IT'IS FOUNDATION 2021

Cover: Personalized simulations were a key component of optimized spinal cord neuromodulation to restore mobility in patients after severe spinal cord injury in a clinical trial led by Grégoire Courtine and Jocelyne Bloch (Nature Medicine, 28, 260–271, 2022; for more details see pages 12–13). Image reprinted with permission. ©EPFL

2021 – THE YEAR IN BETWEEN

The year 2021 was even more challenging, but not less successful, than 2020. We began the year under sustained COVID-19 restrictions (but with a better understanding of the evolving pandemic), returned to on-site operations during the summer, and then were hit by the third wave of corona infections in the fall. Throughout the year, though, we were able to sustain our resilience, continuing to invest countercyclically in defiance of the economic downturn – we hired additional talent to accelerate and expand our internally funded projects and continued to focus on fortifying our foundational hardware and software tools for future research projects.

One major focus of activities has been the development of new *Dosimetric Electromagnetic Tools* for both low-frequency and high-frequency applications, namely, phantoms and probes for dosimetric measurements at <<4 MHz and assessment of absorbed power density at >10 GHz. Thanks to numerous advances made during recent months, we are confident to achieve significant breakthroughs in both areas in 2022. We made a major step towards real-time specific absorption rate (SAR) measurements by greatly improving and accelerating our reconstruction algorithm leading to the record achievement of being able to record three full 3D SAR distributions and peak spatial SAR values per second. This progress has been largely driven by the needs of regulators and industry.

Our second major area of activities, *Computational Life Sciences* (CLS) continues to grow rapidly and is scientifically successful and rewarding even though it presents many challenges. The development of the o^2S^2PARC platform is our largest key investment in the future, and the team, led by Esra Neufeld and Nik Chavannes, succeeded in securing a 5th round of funding from the National Institutes of Health (NIH). Additional CLS funding comes from collaborations supported by various agencies. Our recent activities in the area of artificial intelligence (AI) led to early successes in the creation of improved and automated patient-specific anatomical models, particularly of the spine. Strengthened by these developments, we also made rapid progress on projects in bioelectronics medicine, neuroprosthetics, and central nervous system stimulation that encompass research questions in basic mechanistic research, modeling-based evaluation and optimization of device safety and efficacy, *in silico* trials, and personalized medicine. The most impressive results achieved with personalized simulations in a clinical setting have come from our outstanding and extremely gratifying collaboration with the EPFL and other partners on the rapid recovery of trunk and leg motor function in paralyzed patients, described in detail on pages 12 – 13.

Our third major long-term focus has been on non-invasive deep brain stimulation via *Temporal Interference* (TI). We expect that collaborating groups will soon begin to employ the high-quality investigational TI stimulation device developed jointly with TI Solutions AG, together with the corresponding planning tools based on the o^2S^2PARC platform, for research and clinical studies in summer of 2022.

At the heart of our success is the commitment, creativity, expertise, and enthusiasm of the foundation's committed researchers, students, and external advisors (page 5), and the expert guidance of IT'IS Foundation Board Members (page 4). Constructive and effective collaborations with partner institutions (page 9) also contribute to our innovative growth. We particularly thank Professors Qiuting Huang, Klaas Prüssmann, Lukas Novotny, Alex Dommann, Mathieu Luisier, and Grégoire Courtine for sharing infrastructure and advising our joint PhD students and postdoctoral researchers during the challenging year of 2021. We further owe special thanks to Professors Beatrice Beck Schimmer, Stephan Bodis, and Alvaro Pascual-Leone for invaluable guidance on clinical matters.

We are grateful to our many sponsors and donors (page 8), whose commitment and trust in our vision make it possible for us to pursue our goals year after year.

