



IMAnalytics with MRlxViP

A complete solution for MR implant safety

Patient



- Exposure field library @ 64MHz
- Models® Positions® Birdcages

Patient



- Exposure field library @ 64MHz
- Models® Positions® Birdcages

MRI system



- Positions @ operating mode

Masks



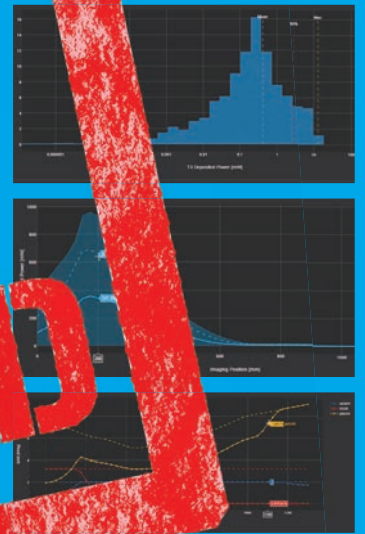
- R...
- R...

Implant device



- Transfer from piX system

Output



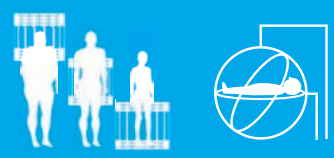
- Statistical data on Tier 3 deposited power
- Deposited power at different operating modes
- Histogram data at imaging positions
- Access to raw data

FDA QUALIFIED

IM Analytics

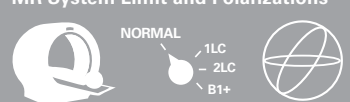
*ISO/TS 10974

MRlxViP 1.5T and 3.0T Field Libraries



ViP phantoms × body coils × scan positions
× polarizations (shim)
= >50 TB indexed database

MR System Limit and Polarizations

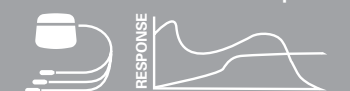


NORMAL
1LC
2LC
B1+


Clinical Routing or Region



Transfer Function Model of Implant



RESPONSE

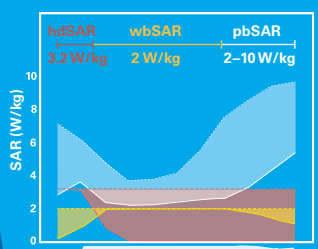


IMAnalytics

User-Friendly GUI
Dynamic Plots
Python Notebook API
Export of Raw Data

Output

Induced fields at system limit for each examination condition

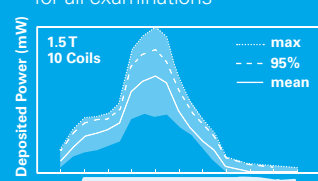


hdSAR 1.2 W/kg wbSAR 2 W/kg pbSAR 2-10 W/kg

SAR (W/kg)

Imaging Position

Statistical distribution of deposited power or induced voltage over all clinical routings for all examinations



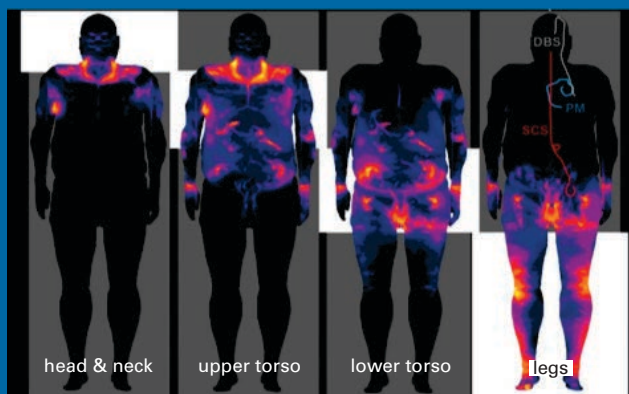
1.5 T
10 Coils

Deposited Power (mW)

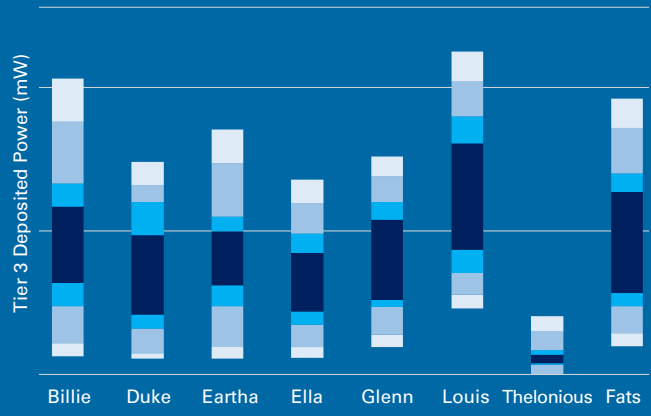
max
95%
mean

Imaging Position

The FDA-qualified Medical Device Development Tool (MDDT), IMAnalytics with MRlxViP, represents the most advanced safety assessment workflow of medical implants for patients undergoing MR examinations. Fully compliant with ISO 10974, the toolset developed by ZMT and the IT'IS Foundation comprises a massive database of patient fields – MRlxViP – and a verified solver with a user-friendly GUI and a powerful scripting API – IMAnalytics. The patient models, MR coils, simulation backend, and calculation engine are all fully verified and FDA-qualified for ISO 10974 evaluations. A regulatory-grade evaluation now just needs a few inputs, a few clicks, and a few seconds!



Maximum local E-field at different landmarks, used for ISO 10974 Tier 2 assessment of implant behavior under worst-case incident fields in the region of interest.



Maximum average E-field tangential to each routing in ViP models Thelonious and Fats in a 3T scanner, for different RF shim settings. With a transfer function model of the implant, the ISO 10974 Tier 3 deposited power or voltage is calculated for all scans in a few seconds, for interactive visualization or export.

The FDA qualification report of the MDDT is available at <https://www.fda.gov/media/148922/download>
A free 30-day trial of the toolset with sample data is available upon request.
Please contact s41-sales@zmt.swiss for further details.

