MDDT SUMMARY OF EVIDENCE AND BASIS OF QUALIFICATION DECISION FOR
IMANALYTICS WITH MRIXVIP1.5T/3.0T AND BCLIB

BACKGROUND

MDDT NAME: *IMANALYTICS WITH MRIXVIP1.5T/3.0T AND BCLIB*

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Tool Description and Principle of Operation

IMAnalytics is a module of the multiphysics software platform Sim4Life (v3.4+) which provides the calculation of the response of an elongated AIMD in human computational models to radiofrequency (RF) fields under Magnetic Resonance Imaging (MRI) scan conditions, using the Tier 3 approach as defined in ISO/TS 10974:2018. MRIxViP is a pair of standard precomputed libraries of RF-induced electromagnetic field (EMF) distributions inside the human body, resulting from exposure to a set of RF birdcage coils used in MRI scanners for 1.5 T (MRIxViP1.5T) and 3 T (MRIxViP3.0T) with eight different human anatomical models. The Birdcage Library (BCLib) includes a set of birdcage models with ten quadrature-driven cylindrical birdcage coils of different dimensions at each field strength. Different polarizations and exposure conditions are considered by sweeping through independent excitation settings of the I and Q channels. Each library consists of induced field data from relevant landmark positions simulated in twelve ViP models for up to 65 imaging landmarks in the supine posture in 20 birdcage coils.