Prof. Niels Kuster

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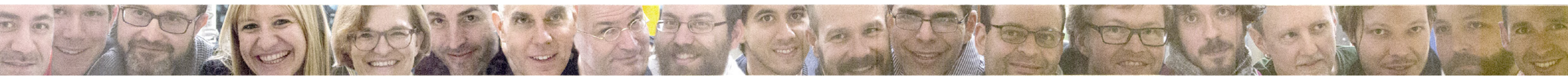

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KEY FIGURES

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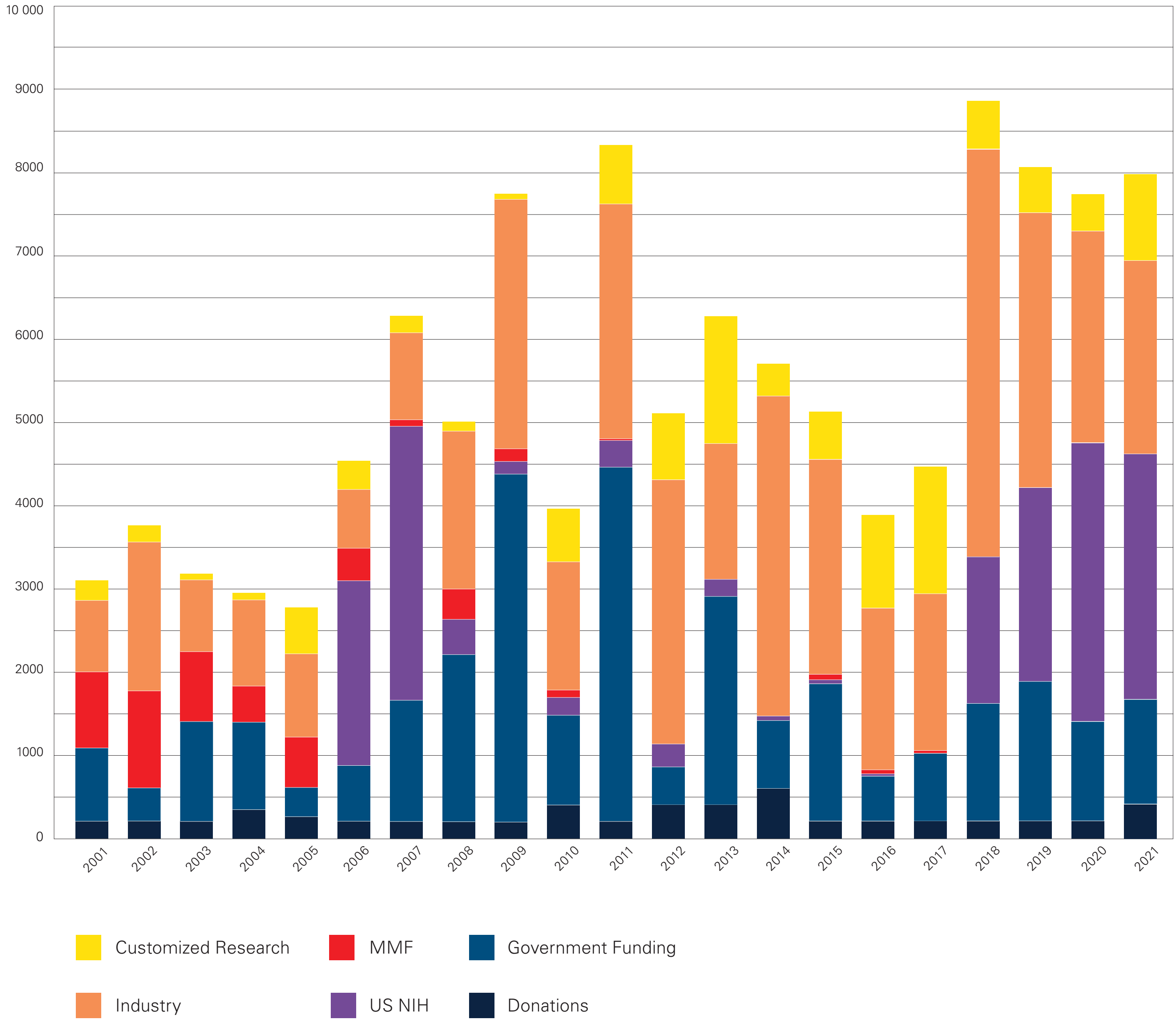
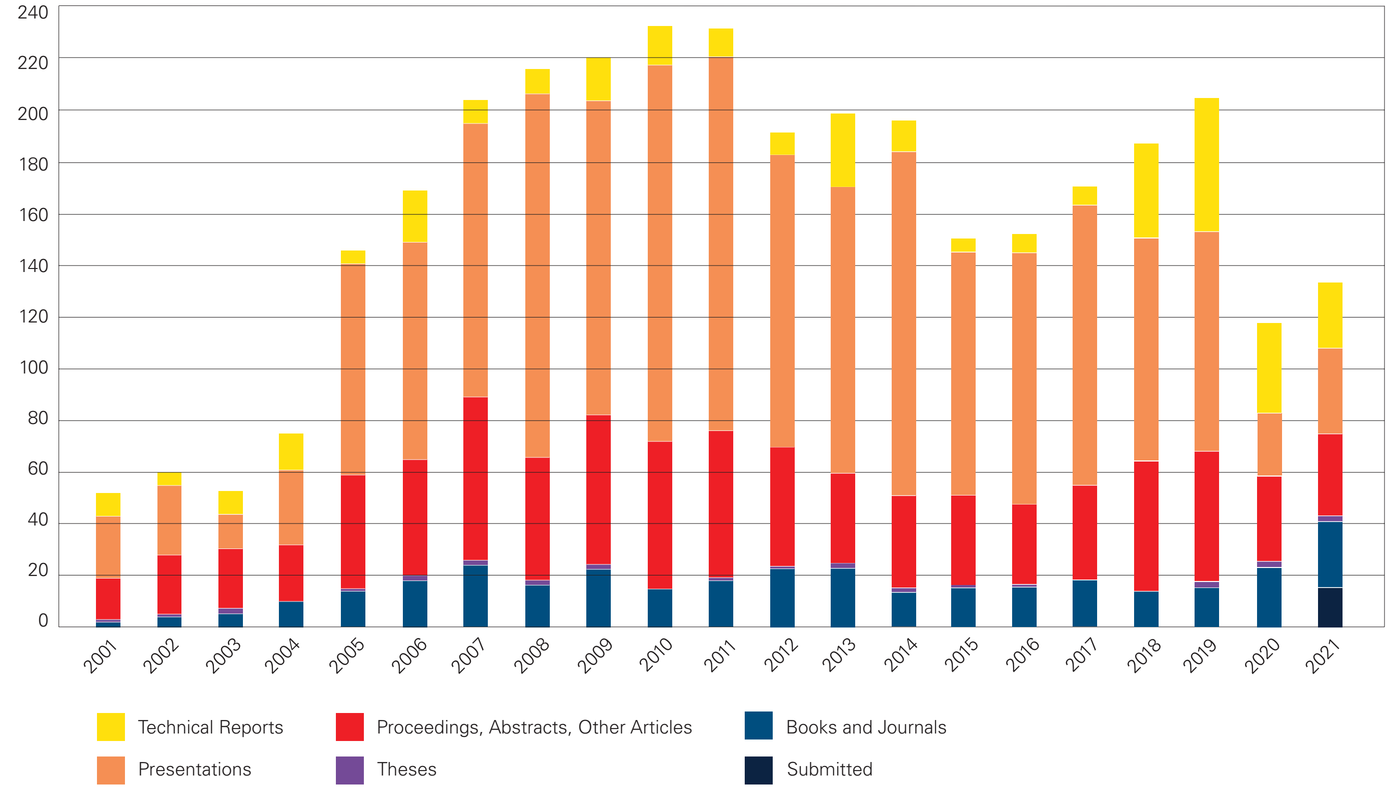


