3.0 / MIDA-FDA	Development of the next generation of high-resolution anatomical models
ViP-P/VM/M	Development of novel posers, of methodology for enhanced volume meshes of anatomical structures and of a physically-based morphing tool
CLS-NEURO	Investigation of EM-neuronal dynamics interactions for low frequency exposure safety, neuroprosthetics, and neurostimulation
CLS-FUS	Transcranial Focused Ultrasound; Sonoknife; Liver motion during FUS interventions
CLS-V&V40	Development of novel concepts for verification and validation of computational life science software platforms and their applications
MRI#	Development of 3T-MRI exposure risk probability based on local temperature safety considerations
MRIneo	Development of MRI exposure risk probability of fetuses and newborns based on local temperature safety considerations
MR Implant Safety - PiX	Improved procedures and instrumentation for MR safety evaluation of medical implants
HT-KSA/UsZ	Development of novel hyperthermia hardware and treatment planning software for superficial soft tissue sarcoma in animals
MagnetoTheranostics	Early detection and treatment of prostate cancer lymph node metastases using superparamagnetic iron oxide nanoparticles (Swiss-NanoTera project)
REPLICATIONS	Validation and mechanistic investigation of modulation-specific cellular EM effects published by Zimmermann et al.
STANDARDIZATION	Participation in regulatory activities (standards committees & governments)

FOCUSED ULTRASOUND MODELING TO ENABLE NOVEL THERAPEUTIC APPLICATIONS

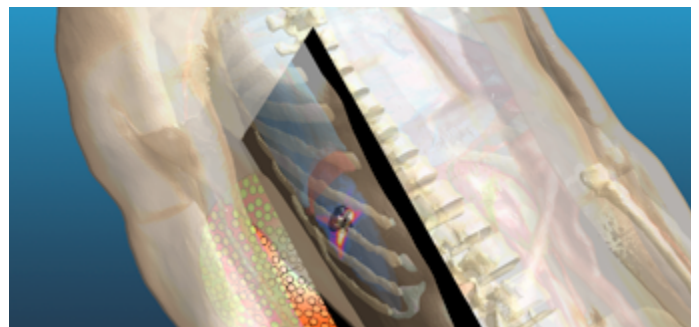
There are currently many exciting and promising therapeutic applications of focused ultrasound (FUS) being discovered. At high intensities, FUS can be used to target and ablate tissues without the need for invasive surgical intervention. At lower intensities, a variety of mechanisms that allow for interaction with neuronal dynamics, the blood-brain barrier, or tissue growth come into play. For therapeutic application in patients, the effectiveness, safety and reliability of the therapy needs to be demonstrated in order to be clinically accepted.



Transcranial FUS

The potential benefits of FUS for targeting locations deep in the head without the need for surgical access, e.g., to treat chronic pain or movement disorder, provided that the energy can be precisely focused to the target location. The technology employed involves the use of phased array applicators with over 1000 transducer elements. However, the presence of the skull causes aberrations that lead to defocusing and focus shifting. While image-based phase correction approaches that rely on ray tracing in combination with MRI thermometry control are used in clinical research, they require highly sophisticated infrastructure and limit applications to central therapeutic targets, thus excluding an important part of the patient population. We have embedded unique features into Sim4Life to tackle these problems: tools for generation of personalized patient models, validated full-wave acoustic modeling, assessment of *in vivo* heating and induced lesioning, and specialized methods to optimize focusing. IT'IS has applied these tools to demonstrate the potential to dramatically extend the range of possible FUS targets, achieving precise steering and sharp focusing while increasing the efficiency of energy delivery, resulting in higher temperatures and thus more effective and targeted therapies. Thanks to the integration of medical image data in Sim4Life, it has been possible

to account for the inhomogeneous skull properties that have been experimentally demonstrated to be crucial for accurate efficiency predictions. Together with clinical partners, IT'IS used modeling prior to the first administration of therapy to investigate safety, resulting in the pioneering application of FUS for the successful treatment of chronic pain.



Hepatic FUS Ablation

FUS has also been used to ablate liver tumors. However, the presence of the ribs between the applicator and the treatment target frequently leads to improper focusing and unwanted heating in the vicinity of bone, which can necessitate rib resection, thus compromising the benefits of minimal invasiveness associated with FUS ablation. Also, the breathing-related organ motion can require triggered sonications during exhalation only, which frequently prevents achievement of therapeutic temperatures. To consider the impact of breathing, IT'IS partnered with the University of Basel (UniBa) to extract transient deformation fields that can be applied to patient models, allowing the evolution of heat to be simulated for the first time. This, in combination with the simulation-based focusing methods, allows us to compensate for breathing during continuous sonication with improved focus quality, reduced collateral damage and treatment duration, and dramatically increased achievable temperatures. Since UniBa has also developed a liver motion model that can be personalized and related to real-time image data, this approach can be used in clinical settings.

