Test Field Diversity Method Using a Tabletop E-field Generator: In vitro Transfer Function Model Validation for Implantable Medical Device Safety Assessment in 1.5 and 3T MRI

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Test Field Diversity method using a Tabletop E-field Generator: In vitro transfer function model validation for implantable medical device safety assessment in 1.5 and 3T MRI

This document provides detailed instruction on measuring the transfer function (TF) of the implantable medical device with the piecewise excitation method [1]. It also covers *in vitro* TF model validation using a tabletop E-field generator required for assessing RF-induced power in the human body (or incident RF voltage in the device) using the Tier 3 method defined in ISO/TS 10974 [2]. We recommend that you start by reviewing this study [3], which shows an example use case.

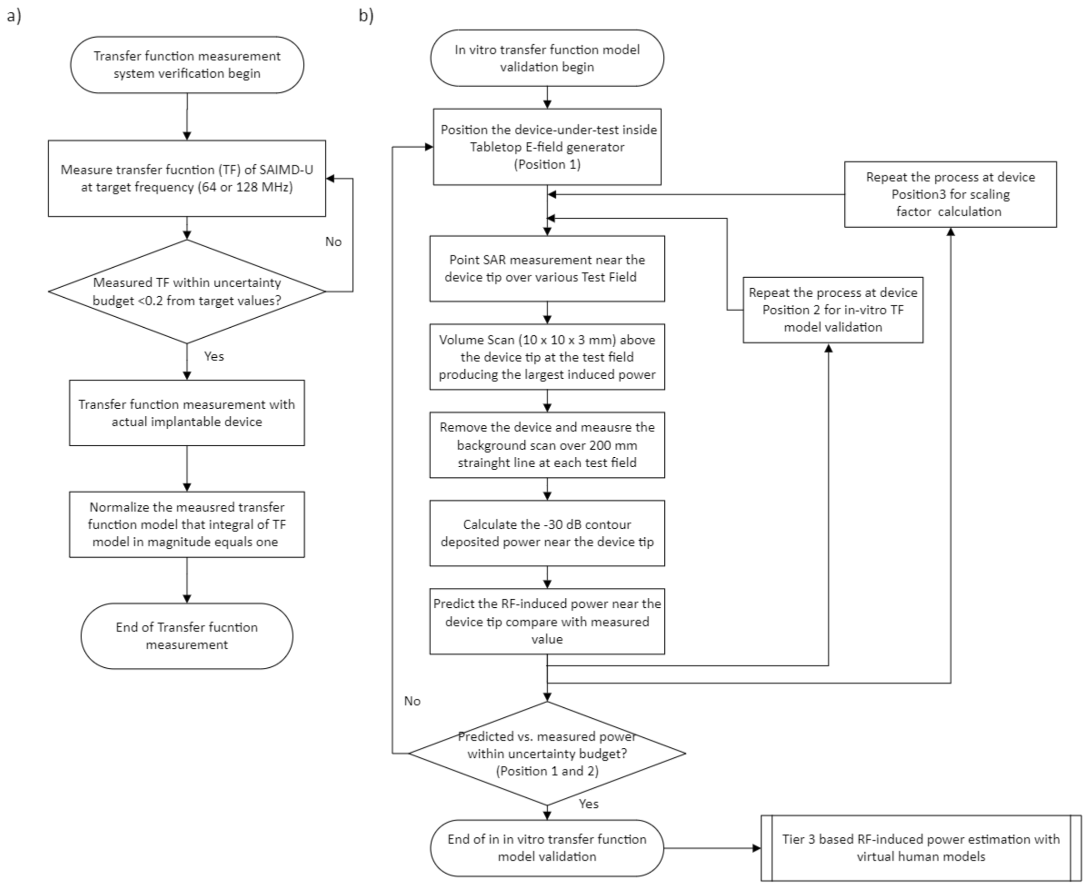

Figure 1. Flowchart for the transfer function (TF) measurement and *in-vitro* TF model validation process. a) Flowchart for the TF measurement of the implantable medical device; b) Flowchart for the in-vitro TF model validation process.