KEY FIGURES

Number of Publications



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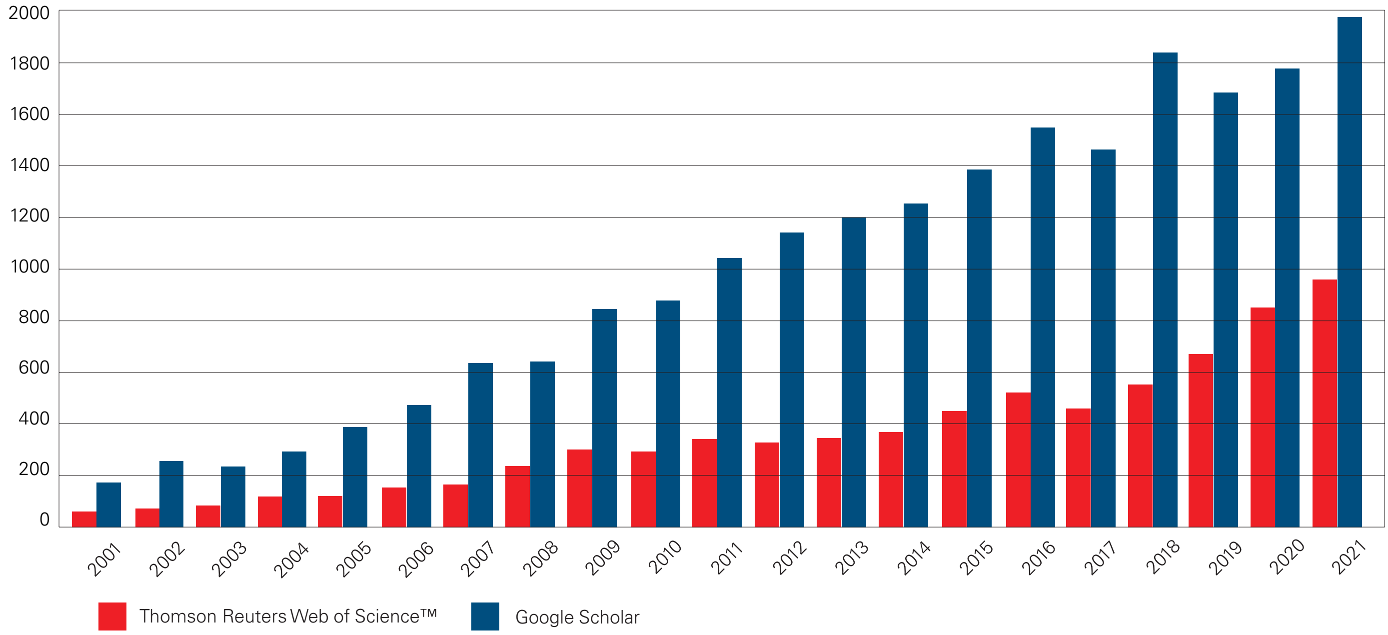

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EM Technology

5&6GEARS	Development of an ultra-miniature wideband 5G and 6G electromagnetic radiation sensor for future mobile communication systems
Dielectric Spectroscopy	Development of novel methodologies for characterization of materials from DC to >100 GHz
Module APD	Module for exposure assessment of the absorbed power density of millimeter wave wireless devices
TD SENSOR	Development of time-domain near-field field sensor technology
TyProxi	Development of a regulatory-grade test system for compliance of wireless devices with proximity sensors
SNSF SPARK	Relativistic particle trapping for compact coherent X-ray sources
WPT	Development of test equipment and software to show compliance with electromagnetic safety guidelines of wireless power transfer systems
WPT4FOIL	Preventing chronic migraine with a novel wirelessly powered implantable bioelectronic foil

EM Exposure and Risk Assessment

RADIODEP	Effects of radiofrequency (5G) in healthy and depressive subjects: behavioral and neurobiological approaches of electromagnetic hypersensitivity in the rat
sXc, sXv, sXh	Development of optimized exposure systems for bio-experiments from static to >100 GHz including the systems for NIEHS *in vivo* follow-up studies

IT'IS for Health

CLS – ART-REWARD	Artificial regulation of reward processing via non-invasive deep brain stimulation
CLS – CRANIO	Modelling of craniospinal compliance in humans to advance the understanding of dynamic compliance and its pathophysiological basis
CLS – DEEP-MCI-T	Development of a novel approach, based on temporal interference stimulation, aimed at deep non-invasive brain stimulation to enhance cognitive function in mild cognitive impairment and traumatic brain injury
CLS – FUS	Advances in transcranial focused ultrasound (FUS), including SonoKnife and investigation of liver motion during FUS interventions
CLS – NeuHeart	Development of a neuroprosthesis to restore the vagal-cardiac closed-loop connection after heart transplantation
CLS – o^{2}S^{2}PARC	Establishment of an interactive, freely accessible online platform for simulating peripheral nervous system neuromodulation/stimulation
CLS – PREP2GO	Development of a pre-operative planning system for neuromodulation surgery for spinal cord injury rehabilitation
CLS – RISE	Implementation of a protocol for reaching deep structures by non-invasive brain stimulation to modulate striatum-based learning
CLS – V&V40	Development of novel concepts for verification and validation of computational life science software platforms and their applications
HT-KSA/UHZ/ETHZ	Development of novel hyperthermia hardware and treatment planning software for human applications
MRI – Implant Safety	Improved procedures and instrumentation for magnetic resonance imaging safety evaluation of medical implants
REPLICATIONS	Co-funding of confirmation studies of bioelectromagnetic experiments
STANDARDIZATION	Participation in regulatory activities (standards committees and governments)
ViP 4.x	Development of the next generation of high-resolution computational anatomical models
ViP – NEUROMAN	Functionalized anatomical models for studying electromagnetic-neuronal dynamic interactions
ViP-P/VM/M	Development of novel posers, of methodology for enhanced volume meshes of anatomical structures, and of a physically-based morphing tool