With Sim4Life, the IT'IS Foundation has already advanced the understanding and technical development of therapeutic FUS. IT'IS is also working to advance clinical implementation of FUS to afford superior treatment quality through application of comprehensive, personalized physico-physiological modeling.

INVESTIGATING EM-INDUCED NERVE ACTIVATION: LOW FREQUENCY EXPOSURE SAFETY

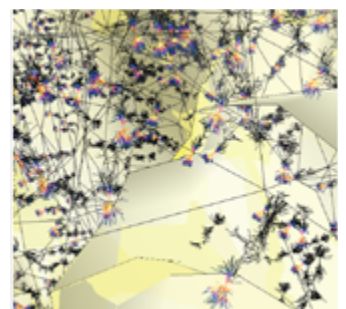
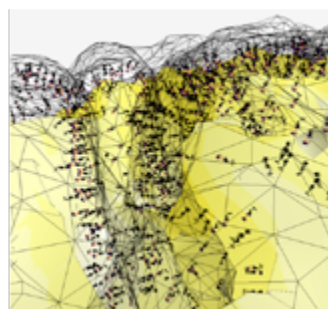
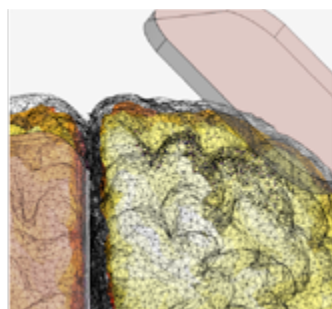
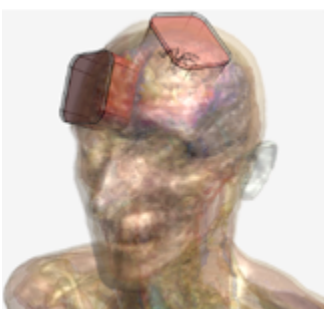
Our mission has always been to advance knowledge in all areas “where Electromagnetic Fields (EMF) meet tissues”. The study of EMF tissue interactions requires an ability to predict field distributions inside complex anatomies, which has prompted us to develop the tools and detailed anatomical models necessary for EM simulation. The Virtual Population (ViP), a set of 10 high-resolution anatomical models of both genders that span a wide range of ages and weights, have become the gold standard computational humans for use in dosimetric applications. However, it has soon become clear that information about the induced effective fields does not sufficiently inform on the potential hazards and beneficial effects that arise in response to tissue heating and/or nerve excitation. Sim4Life, developed jointly with ZMT, offers not only effective multiphysics solvers but also dynamic physiological tissue models for, e.g., perfusion and neuronal processes.

In the context of our current research focus on EM-neuron interactions, we are studying questions in the fields of neuroprosthetics and neurostimulation, e.g., of the brain and spinal cord. To illustrate the necessity for functionalized anatomical models for safety and efficacy evaluations, we present here some approaches to the assessment of low frequency exposure safety.

The need for safety regulations in magnetic resonance imaging (MRI) originates from multiple risks associated with MRI exposure. Besides radiofrequency (RF) exposure related heating, a further risk is the unintended nerve stimulation resulting from rapid switching of the gradient coils. As a result, limitations are imposed on the applicable gradient field strength and switching rates, typically expressed in safety regulations as thresholds on the induced EM field.

To investigate the mechanisms involved and to be able to critically assess current approaches to safety regulations, we have performed simulations of switching-related sciatic nerve stimulation and the impact of local heating. For this, the induced currents determined by means of a quasi-static low frequency solver were coupled to simulations of neuronal dynamics. A novel, local temperature-dependent generic neuron model was developed to account for RF-coil induced heating and its impact on neuronal dynamics. This model is an extension of the SENN model that underlies most safety standards. Among the numerous results we generated, four are particularly interesting: 1) the inhomogeneity of the field distribution inside the body can affect stimulation thresholds; 2) field-strength related end-node activation of neurons is not the only safety-relevant mechanism; 3) realistically occurring temperature increases strongly influence neuronal dynamics; and 4) the assumption of non-focality of the induced fields is not justified in inhomogeneous anatomies, which means that the use of simplified body models is insufficient. These results challenge various assumptions that underlie safety standards, illustrating the importance of coupling EM physics simulations with physiological and biological modeling of tissue heating with consideration of perfusion and neuronal dynamics, and the need for functionalized anatomical models. The developed technology can now be used to investigate alternative approaches for ascertaining and regulating MRI safety with regard to neuronal stimulation.

The novel Sim4Life platform and the constantly evolving ViP models enable IT'IS and its partners to gain a mechanistic understanding of processes that involve the human body and its interaction with external physical stimuli by facilitating the modeling of the complex interactions and coupled phenomena in living organisms.



TURNING DOWN THE HEAT IN MRI FOR PATIENTS WITH IMPLANTS

A growing number of patients are fit with active implantable medical devices (AIMD), such as cardiac pacemakers and neuro stimulators, to allow a return to normal daily activities.

