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Safety Evaluation of SetPoint Wireless Charger

	Name	**Function**	**Date**	**Signature**
Author	Jingtian Xi	Project Leader, IT'IS Foundation		
Approval	Niels Kuster	Quality Manager, IT'IS Foundation		

Prof. Dr. Niels Kuster

Director, IT'IS Foundation
Professor, Swiss Federal Institute of Technology – ETH Zurich
Phone +41 44 245 9690 · kuster@itis.swiss

Safety Evaluation of SetPoint Wireless Charger

conducted by

Jingtian Xi, Tolga Goren

Zurich, August 13, 2024

Confidential

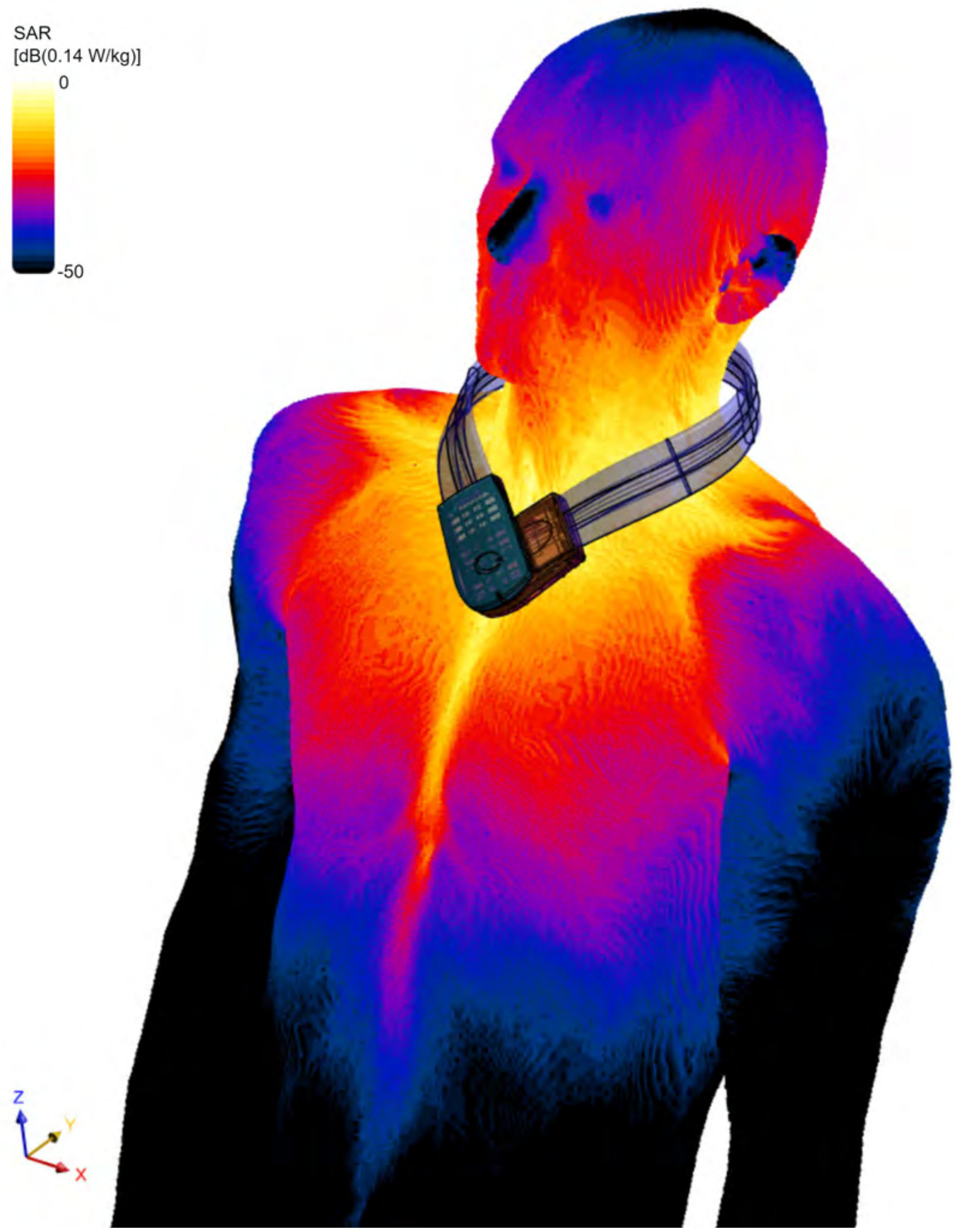

Figure 1: Distribution of SAR (not spatial averaged) on the surface of Duke

Executive Summary

The SetPoint Medical bioelectronic medicine platform delivers targeted electrical pulses to trigger the intrinsic inflammatory reflex. The leadless implant, 24 mm in length, implanted close to the vagus nerve, is intermittently charged by the wireless charger worn around the neck. The objectives of this study were to:

- generate a numerical model of the charger based on customer inputs, and validate the model by H-field measurements with DASY6 Module WPT;
- determine the SAR values (peak spatial-average SAR and whole-body SAR) in ten anatomical models by simulations with the validated charger model;
- evaluate the compliance of the charger by comparing the SAR results against safety limits.

All simulations were performed with the verified Magneto Quasi-static solver of Sim4Life (ZMT Zurich MedTech AG). Two sets of simulations were made:

- a simulation without any anatomical model, to determine the incident H-fields (at validation locations) which are compared against the measurement results;
- simulations with the anatomical models to determine the SAR values which are compared against the safety limits.

The second set of simulations (also called dosimetric simulations) consist of two simulations for each anatomical model:

- a simulation with the whole body for the determination of the whole-body SAR, SAR_{wb};
- a simulation with the anatomical models truncated for the determination of the peak 1 gram and 10 gram mass-averaged SAR $psSAR_{1g}$, $psSAR_{10g}$.

The simulation results of $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} were compared with the SAR limits from FCC regulations and ICNIRP guidelines, applicable to head, neck and trunk.

The results of $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} are summarized in Table 1. They are below their corresponding limits by at least 13, 16, and 21 dB respectively. The uncertainty of the peak spatial-average SAR simulated was evaluated to be 1.82 dB ($k = 2$).

SetPoint Medical engineers were on-site for all of the tests performed, and were responsible for control of the test items. All bench-top tests were performed by the IT'IS Laboratory in Zurich. All equipment was appropriately calibrated, and all procedures were in accordance with the requirements of IEC/IEEE 63184.

Table 1: Simulation results of peak spatial-average SAR and whole-body SAR in ten ViP models. The standard deviations are good estimates of the expected variations due to differences in the anatomy and the charger positioning.

Name	$psSAR_{1g}$ [mW/kg]	$psSAR_{10g}$ [mW/kg]	SAR_{wb} [mW/kg]
Duke cV3.1	57.0	29.6	0.422
Ella cV3.1	31.5	22.9	0.365
Ella BMI30	27.2	20.5	0.278
Fats cV3.1	56.0	34.3	0.345
Fats BMI29	72.6	42.2	0.391
Glenn cV3.1	45.9	28.9	0.483
Eddie cV3.1	80.5	46.5	0.437
Billie cV3.1	55.1	35.6	0.599
Jeduk V4.0	59.4	37.4	0.451
Yoon-sun V4.0	49.8	29.6	0.357
Mean	53.5	32.7	0.413
Std. dev.	16.3	8.13	0.0885

Contents

1 Charger Model and Exposure Scenarios

The charger model provided by SetPoint consists of a 6-turn coil, as shown in Figure 2. The coil current depends on the setting of the transmission power level and the coil resonant frequency. The values used were 0.499 A at power level 10 and 130.1 kHz (used in the measurements for validating the charger model; the same frequency was used to confirm linearity with respect to power level), and 7.33 A at power level 140 and 133.3 kHz (used in the simulation for compliance evaluation, corresponding to the highest power level, and highest resonant frequency, for a production charger).

The charger is worn around the neck of a patient (to charge an implanted neurostimulator mounted on the vagus nerve), as shown in Figure 2. Ten anatomical models from the Virtual Population (ViP) model library [1] were selected by SetPoint, as listed in Table 2. The relative positions of the charger model on all the anatomical models were defined by SetPoint.

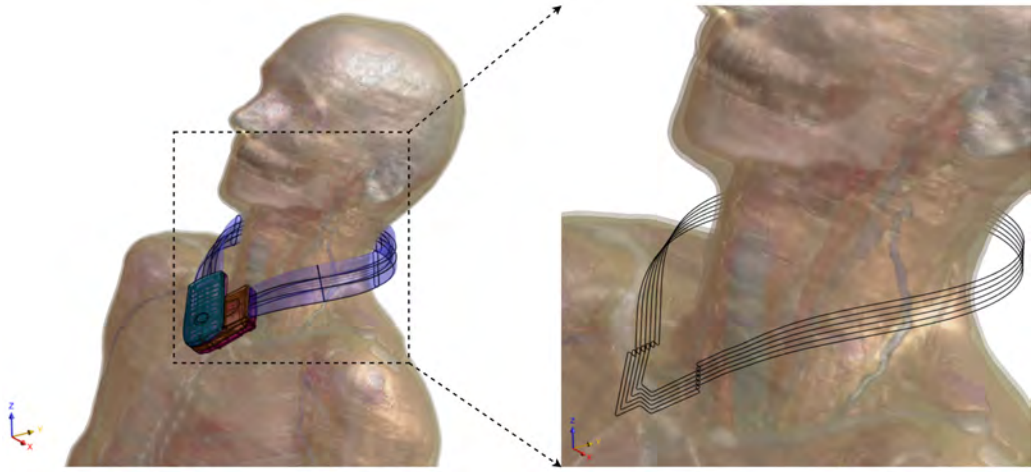

Figure 2: The charger model positioned around the neck of the anatomical model Duke (left: illustration with the charger encapsulation; right: illustration zoomed in on the charger without the encapsulation).

