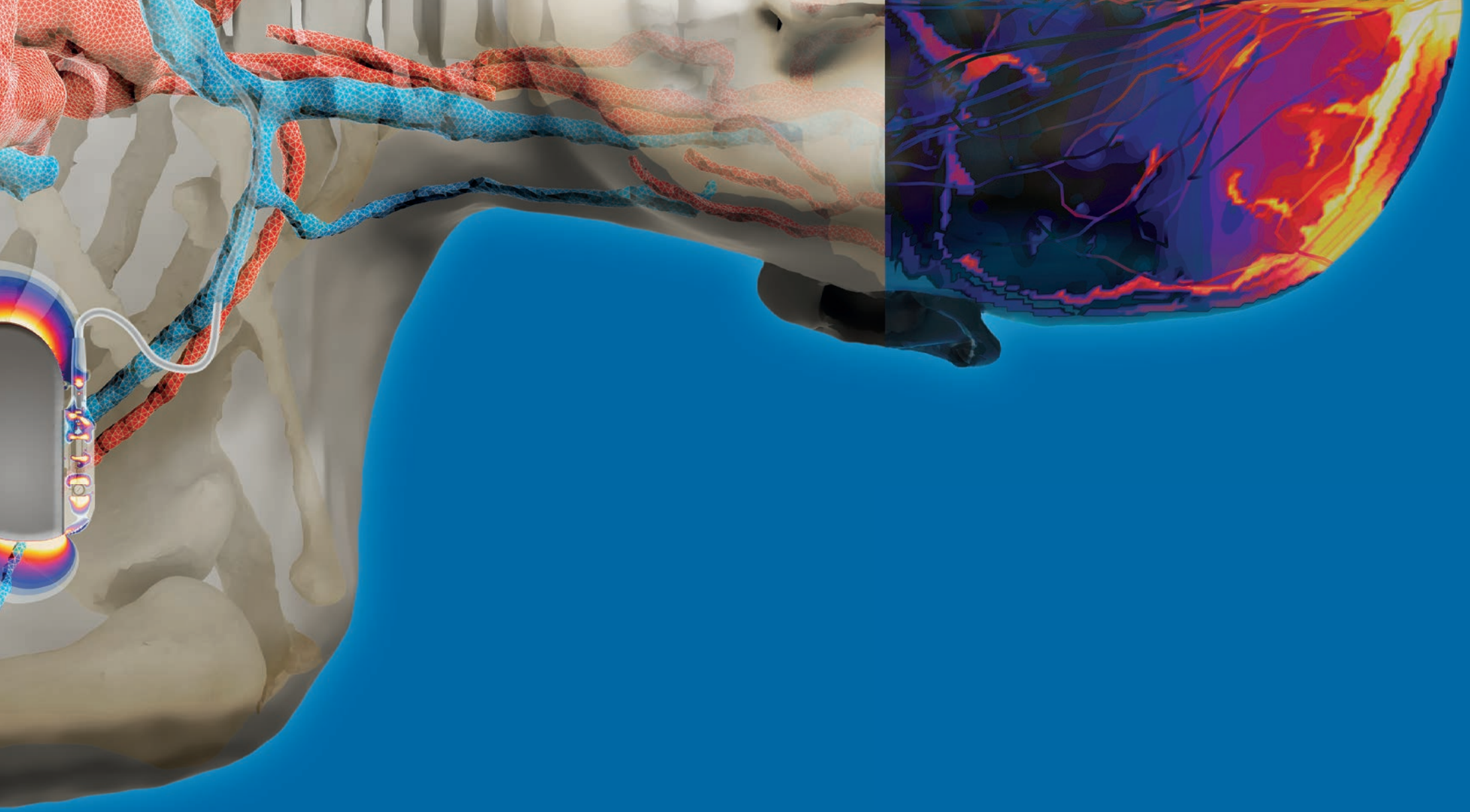


zurich med tech

In Silico **We Trust**

In Silico

The digital revolution is extending the frontiers of medicine and medical technology. Computer modeling and simulation (CM&S), or *in silico* technologies, merge computational tools with biology to intuitively, precisely, and reliably perform complex analyses of life sciences applications. With this emerging paradigm, experimental manipulations that are infeasible or prohibitively complex to conduct in real-life experiments can be created while maintaining superior experimental control: the perfect complement to *in vivo* and *in vitro* studies.

