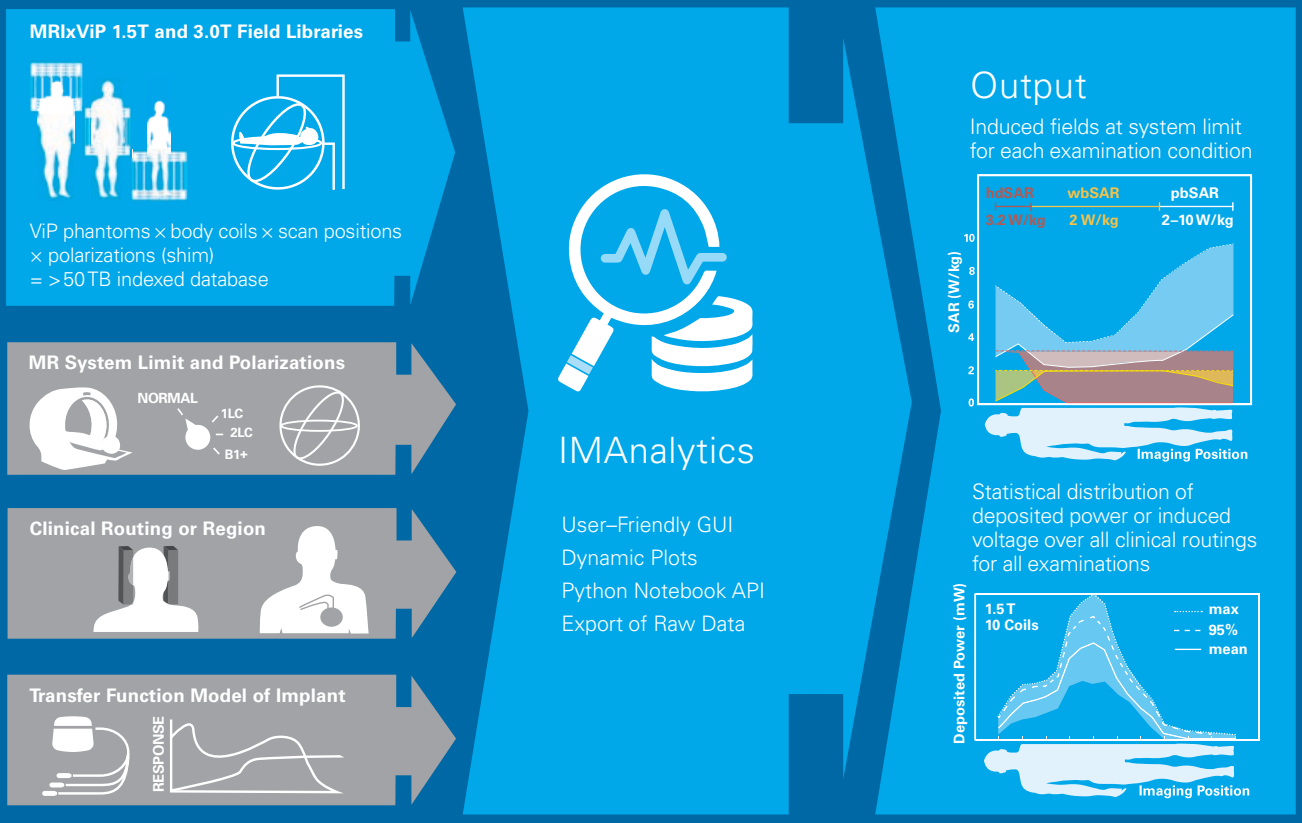
IMAnalytics with MRIxViP

A complete solution for MR implant safety

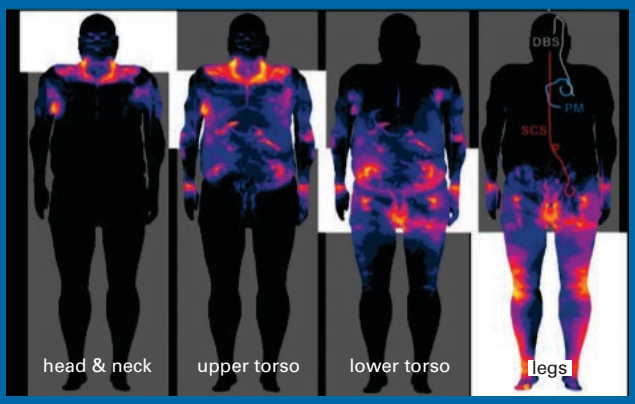
FDA QUALIFIED

zurich med tech

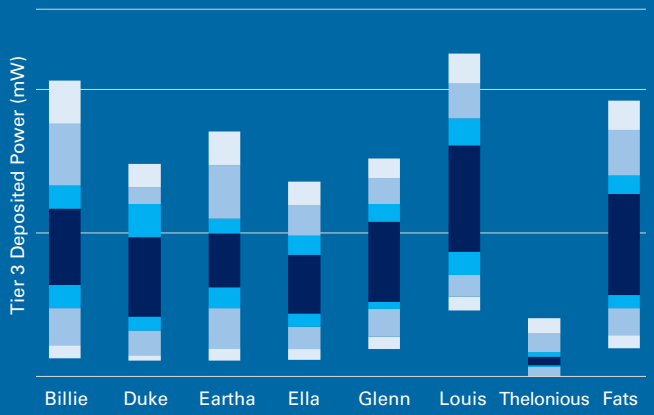
IT'IS FOUNDATION



The FDA-qualified Medical Device Development Tool (MDDT), IMAnalytics with MRIxViP, 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 – MRIxViP – 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 s4l-sales@zmt.swiss for further details.

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