PERSONALIZED SIMULATIONS HELP PATIENTS WITH SPINAL CORD INJURY WALK AGAIN

Epidural electrical stimulation (EES) is a promising neuromodulation strategy for the rehabilitation of spinal cord injury (SCI). In EES, electrical currents are delivered to the spinal cord by means of electrodes surgically implanted in the epidural space[1]. In recent years, EPFL's G-Lab UPCourtine has made great strides in the development of EES-based therapies for SCI[2–6], culminating in a landmark 2022 study published in the journal *Nature Medicine*[7]. In this study, Rowald *et al.* demonstrate the use of EES to restore leg and trunk movement in three patients with complete lower limb paralysis. Whereas previous generations of spinal stimulation technology have achieved only limited restoration of motor function in SCI patients after months of intense training assisted by physical therapists[8,9], the pioneering treatment paradigm described by Rowald *et al.* allowed all three subjects to stand, walk, cycle, and swim within a single day.

The key to the success of Rowald *et al.*'s latest EES approach was their development of a personalized, Sim4Life-based pipeline for preoperative treatment planning, with models and simulation data hosted on o²S²PARC. Using images obtained from computed tomography and magnetic resonance imaging scans, the researchers were able to build custom finite element models of each patient's spine in Sim4Life, and functionalize these anatomical models with biophysically realistic axonal fibers. IT'IS' verified library of material properties was used to assign physical parameters to each tissue/model object before passing the ensemble to a simulation engine. Using this approach, the researchers could simulate the effects of electrical stimulation at various locations along the spine, and for various combinations of active sites on the electrode lead. Next, Rowald *et al.* assembled an atlas of spinal reconstructions obtained from the MRI data of 15 healthy volunteers. This allowed the researchers to assess how natural variations in individual anatomy influence the efficacy of different stimulation confi-gurations. For instance, would inter-subject variability be low enough that a single, optimized stimulation configuration could suffice for most or all SCI patients with lower limb paralysis? The results of the simulations carried out across the atlas of spine models revealed high variability in the sample population, and implied that patient-specific treatment planning would likely be required for optimal outcomes. However, it was determined that a reference spine model obtained by averaging the anatomies in the spine atlas was sufficient for optimizing the design of the electrode lead itself. Using Sim4Life, Rowald *et al.* systematically altered various aspects of the spatial arrangement of active sites on the lead paddle until maximally selective recruitment of individual spinal roots (and therefore target muscle groups) was achieved. In the future, it may even be possible to custom manufacture lead designs that are optimized *in silico* to the individual anatomies of specific patients, rather than relying on a standardized reference model.

Having finalized the design of the electrode lead, Rowald *et al.* turned their attention to determining the optimal placement of the lead along the spine of each patient. The researchers proceeded by carrying out Sim4Life simulations of EES for various lead positions to determine which location permitted the most selective recruit of nerves and muscles given each patient's unique anatomy. These predictions were later tested intraoperatively by perturbing the lead away from the theoretically optimal location and reassessing selectivity. In all cases, the locations predicted in Sim4Life on the basis of patient-specific anatomies were optimal and outperformed similar predictions made on the basis of a generic reference model. The enhanced selectivity of muscle fiber recruitment made possible by Sim4Life's extensive tissue library, its biophysically accurate axon models, and the precision of its solvers enabled patients with complete lower limb paralysis not only to regain lost motor function, but to walk, cycle, and swim with assistance within a single day of commencing EES. Furthermore, these functions improved dramatically over the ensuing three days, with all three participants progressively regaining full weight-bearing capacities, and, ultimately, unassisted walking (with a front-wheel walker for stability) in a community setting. Finally, in two patients, recovery of some volitional muscle activation *without* EES was observed following neurorehabilitation, suggesting that EES boosted signaling from residual descending pathways. The Sim4Life models and selected simulation results are publicly available on the o²S²PARC platform.