Table 2: Information of ten ViP models used in this study

Name	Gender	Age [year]	Height [m]	Weight [kg]	BMI [kg/m^2]
Duke cV3.1	Male	34	1.77	70.2	22.4
Ella cV3.1	Female	26	1.63	57.3	21.6
Ella BMI30	Female	26	1.63	79.7	30.0
Fats cV3.1	Male	37	1.82	119	35.9
Fats BMI29	Male	37	1.82	96.0	29.0
Glenn cV3.1	Male	84	1.73	61.1	20.4
Eddie cV3.1	Male	38	1.81	106	32.4
Billie cV3.1	Female	11	1.49	34	15.3
Jeduk V4.0	Male	33	1.62	64.5	24.6
Yoon-sun V4.0	Female	26	1.52	54.6	23.6

2 Simulation Protocol

All simulations were made with the Magneto Quasi-Static (MQS) solver in the multi-physics simulation platform Sim4Life V7.2 (ZMT Zurich MedTech AG, Zurich, Switzerland). Two sets of simulations were made:

- a simulation without any anatomical model and using the excitation 0.499 A (rms) at 130.1 kHz, to determine the incident H-fields (at validation locations) which are compared against the measurement results, see Appendix A;
- simulations with the anatomical models and using the excitation 7.33 A (rms) at 133.3 kHz (corresponding to the highest power level), to determine the SAR values which are compared against the safety limits.

The second set of simulations (also called dosimetric simulations) consist of two simulations for each anatomical model:

- a simulation with the whole body for the determination of the whole-body SAR SAR_{wb};
- a simulation with the anatomical models truncated for the determination of the peak 1 gram and 10 gram mass-averaged SAR $psSAR_{1g}$, $psSAR_{10g}$.

In the first dosimetric simulation which used the full anatomical models, all tissues were discretized with a resolution of 1.5 mm. In the second dosimetric simulation which used the truncated anatomical models, the computation domain included all tissues in the space corresponding to H-field decays (relative to its maximum) less than 50 dB. Thus, the lower limbs (or a part of them, depending on the model dimensions) of the anatomical models were excluded from the computation domain. The tissues surrounding the peak SAR were discretized with a finer resolution of 0.8 mm.

The dielectric properties of the tissues of the anatomical models were configured automatically by Sim4Life software following the tissue database IT'IS LF V4.1 [2]. Results of $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} were extracted from the dosimetric simulation results with the dosimetry tool in Sim4Life software.

3 Results

The simulation results of $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} are provided in Table 3. They are further compared with the safety limits in Table 4. The SAR limits adopted here are 1.6, 2.0, and 0.08 W/kg for $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} respectively. The $psSAR_{1g}$ and $psSAR_{10g}$ limits are from FCC regulations [3] and ICNIRP guidelines [4] respectively, and are both applicable to head, neck and trunk. Note that the $psSAR_{10g}$ limit from FCC (i.e., 4 W/kg) is only applicable to limbs and hence not relevant to the exposure scenarios under study. The comparisons of the peak spatial-average SAR and whole-body SAR against the corresponding limits are also illustrated in Figures 3–5 for $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} respectively.

Table 3: Simulation results of peak spatial-average SAR and whole-body SAR in ten ViP models. The standard deviations are good estimates of the expected variations due to differences in the anatomy and the charger positioning.

Name	$psSAR_{1g}$ [mW/kg]	$psSAR_{10g}$ [mW/kg]	SAR_{wb} [mW/kg]
Duke cV3.1	57.0	29.6	0.422
Ella cV3.1	31.5	22.9	0.365
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Jeduk V4.0	59.4	37.4	0.451
Yoon-sun V4.0	49.8	29.6	0.357
Mean	53.5	32.7	0.413
Std. dev.	16.3	8.13	0.0885

Table 4: Comparison of peak spatial-average SAR and whole-body SAR in ten ViP models against safety limits (1.6, 2.0, and 0.08 W/kg for $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} respectively)

Name	$psSAR_{1g}$ [dB]	$psSAR_{10g}$ [dB]	SAR_{wb} [dB]
Duke cV3.1	-14.5	-18.3	-22.8
Ella cV3.1	-17.1	-19.4	-23.4
Ella BMI30	-17.7	-19.9	-24.6
Fats cV3.1	-14.6	-17.7	-23.6
Fats BMI29	-13.4	-16.8	-23.1
Glenn cV3.1	-15.4	-18.4	-22.2
Eddie cV3.1	-13.0	-16.3	-22.6
Billie cV3.1	-14.6	-17.5	-21.3
Jeduk V4.0	-14.3	-17.3	-22.5
Yoon-sun V4.0	-15.1	-18.3	-23.5
Mean	-14.8	-17.9	-22.9
Rel. std. dev.	-5.15	-6.05	-6.69

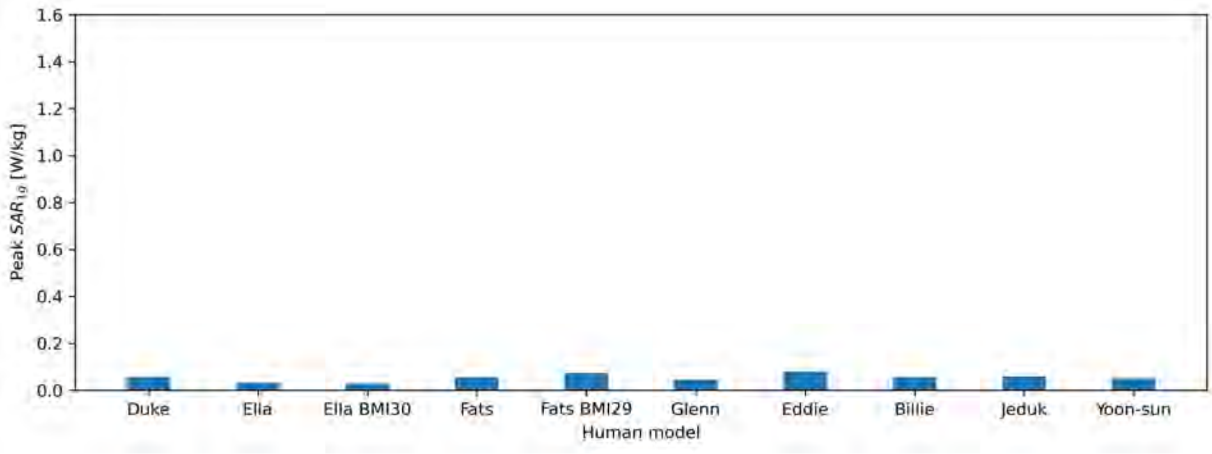


Figure 3: Simulation results of $psSAR_{1g}$ in ten ViP models. The maximum value of the vertical axis corresponds to the limit 1.6 W/kg.

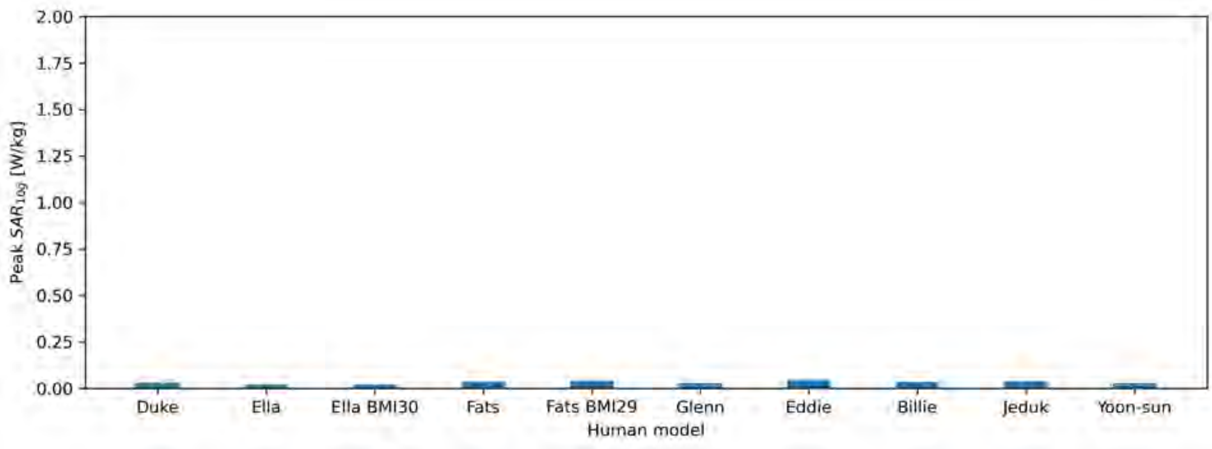


Figure 4: Simulation results of $psSAR_{10g}$ in ten ViP models. The maximum value of the vertical axis corresponds to the limit 2.0 W/kg.