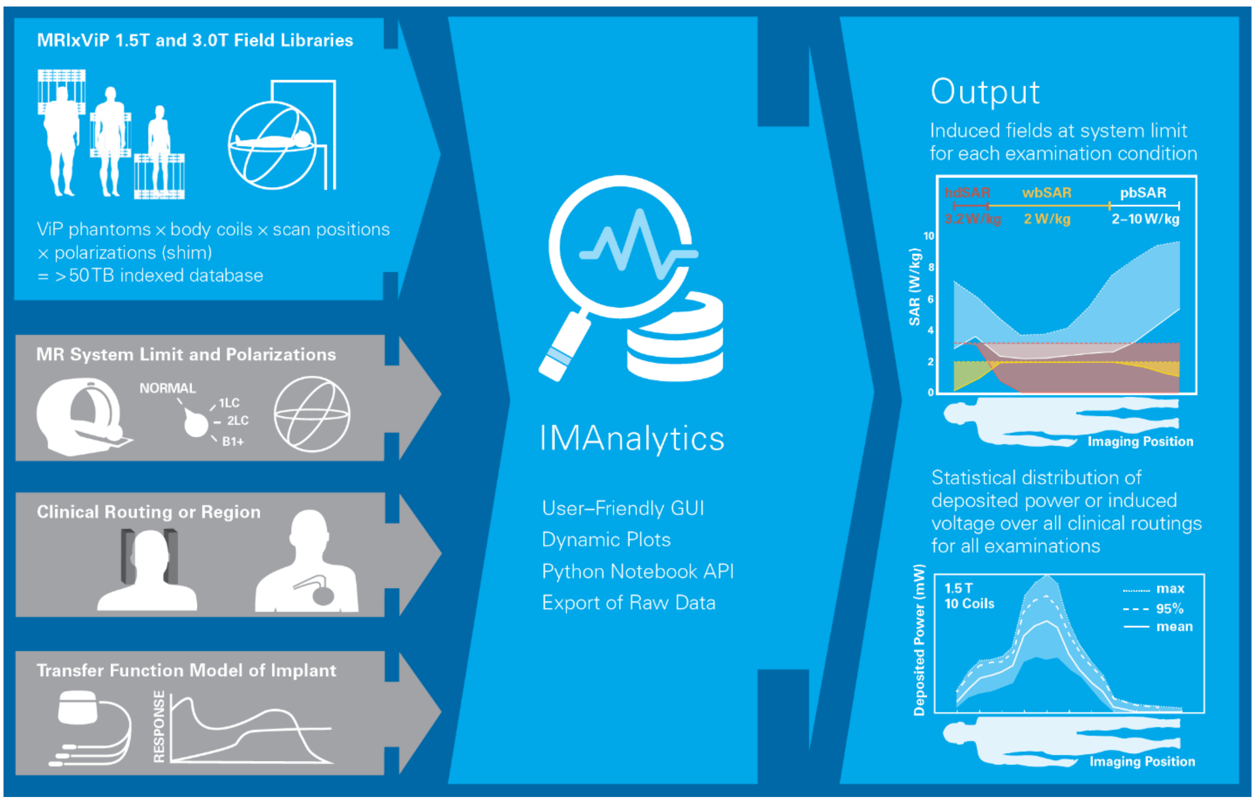


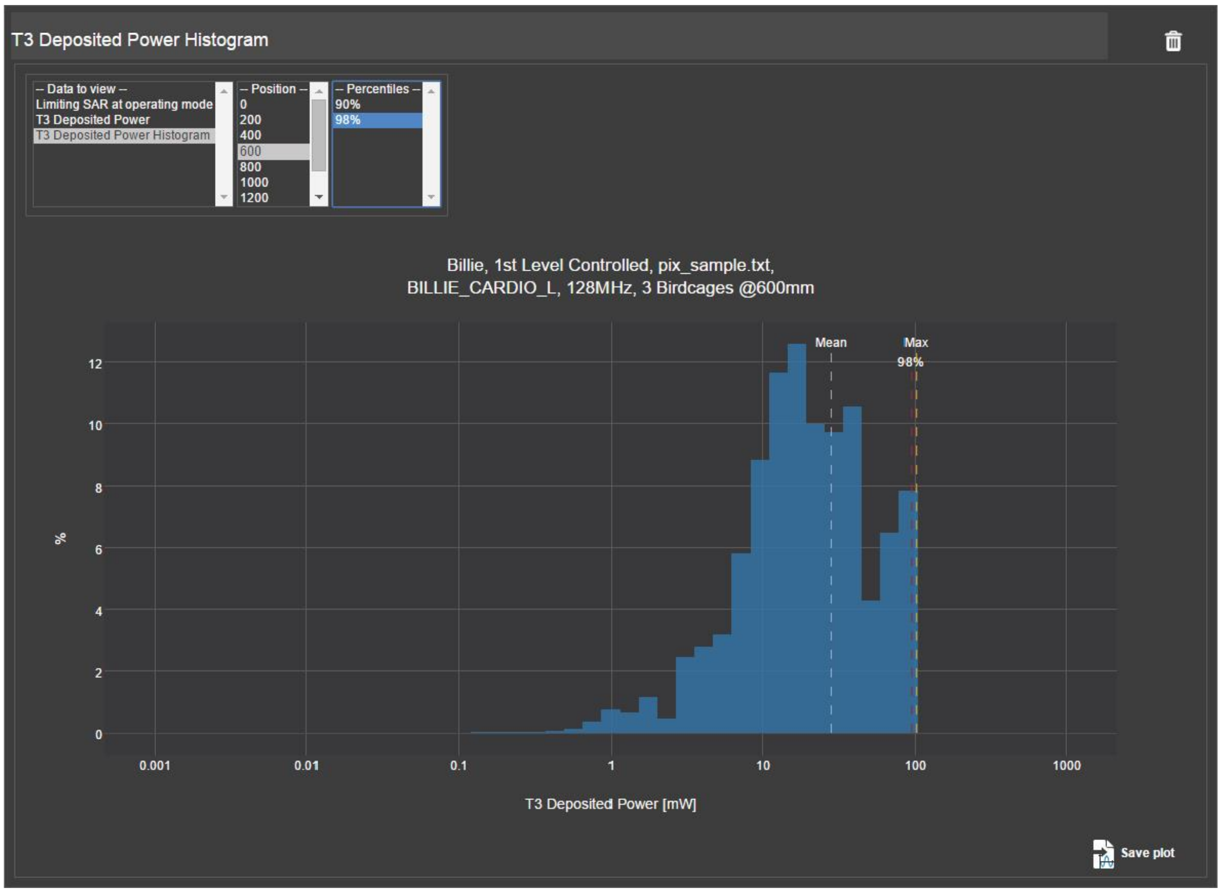
Figure 1: IMAnalytics with MRIxViP. User-defined inputs are highlighted in gray and the MDDT parts are shown in blue.