Every bit as important to the therapy provided by AIMDs, medical diagnostic tools play a vital role in patient care. Modern medical diagnostic tools are key to prescribing the best possible therapy, and any contraindication regarding the use of these tools can severely impact patient outcome.

Magnetic resonance imaging (MRI) is a widely-used diagnostic modality that is rightly considered a major technological breakthrough in modern medicine. The several hardware components of an MRI scanner comprise a strong static magnet, a series of high-current gradient coils/loops, and a radiofrequency (RF) antenna. These components subject the patient to high-intensity electromagnetic (EM) radiation over a broad EM spectrum. The accreditation of MRI scanners is subject to a set of guidelines (ICE 60601-2-33) that strictly ensure patient safety.

Although both MRI and AIMDs are beneficial to patient health, their combined application can cause unintended and undesirable interactions that are potentially hazardous, even fatal, to the patient. The interactions between active implants and the various MRI scanner components can cause impaired, unintended, or failed delivery of therapy or harmful local tissue heating. The presence of most AIMDs in patients is considered a sufficient safety risk during an MRI examination that these patients are often excluded from the benefits of MRI-based diagnosis. To overcome the disadvantage for these patients, the risks associated with MRI exposure of patients with implants is being addressed by groups of experts from both the MRI and implant communities, and a series of guidelines (ISOTS 10974) have been formulated as specifications for evaluation of patient risk.

We have recently been investigating ways to circumvent potentially harmful local tissue heating in patients with AIMDs exposed to EM radiation during MRI scanning. Excessive local tissue heating is caused by the interaction between the implant and the RF-component of the MRI.

The risk is greatest for implants with characteristically long leads, e.g., cardiac pacemakers or neurostimulators. The severity of the heating hazard depends on the type of implant and the surrounding at-risk tissue region; for example, tissue heating caused by a deep brain stimulator may be fatal, whereas that caused by a cardiac pacemaker may be far less adverse.

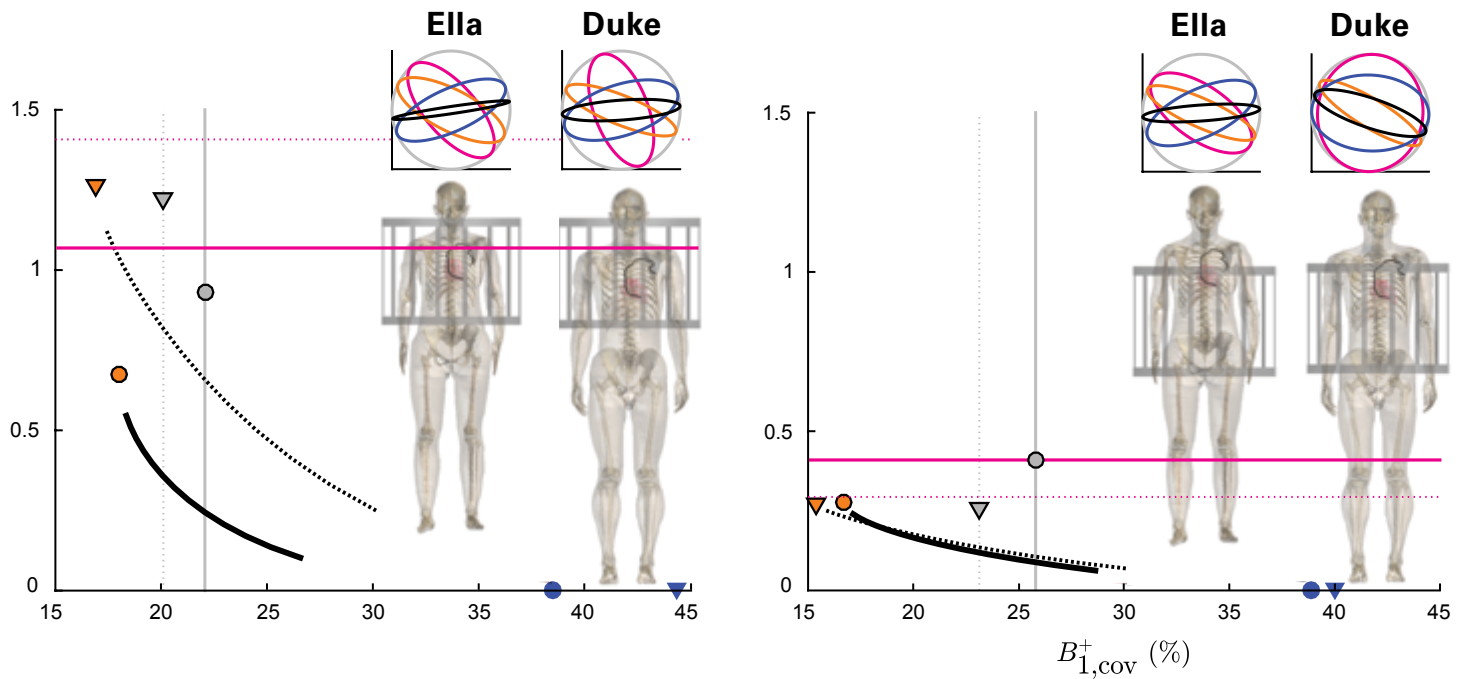
There are two ways to prevent tissue-heating hazards caused by implants during MRI scans: 1) revise the specifications for and designs of implants to make them more MRI-friendly; or 2) limit the RF exposure during MRI examinations; or both of these options can be applied simultaneously to ensure the best possible outcome for the patient. While the first option can benefit future AIMD patients, the needs today of patients with existing non-MRI-friendly implants are better served by the second intuitive option, to limit the power of the RF antenna to a value small enough to minimize adverse interactions. However, this approach can negatively impact the diagnostic value of the resulting MRI data. Our recent study shows that an alternative to the second option – to apply RF-shimming to alter, rather than lower, the power of the RF-antenna in such a way as to specifically minimize interactions with the implant – may be feasible with very little sacrifice of MRI diagnostic power.