Spine models of the 15 healthy volunteers are available at:
osparc.io/study/3c62d60a-319d-11ec-8033-02420a0b2de3

Spine models for the three SCI patients may be accessed with the following links:
participant 1:
osparc.io/study/423e27aa-319d-11ec-8033-02420a0b2de3
participant 2:
osparc.io/study/389ac42e-319d-11ec-8033-02420a0b2de3
participant 3:
osparc.io/study/3f4ea128-319d-11ec-8033-02420a0b2de3

The groundbreaking advancements described by Rowald *et al*. are helping to usher in a new era in the treatment of SCI, powered by *in silico* approaches to personalized medicine. With the unrivaled commitment to accuracy and precision provided by Sim4Life and o²S²PARC, the IT'IS Foundation stands at the vanguard of this revolution, helping to improve quality of life following SCI, and moving us towards a future where patients can fully resume pre-injury activities without limitations.

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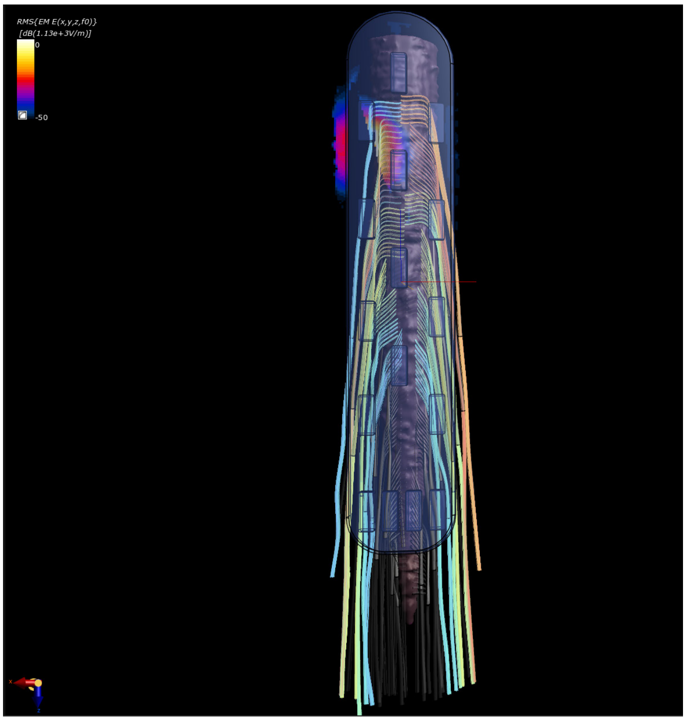

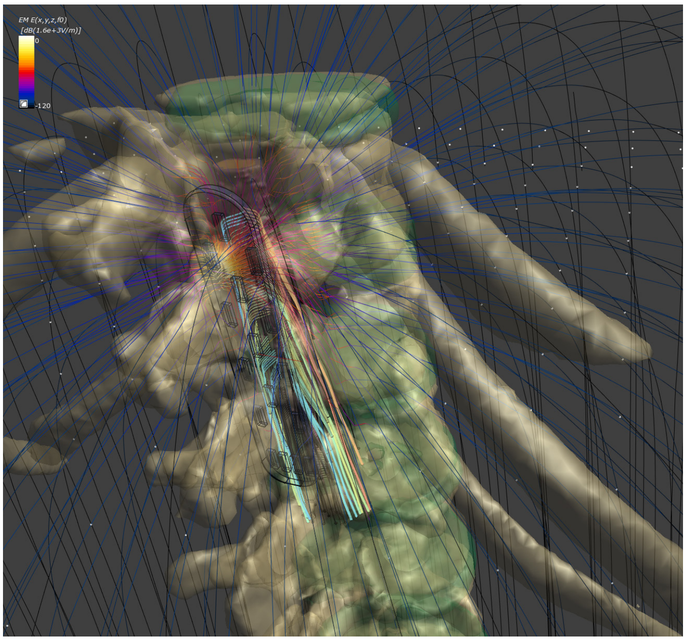

image top
Sim4Life visualization of simulated epidural electrical stimulation showing spinal roots, white matter and electrode lead paddle with electromagnetic field heatmap overlay (active electrode: top-left). Colorbar indicates root mean square field magnitude. Individual spinal roots are colored by activation thresholds.

image middle
Sim4Life visualization of simulated epidural electrical stimulation showing bone, vertebrae, spinal roots, white matter and electrode lead paddle with electro-magnetic field line overlay (active electrode: top-left). Colorbar indicates electric field strength. Individual spinal roots are colored by activation threshold.

image bottom
Time-lapse of a spinal cord injury patient walking independently with the assistance of a portable epidural electrical stimulation system and a front-wheel walker for stability. Video source with permission. ©NeuroRestore/Jimmy Ravier

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 interference tests, magnetic resonance imaging safety tests 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, compliance testing of implants, etc.