1. Transfer Function (TF) measurement and TF measurement system verification

Fig.1a shows the flow chart for measuring the implantable devices' transfer function (TF) inside tissue simulating liquid. The proposed process includes the TF measurement system verification process using a 'Universal Active Implantable Device for Systems Verification at 64 MHz and 128 MHz' (SAIMD-U; Zurich MedTech). The RF-induced power deposition (or the incident RF voltage) can be estimated using (1),

$$P_{tip} = A\left|\int_0^L S(l) \cdot E_{tan}(l)dl\right|^2 \qquad (1)$$

where P_{tip} is the estimated local power deposition near the device tip [mW]; A is the scaling factor [μW/(V_{rms}/m)^2] to estimate deposited power; $S(l)$ is the normalized transfer function [1/m]; $E_{tan}(l)$ is the incident tangential electric field over the lead trajectory without the device [V_{rms}/m]; and l is the specific point along the device trajectory [m] [4].

> Note: Same procedure applies to the incident RF voltage estimation by replacing the P_{tip} [mW] into V [mV], and unit of A [μW/(V_{rms}/m)^2] into A [mV/(V_{rms}/m)]) and without the squaring the absolute term on the right-hand side of equation (1).

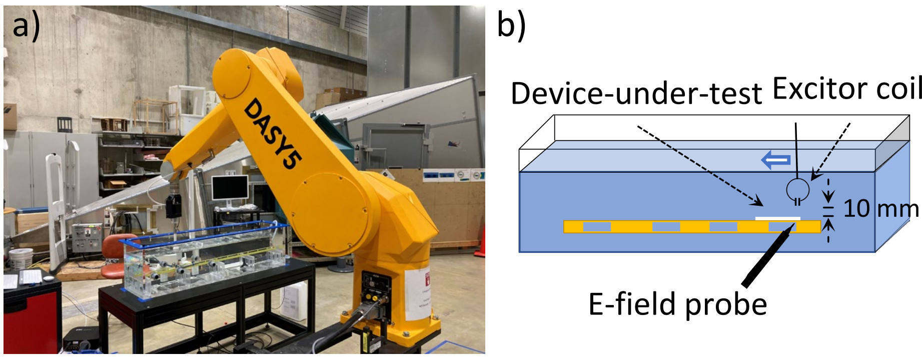

Figure 2. Transfer function measurement system using a piecewise excitation method. a) Experimental setup for the TF measurement where the excitor coil is positioned with a robot arm; (b) graphical presentation of the DUT and excitor coil inside tissue simulating liquid (σ: 0.47 S/m, ε_r: 78).

TF measurement system verification: RST users can choose a well-defined TF measurement method, such as a piecewise excitation method [1], a reciprocity method [5], or an MR-based measurement method [6]. The TF measurement system verification process assesses the accuracy of the TF measurement system using a University Active Implantable Device for Systems Verification at 64 MHz and 128 MHz (SAIMD-U; Zurich MedTech AG, Switzerland) [2]. The SAIMD-U comprises an insulated lead (length: 620mm) connected to a generic Implantable Pulse Generator (IPG, diameter: 34 mm, height: 10 mm), and is designed for measurement system verification at 64 MHz and 128 MHz.

Figure 2 shows the TF measurement set-up using a piecewise excitation (piX) method. The SAIMD-U is positioned on a non-conductive straight device holder submerged in conductive tissue simulating liquid (σ: 0.47 S/m, ε_r: 78 at 64 MHz or 128 MHz; TLe78c0.47, Zurich MedTech). The E-field response near the SAIMD-U tip is measured using a time-domain active optical Electric-field probe (E1TDSz/MRI; SPEAG, Switzerland) positioned 10 mm perpendicular to the SAIMD-U lead tip. The piX excitor coil (Zurich MedTech) tuned to 64 MHz (1.5T MRI) or 128 MHz (3T MRI), is attached to the robot arm (DASY52; SPEAG) and placed 10 mm above the SAIMD-U lead tip. The piX excitor coil is swept every 10 mm along the SAIMD-U trajectory while measuring the E-field response at the SAIMD-U lead tip using a time-domain E-field sensor. Additional response measurements are taken at 20mm before the SAIMD-U tip (two measurement points) and 10 mm after the end of the SAIMD-U (one measurement point), which are excluded during post-processing. After the TF measurement is completed, the SAIMD-U is removed, and the piX excitor coil is swept every 10 mm along the same SAIMD-U lead trajectory used for the TF measurement as the background response recording. Finally, the SAIMD-U TF model is subtracted from the background response, and the data range outside the device (i.e., two measurement points before the SAIMD-U lead tip and one after the SAIMD-U lead's proximal end) is excluded during post-processing. The measured TF model of SAIMD-U is scaled such that the maximum magnitude of the TF model equals 1, and the phase at the SAIMD-U tip equals zero to compare with the target value measured at the FDA/OSEL laboratory using the equation (2),