RF-shimming refers to a method by which the RF magnetic field (B1) can be manipulated through control of the excitation of each element in the RF transmit antenna array with the objective of maximizing the B1 homogeneity, which is correlated with image quality. We have applied RF-shimming to design an implant-friendly B1 exposure environment, with an investigation of the trade-off between image quality – as measured by B1 homogeneity – and implant-heating. The study was a proof-of-concept, and we are now in the process of extending the investigation to increasingly realistic clinical scenarios. We have shown that it is possible to reduce RF-heating of a generic cardiac implant by three orders of magnitude with a sacrifice of only 5% of the B1 homogeneity during MRI scanning at 1.5T.

At 3T, B1 homogeneity is more difficult to achieve and RF-shimming is commonly integrated in 3T clinical MRI scanners. However, RF-shimming for patients with

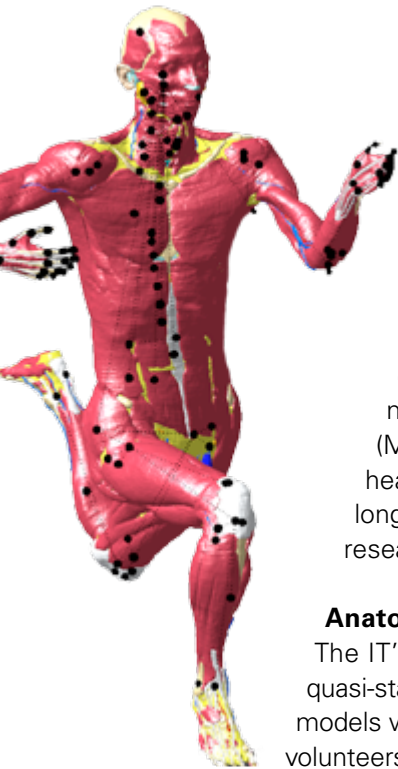
implants must be applied with extreme caution, and the importance of heat-mitigation planning in 3T imaging to ensure patient safety is becoming increasingly clear. An example of patient-specific heat-mitigation planning for 3T imaging is demonstrated in the figures below, where the amount of deposited power from a cardiac implant is estimated for the virtual patients Ella and Duke of the Virtual Population (ViP). The impact of RF-shimming on heating of tissues in the vicinity of the implant's stimulation electrode during traditional MRI RF-exposure versus a typical exposure with RF-shimming is shown.

This demonstrates that heat-mitigation through the design of implant-friendly MRI scanning routines at 1.5T and 3T is both possible and worth pursuing. As the severity of the risk from heating varies with type of implant, e.g., pacemakers versus brain stimulators – and is indeed specific to each patient and implant – the appropriate amount of tissue-heating mitigation must be personalized on a case-by-case basis to ensure patient safety and the best possible diagnostic and therapeutic outcome. There are still many considerations to be explored before this concept can be clinically realized, and, in future studies, we plan to demonstrate the feasibility of our approach in a broader patient population with more types of implants.



CAPTION: Patient-specific heat-mitigation of a cardiac implant at a thoracic imaging position (left) and abdominal imaging position (right) for ViP models Ella (triangles) and Duke (circles), with (orange) and without (gray) RF-shimming. The position of the model inside the RF coil is depicted on the right, and the polarization ellipses of the B1 field for the exposures are depicted above each model. The amount of power locally absorbed in tissues in the vicinity of the implant's stimulation electrode during typical RF-exposures with and without RF-shimming is simulated for the same cardiac implant. Implant-friendly RF-exposures for Ella (black dotted lines) and Duke (black solid lines) are also shown.

NEW APPROACH FOR REALISTIC POSING OF ANATOMICAL MODELS



The development and application of anatomical models for *in silico* safety assessment and device optimization in various scenarios – including electromagnetic (EM) exposure, magnetic resonance imaging (MRI) implant safety, thermal heating, and hyperthermia – have long been important aspects of research at IT'IS.