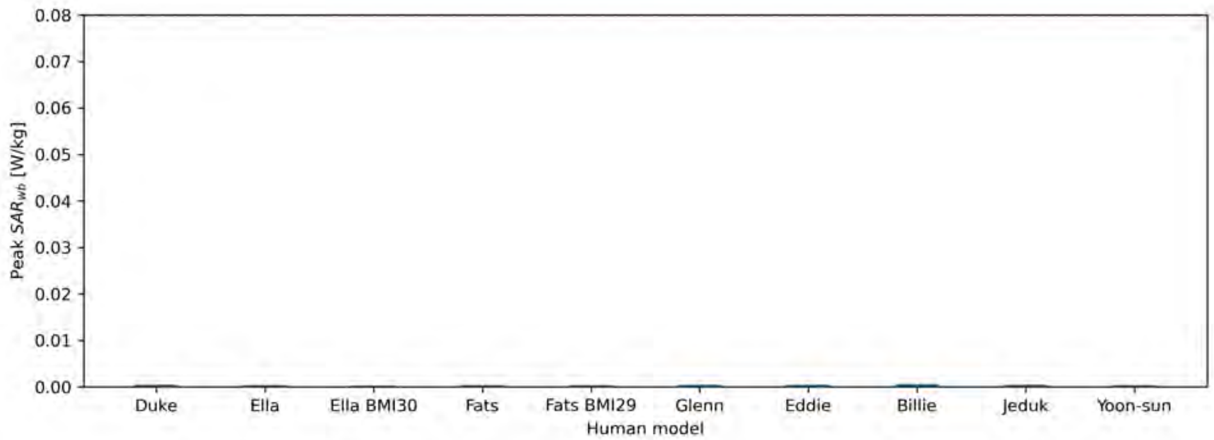


Figure 5: Simulation results of SAR_{wb} in ten ViP models. The maximum value of the vertical axis corresponds to the limit 0.08 W/kg.

4 Uncertainty Budget

The uncertainty of the simulated peak spatial-average SAR is assessed to be 1.82 dB ($k = 2$) following the procedures described in [5]. The detailed uncertainty budget is provided in Table 5. Definitions of the uncertainty components can be found in [5, 6]. The uncertainty of the tissue parameters corresponds to the variation of the conductivities of all tissues by 10%.

Table 5: Uncertainty budget for the simulated peak spatial-average SAR

Unc. component	Unc. [dB]	Probability distribution	Divisor	c_i	Std. unc. [dB]
DUT model	1.33	Normal	2	1	0.67
Grid resolution	0.10	Normal	1	1	0.10
Convergence	0.00	Rectangular	$\sqrt{3}$	1	0.00
Power budget	N.A.	Normal	1	1	N.A.
Boundary conditions	0.10	Rectangular	$\sqrt{3}$	1	0.06
Quasistatic approximation	0.10	Rectangular	$\sqrt{3}$	1	0.06
Tissue parameters	1.05	Rectangular	$\sqrt{3}$	1	0.61
Exposure position	0.10	Rectangular	$\sqrt{3}$	1	0.06
Representation of exposure scenarios	N.A.	Normal	1	1	N.A.
Combined std. uncertainty [dB]					0.91
Expanded uncertainty ($k = 2$) [dB]					1.82

5 Conclusions

In this study, the charger model provided by SetPoint was first validated by H-field measurements made with DASY6 Module WPT. Then the peak spatial-average SAR (i.e., $psSAR_{1g}$, $psSAR_{10g}$) and the whole-body SAR (i.e., SAR_{wb}) were determined by simulations in Sim4Life V7.2 with ten anatomical models selected and posed by SetPoint. It has been demonstrated that $psSAR_{1g}$, $psSAR_{10g}$, and SAR_{wb} are below their corresponding limits by at least 13, 16, and 21 dB respectively. The uncertainty of the peak spatial-average SAR simulated was evaluated to be 1.82 dB ($k = 2$).

A Numerical Model Validation

A.1 Measurement Setup

The H-field measurements for validating the numerical charger model were made with DASY6 Module WPT V2.2 (Schmid & Partner Engineering AG, Zurich, Switzerland). The measurement setup is shown in Figure 6. The system configuration is listed in Table 6.

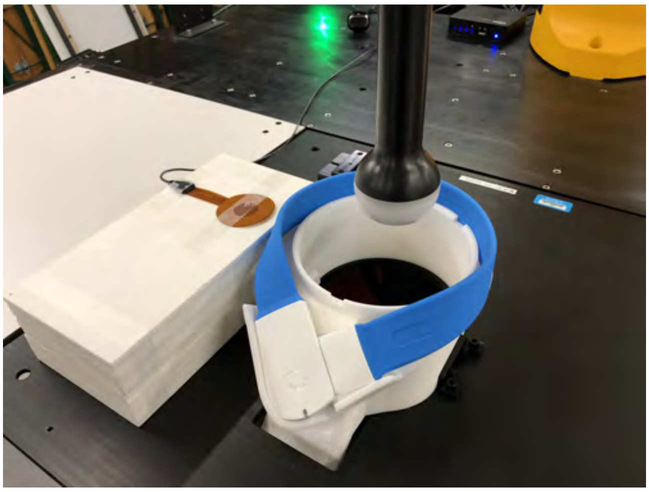


Figure 6: Setup of the validation measurement

System	Type:	DASY6 Module WPT
	Software Version:	V2.2
	Manufacturer:	Schmid & Partner Engineering AG, Switzerland
Positioner	Robot:	TX90 XL
	Serial No:	F/18/0004593/A/001
	Controller:	CS8C
	Serial No:	F/18/0004593/C/001
	Manufacturer:	Stäubli, France
Probe	Type:	MAGPy-8H3D+E3D V2
	Serial No.:	3065
	Calibrated On:	Apr. 6, 2023
	Next Calibration:	Apr., 2024
	Frequency Range:	3 kHz–10 MHz
	H-Field Dynamic Range:	0.1–3200 A/m
	E-Field Dynamic Range:	0.1–2000 V/m
	H-Field Sensor Area:	1 cm^2
	E-Field Sensor Length:	5 cm
	Probe Length:	335 mm
	Probe Tip Diameter:	60 mm (flat tip)
	Manufacturer:	Schmid & Partner Engineering AG, Switzerland
V&V Source	Model:	V-Coil50/400 V2
	Serial No:	1013
	Dimensions:	250 mm×125 mm×35 mm
	Output Frequency:	400 kHz
	Evaluated On:	Feb. 1, 2024
	Manufacturer:	Schmid & Partner Engineering AG, Switzerland

Table 6: DASY6 Module WPT system and the system verification & validation (V&V) source

A.2 System Check

A system check of the measurement system DASY6 Module WPT V2.2 was made with the V&V source V-Coil50/400 V2 (see Table 6) before the DUT model validation measurement. The system check consists of a volume scan covering a volume with dimensions of $125\times125\times36.7\,\text{mm}^3$ on top of the source. The volume scan was made with a uniform step of 7.33 mm on Feb. 1, 2024. The deviations between results of the system check and the numerical target values are listed in Table 7. The relevant uncertainties ($k = 2$), which include uncertainties from the measurement, the simulation, and the source current, are also provided in Table 7. Since all deviations are within the combined uncertainties, the system check is considered successful.

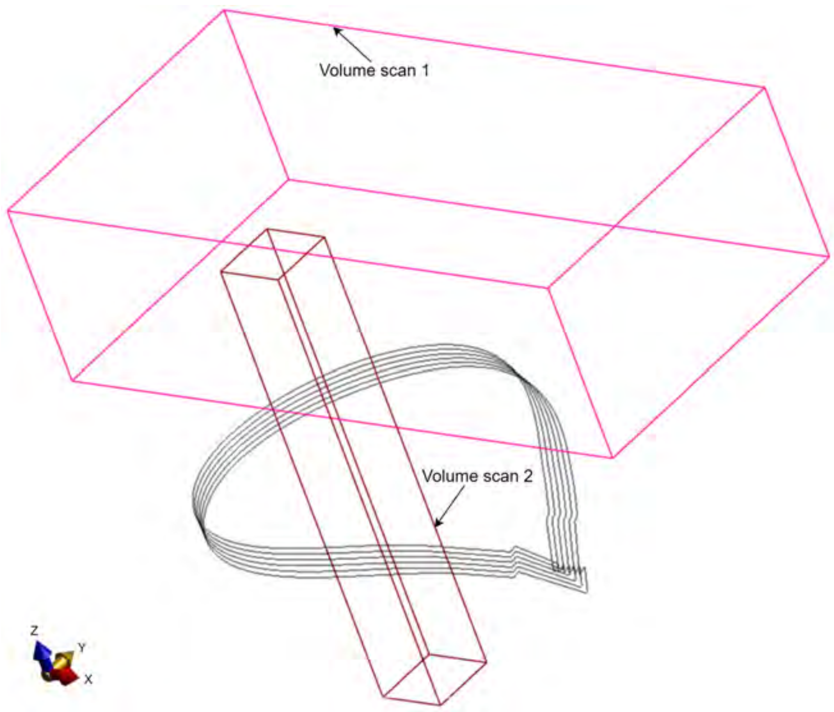
Table 7: Results of the system check presented in terms of the deviations between the measured peak incident H-field (i.e., H_{inc}) and peak 1 gram and 10 gram mass-averaged SAR (i.e., $\text{psSAR}_{1\text{g}}$, $\text{psSAR}_{10\text{g}}$) and their numerical target values. The associated uncertainties ($k = 2$) are also provided.

