

IT^{IF}FOUNDATION <u>s p e a g</u> ZMZ zurich med tech

Dear Z43 Partners, Friends, and Followers

The last few months have been busy, but the effort has paid off with the release of two major important new product lines: MAGPy V1.0 and DASY8. These and other highlights are summarized in this edition of our Z43 Newsquarter. We wish you a fun and memorable summer!

MEASUREMENT



MAGPy V1.0: In Situ Compliance <10 MHz

All-new and all-smart: SPEAG's Magnetic Amplitude and Gradient Probe System (MAGPy) is the first hand-held device for compliance testing of induced fields for basic restrictions. MAGPy, which integrates and analyzes the information from 27 miniaturized time-domain sensors, comes with a highly intuitive user interface, as demonstrated in this video. For further information, please visit our website or contact us at info@speag.swiss.

MEASUREMENT

DASY8 is Born

Since the release of DASY8 in May, SPEAG has been shipping at least one of its next generation measurement systems per week to customers. DASY8 is faster, easier-to-use, and more modular than its predecessors. Until now, Modules SAR V16.0, mmWAVE 2.4, and WPT 1.2 have been released, and the release of new Modules HAC2019, R&D, and AIMD will follow later this year. Read more about our new flagship system and its new features on our website.





VIRTUAL POPULATION

IT'IS Annual Report 2020

IT'IS is pleased to share the release of its 2020 Annual Report!

Despite the many difficulties caused by lockdowns and other measures, 2020 was a productive year for us with many exciting research developments and projects.

You can view and download the report **here**. We hope you enjoy the read!

MEASUREMENT

Latest Decisions by Regulators

The Canadian government has largely accepted IEC/IEEE 62209-1528. The U.S. Federal Communications Commission (FCC) has adopted procedures from IEC/IEEE 62209-1528 for the 6–10 GHz frequency range and will update their guidance in the fall. The Head-Stand, Face-Down, and Wrist phantoms for wearable devices have been accepted by the FCC. IEC 62209-3 is not yet accepted by any of these regulators for specific absorption rate compliance testing. Any questions? Contact us at info@speag.swiss!





VIRTUAL POPULATION

ZMT and IT'IS continue to join forces in the development of tools for magnetic resonance imaging (MRI-) safe implant evaluations. We are thrilled to report that the U.S. Food and Drug Administration has extended the qualification of our Medical Device Development Tool (MDDT), which now includes not only MRI safety assessment of elongated active medical implants but also passive implant evaluations according to the latest ASTM standard (ASTM F2182-19^{e2}), with IMAnalytics V3.0 together with the new MRIxViP1.5T/3.0T V2.1 libraries. Note that the qualified context of use now also encompasses Tier 2 as well as Tier 3 approaches as defined in Clauses 8 and 15 of ISO 10974. More information can be found here.

Z43 SOCIAL

Safe Return to Work

Since the beginning of July, Z43 welcomes all teams back on site at the office. While precautionary measures remain in place, we look forward to a bit of normalcy and to the resumption of personal interactions and effective team-work of our pre-pandemic work culture, just in time for the DASY8 and MAGPy teams to organize a small release celebration party on our roof-top terrasse and at a local bar across the street.



Extended MDDT Tool Qualified by FDA





RESEARCH

PUBLICATIONS

Computational and Phantom-Based Feasibility Study of 3D dcNCI with Ultra-Low Field MRI

N. Höfner, et al., 2021, Frontiers in Physics, 9, 647376, doi: 10.3389/ fphy.2021.647376 (online 26 April 2021)

The Impact of CT Image Parameters and Skull Heterogeneity Modeling on the Accuracy of Transcranial Focused Ultrasound Simulations

H. Montanaro, et al., 2021, Journal of Neural Engineering, 18(4), 046041, doi: 10.1088/1741-2552/abf68d (online 04 May 2021)

Radiofrequency-Induced Heating of Broken and Abandoned Implant Leads During Magnetic Resonance Examinations A. Yao, et al., 2021, Magnetic Resonance in Medicine, doi: 10.1002/mrm.28836 (online 03 June 2021)

In Silico Voltage-Sensitive Dye Imaging Reveals the Emergent Dynamics of Cortical Populations

T. H. Newton, et al., 2021, Nature Communications, 12, 3630, doi: 10.1038/s41467-021-23901-7 (online 15 June 2021)

Compliance Assessment of the Epithelial or Absorbed Power Density above 6 GHz Using SAR Measurement Systems T. Samaras, et al., Bioelectromagnetics, doi: 10.1002/bem.22355 (online 15 June 2021)

The SPARC DRC: Building a Resource for the Autonomic Nervous System Community

M. Osanlouy, et al., 2021, Frontiers in Physiology, doi: 10.3389/ fphys.2021.693735 (online 24 June 2021)

Feasibility of Temperature Control by Electrical Impedance Tomography in Hyperthermia

R. Poni, et al., 2021, Cancers, 13, 3297, https://doi.org/10.3390/cancers13133297 (online 30 June 2021)