ZMT provides *in silico* solutions to the medical device and life sciences industries. Our comprehensive simulation platform, Sim4Life, provides a powerful 3D validated biological and anatomical modeling environment for optimizing the effectiveness and performance of medical devices, improving patient safety, and discovering potential new treatments. Built from the ground up, Sim4Life provides smooth and fully automated or customizable workflows for applications ranging from exploratory research and medical device development to regulatory documentation for clinical trials and device certification.

... we trust

Our software tools are thoroughly and continually verified to ensure their reliability and performance as they evolve.

We place high emphasis on the validation of our computable functionalized models and medical device and life sciences applications.

ZMT also provides test systems for experimental validation procedures that support complex requirements with software tools optimized for test and measurement systems.

At ZMT, we leverage the combined strength of our expertise, experience, cost-effective solutions, and commitment to long and fruitful client relationships to guide you through the long and complex regulatory submission process.

Sim4Life Workflow

WORKFLOW

Posing
Segmentation
Morphing

CAD
Human Phantoms
Discretization

Multiphysics
High Performance
Solvers

Physiology
and Tissue
Models

Optimization
Analysis
Visualization

OPEN SCRIPTABLE FRAMEWORK WITH A POWERFUL GRAPHICAL USER INTERFACE AND HIGH PERFORMANCE COMPUTING SUPPORT

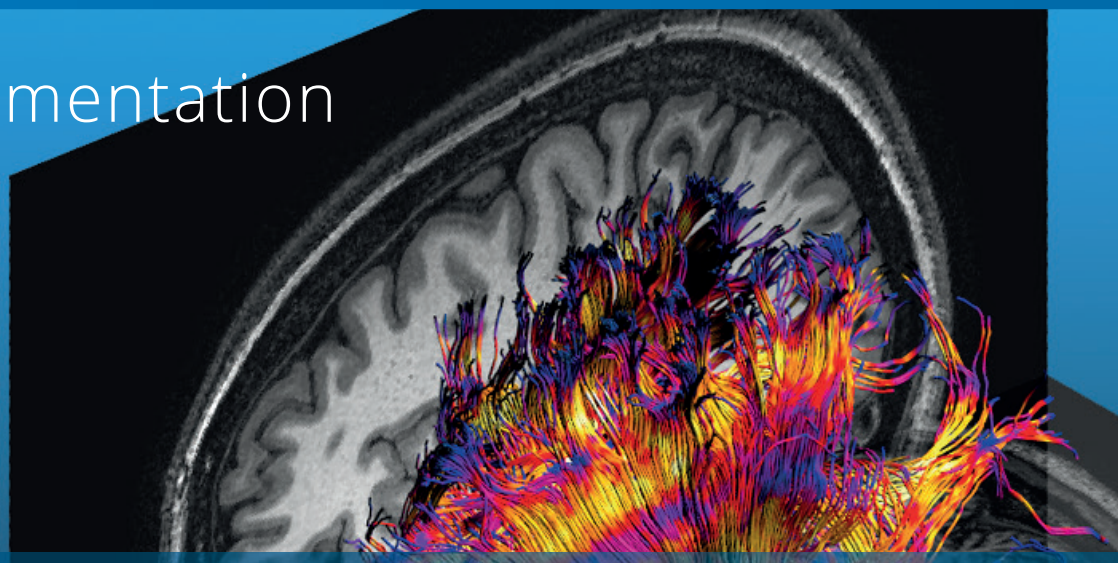
Sim4Life is the first computational life sciences platform to integrate computable human phantoms with the most powerful physics solvers and the most-advanced tissue models for direct analysis of biological real-world phenomena and complex technical devices in a 3D validated biological and anatomical environment.