$$Difference_{transfer\ function} = \sqrt{\frac{\sum_0^n (Meas(l) - Target(l))^2}{\sum_0^n (Target(l))}} \quad (2)$$

where the $Difference_{transfer\ function}$ is the measurement difference compared to the target value, *Meas(l)* is the measured TF at position *l*, *Target(l)* is the target value at position *l*. Differences are calculated in magnitude [1/m], and phase [radian], then if the deviation is less than 0.2 for both magnitude and phase, TF measurement system is considered verified.

The provided MATLAB script [7] allows transfer function measurement system verification using SAIMD-U with a target value measured at the FDA OSEL laboratory. (Alternatively, RST users can use the target value that will be included in a future revision of ISO/TS 10974 [2])

> Note 1: RST users can decide how often the TF measurement system will be verified based on their laboratory practice.
> Note 2: We recommend that RST users measure the dielectric properties of the tissue simulating liquid at the target frequency (64 or 128 MHz) using a dielectric properties measurement kit or using a validated liquid solution that the vendor verifies.
> Note 3: A low-cost conductivity meter (e.g., EcoTestr EC High, Eutech Instruments Pte Ltd, Singapore) can be used for maintenance purpose for tissue simulating liquid verified at the target frequency. Measure the direct current (DC) conductivity in at least three different locations. (Per FDA OSEL laboratory measurement, conductivity measurement at DC results in a range between 0.53 and 0.54 S/m at liquid temperature between 20-25°C, reflecting the conductivity of tissue simulating liquid between 0.47 – 0.49 S/m at 64 MHz or 128 MHz.

TF measurement with device-under-test: Once the TF measurement system is verified, RST users can position the device-under-test (DUT) inside the tissue simulating liquid and repeat the aforementioned TF measurement steps. The measured TF of the DUT is normalized such that the integral of the TF model in magnitude over the DUT length equals 1 (3),

$$1 = \left(\int_0^L S(l)dl\right)\left(\int_0^L S(l)dl\right)^* \quad (3)$$

where the phase of the TF model equals 0 at the device tip. The scaling process (3) is included in the attached MATLAB script.

2. *In vitro* TF model validation using a tabletop E-field generator

The measured TF model can be validated using a tabletop E-field generator (or whole-body sized RF transmit coil) tuned to 64 MHz or 128 MHz. The tabletop E-field generator, Medical Implant Test Tabletop (MITS-TT; Zurich MedTech), is a commercially available system. It is recommended that the EM field exposure system of the MITS-TT be verified during the system installation process.

<u>*In vitro TF model validation*</u>: The TF model of the DUT can be validated at 64 and 128 MHz using a tabletop E-field generator by exposing the device under various test fields. RST users can accurately control the DUT position inside of tissue simulating liquid using an FR-4 glass-reinforced racetracks available from the vendor (Fig.3a). The following steps are required (start from Position 1):

1) Deposited power measurement near the DUT tip: The deposited power is measured near the DUT tip using a dosimetric probe (EX3DV4; SPEAG). The set of relative phase and gain values between two transmit channels of the tabletop E-field generator is selected to generate various incident field exposure scenarios (An example set of relative phase and gain between two-channel is shown in Tables 1 and 2).

> Note 1: RST users can use customized TFD sets optimized for their device conditions with justification.
> Note 2: The RF-induced power measurement near the DUT tip takes less than 5 seconds for each test field.

2) Volume scan: Once the DUT tip measurement is finished, the volume scan is performed near the DUT tip (10 x 10 x 3 mm, Fig.3b). This volume scan is used for calculating the -30 dB contour power deposition during post-processing.

> Note: The measurement of volume scan (10 x 10 x 3 mm) takes about 15 minutes.