Anatomical Models

The IT'IS Foundation's widely used quasi-standard Virtual Population (ViP) models were created from MRI scans of volunteers in which more than 300 important tissues were segmented, and surface meshes of these tissues were generated. Due to the nature of the acquisition technique, i.e., the volunteer lying prone in a scanner with the arms close to the body, the postures of all models are the same. This limits the range of studies and applications for safety assessment, which often requires a variety of different body postures.

Improved Posing

In collaboration with ZMT Zurich MedTech AG, IT'IS has developed a new physics-based approach to adjusting the posture of the ViP models. The approach discretizes the body into soft tissue and bone tetrahedral mesh regions, which are used in conjunction with a biomechanical finite element method (FEM) solver to simulate articulation and tissue deformation in a realistic fashion. The body is treated as a deformable hyper-elastic Saint-Venant Kirchhoff material with rigid bones. The articulation is controlled by the user, who prescribes rotations around the articulated joints between the bones. The new positions of the bones are applied as constraints to the biomechanical simulation.

Compared to ZMT's previous Poser engine, which was based on linear blending of bone transformations within user-defined influence regions, the new FEM-based Poser for the first time overcomes many obstacles to achieving realistic postures with complex multi-tissue

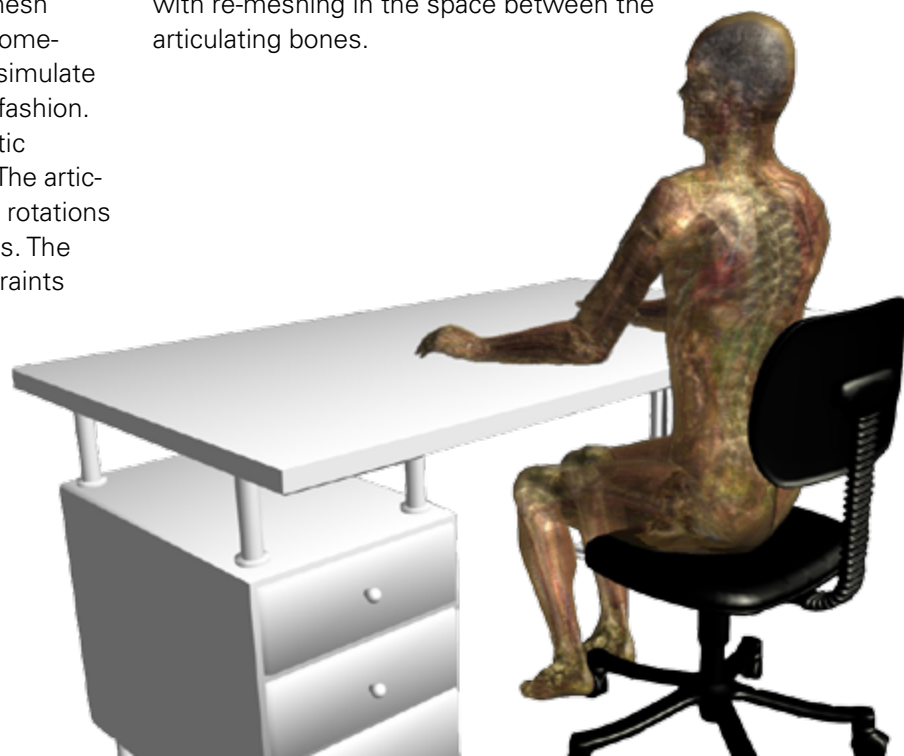
anatomical phantoms:

- The ripping or tearing of tissues that are close together in Euclidean space (inside the influence region) but are not involved in articulation is avoided, improving posing around the fingers, armpits, and in the groin region.
- The hyper-elastic material properties enforce volume preservation, typically better than with the linear-blending approach.
- Local inversions of thin tissues, which occurred with the linear-blending method, can be controlled or completely avoided.
- The effort required to make a model posable – it is sufficient to generate a tetrahedral mesh from the model geometry – is reduced compared to the linear-blending approach, which required the user to manually set up influence regions for each bone.

Future Development

The new Poser tool does not yet include collision detection or similar techniques to automatically avoid self-intersecting body parts. Approaches for detection of possible overlaps and prevention via collision handling are under development.

In the FEM-based approach, a single, continuous tetrahedral mesh is used, and the rigid placement of the bones is enforced as defined by the user, leading to stiffness near the joints. In future work, we will focus on improved joint handling, which may require collision detection with re-meshing in the space between the articulating bones.



CUSTOMIZED RESEARCH

The IT'IS Foundation offers a wide range of customized research to both academic and commercial partners to develop solutions and applications in the fields of physics, engineering, and medical technology. These service platforms engage the broad expertise and skills of our researchers and are performed in our advanced and accredited laboratories. Customized research includes, but is not limited to:

Functionalized Human and Animal Models

Our Virtual Population (ViP) suite of high-end *in silico* human and animal models have long been considered the gold standard in physiological modeling. Even so, we are working continuously to expand, improve, and further functionalize the models. We are also able to generate customized models optimized for specific applications.