	H_{inc}	$\text{psSAR}_{1\text{g}}$	$\text{psSAR}_{10\text{g}}$
Deviation [dB]	-0.51	-0.52	-0.46
Uncertainty [dB]	1.41	1.34	1.32

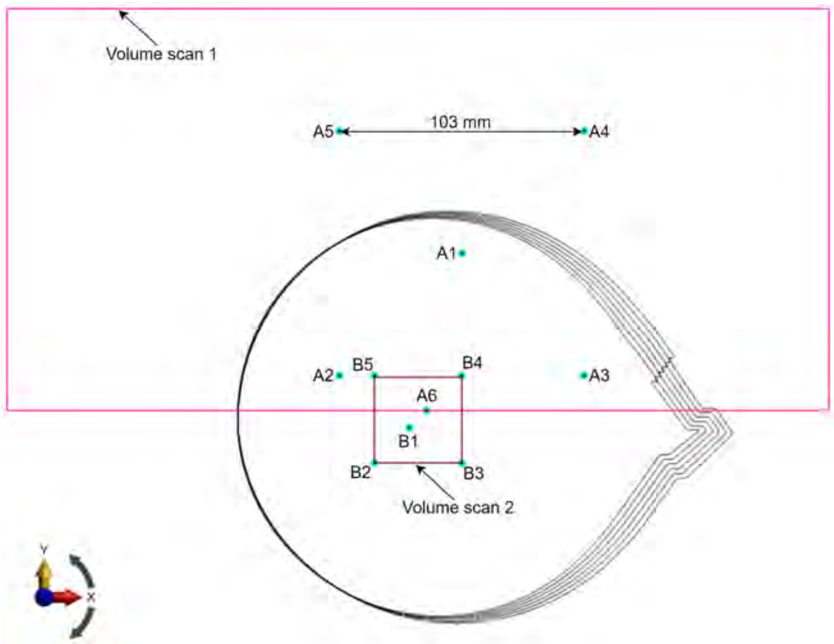
A.3 Validation Method

The validation measurement consists of two volume scans as shown in Figure 7. The first scan covers a volume with dimensions of $345\times169\times96.5\,\text{mm}^3$ on top of the coil. The lowest measurement plane of the first scan is at z=0 mm (which is less than 2 mm above the top edge of the charger encapsulation). The second scan covers a volume with dimensions of $36.7\times36.7\times242\,\text{mm}^3$ through the coil. The lowest measurement plane of the second scan is at z=-145.5 mm. The volume scans were made with a uniform step of 7.33 mm on Feb. 1, 2024.

A set of validation points were selected according to the guidelines in [5]. First, a few anchor points at the horizontal plane z=0 were selected. For the first volume scan, point A1 (see Figure 7b) indicates the location of the maximum H-field at the horizontal plane z=0, while A2–A5 are points surrounding A1 with offsets approximately corresponding to half of the mean radius of the coil. The extra validation point A6 basically corresponds to the origin of the coordinate system (with a half-step offset along x and y axes). For the second volume scan where the field distributions at horizontal planes are relatively uniform, a point within the volume (i.e., B1) and the four corner points (i.e., B2–B5) were selected. Second, eleven vertical observation lines were defined based on the anchor points (i.e., A1–A6 and B1–B5). Each observation line passes through a specific anchor point and travels through the height of the corresponding volume. There are in total 254 validation points distributed uniformly along the eleven observation lines. For validation purpose, the simulated and measured total H-fields at the validation points were compared.



(a) Volume scanned

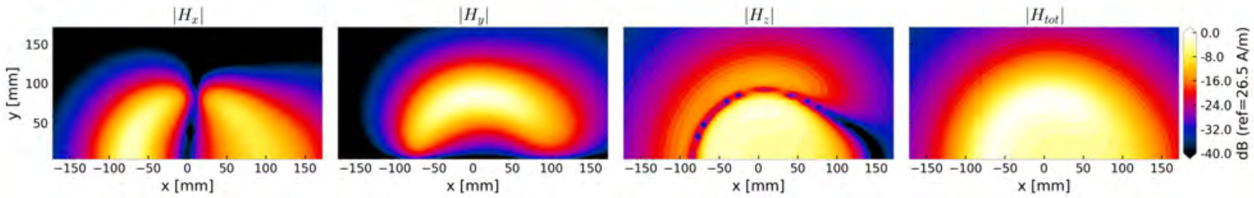


(b) Anchor points

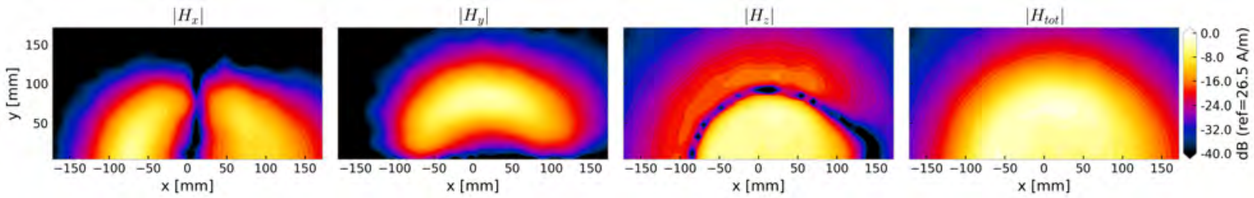
Figure 7: Volumes scanned to record the H-field (perspective view at the top) and anchor points for defining the vertical observation lines and the validation points (top view at the bottom).

A.4 Visualization of Field Distributions

The simulated and measured H-fields were compared in Figure 8–10 for the lowest and highest horizontal measurement planes in the first volume scan and the most left vertical measurement plane in the second volume scan.

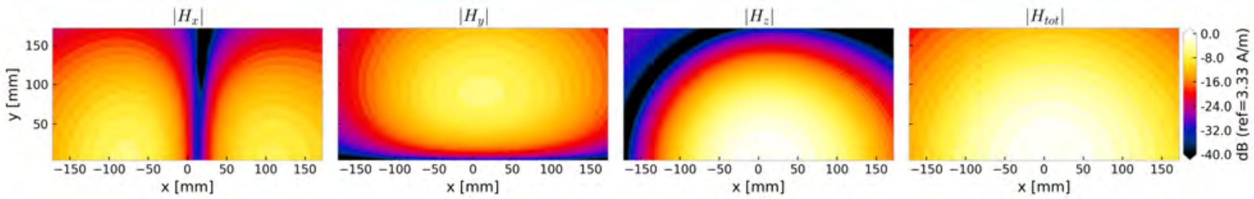


(a) Simulation results

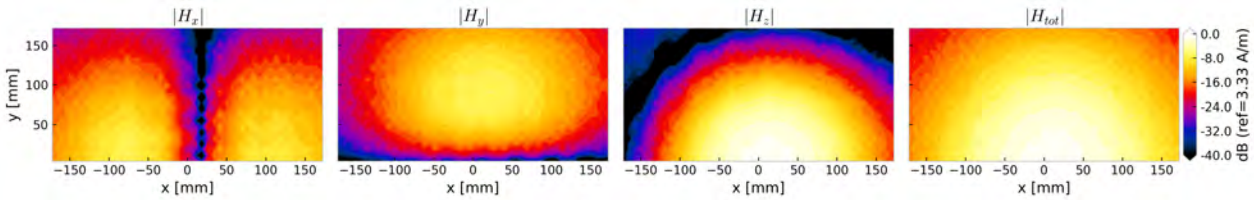


(b) Measurement results

Figure 8: Simulated and measured H-field distributions at the horizontal plane z=0 mm. The measurement results were extracted from volume scan 1.