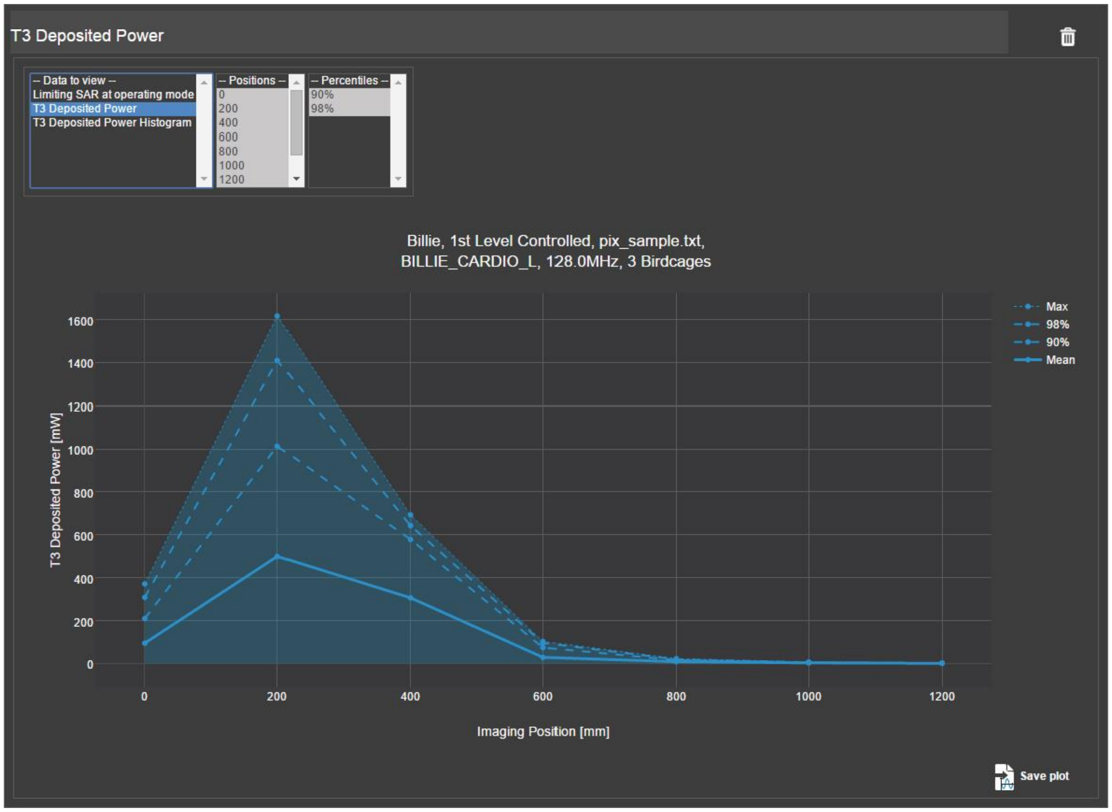
The inputs and outputs of IMAnalytics with MRIxViP are shown in Figure 1 with user-specified inputs in gray and the MDDT in blue. The user-defined inputs consist of:

- the MRIxViP database
- the transfer function model (e.g., a piecewise excitation model) of the implant's RF response, for Tier 3 evaluations

- the implant routings within the defined anatomy, and regions of interest
- the MRI operating modes (normal, first level controlled) and, if applicable, shimming space
- the relevant scanner limits for the user's application, which may be whole-body, partial-body, or head specific absorption rate (SAR), or B1 field value.

The output is the statistical data on deposited power and/or induced voltage for the entire exposure space as shown in Figure 2.




T3 Deposited Power
-- Data to view --
Limiting SAR at operating mode
T3 Deposited Power
T3 Deposited Power Histogram
-- Positions --
0
200
400
600
800
1000
1200
-- Percentiles --
90%
98%
Billie, 1st Level Controlled, pix_sample.txt,
BILLIE_CARDIO_L, 128.0MHz, 3 Birdcages
Max
98%
90%
Mean
T3 Deposited Power [mW]
Imaging Position [mm]
Save plot