Tissue Properties Database

We are committed to continue updating and refining our publically available database of the physical and physiological parameters of biological tissues (www.itis.ethz.ch/database/).

EMF Exposure Systems

The IT'IS Foundation designs and develops specific exposure systems for *in vitro*, *in vivo*, and human studies on interactions of electromagnetic fields (EMF) – from static to radiofrequency (RF) fields – with living tissue.

MRI Safety Evaluation

IT'IS provides contract research, collaborations, and evaluation of magnetic resonance imaging (MRI) scanners with respect to EMF safety (IEC 60601-2-33). We also offer to guide the development of advanced safety concepts for MRI manufacturers. As a partner laboratory of the Institute of Biomedical Engineering of the ETH Zurich, and with several staff members active participants at IEC MT40, we have a broad range of in-house expertise and access to MRI facilities from 1.5 to 7T.

MRI Implant Safety

The IT'IS Foundation also pioneers methodologies for MRI safety assessment of active medical device implants. We collaborate closely with the FDA, the JWG ISO/IEC standard group, and ZMT Zurich MedTech AG to

develop the best and most advanced methodologies and instruments. We not only perform evaluations of implants but also conduct investigations on the fundamental mechanisms of interactions of RF fields with implants and provide customized solutions for mitigation of patient risk.

5G Safety Evaluation

The IT'IS Foundation has the necessary toolboxes to conduct 5G safety evaluations. Our broad involvement with standardization bodies allows us to implement the latest testing procedures as they are developed.

In- and On-Body Antennas

The IT'IS Foundation provides expert consultations and design services for the full development of custom-specific antennas with optimized link budgets for operation in complex environments, particularly for on-body and embedded in-body devices.

SAR Evaluation

The IT'IS Foundation is regarded as the pre-eminent, truly independent institute for dosimetric specific absorption rate (SAR) evaluation. We are committed to continue developing the most accurate, flexible, and suitable testing procedures in conjunction with regulators, national standards laboratories, and industry. Our close cooperation with leading system manufacturers – partners SPEAG and ZMT – allows us to provide the best possible services based on the most recent and cutting-edge testing technologies.

Safety Evaluations of Wireless Power Transfer

Wireless power transfer (WPT) is the next big evolution for many applications. IT'IS provides safety assessment solutions that combine both numerical and experimental assessments.

CLS Consulting

The IT'IS Foundation – the co-developer of Sim4Life – couples expertise in physiological and biological modeling, computational engineering, and regulatory processes to provide excellence in computational life sciences (CLS) services for design, analyses and evaluations of specific medical diagnostic and therapeutic applications.

INFRASTRUCTURE

Dosimetric, Near-Field, and EMC/EMI Facilities

Semi-Anechoic Chamber

This shielded, rectangular chamber has the dimensions 7 × 5 × 2.9 m (L × W × H). It is equipped with a reflecting ground plane floor, and half of its walls are covered with electromagnetic absorbers. The chamber contains an integrated DASY52NEO system and can be utilized for all research activities involving dosimetric, near-field and far-field evaluations, the optimization and synthesis of handheld devices, body-mounted transmitters, implants, desktop applications, micro-base and pico-base station antennas, exposure setups, calibration procedures, EMI tests, MRI safety tests, compliance testing of implants, etc.

Two Reverberation Chambers

The Blue and NIEHS **reverberation** chambers have the dimensions 4 × 3 × 2.9 m and 3.7 × 2.2 × 2.7 m (L × W × H), respectively. Both chambers are equipped with two mechanical stirrers each and provide controlled and consistent environments for EM emissions and immunity testing, as well as shielding effectiveness and susceptibility testing of electromagnetic equipment.

Facility for Dosimetric Compliance Testing

IT'IS shares a facility with Schmid & Partner Engineering AG, which meets the requirements for dosimetric evaluations. The documentation of Class C accreditation has been completed.

Technical Equipment and Instrumentation

Spectrum and Network Analyzers

- 1 HP 8753E Network Analyzer, 30 kHz–6 GHz
- 1 HP APC 85033B Calibration Kit
- 1 Rohde & Schwarz FSP Spectrum Analyzer, 9 kHz–30 GHz
- 1 Rohde & Schwarz ZVA24 Vector Network Analyzer, 10 MHz–24 GHz
- 1 Rohde & Schwarz ZVA50 Vector Network Analyzer, 10 MHz–50 GHz
- 1 Rohde & Schwarz ZV-Z52 Calibration Kit