3) Reference scan (without DUT): Once the volume scan is finished, remove the DUT and measure the background E-field response at each test field along the 200mm straight line at 10 mm intervals (e.g., [x,y,z] = (-100, 100, 150) to (100, 100, 150)).

> Note: The background scan for one test field takes about 1 minute.

4) Locate the DUT at 'Position 2' where a different E-field exposure is expected and repeat the aforementioned procedure 1)-3) (use the two types of racetracks, 'oval-shaped' and 'e-shaped', to alter the test position accurately)

5) An additional measurement at an independent DUT position (Position 3) is required to calculate the scaling factor *A*. Repeat the abovementioned procedure 1)-3).

> Note: RST users may reduce the number of test field by half for the scaling factor calculation [8].

6) Post-process the data and compare the predicted power deposition against the measured power near the DUT tip. Confirm whether the amount of error is within the uncertainty budget.

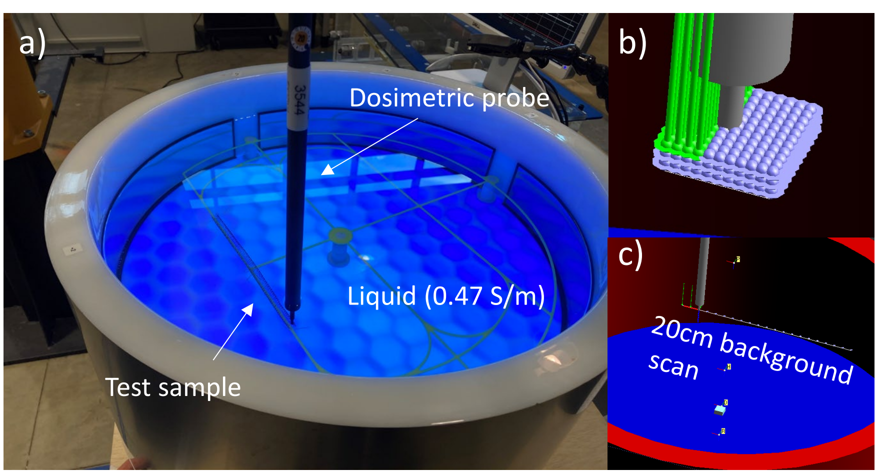

Figure 3. TF measurement system. a) Experimental set up for the TF measurement; (b) zoomed view of the DUT inside tissue simulating liquid and excitor coil.

Tables 1 and 2 show example sets of relative phase and gain values that can be used in the experiment. The example sets of relative phase and gain are designed to expose the DUT to various incident E-fields. RST users could develop customized relative phase and gain sets with justification [8].

Example 1	Phase	Gain		Phase	Gain
TFD1	0	0	**TFD9**	180	0
TFD2	30	4	**TFD10**	210	4
TFD3	45	1	**TFD11**	225	1
TFD4	60	3	**TFD12**	240	3
TFD5	90	0	**TFD13**	270	0
TFD6	120	4	**TFD14**	300	4
TFD7	135	1	**TFD15**	315	1
TFD8	150	3	**TFD16**	330	3

Table 1. Example set of TFDs to generate various incident fields with relative phase ranges between 0 and 330° and gain ranges between 0 and 4, testing multiple levels of power deposition tested suitable for device length ≤ 160 mm.

Example 2	Phase	Gain		Phase	Gain
TFD1	0	0	**TFD11**	120	0
TFD2	0	3	**TFD12**	120	3
TFD3	0	-3	**TFD13**	120	-3
TFD4	0	6	**TFD14**	120	6
TFD5	0	-6	**TFD15**	120	-6
TFD6	60	0	**TFD16**	180	0
TFD7	60	3	**TFD17**	180	3
TFD8	60	-3	**TFD18**	180	-3
TFD9	60	6	**TFD19**	180	6
TFD10	60	-6	**TFD20**	180	-6

Table 2. Example set of TFDs to generate various incident fields with relative phase ranges between 0° and 180° and gain ranges between -6 and 6. This example set uniformly covers the relative phase and gain difference between two transmit sources, and may be suitable for testing devices with length up to 1050 mm.

Once the experimental measurements are completed, post-processing is required. Details of the post-processing can be found in the following publications.