All modeling capabilities – from the segmentation of medical image data, anatomical and CAD model import, discretization, and simulation to visualization and analysis – are embedded and streamlined to offer the most versatile and efficient simulation environment possible.

At the core of Sim4Life are the computable, high-fidelity 3D Virtual Population (ViP) human anatomical models. Carefully selected to fully represent global variability in human anatomy, the fully posable, morphable, and validated ViP models, along with the IT'IS tissue properties database, depict 15 different body types with 120 vital anatomical features and over 300 precisely identified tissues and organs.

Sim4Life is designed to simulate the most complex scenarios, and all features have been thoroughly verified and validated to ensure that the results generated accurately and reliably reflect reality and are ready for regulatory submissions.

Segmentation



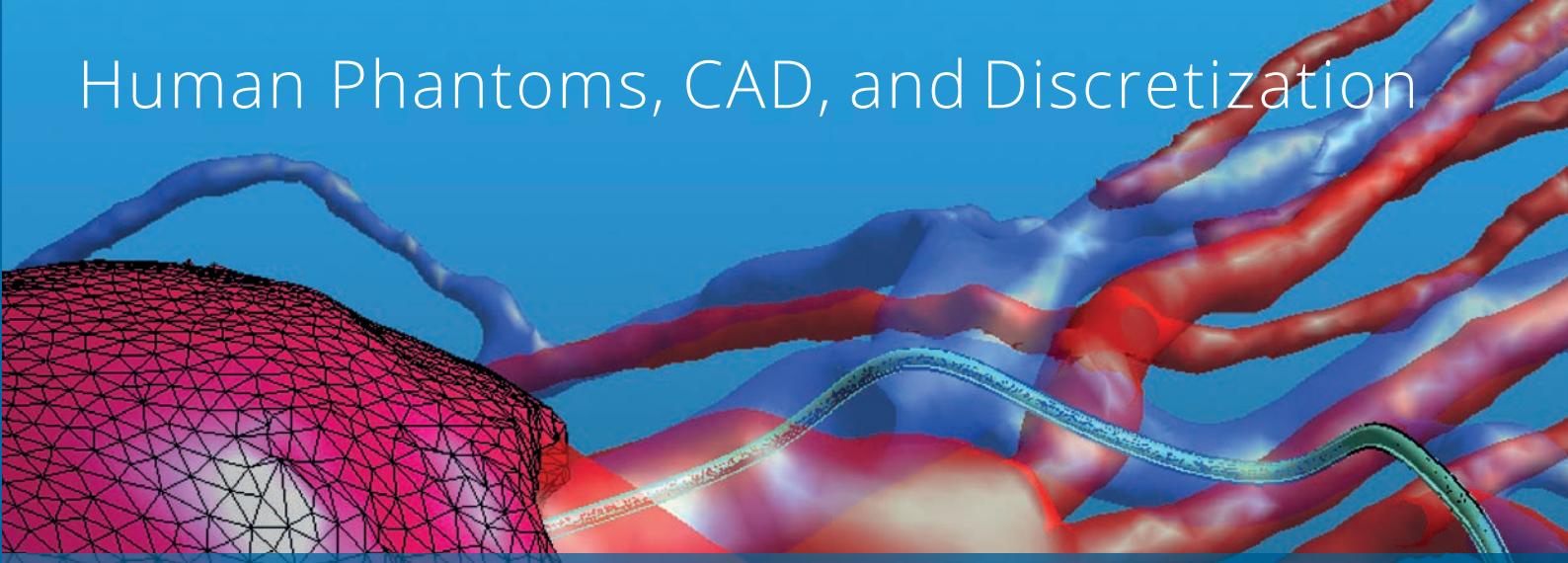
From imaging to modeling

To enable the delivery of safe and effective medical care, personalized 3D patient models that accurately depict specific anatomical structures are often needed. The manual segmentation of 2D medical image data into 3D structures is time-consuming, subjective, and error-prone.