Signal Generators and Testers

- 3 Agilent 33120A, Waveform Generators
- 1 Agilent 33250A, Waveform Generator
- 1 Agilent E8251A Signal Generator, 250 KHz–20 GHz
- 3 Anritsu 3700A
- 2 Anritsu MG3700A
- 1 HP 8647A, Signal Generator 250 KHz–1000 MHz
- 1 Rohde & Schwarz CMU200
- 1 Rohde & Schwarz CMW500
- 1 Rohde & Schwarz CTS55, Digital Radio Tester
- 1 Rohde & Schwarz SMIQ02B, Signal Generator
- 2 Rohde & Schwarz SML02, Signal Generators
- 1 Rohde & Schwarz SML03, Signal Generator
- 1 Rohde & Schwarz SMT06, Signal Generator
- 1 Rohde & Schwarz SMU200A, Signal Generator
- 1 Rohde & Schwarz SMY02, Signal Generator

DASY, cSAR3D, EASY4MRI, MITS, PiX

- 1 INDY (3 year old child head) Phantom
- 1 ISABELLA (6 year old child head) Phantom
- 1 METROLAB, THM 1176, Magnetic Field Sensor
- 1 SPEAG AMIDV2, Audio Magnetic Field Probe
- 1 SPEAG AMIDV3, Audio Magnetic Field Probe
- 3 SPEAG ASTM Phantoms
- 1 SPEAG cSAR3D System (2 Flat, 2 Head & 1 Quad)
- 2 SPEAG DAE4, Data Acquisition Electronics
- 4 SPEAG DAEasy4MRI, Data Acquisition Electronics
- 1 SPEAG DAK 12/3.5/1.2E
- 2 SPEAG DASY52NEOs
- 4 SPEAG EASY4MRI
- 1 SPEAG EE3DV1, E-Field Probes
- 1 SPEAG EE3DV3, E-Field Probes
- 1 SPEAG EF3DV6, E-Field Probe
- 2 SPEAG ELI4 Phantoms
- 2 SPEAG ER3DV6, E-Field Probes
- 1 SPEAG ET1DV4, Dosimetric Probe
- 2 SPEAG ET3DV6, Dosimetric Probes
- 1 SPEAG EU2DV2, Probe

- 1 SPEAG EX3DV3, Dosimetric Probe
- 3 SPEAG EX3DV4, Dosimetric Probes
- 1 SPEAG H1TDS7zV1, H-field Time Domain Sensor
- 1 SPEAG, H1TDSxV1, H-field Time Domain Sensor
- 4 SPEAG H3DV6, H-Field Probes
- 3 SPEAG H3DV7, H-Field Probes
- 1 SPEAG HAC RF Extension
- 1 SPEAG HAC T-Coil Extension
- 1 SPEAG HU2DV1, Probe
- 4 SPEAG iSAR2 (2 Flat, 1 Head)
- 1 SPEAG SAM V6.0 Phantom
- 3 SPEAG T1V3LA, Temperature Probes
- 2 SPEAG T1V3, Temperature Probes
- 1 SPEAG T1V3LAB, Temperature Probe
- 1 SPEAG ES3DV2, Temperature Probe
- 1 SPEAG TSIL, Temperature Probe
- 1 ZMT MITS 1.5 w/Phantoms
- 1 ZMT MITS 3.0 w/Phantoms
- 1 ZMT MITS Gradient
- 1 ZMT PiXE64

- 1 SPEAG D900, Validation Dipole
- 1 SPEAG D835, Validation Dipole
- 1 SPEAG D1640, Validation Dipole
- 1 SPEAG D1800, Validation Dipole
- 1 SPEAG D1900, Validation Dipole
- 1 SPEAG D5GHz, Validation Dipole
- 1 SPEAG CD835V3, Validation Dipole
- 1 SPEAG CD1880V3, Validation Dipole
- 1 SPEAG CD2450V3, Validation Dipole
- 2 SPEAG PiXitor 64 MHz
- 1 Log-Periodic Antenna (650–4000 MHz)
- 2 Generic Phones (835/1900 MHz)

Meters

- 3 Agilent 34970A Data Acquisition Units
- 2 Agilent E4419B, 4 HP 8482A, Power Meters
- 1 Handyscope HS3 Data Acquisition Unit
- 1 Handyscope HS4 Data Acquisition Unit
- 3 HP 436A, 3 HP 8481A, Power Meters
- 1 Magnet Physik FH49–7030, Gauss/Teslameter
- 2 Rohde & Schwarz NRP2 Power Meters

Amplifiers

- 1 Amplifier Research 10S1G4A, Amplifier, 800 MHz–4.2 GHz
- 1 Kalmus 717FC RF Power Controller, 200–1000 MHz
- 1 LS Elektronik 2450 Amplifier, 400 W / 900 MHz
- 3 LS Elektronik 2449 Amplifiers, 200 W / 900 MHz
- 2 LS Elektronik 2448 Amplifiers, 60 W / 900 MHz
- 3 LS Elektronik 2452 Amplifiers, 200 W / 1800 MHz
- 1 LS Elektronik 2451 Amplifier, 60 W / 1800 MHz
- 1 LS Elektronik 2447 Amplifier, 5 W / 1800 MHz
- 2 LS Elektronik 2780 Amplifiers, 40 W / 2140 MHz
- 8 Mini-Circuits Amplifiers, ZHL42, 700–4200 MHz
- 2 Mini Circuits Amplifiers, ZVE-8G, 2–8 GHz
- 1 Nucletrides ALP336 Amplifier, 1.5–2.5 GHz
- 2 Ophir 5141, 700 MHz–3 GHz