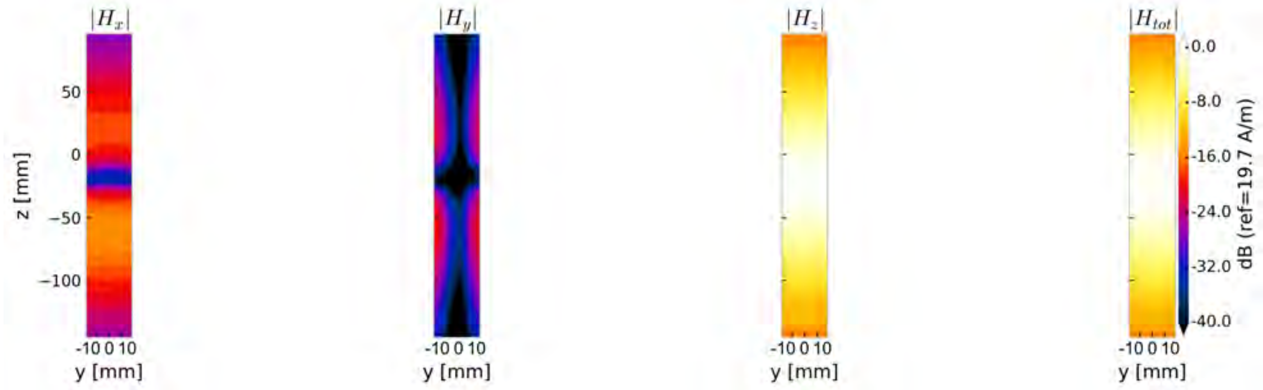


(a) Simulation results

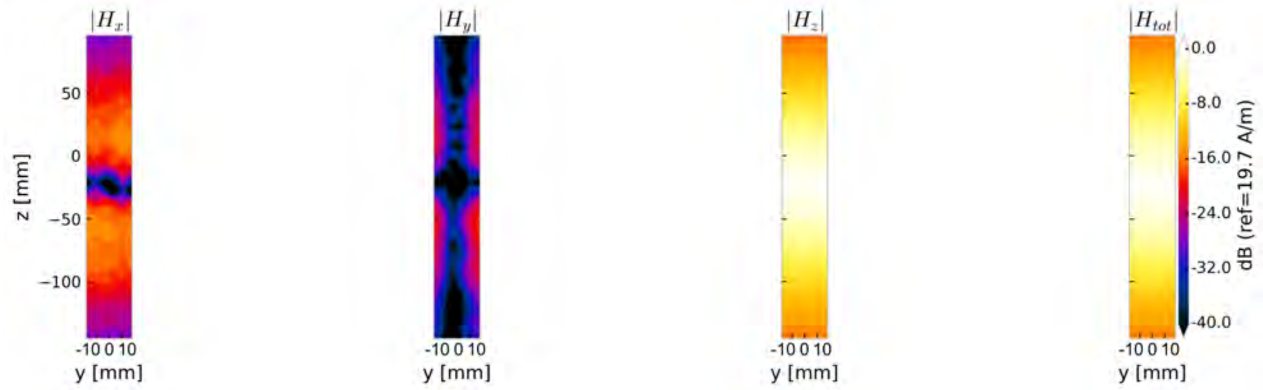


(b) Measurement results

Figure 9: Simulated and measured H-field distributions at the horizontal plane z=96.5 mm. The measurement results were extracted from volume scan 1.



(a) Simulation results



(b) Measurement results

Figure 10: Simulated and measured H-field distributions at the vertical plane x=-18.33 mm. The measurement results were extracted from volume scan 2.

A.5 Results of the Validation Metric E_n

The validation metric E_n was derived for all validation points on the eleven observation lines according to Equation 1 (where U_{simu} and U_{meas} are uncertainties ($k = 2$) of the simulated and measured H-fields, H_{simu} and H_{meas}, respectively) [6]. The results are provided in Figures 11 and 12. The uncertainties of the DUT model and the measurement, which were used to derive E_n, are listed in Tables 8 and 9. The uncertainty budget of the DUT model was assessed in accordance with [5], while the measurement uncertainty is from the manual of DASY6 Module WPT [7]. As all E_n are smaller than 1, the numerical charger model was successfully validated.

$$E_n = \sqrt{\frac{(H_{simu} - H_{meas})^2}{(H_{simu} \times U_{simu})^2 + (H_{meas} \times U_{meas})^2}} \quad (1)$$

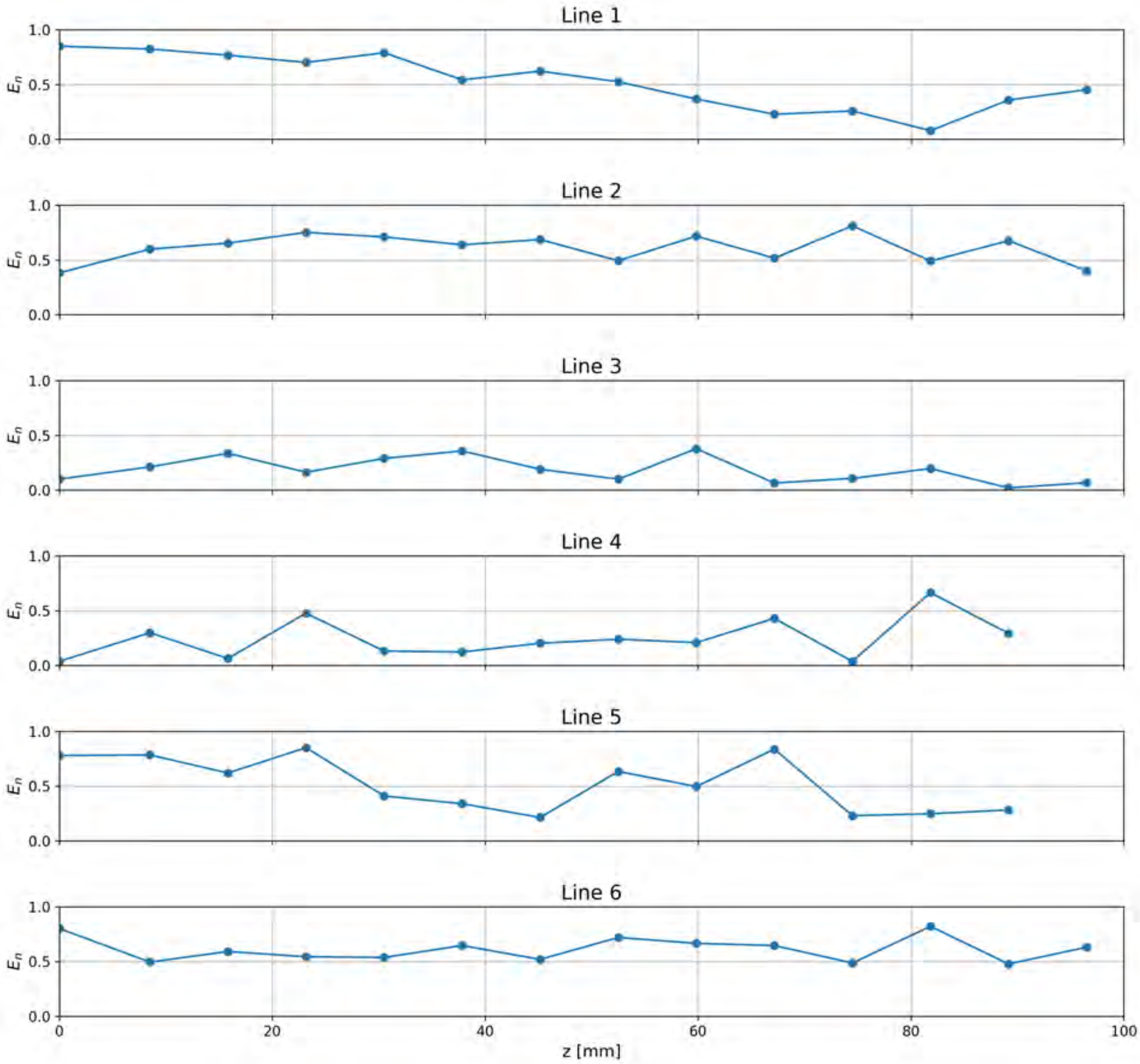


Figure 11: Results of the validation metric E_n derived based on volume scan 1. The six vertical observation lines pass through anchor points A1–A6 respectively. Note that E_n at z=0 mm were derived with the measurement uncertainty of 1.33 dB (since H-fields at z=0 mm were determined with the surface field reconstruction in Module WPT), while E_n at all other locations were derived with the measurement uncertainty of 1.19 dB.