- A. Yao, E. Zastrow, and N. Kuster, "Data-Driven Experimental Evaluation Method for the Safety Assessment of Implants With Respect to RF-Induced Heating During MRI," Radio Science, vol. 53, no. 6, pp. 700–709, Jun. 2018, doi: 10.1029/2017RS006433.
- A. Yao, E. Zastrow, E. Neufeld, M. Cabanes-Sempere, T. Samaras, and N. Kuster, "Novel test field diversity method for demonstrating magnetic resonance imaging safety of active implantable medical devices," *Physics in Medicine & Biology*, vol. 65, no. 7, p. 075004, Apr. 2020, doi: 10.1088/1361-6560/ab7507.
- H. Jeong, J. W. Guag, and A. Kumar, "RF-induced Heating Estimation of a Stent in a 3T MRI using Transfer Function Approach with a Tabletop E-field Generator," *IEEE Access*, vol. 12, pp. 191945–191954, 2024, doi: 10.1109/ACCESS.2024.3518974.

Appendix 1. Target values for the SAIMD-U transfer function model

The following are reference transfer function model values (target values) measured at the FDA OSEL laboratory that can be used for the measurement system verification.

SAIMD-U	64 MHz		128 MHz	
Distance from Position 0 (mm)	Mag	Phase	Mag	Phase
0	0.40	0.00	0.48	0.00
20	1.00	0.08	1.00	-0.24
40	0.95	0.01	0.91	-0.44
60	0.89	-0.06	0.83	-0.64
80	0.82	-0.13	0.78	-0.87
100	0.76	-0.19	0.73	-1.10
120	0.70	-0.27	0.70	-1.36
140	0.63	-0.36	0.70	-1.63
160	0.56	-0.47	0.72	-1.87
180	0.49	-0.59	0.74	-2.09
200	0.43	-0.76	0.77	-2.27
220	0.38	-0.95	0.80	-2.43
240	0.35	-1.20	0.81	-2.58
260	0.34	-1.50	0.81	-2.72
280	0.35	-1.79	0.78	-2.85
300	0.39	-2.02	0.74	-2.98
320	0.44	-2.21	0.69	-3.10
340	0.49	-2.36	0.62	-3.23
360	0.56	-2.48	0.54	-3.37
380	0.62	-2.57	0.44	-3.54
400	0.67	-2.65	0.34	-3.81
420	0.72	-2.71	0.28	-4.22
440	0.76	-2.75	0.26	-4.73
460	0.80	-2.79	0.30	-5.21

480	0.83	-2.82	0.38	-5.54
500	0.85	-2.85	0.46	-5.72
520	0.87	-2.87	0.54	-5.86
540	0.89	-2.89	0.61	-5.95
560	0.93	-2.90	0.68	-5.99
580	0.98	-2.90	0.76	-6.03
600	0.87	-2.89	0.69	-6.17
620	0.31	-3.09	0.27	-6.64

Table 3. Target values for deposited power using SAIMD-U at 64 MHz and 128 MHz in tissue simulating medium (σ = 0.47 S/m, ε_r = 78). The magnitude is normalized so that the maximum equals one, and the phase (in radians) equals zero at the SAIMD-U tip.

Reference

[1] E. Zastrow, M. Capstick, and N. Kuster, "Experimental systems for RF-heating characterization of medical implants during MRI," presented at the ISMRM 2016 24th Ann. Meeting and Exhibition, Singapore, May 2016.

[2] ISO/TS 10974:2018, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*. [Online]. Available: https://www.iso.org/standard/65055.html

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[4] S.-M. Park, R. Kamondetdacha, and J. A. Nyenhuis, "Calculation of MRI-induced heating of an implanted medical lead wire with an electric field transfer function.," *J Magn Reson Imaging*, vol. 26, no. 5, pp. 1278–1285, Nov. 2007, doi: 10.1002/jmri.21159.

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[8] A. Yao, E. Zastrow, E. Neufeld, M. Cabanes-Sempere, T. Samaras, and N. Kuster, "Novel test field diversity method for demonstrating magnetic resonance imaging safety of active implantable medical devices," *Physics in Medicine & Biology*, vol. 65, no. 7, p. 075004, Apr. 2020, doi: 10.1088/1361-6560/ab7507.