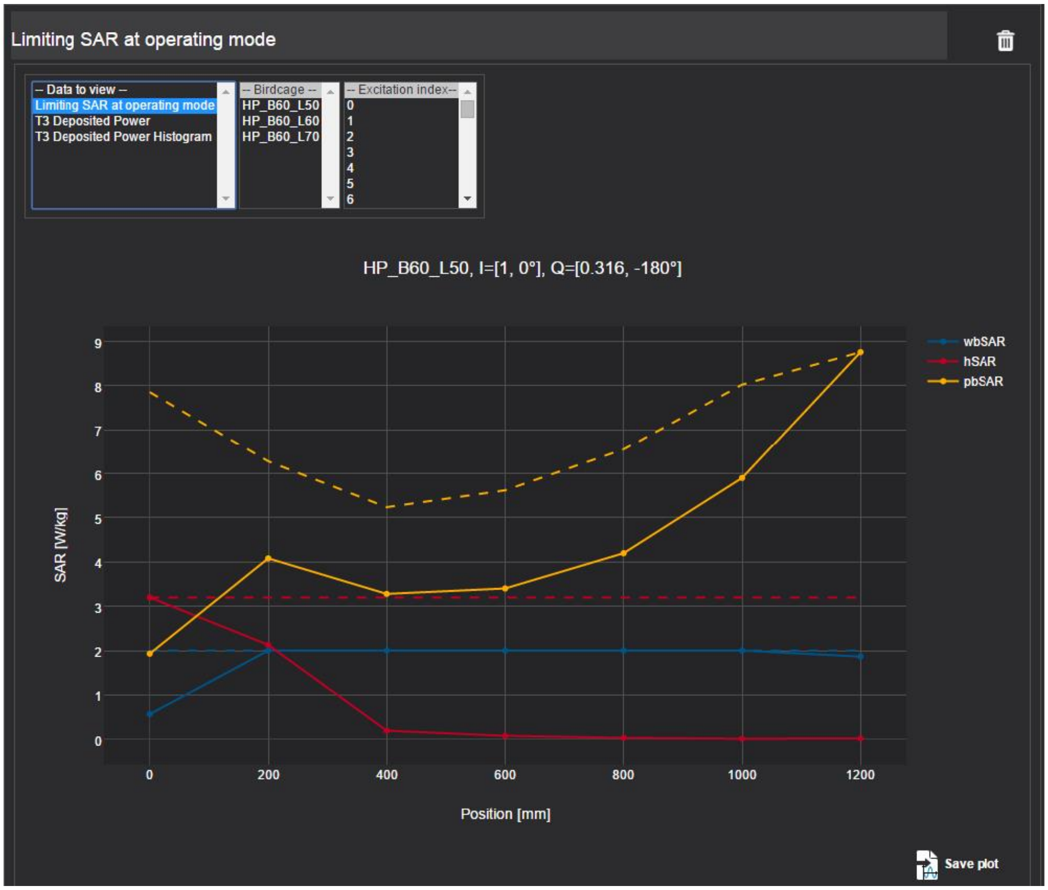

Limiting SAR at operating mode
-- Data to view --
Limiting SAR at operating mode
T3 Deposited Power
T3 Deposited Power Histogram
-- Birdcage --
HP_B60_L50
HP_B60_L60
HP_B60_L70
-- Excitation index--
0
1
2
3
4
5
6
HP_B60_L50, I=[1, 0°], Q=[0.316, -180°]
wbSAR
hSAR
pbSAR
SAR [W/kg]
Position [mm]
Save plot

Figure 2: Example Tier 3 output of IMAnalytics: histogram of deposited power (top), max/98%/90%/mean statistics with respect to imaging position (middle), and corresponding whole-body SAR (wbSAR), head SAR (hSAR) and partial body SAR (pbSAR) values (bottom).

The version numbers for each part of the MDDT are as follows:
Sim4Life: V3.4+*
IMAnalytics: V2.0 or V3.0
BCLib: V1.0
MRIxViP1.5T: V1.0 or V2.1
MRIxViP3.0T: V1.0 or V2.1

*Version 3.4 is the earliest version of Sim4Life which supports the modules listed above. Note: Sim4Life V3.4 – 5.2 are distributed by default with Python 2, while Sim4Life V6.0+ are distributed by default with Python 3.

QUALIFIED CONTEXT OF USE

The IMAnalytics with MRIxViP1.5T/3.0T and BCLib Toolset may be used in the premarket submissions of active implantable medical devices (AIMDs) to obtain the E-fields in human computational models in a region of interest or along a clinical routing, to determine the statistical distribution of the deposited power and/or induced terminal voltage in human computational models to support the MR Conditional labeling of these medical devices for 1.5 T or 3 T MR systems, according to the Tier 2 or Tier 3 approach defined in ISO/TS 10974:2018, and to ASTM F2182-19ϵ2.

