# MITS-TT

System for Validation of Implant Models at 64 / 128 MHz

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zurich med tech

## MITS-TT

### What is MITS-TT

The Medical Implant Test System Table-Top (MITS-TT) is a compact desktop solution optimized for the efficient validation of electromagnetic implant models at 64 MHz and 128 MHz in high- and low-permittivity tissue simulating media (TSM). MITS-TT is compatible with ISO 10974 and can also be used to characterize the field enhancement by passive and active implants.

#### Background

Our MITS for 1.5 T and 3.0 T magnetic resonance imaging (MRI) exposure simulators in combination with ZMT's piecewise excitation (piX) system are powerful and versatile instruments for determining the safety of patients during MRI examinations, but are not, however, efficient for high-throughput testing. The solution is MITS-TT, which offers easy and fast on-the-benchtop testing with even higher precision than MITS 1.5/3.0 and thus optimally complements the MITS product line.

#### Description

MITS-TT enables benchtop implant evaluations without the need for a shielded room or high-power amplifiers. MITS-TT generates the required variation of high-precision electric (E-)fields incident to the implant inside the phantom filled with TSM needed to scale and validate the transfer function or any other electromagnetic model of the implant under test.

Two versions of MITS-TT units are available: MITS-TT HP for evaluation in high permittivity TSM at 64 MHz and 128 MHz and MITS-TT LP for tests requiring low permittivity TSM at 64 MHz and 128 MHz. Both units comprise a cylindrical phantom with four integrated electrodes and the liquid-specific matching network and are connected to a common instrumentation rack with a dual-band source, amplifiers, and a control PC. Positioning of the implant under test is supported by a set of racetracks. The E-field polarization within the phantom can be continuously adjusted to generate linear, circular, or arbitrary user-defined polarizations. MITS-TT is compatible with the test field diversity method, as well as specific absorption rate and temperature measurements. The system is also fully compatible with DASY Module AIMD and EASY6.

#### Compliance

MITS-TT is fully compliant with all relevant test specifications, such as ISO 10974, ASTM F2182, PC76, or the FDA guidance on *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment*. The system and its integrated sensors are fully verified and validated, for which supporting documentation is available, including a Sim4Life numerical model.

#### **Specifications**

| MITS-TT High Permittivity Unit       |  | MITS-TT Low Permittivity Unit        |   |
|--------------------------------------|--|--------------------------------------|---|
| Operating frequencies                | 64 MHz, 128 MHz  | Operating frequencies                | 64 MHz, 128 MHz                                 |
| Maximum induced E-field <sup>1</sup> | 60 V/m   | Maximum induced E-field <sup>1</sup> | >60 V/m   |
| Diameter / height                    | 500 mm / 330 mm  | Diameter / height                    | 500 mm / 330 mm                                 |
| Weight                               | 13.5 kg  | Weight                               | 13.5 kg   |
| Compatible TSM                       | $\sigma = 0.47 \text{ S/m}, \epsilon_r = 78$<br>$\sigma = 0.65 \text{ S/m}, \epsilon_r = 78$ | Compatible TSM                       | $\sigma = 0.045 \text{ S/m}, \epsilon_r = 11.5$ |
| Rack System                          | 19" rack, 20 kg  | Rack System                          | 19" rack, 20 kg                                 |
| System compatibility                 | Stand-alone, EASY6,<br>or DASY Module AIMD   | System compatibility                 | Stand-alone, EASY6,<br>or DASY Module AIMD      |

<sup>1</sup> with included 30 W amplifiers; target E-Field of 30 V/m recommended for temperature-based measurements

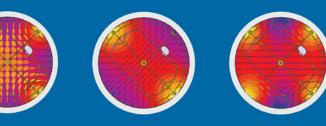


Figure 1: Examples of polarizations produced within the MITS-TT phantom to create diverse incident fields for generation and validation of the electromagnetic implant model.



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