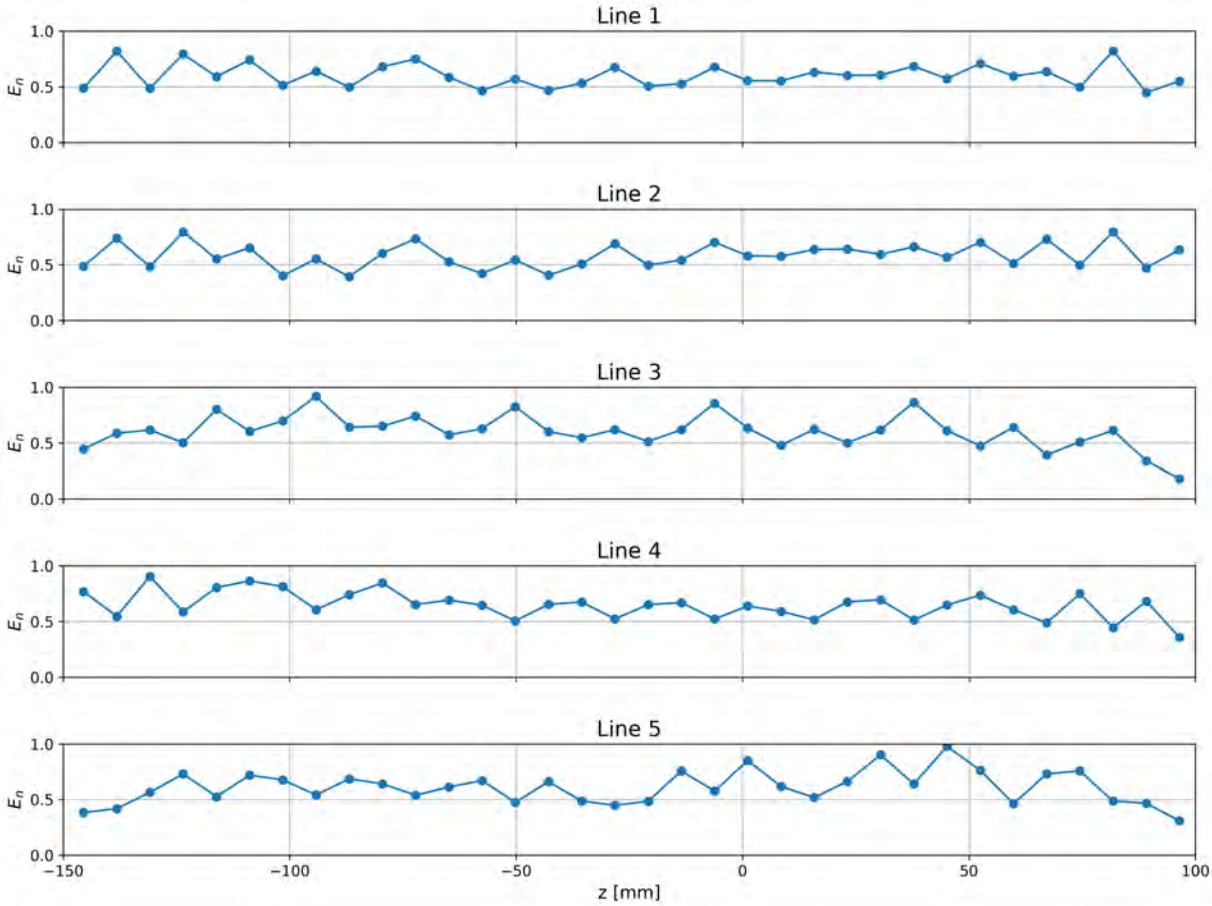


Figure 12: Results of the validation metric E_n derived based on volume scan 2. The five vertical observation lines pass through validation points B1–B5 respectively. All E_n were derived with the measurement uncertainty of 1.19 dB.

Table 8: Uncertainty budget of the DUT model

Unc. component	Unc. [dB]	Probability distribution	Divisor	c_i	Std. unc. [dB]
Grid resolution	N.A.	Normal	1	1	N.A.
Location of evaluation points	0.14	Rectangular	$\sqrt{3}$	1	0.08
Convergence	N.A.	Rectangular	$\sqrt{3}$	1	N.A.
Power budget	N.A.	Normal	1	1	N.A.
Boundary conditions	N.A.	Rectangular	$\sqrt{3}$	1	N.A.
Quasistatic approximation	0.10	Rectangular	$\sqrt{3}$	1	0.06
Model parts and geometry	0.00	Rectangular	$\sqrt{3}$	1	0.00
Dielectric parameters	0.00	Rectangular	$\sqrt{3}$	1	0.00
Ferrite parameters	0.00	Rectangular	$\sqrt{3}$	1	0.00
Exposure sources other than coils	0.00	Normal	1	1	0.00
Coil current	0.26	Rectangular	$\sqrt{3}$	1	0.15
Coil positioning	0.28	Rectangular	$\sqrt{3}$	1	0.16
Combined std. uncertainty [dB]					0.24
Expanded uncertainty ($k = 2$) [dB]					0.48

Table 9: Uncertainty budget for the measurement values for the model validation

Unc. component	Unc. [dB]	Probability distribution	Divisor	c_i	Std. unc. [dB]
Measured field values (probe spec.)	1.19	Normal	2	1	0.59
Surface field reconstruction	0.30	Normal	1	1	0.30
Combined std. uncertainty [dB]					0.67
Expanded uncertainty ($k = 2$) [dB]					1.33

B Validation Test Certificate

Test Laboratory of IT'IS Foundation
Zeughausstrasse 43, 8004 Zurich, Switzerland

TEST CERTIFICATE

Test Item	SetPoint Wireless Charger
Test Item ID	(specified by customer)
Client	SetPoint Medical, Rachel Wylde, rwylde@setpointmedical.com
Test Protocol	Evaluation of EM fields of test items under near- and far-field conditions with DASY
Test Frequency	Close to 130 kHz
Test Date	February 1, 2024
Certificate No.	DASY2024061901
Issue Date	August 9, 2024

Calibrated Equipment	ID /#	Last Calibration	Next Calibration
MAGPy-8H3D+E3D V2	3065	April 2023	April 2024

Validation Item	S/N	Validation Date	Validation Result
V-Coil50/400 V2	1013	1 Feb 2024	PASS

Software	Version
DASY6 Module WPT	V2.2

Comments
-

	Name	Function	Initials
Test Performed By	Jingtian Xi	Test Engineer	**MAX**
Certificate Approved By	Tolga Goren	Technical Manager	**TG**

This test report documents testing in accordance with IEC/IEEE 63184. Results relate only to the items tested. This test certificate shall not be reproduced except in full without Laboratory approval.

Description of Standard Test Method

The procedure, "Evaluation of electromagnetic (EM) fields of test items under near- and far-field conditions", describes the measurement and evaluation of electromagnetic fields generated by any type of EM source in very close near to far-field conditions. The measurement results are assessed and reported in quantities such as:

- incident vector E-field (Einc) distributions (peak, point, surface or volume);
- incident vector H-field (Hinc) distributions (peak, point, surface or volume);
- incident power flux density distributions with respect to any evaluation surface up to 200 mm: sPDn+, sPDtot+, sPDmod+ (peak, surface);

and are specified with respect to the coordinate system of the device under test (DUT).

The accurate measurement of EM fields from a source, in its environment and at a given measurement distance, involves:

- classification of field as near- (radiating / reactive) or far-field, based on frequency, measurement distance and DUT size;
- determination of field quantities to be measured (E, H, or combination) based on field classification;
- determination of measurement conditions, based on the source and its use environment: inside lab, outdoors, or any special measurement conditions;
- selection of the measurement system: DASY8 Module WPT, mmWave, R&D, HAC or others, with associated probes and data acquisition electronics;
- test setup and measurement of the relevant field quantities with the selected measurement system;
- post-processing of the measurements results to derive the desired output field metric;
- evaluation of measurement uncertainty, considering various contributing factors based on DUT, measurement system, post processing, reflections by the environment, etc.

Devices emitting electromagnetic fields in the frequency range from 3 kHz to 110 GHz can be measured using this test procedure. The test results are valid for the tested scenario (DUT configuration in terms of power level / frequency, communication mode/modulation, measurement / evaluation plane location, and environment). A comprehensive evaluation of a device would require repeated application of this procedure for all relevant frequencies, modulations, embedded transmitters, antennae, and phantoms, in order to encompass all possible test scenarios.

The confidence interval (uncertainty) of the measurement is evaluated according to the GUM and ASME V&V guidelines, considering all uncertainty components detailed in the relevant standards such as DUT factors (power stability, etc.); environmental factors (reflections, noise, temperature, etc.); measurement system factors; repeatability or type A evaluations.

Quality of test results is ensured through system check / verification in accordance with the requirements of the normative and protocol references. The system check procedure consists of complete measurement of the relevant field quantity (E-Field, H-Field or sPD) for calibrated verification sources or other sources with numerical target values. The measured results are compared to targets with confidence intervals defined in the normative standards.

Normative, Protocol and Validation References

- IEC/IEEE 63184 CDV 2023: Assessment methods of the human exposure to electric and magnetic fields from wireless power transfer systems – Models, instrumentation, measurement and numerical methods and procedures (frequency range of 1 kHz to 30 MHz)
- DASY8/6 Module WPT V2.2 System Handbook
- Application note: "Testing compliance of WPT devices by simulations: best practice", https://speag.swiss/downloads/dasy/appnotes/

Specific Comments on Test Method

The validation measurement consists of two volume scans as shown in Figure 1.