Conditions for Qualified Use:
The MDDT (IMAnalytics with MRIxViP1.5T/3.0T and BCLib) gives results for AIMDs and exposure conditions where the Tier 2 or Tier 3 approach of ISO/TS 10974:2018, or ASTM F2182-19ϵ2, is appropriate, and applies to commercial MR systems with cylindrical RF resonators using high-pass birdcage topology with design parameters bound by those listed in Table 1 and driven in the I/Q or CP configurations. Implant-specific inputs required from the users include valid transfer function (e.g., piecewise excitation) models in appropriate media, verified routings and/or regions of interest defined for the ViP models in MRIxViP1.5T/3.0T, and the appropriate selection of scan conditions.

Table 1: Physical dimensions of the cylindrical RF (birdcage) coils. The RF coils are referred to by their topology and dimensions as HP_Bd_Lz, where HP, d, and z denote the high-pass topology, bore-diameter, and length of the RF coil, respectively (e.g., HP_B60_L50 refers to a generic high-pass RF-coil, for a 60-cm bore MR system, with rung length of 50 cm). The inner diameter (ID) and the length of the RF coil, as well as the metallic shield ID are provided in centimeters.

Bore size (cm)	Coil ID (cm)	Coil length (cm)	Shield ID (cm)	Coil name
60	65	50 60 70	70	HP_B60_L50 HP_B60_L60 HP_B60_L70
70	75	40 50 60 70	80	HP_B70_L40 HP_B70_L50 HP_B70_L60 HP_B70_L70
75	80	50 60 70	85	HP_B75_L50 HP_B75_L60 HP_B75_L60

SUMMARY OF EVIDENCE TO SUPPORT QUALIFICATION

IMAnalytics is an extraction and evaluation tool which generates a mathematically correct result, namely the E-fields in human computational models in a region of interest or along a clinical routing, when used together with a database of patient exposures (such as the MRIxViP database). These E-fields can be used as an input for safety evaluations, and/or to determine the power deposition at an implant hotspot or induced voltage in a lead channel terminal, with a valid transfer function model of implant response to applied tangential electric fields (E_{tan}). The IMAnalytics verification benchmarks use as reference either analytic results from simple setups or results produced by different implementations of similar algorithms. The approach combines some simplified test fixtures with realistic scenarios. In the first case, the reference results are derived analytically, while in the second case they are obtained using an alternative algorithm or implementation.

- The verification report included eight tests, their results, and acceptance criteria to verify the software module IMAnalytics showing that:
- Q-matrices (relation between coil excitation and patient-induced SAR, provided by the exposure database) and masses are correctly evaluated
- B_1 values (total magnitude, B_1^+ and B_1^-) are correctly computed
- E_{tan} along curved trajectories (splines) are correctly computed
- E_{10g} over defined regions of interest are correctly computed
- SAR limits at different exposure constraints (e.g., MR operating modes) are correctly computed
- B_1 limits are correctly computed
- Deposited power is correctly computed
- Induced voltage is correctly computed
- The different algorithms are correctly integrated in the IMAnalytics workflow.

The Birdcage Library (BCLib)
The IT'IS Foundation conducted experimental surveys of commercial MR systems as part of an occupational hazard evaluation [1] and an internal survey [2], where the strength of the fields (B_0, G and B_1) during preselected scan procedures were measured; the physical dimensions of the RF coils may be approximated from the measured B1 profiles.

From that dataset, BCLib was developed, comprising ten cylindrical RF (birdcage) coils of different dimensions for each field strength. All birdcage coils are assumed to have high-pass topology with 16 rungs, a constant shield length of 150 cm, and rungshield spacing of 2.5 cm. The nominal resonating frequencies of the coils are chosen to be either 64 MHz or 128 MHz, for 1.5 T and 3.0 T MR systems, respectively. The physical parameters of the RF coils are summarized in Table 1, and the physical dimensions in Figure 3. The numerical representation of the RF coils comprises the physical birdcage, RF shield, and equally distributed lumped capacitances with a lumped capacitance per rung. The nominal resonating frequencies of the coils are obtained through iterative numerical evaluation of the lumped capacitances. The use of the birdcage models as exposure systems for simulations has been demonstrated at 64 MHz by interlaboratory comparison. [3]

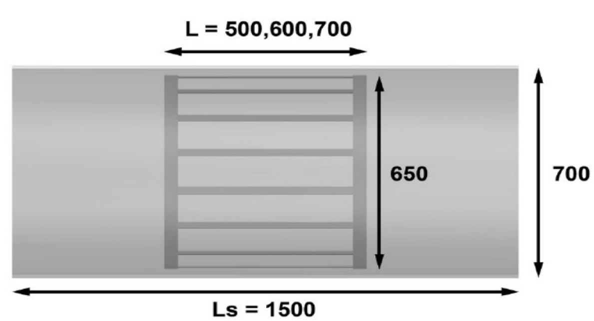


Figure 3: Physical dimensions of the cylindrical RF (birdcage) coils, HP_B60_Lz. All dimensions are provided in millimeters.