The fully integrated iSEG toolbox simplifies the segmentation process in Sim4Life. iSEG offers classical segmentation algorithms and dedicated vasculature segmentation approaches with supplemental advanced image pre- and post-processing functions and feature analysis. Automatic and interactive algorithms are embedded in a user-friendly environment and can be flexibly combined. Anatomical reference atlases guide the user through the process. The resulting 3D patient models have smooth non-intersecting surfaces and can be well discretized.

All parts of the segmentation tool pass the highest quality assurance (QA) and verification standards.

Human Phantoms, CAD, and Discretization



Creating a virtual world

Sim4Life is currently the only simulation platform that can fully exploit the state-of-the-art functionality of the ViP models. Global variability in the human anatomy in terms of age, sex, and anthropometric measures are fully represented. The models and the associated database are continually and meticulously updated, refined, and expanded. Robust morphing and posing tools can extend the population coverage further.

Sim4Life also offers superior modeling capabilities, including the interactive visualization of large datasets and computer-aided design (CAD) models and the seamless import and export of the most commonly used CAD formats by an efficient data-exchange interface.

The posable, morphable, and customizable human models can be combined with any parameterized complex device to create realistic application-specific scenarios for patient-specific analyses.

All human anatomical models, the tissue database, and all tools and features are subject to the highest QA and verification standards.

High-Performance Solvers and Multiphysics

Multiphysics modeling

Sim4Life consists of a modern coupling framework that integrates and couples a variety of numerical models and methods to accurately and reliably simulate the complex physical and physiological processes within the human body and the body's interactions with the environment. Optimized, high-performance solvers tackle a range of problems from electromagnetics and thermodynamics with perfusion to sound propagation and fluid dynamics. Sim4Life offers high-performance parallel computing, visualization, and postprocessing and ensures interoperability among the solvers. Moreover, the coupling framework is customizable and extendable through additional solvers.

The elegant and intuitive graphical user interface (GUI) and the powerful Python scripting language provide a high level of automation to the reconstruction and parameterization procedures in Sim4Life, allowing both skilled and non-skilled users to efficiently generate 3D CAD anatomical models.

Sim4Life offers an effective and easy-to-use optimizer, featuring state-of-the-art multi-goal global optimization methods such as stochastic response surface methods that are particularly efficient for engineering and medical applications. With full exploitation of the superior speed of the solvers, the optimizer is the tool of choice for device optimization, virtual prototyping, and sensitivity analysis.

Fully documented and rigorous QA and verification procedures guarantee the reliability, efficacy, and realism of simulations generated with Sim4Life.

Physiology and Tissue Models

Multiscale modeling

Integrated physiology and tissue models are used to assess the physiological impact of any implanted, body-mounted, or external device at the tissue level in human phantoms.

Sim4Life accounts for thermal effects in living tissues and is capable of taking thermoregulation and body-core heating into consideration in blood.

The neuronal tissue model allows modeling of electro-magnetically induced neuronal dynamics. Through application of the safety-standard-relevant SENN model inside human models, the interaction mechanisms can be investigated and the safety of medical devices assessed. The GUI facilitates the integration of neuronal models from independent databases. The neuronal model is an indispensable assistant for optimization of neurostimulation devices, development of cutting-edge designs, and reducing costs and time to market.

Thermally induced tissue damage models are also incorporated in Sim4Life, including the thermal-dose model of cumulative equivalent minutes at 43°C (CEM43) and Arrhenius damage integrals.

All tissue models are seamlessly integrated into the Sim4Life workflow and subject to the highest QA and verification standards.

Analysis and Visualization Reports

Looking deeper

Sim4Life provides maximum insight into the complexities of dynamic biological and physiological processes and interactions in the human body through an advanced and interactive visualization pipeline architecture.