Other Equipment

- 8 Maury 1878B, 3-Step Tuners
- 1 Narda EHP-50 EM Field Probe Analyzer, 5 Hz–100 KHz
- 1 Narda ELT-400 Magnetic Field Probe, 1 Hz–400 KHz
- 1 Siemens, Universale Messleitung, (0.5) 1–13 GHz
- 2 SPEAG Dipoles SCC34 Benchmark
- 3 SPEAG, SHO V2 RB, RC & RP, OTA Hand Phantoms
- 6 Validation Dipoles D835, D900, D1640, D1800, D2450, D5GHz

Computers

- 54 Laptop Computers (from Apple, Asus, Lenovo)*
- 14 Intel Core i7 based, 16–31GB RAM
- 15 Intel Core i7 based, 4–15GB RAM
- 10 Intel Core i5 based, 4–15GB RAM
- 3 Intel Core2Duo based, 1–3GB RAM
- 12 Intel Core2Duo based, 4–15GB RAM
- 55 Workstation Computers (custom built, and from Dalco, HP)*
- 1 Intel Xeon based, dual socket, 16–31GB RAM
- 3 Intel Xeon based, 16–31GB RAM
- 2 Intel Core i7 based, 64GB RAM
- 22 Intel Core i7 based, 32–63GB RAM
- 11 Intel Core i7 based, 16–31GB RAM
- 10 Intel Core i7 based, 4–15GB RAM
- 2 Intel Core2Duo based, 4–15GB RAM
- 2 AMD Opteron based, Dual socket, 16–31GB RAM
- 1 AMD Opteron based, Dual socket, 4–15GB RAM
- 1 Intel Pentium 4 based; Dell, 1–3GB RAM
- 11 Clusters and Specialized Computational Systems (from Dalco, NVidia)*
- 1 NVidia S1040 based computational cluster, 4 nodes*
(each with 4 x NVidia T10 GPUs, 16GB VRAM, QuadCore CPUs, 32GB RAM)
- 3 Intel Xeon based, Dual socket, 64–255GB RAM, Quad Tesla GPU
- 3 Intel Xeon based, Dual Socket, 64–255GB RAM
- 3 Intel Xeon based, Dual Socket, 256–1023GB RAM
- 1 Intel Xeon based, Quad Socket, 512GB RAM
- 6 Servers (from Apple, Dalco, Synology)*
- 1 Intel Xeon based, Dual socket, 4–15GB RAM
- 1 Intel Core2Duo based, 8GB RAM
- 2 Intel Atom based NAS, >30TB network file storage
- 2 Marvell ARM based NAS, >8TB network file storage
- 19 Miscellaneous Computer Hardware*
- 5 NVidia Tesla GPU PCIe Cards (attached to workstations)
- 10 Apple AirPort Extreme WiFi base stations
- 1 Xerox Monochrome Laser Printer
- 1 Xerox Color Laser Printer
- 2 Personal Tablet

SELECTED PUBLICATIONS 2015

Yijian Gong. *Extended Methods for Analysis of EM Exposure for Human, In Vivo and In Vitro*, PhD Thesis, Swiss Federal Institute of Technology, Zurich, 2015.

Gernot Schmid and Niels Kuster. The discrepancy between maximum in vitro exposure levels and realistic conservative exposure levels of mobile phones operating at 900/1800 MHz, in *Bioelectromagnetics*, Volume 36, Issue 2, pp. 133–148, February 2015.

Jagadish Nadakuduti, Mark Douglas, Lin Lu, Andreas Christ, Paul Guckian, and Niels Kuster. Compliance testing methodology for wireless power transfer systems, in *IEEE Transactions on Power Electronics*, Volume 30, Issue 11, pp. 6264–6273, February 2015.

Valerio De Santis, Mark Douglas, Jagadish Nadakuduti, Stefan Benkler, Xi Lin Chen, and Niels Kuster. Human exposure from pulsed magnetic field therapy mats: a numerical case study with 3 commercial products, in *Bioelectromagnetics*, Volume 36, Issue 2, pp. 149–161, February 2015.

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The IT^{IS} Foundation was established in 1999 through the initiative and support of the Swiss Federal Institute of Technology in Zurich (ETHZ), the global wireless communications industry, and several government agencies. IT^{IS} stands for Information Technologies in Society.

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IT^{IS} Foundation is a non-profit tax-exempt research foundation.

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