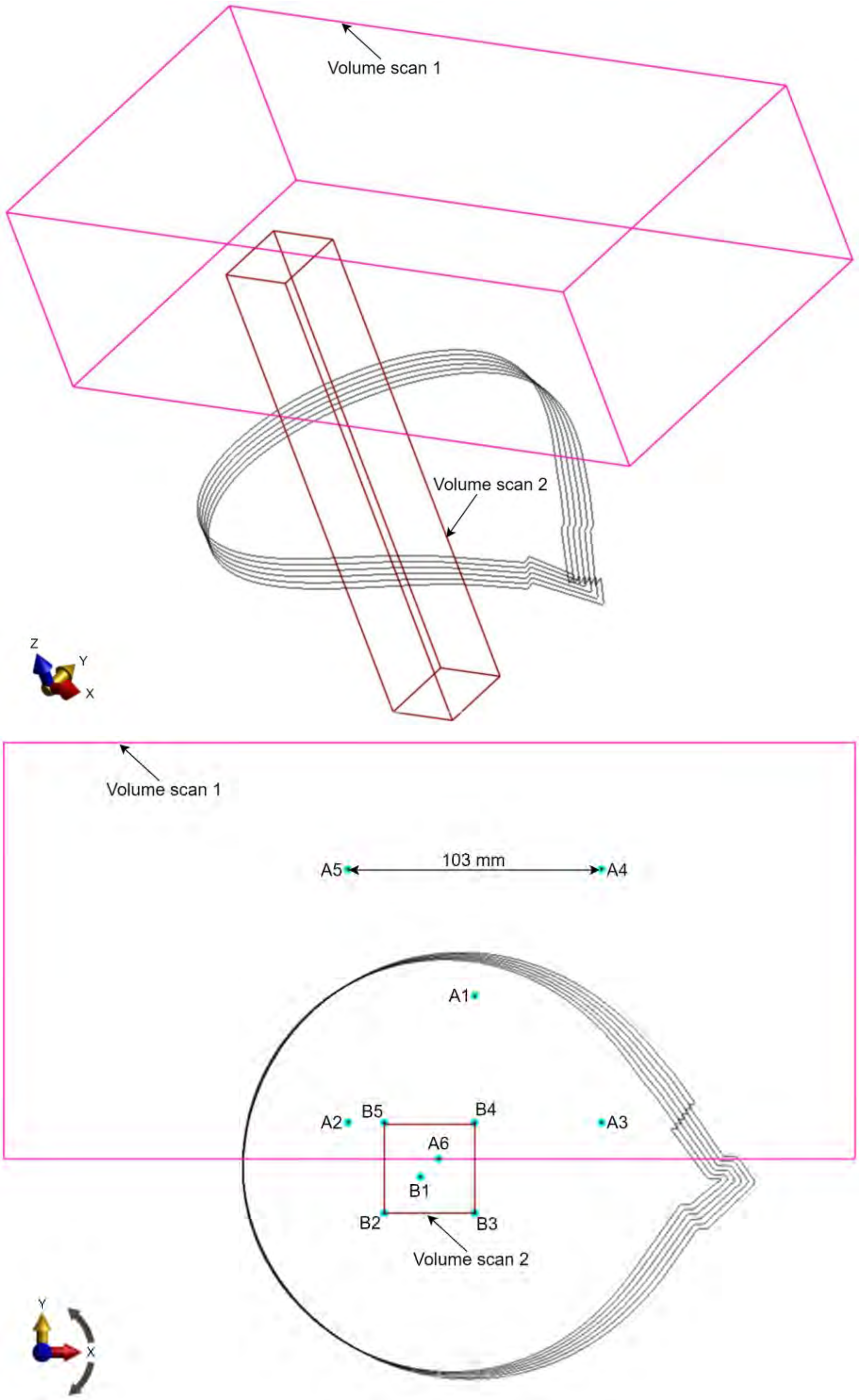


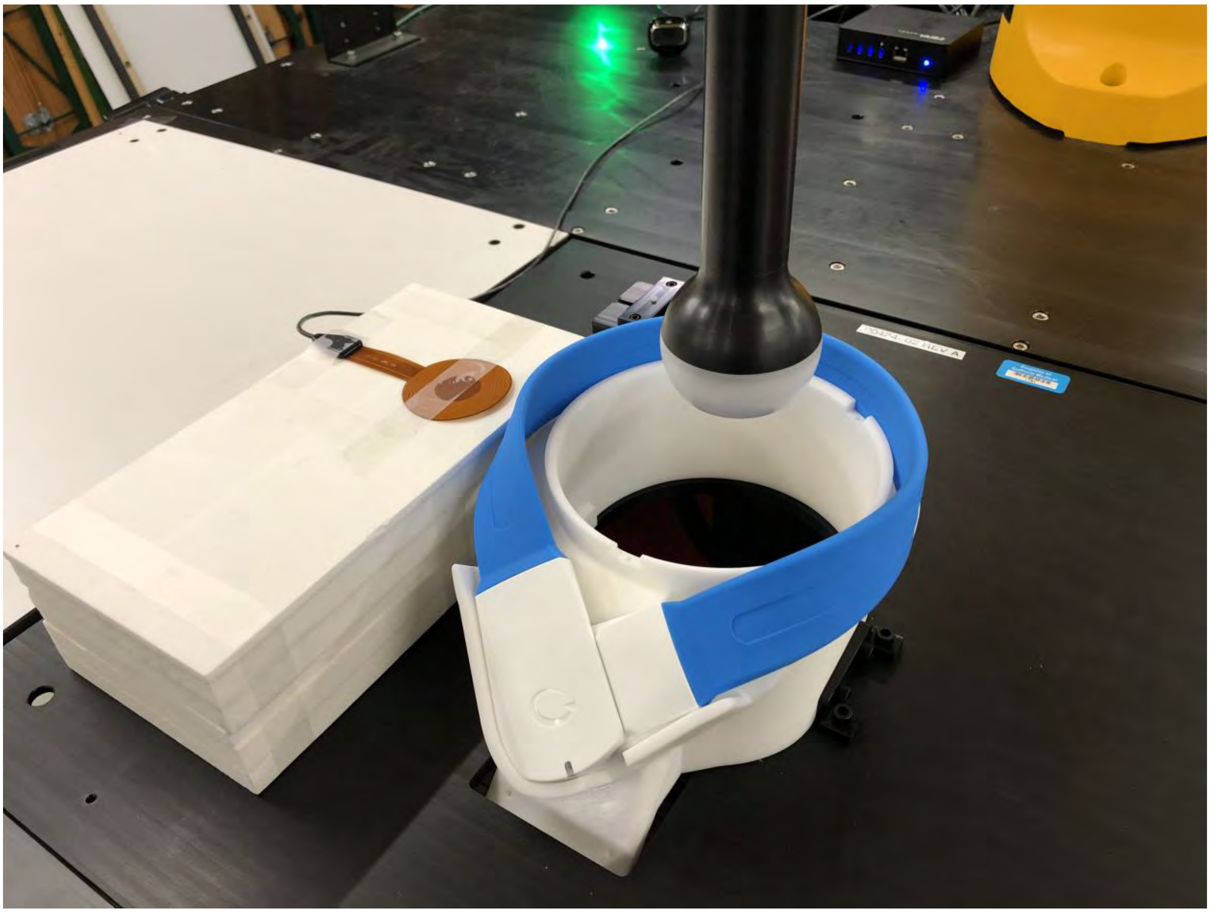
Figure 1: Volumes scanned to record the H-field (perspective view at the top) and anchor points for defining the vertical observation lines and the validation points (top view at the bottom)

The first scan covers a volume with dimensions of 345×169×96.5 mm^3 on top of the coil. The lowest measurement plane of the first scan is at z=0 mm (which is less than 2 mm above the top edge of the charger encapsulation). The second scan covers a volume with dimensions of 36.7×36.7×242 mm^3 through the coil. The lowest measurement plane of the second scan is at z=-145.5 mm. The volume scans were made with a uniform step of 7.33 mm. A set of validation points were selected according to the guidelines in the application note. First, a few anchor points at the horizontal plane z=0 were selected. For the first volume scan, point A1 indicates the location of the maximum H-field at the horizontal plane z=0, while A2–A5 are points surrounding A1 with offsets approximately corresponding to half of the mean radius of the coil. The extra validation point A6 basically corresponds to the origin of the coordinate system (with a half-step offset along x and y axes). For the second volume scan where the field distributions at horizontal planes are relatively uniform, a point within the volume (i.e., B1) and the four corner points (i.e., B2–B5) were selected. Second, eleven vertical observation lines were defined based on the anchor points (i.e., A1–A6 and B1–B5). Each observation line passes through a specific anchor point and travels through the height of the corresponding volume. There are in total 254 validation points distributed uniformly along the eleven observation lines. For validation purpose, the simulated and measured total H-fields at the validation points were compared.

Test Item

SetPoint Medical engineers were on-site for all of the tests performed, and were responsible for control of the test items (wireless charger and supporting equipment).

Test Photo



System Check

A system check of the measurement system DASY6 Module WPT V2.2 was made with the V&V source V-Coil50/400 V2 before the DUT model validation measurement. The system check consists of a volume scan covering a volume with dimensions of 125×125×36.7 mm^3 on top of the source. The volume scan was made with a uniform step of 7.33 mm.