Facility for RF Compliance Testing

IT'IS shares a facility with Schmid & Partner Engineering AG, which is equipped with the latest DASY8 systems for testing compliance with any national and international guidelines, standards, and regulations as well as for a wide range of research and development measurement tasks related to electromagnetic exposure from 3 kHz – 110 GHz. 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 FPL1003 Spectrum Analyzer, 5 kHz – 26 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 ZVA67 Vector Network Analyzer, 10 MHz – 67 GHz
1 Rohde & Schwarz ZV-Z52 Calibration Kit
1 Copper Mountain R60 Vector Reflectometer
1 Keysight E5061B Vector Network Analyzer, 5 Hz – 1.5 GHz
1 NI PXIe-5668R Vector Signal Analyzer, 100 kHz – 26.5 GHz

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, DAE, EASY4MRI, MITS, PiX, Phantoms, Resonators

1 INDY (3 year old child head) Phantom
1 ISABELLA (6 year old child head) Phantom
1 SPEAG ASTM Phantom
2 SPEAG DAE4, Data Acquisition Electronics
1 SPEAG DAE4A, Data Acquisition Electronics
2 SPEAG DAE4ip, Data Acquisition Electronics
4 SPEAG EASY6 DAE, Data Acquisition Electronics
4 SPEAG DAEasy4MRI, Data Acquisition Electronics
2 SPEAG DASY52NEOs
1 SPEAG EASY4MRI
2 SPEAG EASY6
2 SPEAG ELI4 Phantoms
1 SPEAG HAC RF Extension
1 SPEAG HAC T-Coil Extension
5 SPEAG cSAR3D (2 Flat, 1 Left Head, 1 Right Head and 1 Quad)
1 SPEAG SAM V6.0 Phantom
1 ZMT MITS 1.5 with ELIT Phantoms
1 ZMT MITS 3.0 with ELIT Phantoms
2 ZMT Dual Cylinder Phantoms
1 ZMT MITS Gradient v1
1 ZMT MITS Gradient v2
1 ZMT PiXE64
1 ZMT MITS-HFR1.5
1 ZMT MITS-HFR3.0
1 ZMT MITS-TT
3 SPEAG SHO V2 RB, RC, and RP OTA Hand Phantoms
1 SPEAG ICEy-EMC and -mmW

Probes

1 METROLAB THM 1176, Magnetic Field Sensor
1 SPEAG AMIDV2, Audio Magnetic Field Probe
1 SPEAG AMIDV3, Audio Magnetic Field Probe
2 SPEAG T1V3, Temperature Probes
3 SPEAG T1V3LAB, Temperature Probes
3 SPEAG T1V4LAB, Temperature Probes
2 SPEAG T1V3, Temperature Probes
1 SPEAG EE3DV1, E-Field Probes
1 SPEAG EF3DV3, E-Field Probe
1 SPEAG EL3DV2, E-Field Probe for WPT
2 SPEAG ER3DV6, E-Field Probes
1 SPEAG ES3DV2, E-Field Probe
1 SPEAG ET1DV4, Dosimetric Probe
2 SPEAG ET3DV6, Dosimetric Probes
1 SPEAG EU2DV2, Dosimetric Probe
1 SPEAG EUmmW E-Field Probe
1 SPEAG EX3DV3, Dosimetric Probe
4 SPEAG EX3DV4, Dosimetric Probes
3 SPEAG H1TDSx, H-Field Time Domain Sensor and Remote Units
2 SPEAG E1TDSz, E-Field Time Domain Sensor and Remote Units
1 SPEAG 1RU1PXI TDS Remote Unit
1 SPEAG H1TDSx-ICEy H-Field Time Domain Sensor
1 SPEAG H1TDSz-ICEy H-Field Time Domain Sensor
1 SPEAG E1TDSx-ICEy E-Field Time Domain Sensor
1 SPEAG E1TDSz-ICEy E-Field Time Domain Sensor
4 SPEAG H3DV6, H-Field Probes
3 SPEAG H3DV7, H-Field Probes
1 SPEAG HL3DV2, H-Field Probe for WPT
1 SPEAG HU2DV1, H-Field Probe
1 SPEAG DAK Kit 12/3.5/1.2E
1 SPEAG DAKS-12 Probe
6 SPEAG RFoF1P4MED Probes and 1 Remote Unit
1 Greisinger GMH 5430 Conductivity Meter