Details of the survey procedure, the resulting coils which are described in Annex J of ISO/TS 10974:2018 for 1.5 T [4], and their verification against commercial scanners as well as inter-laboratory comparison, are given in the literature [1] [3] [5].

The Virtual Population (ViP) [6] [7] [8] is a set of highly detailed computational human anatomical models based on MR examinations of healthy volunteers, plus a new Korean model, Yoon-sun, derived from cryo-sections of a cadaver, and morphed versions of Ella and Fats with different fat content, to improve population BMI coverage. MR images were upsampled using Lanczos interpolation from the original MR data acquired with up to 2 mm resolution. The cryo-sectioned model Yoon-sun was obtained from high image quality and resolution (0.1 × 0.1 × 0.2 mm) images obtained in the Visible Korean project, which made it possible to segment previously unaccomplished details in the peripheral nerves, arteries, veins and other small structures. All models were segmented at a resolution of 0.5 × 0.5 × 0.5 mm^3 in the whole body. The label fields were converted to improve quality (no gaps or overlaps between tissue surfaces), and to remove self-intersections. Morphed versions of Ella and Fats with different fat content were developed using physics-based morphing based on a realistic biomechanics simulation. Volume change of the tissues is introduced using a thermal expansion analogy, leading to elastic deformation of surrounding tissues, constrained by rigid bones.

The anatomical models are associated with a publicly available on-line tissue properties database [9] compiled from literature data, which offers information about the average value and the variation of reported tissue properties drawn from a comprehensive scientific literature review. The database also includes statistical information about the spread and standard deviation per tissue for the different parameters, which is important for assessment of the contribution to the uncertainty in a quantity of interest due to the selection of the material parameters.

Traceability of the ViP is assured through version control associated with unique digital object identifiers (DOI); previous versions remain accessible, together with a log file documenting the changes. The verification report of ViP 3.x included as follows:

- results of verification of anatomy, physiology, and segmentation
- lists of tissues
- minimal standard guidelines for segmentation
- external verification performed by external anatomists, who were aware of the provenance of each model (i.e., whether based on MR data from healthy volunteers; morphed from MR data; or obtained via cryo-sectioning).

MRIxViP is a combination of the Sim4Life Finite-difference Time-domain (FDTD) solver, the BCLib as exposure sources, and the ViP models. The MRIxViP libraries consist of the pre-computed 3D-distributions of EMF for 64 MHz and 128 MHz exposures. Twelve different adult and pediatric ViP 3.x phantom models (Duke, Ella, Billie, Thelonious, Fats, Glenn, Louis, Eartha, Yoon-sun, morphed Fats (BMI 29), and morphed Ella (BMI 26 and 30)) were exposed to the 20 birdcage coils (ten for 1.5 T and ten for 3.0 T, respectively). Head-to-foot imaging landmarks of the ViP models inside the RF coils were simulated with the Huygens' box approach, at 5 cm and 2.5 cm imaging steps for 1.5 T and 3.0 T, respectively. The libraries comprise the resulting 3D electric and magnetic fields at a resolution finer than 2 x 2 x 2 mm^3 for both ports separately, such that any polarization can be obtained by superposition. The combined dataset exceeds 50 TB.