Automatic report generation is a standard feature of Sim4Life.

The state-of-the-art visualization components include volume rendering, streamlines, maximum intensity projection, surface fields on arbitrary 3D structures, and calculators for resampling, filtering, functional evaluation, and statistical data analysis.

Sim4Life also offers unique application-specific analysis tools that allow users to perform required assessments and fast-track regulatory submissions. Examples of such tools include IMAnalytics, pre-computed induced field libraries (MRIxViP1.5T/3.0T), and a 5G simulation toolbox.

All analysis and extraction tools are subject to the highest QA and verification standards.

Validation Hardware piX

piX System

Piecewise eXcitation System for RF-heating evaluations of active implanted medical devices in magnetic resonance imaging (MRI) environments

The piX system can generate a validated radiofrequency (RF) model of any implant at 64 or 128 MHz (other frequencies are available on request) within minutes. All instrumentation required for evaluation is included. The system is in full compliance with with the Tier 3 procedure of the IEC/ISO TS10974 guidelines.

A variety of optimized piX Exciters are available for various frequencies and for a range of media to generate a locally uniform tangential excitation of less than 10 mm. Crosstalk with the device under test at RF frequencies is eliminated with time-domain sensor (TDS) probes.

MITS

MITS 1.5/3.0

Medical Implant Test System (MITS) for RF safety evaluations at 1.5 and 3.0 Tesla

MITS simulates high-precision incident fields with user-defined modulation and time sequences, as generated by commercial MRI scanners, and also enables worst-case incident field conditions. Optimized for testing implants and for validating implant RF models, both systems fully comply with all MRI implant safety standards, such as ASTM F 2182 and IEC/ISO TS10974.

The systems combine cutting-edge technology with accuracy, versatility, and user-friendliness, while the open user interface facilitates customized and automated evaluations.

Optional: ZMT offers additional metrology equipment from its sister company SPEAG. The robot-based scanning system DASY52 AIMD is fully supported for rapid and high-precision SAR and temperature evaluations. The TDS B1-Field System complements the MITS for test-field diversity (TFD), allowing the B1 field to be monitored during shimming of the birdcage. RFoF1P4MED is used for determining the risk of device malfunction due to RF exposure within MRI environments.

MITS-HFR

MITS HFR 1.5/3.0

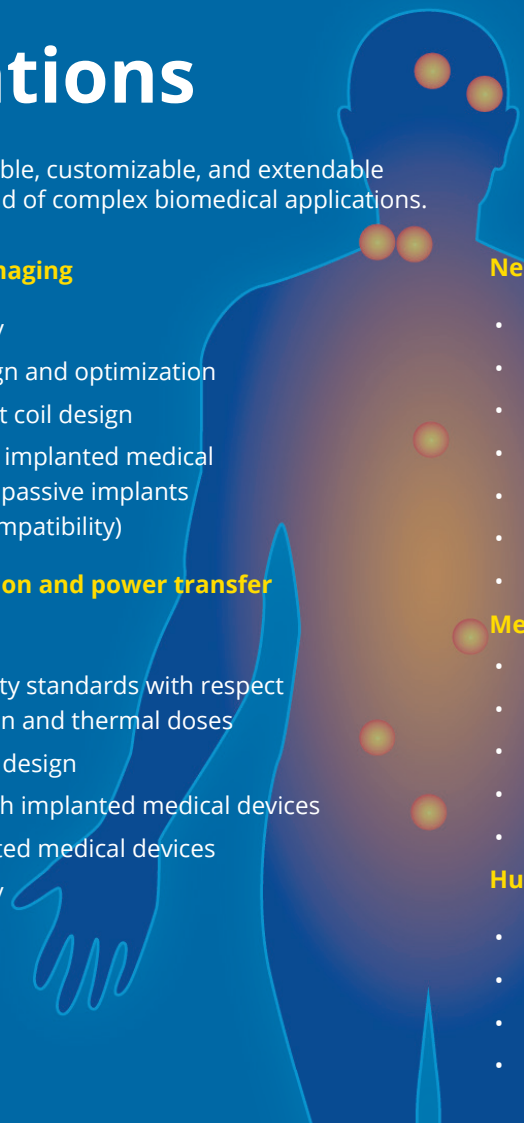
MITS High-Field Resonators (HFR) at 1.5 and 3.0 Tesla