Antennas

1 SPEAG D835, Validation Dipole
1 SPEAG D900, Validation Dipole
1 SPEAG D1640, Validation Dipole
1 SPEAG D1800, Validation Dipole
1 SPEAG D1900, Validation Dipole
1 SPEAG D3500, Validation Dipole
1 SPEAG D5GHz, Validation Dipole
1 SPEAG CD835V3, Validation Dipole
1 SPEAG CD1880V3, Validation Dipole
1 SPEAG CD2450V3, Validation Dipole
2 ZMT PiX Excitor 64 MHz
1 Log-Periodic Antenna (650 – 4000 MHz)
2 Generic Phones (835/1900 MHz)
3 SPEAG HAC Dipoles

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
6 LS Elektronik 24xx Amplifiers
8 Mini-Circuit Amplifiers, ZHL42, 700 – 4200 MHz
2 Mini-Circuit Amplifiers, ZVE-8G, 2 – 8 GHz
1 Nucletudes 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
1 Thermoconcept THW L2 Thermal Conductivity Meter
1 SPEAG RFoF4MED CU Calibration Unit
2 OPUS 20 THI Humidity and Temperature Monitors

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IT'IS FOUNDATION

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

Legal status
The IT'IS Foundation is a non-profit tax-exempt research foundation.

Mission
The IT'IS Foundation is dedicated to expanding the scientific basis of the safe and beneficial application of electromagnetic energy in health and information technologies.

The IT'IS Foundation is committed to improving and advancing precision medicine and the quality of life of people with disabilities, in particular, through innovative research.

The IT'IS Foundation is an independent research institute.

The IT'IS Foundation provides a proactive, creative, and innovative research environment for the cultivation of sound science and research, and education.

Funding
National and international public funding, research projects sponsored by agencies and industry, and customized research.

President
Prof. MD Stephan Bodis
+41 44 245 9696
foundationboard@itis.swiss

Director
Prof. Niels Kuster
+41 44 245 9690
nk@itis.swiss

Associate Director
Hardware Development
Dr. Myles H. Capstick
+41 44 245 9743
capstick@itis.swiss

Associate Director
Computational Life Sciences
Dr. Esra Neufeld
+41 44 245 9698
neufeld@itis.swiss

Office
IT'IS Foundation
Zeughausstrasse 43
CH–8004 Zurich
Switzerland
+41 44 245 9696
info@itis.swiss

Antenna-, Hyperthermia- and Exposure Systems
Dr. Myles H. Capstick
+41 44 245 9743
capstick@itis.swiss

Certification Research
Dr. Mark G. Douglas
+41 44 245 9861
douglas@itis.swiss

Computational Brain Stimulation
Dr. Taylor Newton
+41 44 245 9826
newton@itis.swiss

Computational Electromagnetics
Dr. Arya Fallahi
+41 44 245 9833
afallahi@itis.swiss

Customized Research
Dr. Tolga Goren
+41 44 245 9680
goren@itis.swiss

Dielectric Spectroscopy
Dr. Sina Hashemi Zadeh
+41 44 245 9760
sina@itis.swiss

EM Phantoms
Dr. Ioannis Koufogiannis
+41 44 245 9711
koufogiannis@itis.swiss

Neurostimulation
Dr. Antonino M. Cassarà
+41 44 245 9813
cassara@itis.swiss

Sensors, EMC, EMI, Dosimetry
Dr. Sven Kühn
+41 44 245 9694
kuehn@itis.swiss

Virtual Population and Tissue Properties Database
Dr. Bryn Lloyd
+41 44 245 9831
lloyd@itis.swiss

www.itis.swiss

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is a member of