Similarly to the ViP models, traceability of MRIxViP is assured through version control associated with unique DOI; previous versions remain accessible, together with a log file documenting the changes. The verification report confirms the following points:

- the database is complete for all documented configurations
- the database is correctly indexed and structured, and all data can be retrieved
- all simulations are complete, converged appropriately, and produced output files of the expected size and structure
- the conversion of output files has not introduced any artifacts

- masses and SAR values computed across the whole database give correct values (when these are known) and vary in a consistent fashion
- the results of the test trajectories are correct and reproducible
- the verification report of the FDTD solver
- the validation report of the FDTD solver in the MITS1.5 and MITS3.0 with the ASTM 2009 phantom

DISCUSSION OF THE EVIDENCE STRENGTH TO SUPPORT QUALIFICATION

The confidence interval of the use of IMAnalytics with the MRIxViP library for a generic elongated implant, which was estimated by following the standard guidelines defined by the Guide to the Measurement of Uncertainty (GUM) and by the ASME V&V 10, is shown in Table 2. The procedure is based on describing the total uncertainty of the evaluation as the convolution of independent uncertainty sources using Type B evaluation. Each uncertainty term was evaluated in terms of its contribution to variation of the final result (power deposition at a hotspot or induced voltage at lead terminal). Therefore, the uncertainty contribution of each term comprises both the intrinsic variation of the source of uncertainty, and the local sensitivity of the final result to that variation − thus the uncertainties are presented as unitless factors, in decibels (as they are applicable for deposited power and for voltage).

The uncertainty associated with other IMAnalytics inputs, such as uncertainty of the transfer function models or routings/regions of interest, must be assessed separately and included in the final confidence interval.

Table 2: Confidence interval of IMAnalytics output (deposited power or induced voltage) due to uncertainty of in vivo exposure conditions.

Description	Specific Uncertainty (dB)	Probability distribution	Divisor	Standard uncertainty (dB)
Numerical modeling	0.2	N	1	0.2
The uncertainty of the simulation to generate the exposure data of MRIxViP attributed to grid resolution, simulation time, and absorbing boundary conditions was evaluated for the ViP phantom Duke.				
Anatomy	-	-	-	-
The uncertainty attributed to anatomical variation of patients can be large and is very difficult to assess. While the MRIxViP dataset comprises twelve patients in numerous scan conditions which aim to cover the patient population, typically the worst-case exposure condition observed is used to determine safety.				
RF-coil	-	-	-	-
In order to capture the uncertainty due to the physical variation of the RF-coils, we consider 10 RF birdcage resonators with dimensions concluded from the survey summarized above. Exposures from all 10 resonators are used, and the highest induced power deposition or terminal voltage condition is used to determine safety.				
Clinical routing / region of interest	0.15	R	√3	0.09
The power deposition was evaluated for six different generic implant routing groups defined in [10]. The number of clinical routings per group vary from 1, 5, 10, and 100 routings. The uncertainty was taken to be the maximum difference in the power deposition obtained from the different number of routings per group.				
ViP model and tissue parameters	1.37	R	√3	0.79
To date, we are able to establish only the upper bound of the uncertainty associated with the anatomical fidelity of the models (e.g., tissue segmentation, tissue composition, and tissue parameters). The power deposition of a generic implant (insulated wire of 40 cm in length) was evaluated for five ViP phantoms (Fats, Duke, Ella, Billie, and Thelonious) with the nominal dielectric properties of tissue follow that published in the IT'IS tissue database. The same procedure was repeated for the five ViP phantoms assuming homogeneous dielectric properties of tissue taken from the body average of each phantom.				
Patient position	0.5	N	1	0.5
The power deposition was evaluated for the ViP phantom Duke at the z = 70 cm imaging position. The phantom is translated in the transverse plane by 10 cm from the nominal position; two positions in the anterior-posterior direction and two positions in the medial-lateral direction.				
B1 exposure limit	0.1	R	√3	0.06
The numerical simulations of RF exposure were obtained from Huygens' boxes (equivalence theorem) where the birdcage coil is replaced by an equivalent boundary condition over a Gaussian surface surrounding the ViP phantoms. The evaluation was conducted at the normal-mode exposure limit, where exposure is limited by wbSAR, hSAR, or pbSAR. The uncertainty budget of the exposure limit is determined from the maximum difference, between the wbSAR obtained with and without Huygens' box, of the five ViP phantoms.				
Combined Std. Uncertainty (RSS, k=1)				**0.96 dB**
Expanded 95% Confidence Interval (RSS, k=2)				**1.92 dB**

ASSESSMENT OF ADVANTAGES/DISADVANTAGES OF QUALIFICATION

Assessments of Advantages of Using the MDDT:

Table 3: Comparison of current Tier 3 workflow vs. Tier 3 workflow with this MDDT tool