ZMT's high E-field strength resonators (HFR) complement the MITS systems and are designed to support simplified Tier 1 and Tier 2 testing of implantable medical devices as defined in the ISO/IEC standard TS 10974 Ed.2. The MITS-HFR system enables evaluation of short implants (<100 mm) directly at the maximum peak and root-mean-square (rms) electric (E-) field strengths without the need for scaling and/or implant model generation and validation.

The test conditions that allow access to these simplified assessments cannot typically be met with any other testing environment. ZMT is uniquely able to provide equipment for these field strengths at both 1.5 and 3 T. The resonators can be integrated with any existing MITS System. MITS-HFR1.5 and MITS-HFR3.0 have been rigorously validated. Each system can be used as a stand-alone or with the DASY6 AIMD scanner for rapid and high-precision specific absorption rate (SAR) and temperature evaluation.

Applications

Sim4Life provides a flexible, customizable, and extendable environment for a myriad of complex biomedical applications.



Magnetic resonance imaging

- MRI scanning safety
- MRI sequence design and optimization
- MRI RF and gradient coil design
- MRI safety of active implanted medical devices (AIMD) and passive implants (heating and EM compatibility)

Wireless communication and power transfer

- Antenna design
- Dosimetry and safety standards with respect to neural stimulation and thermal doses
- Body-area-network design
- Communication with implanted medical devices
- Charging of implanted medical devices
- Wireless endoscopy

Neural stimulation

- Transcranial electric and magnetic stimulation (TES, TMS)
- Transcutaneous electric nerve stimulation
- Deep brain stimulation (DBS)
- Functional electric stimulations
- Neural implants, electroceuticals
- Neuroprosthetics
- Low-frequency EM safety

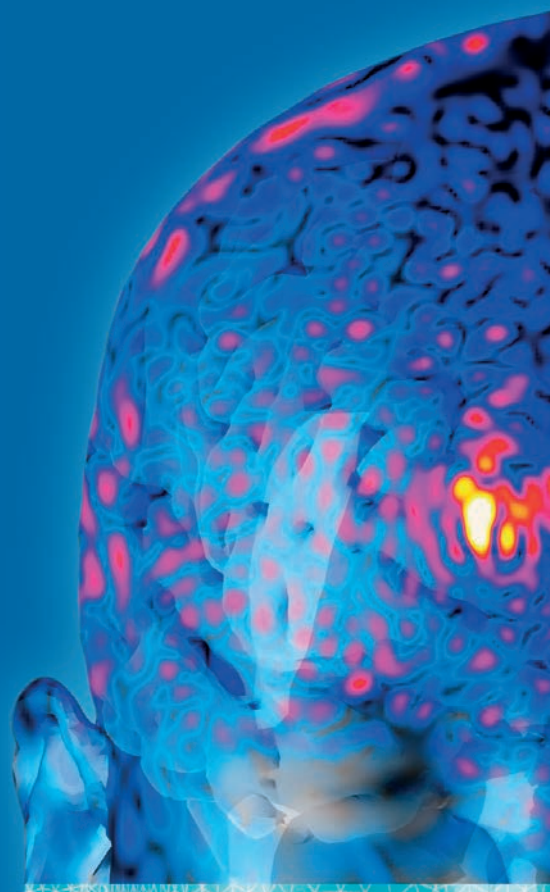
Medical treatments

- Hyperthermia for cancer treatment
- RF and microwave ablation
- High intensity focused ultrasound
- Analysis of vascular flows and biofluidics
- Stent design and optimization