<table>
<tr><th>Standard Tier 3 Evaluation Workflow</th><th>Tier 3 Evaluation Workflow with MDDT</th></tr>
<tr><td colspan="2">Test item definition and hot spot/lead channel to be tested</td></tr>
<tr><td colspan="2">Test equipment (hardware and software)</td></tr>
<tr><td colspan="2">Generation and calibration of piX model</td></tr>
<tr><td colspan="2">V&V&UA of piX model</td></tr>
<tr><td>Description of patient exposure conditions to be evaluated: representative coils, anatomies, scan positions, polarizations, landmarks</td><td rowspan="4">Reference to precomputed, comprehensive MRIxViP dataset and associated confidence interval</td></tr>
<tr><td>Justification of conditions as conservative/worst-case</td></tr>
<tr><td>Simulation of induced fields</td></tr>
<tr><td>V&V&UA of simulations</td></tr>
<tr><td colspan="2">Definition of clinically relev ant implant trajectories</td></tr>
<tr><td>(trajectory defined in some anatomical models)</td><td>(trajectory defined in standard ViP models)</td></tr>
<tr><td colspan="2">Extraction of E-fields tangential to defined trajectories for all exposure conditions</td></tr>
<tr><td>(calculated “by hand” or with a script)</td><td>(calculated automatically by IMAnalytics)</td></tr>
<tr><td colspan="2">Convolution of Etans with transfer function to obtain terminal voltage or deposited power</td></tr>
<tr><td>(calculated “by hand” or with a script)</td><td>(calculated automatically by IMAnalytics)</td></tr>
<tr><td>V&V&UA of calculation tool</td><td>Reference to IMAnalytics verification</td></tr>
<tr><td colspan="2">Report of results across all models, exposure conditions, and operating modes, including statistical analysis and conclusion</td></tr>
<tr><td>(approach varies)</td><td>(generated automatically by IMAnalytics)</td></tr>
</table>

The MDDT can also produce the E-field in a region of interest (optionally averaged over any 10g of tissue), which may be used as input for measurement or simulation for an evaluation by the user based on ISO/TS 10974:2018 Tier 2, or for scaling of ASTM phantom measurements to clinical incident field conditions in human computational models per the requirements of ASTM F2182-19$^{\epsilon 2}$.

Assessments of Disadvantages of Using the MDDT:
List of Limitations

- The tool has demonstrated that it predicts electromagnetic fields in uniform ASTM gel phantoms for 1.5T and 3T cylindrical whole-body coils with circular cross-section and up to 16 uniformly distributed rungs. The simulated B1+ field map of Duke (head imaging position) was compared with an MR scanner (Philips Achieva 3T) B1+ measurement of the actual person the Duke model is based on. No animal validation was performed using this software. The tool and its components have not been validated for predicting deposited power in ex vivo or in vivo tissues.
- This tool is not to be utilized with AIMDs that are intended to stimulate or provide current during MR examinations.
- The Tier 3 approach defined in ISO/TS 10974:2018 may not be applicable to systems with multiple leads or with looping clinical routings, if inter-lead coupling cannot be excluded or bounded by an error term [11].
- The computed incident E-fields in MRIxViP may not be accurate for superficial implants (e.g., surface of skull or partially exposed), where the RF conditions during an MR examination are not well defined [12].
- The Tier 2 approach defined in ISO/TS 10974:2018 is applicable only to AIMDs that are electrically short.
- The tool is designed to compute the statistical range of potential induced E-fields and AIMD responses. If the evaluation shows unexpected statistical outliers the cause for these outliers shall be evaluated. The table below presents some of the tissue types, the presence of which in the computational domain may result in such unexpected statistical outliers.

Tissue Types
Tissues Near Skin
Cartilage
Lymph Node
Tendon Ligament
Phalanx Distalis III Cortical Right
Phalanx Distalis V Cortical Right
Phalanx Media II Cortical Foot Left
Phalanx Media IV Cortical Right
Carpalia Metacarpalia Cancellous Left
Foot Cancellous Left
Foot Cancellous Right
Foot Cortical Left
Foot Cortical Right

CONCLUSIONS

The qualification of IMAnalytics, MRIxViP, and BClib as an MDDT reduces the burden on sponsors preparing MRI RF safety test results for their AIMDs by defining a verified GUI-based toolset that generates statistical data based on various clinically relevant scenarios.

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