Human modeling

- Segmentation of medical image data
- Posing and morphing of phantoms
- Modeling for treatment planning
- Image registration

About



Zurich43

Zurich43 is a strategic alliance composed of three partner organizations: the non-profit Foundation for Research on Information Technologies in Society (IT'IS) and two commercial SMEs – Schmid and Partner Engineering AG (SPEAG) and ZMT Zurich MedTech AG (ZMT). Z43's dedicated mission is to expand the boundaries (1) for accurate evaluation of electromagnetic (EM) near- and far-fields from static to optical frequencies and (2) for predictive modeling in validated biological and anatomical environments. Z43 is a leading global player that collaborates with over 100 research partners and serves more than 500 customers worldwide.

ZMT Zurich MedTech AG *www.zurichmedtech.com*

ZMT was founded in 2006 as a spin-off of the Swiss Federal Institute of Technology (ETH Zurich) and the IT'IS Foundation with the mission 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, a revolutionary simulation platform that combines computable human phantoms with incredibly powerful physics solvers and the most-advanced tissue models. Sim4Life is used to analyze real-world biological phenomena and complex technical medical devices and therapies in validated computational biological and anatomical environments. ZMT also provides fully characterized and ISO17025-calibrated measurement systems for model generation, verification, and validation of in silico based evaluations. All systems are user-friendly and are seamlessly integrated with Sim4Life.

SPEAG – Schmid & Partner Engineering AG *www.speag.com*

SPEAG was founded in 1994 to develop and manufacture electromagnetic systems and components as a spin-off of the ETH Zurich's Bioelectromagnetics/EM Compatibility research group (which later became the IT'IS Foundation). SPEAG is the leading developer and manufacturer of advanced, efficient, and reliable test equipment for the evaluation of the EM near- and far-fields at frequencies from a few kHz up to 110 GHz. SPEAG's key products are: DASY6 – SAR measurements for safety compliance; cSAR3D – fast SAR testing; ICEy – automated near-field scanning for EM interference and compatibility (EMI/EMC); DAK – dielectric measurement systems; EM Phantoms – body simulators for radiofrequency (RF) testing; and SEMCAD X – RF performance modeling of devices used in and on the human body.

To better serve its customers and those of ZMT and the IT'IS Foundation, a calibration laboratory, certified by the Swiss Accreditation Service (SAS) for ISO/IEC 17025 Accreditation and multilaterally recognized by EA, IFA, and ILAC, was established in 2001. The laboratory provides extensive calibration services to the entire Zurich43 family for systems, probes, antennas, dielectric probe kits, phantoms, materials, etc.

A number of satellite facilities have been co-founded to bring calibration services closer to SPEAG's global customer base. These include the SPEAG Calibration Laboratory Korea, established in 2011 in collaboration with DYMSTEC, and the BNNSPEAG Test & Calibration Laboratory instituted in 2012 in India together with BNN Communication Engineers.

IT'IS Foundation – Foundation for Research on Information Technologies in Society *www.itis.ethz.ch*

The IT'IS Foundation was established in 1999 through the initiative and with the support of the ETH Zurich and the global wireless communications industry, together with several governmental agencies. IT'IS is the leading independent non-profit research institute dedicated to improving and advancing the quality of people's lives by advancing personalized medicine and computational life sciences (IT'IS for Health) and beneficial applications of EM energy and wireless communications (EM Research).

The IT'IS Foundation provides an innovative proactive and interdisciplinary research environment for the cultivation of sound science and research and good education. IT'IS supports the R&D efforts of its many industrial partners, in particular SME's such as SPEAG and ZMT, to advance precompetitive and noncompetitive research initiatives, and offers a variety of customized research solutions to the wireless and medical device industries, to academic and national institutions, as well as to governments and regulatory bodies.

Regional Sales Channels and Partners

A complete list of local sales channels and partners can be found at:
www.zurichmedtech.com/about

ZMT zurich med tech

ZMT is a member of Z43

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