	H_{inc}	$psSAR_{1g}$	$psSAR_{10g}$
Deviation [dB]	-1.20	-0.70	-0.52
Uncertainty [dB]	1.41	1.34	1.32

Table 1: Results of the system check presented in terms of the deviations between the measured peak incident H-field, and peak 1 gram and 10 gram mass-averaged SAR, and their numerical target values. The associated uncertainties (*k = 2*) are also provided.

Results

Representative H-field distributions are shown below. The confidence interval of the measured field values is derived from the probe specifications and DASY Handbook to be 1.19 dB (*k=2*).

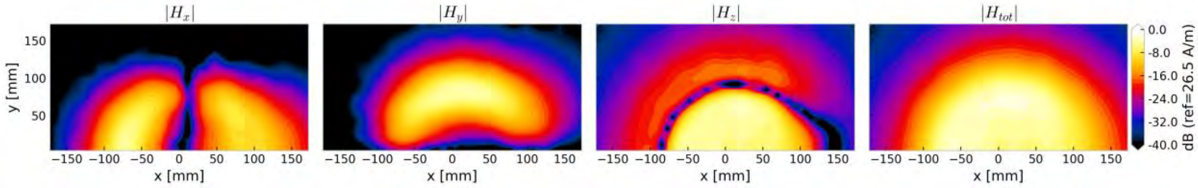


Figure 2: Measured H-field distributions at the horizontal plane z=0 mm. The measurement results were extracted from volume scan 1.

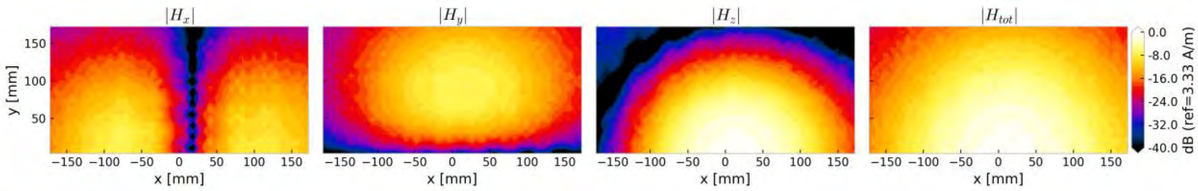


Figure 3: Measured H-field distributions at the horizontal plane z=96.5 mm. The measurement results were extracted from volume scan 1.

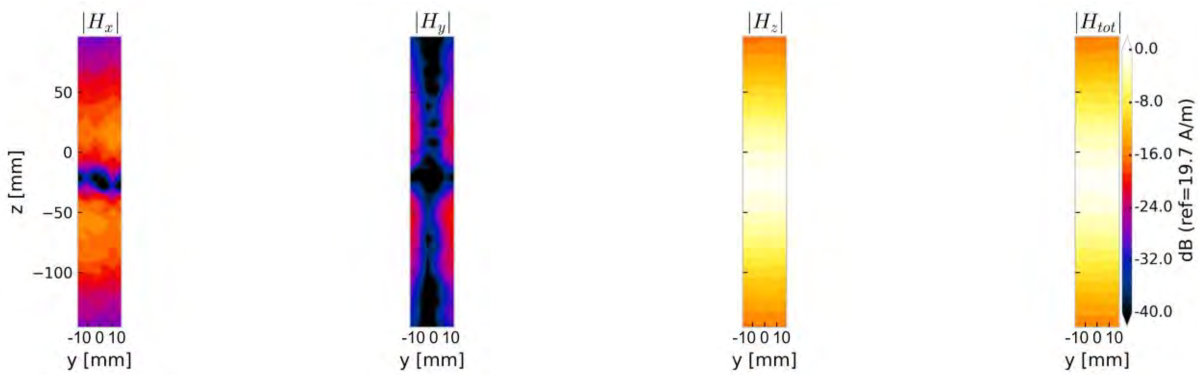


Figure 4: Measured H-field distributions at the vertical plane x=-18.33 mm. The measurement results were extracted from volume scan 2.

C About Us

Z43 (www.z43.swiss)

Zurich43 (Z43) is a strategic alliance composed of four partner organizations: the nonprofit Foundation for Research on Information Technologies in Society (IT'IS) and three commercial SMEs – Schmid and Partner Engineering AG (SPEAG), ZMT Zurich MedTech AG (ZMT) and TI Solutions AG (TI Solutions). Z43's dedicated mission is to expand the boundaries of (i) accurate evaluation of electromagnetic (EM) near- and far-fields from static to optical frequencies and (ii) predictive modeling in validated anatomical and physiological environments for precision medicine. Z43 is a leading global player that collaborates with over 100 R&D centers and serves more than 500 customers worldwide. In addition, Z43 maintains two ISO17025 accredited laboratories to better serve its research partners and customers, i.e., the SPEAG Calibration Laboratory and the IT'IS Test Laboratory (formal accreditation expected in 3Q24).

IT'IS – Foundation for Research on Information Technologies in Society (www.itis.swiss)

The IT'IS Foundation was established in 1999 through the initiative and with the support of the Federal Institute of Technology (ETH) Zurich and the global wireless communications industry, together with several governmental agencies. IT'IS is the leading independent nonprofit research institute dedicated to improving the quality of people's lives by advancing personalized medicine and computational life sciences and beneficial applications of EM energy and wireless communications (EM Research). IT'IS supports the R&D efforts of the alliance members, as well as its many academic and industrial partners, to advance precompetitive and non-competitive research initiatives; and offers a variety of customized research solutions to the wireless and medical device industries, to academic and national institutions, and to governments and regulatory bodies. IT'IS is very active in numerous standards, including IEC 62209, 62232, 62704, 63195, and 63184 (wireless transmitting devices), and IEC 60601-2-33, ISO 10974, and ASTM F2182 (magnetic resonance systems and implant safety).

SPEAG – Schmid & Partner Engineering AG (www.speag.swiss)

SPEAG was founded in 1994 to develop and manufacture EM systems and components as a spin-off of the ETH Zurich's Bioelectromagnetics/EM Compatibility research group (which later became the IT'IS Foundation). SPEAG is the leading developer and manufacturer of advanced, efficient, and reliable test equipment for the evaluation of the EM near- and far-fields at frequencies from a few kHz up to 110 GHz. SPEAG's key products are: DASY8 – specific absorption rate (SAR) measurements for safety compliance; cSAR3D – fast SAR testing; ICEy – automated near-field scanning for EM interference and compatibility (EMI/EMC); MAGPy – exposure assessments below 10 MHz; DAK – dielectric measurement systems; EM Phantoms – body simulators for radiofrequency (RF) testing; and SEMCAD X – RF performance modeling of devices used in and on the human body.

ZMT – ZMT Zurich MedTech AG (www.zmt.swiss)

ZMT was founded in 2006 as a spin-off company of ETH Zurich and the IT'IS Foundation, with the mission to develop innovative and validated simulation tools and best practices for the analysis and prediction of complex, multifaceted, and dynamic biological processes and interactions. ZMT's flagship product is Sim4Life, a state-of-the-art simulation platform that combines computable human phantoms with powerful physics solvers and the most advanced tissue models. Sim4Life is used to analyze real-world biological phenomena and complex technical medical devices and therapies in validated computational biological and anatomical environments. ZMT also provides fully characterized and ISO17025-calibrated measurement systems for model generation, verification, and validation of *in silico*-based evaluations.

TI Solutions – TI Solutions AG (www.temporalinterference.com)

TI Solutions is a young start-up developing highly flexible stimulation devices and planning tools to support investigations of non-invasive temporal interference stimulation of brain and peripheral nervous system activity. The long-term goal is to enable personalized treatments by providing the most advanced stimulation devices.

IT'IS Test Laboratory (www.itis.swiss/customized-research/)

The IT'IS Test Laboratory performs accurate electromagnetic near-field evaluations. Its scope is to (i) design, validate and perform electromagnetic and temperature measurements in free space and in lossy media, (ii) characterize test items and materials relating to such measurements, and (iii) provide service assistance in the areas of testing and verification. The primary applications are in areas of wireless and medical devices in which product standards have not been established yet. ISO 17025 calibrated probes, verified test equipment, and validated methodologies are utilized to ensure quality and traceability of tests. In 2022, the IT'IS Laboratory formally applied to the Swiss Accreditation Service for ISO 17025 Type C accreditation with the main objective to develop new robust and validated test procedures which extend the scope and methodology beyond what is addressed by current norms or technical specifications and to work with the relevant standards organizations and national regulators to introduce these techniques into the next generation of standards and national regulations. Formal accreditation is expected in 3Q24.

SPEAG Calibration Laboratory (https://speag.swiss/services/cal-lab/accreditation/)

To better serve Z43 partners and customers, SPEAG established a calibration Laboratory in 2001 that is certified by the Swiss Accreditation Service for ISO/IEC 17025 Accreditation and multilaterally recognized by EA, IFA, and ILAC. The laboratory provides extensive calibration services to the entire Z43 family for systems, probes, antennas, dielectric probe kits, phantoms, materials, etc. A number of satellite facilities have been co-founded, such as the SPEAG Calibration Laboratory Korea, established in 2011 in collaboration with DYMSTEC, in order to bring calibration services closer to SPEAG's global customer base.

References

[1] Marie-Christine Gosselin, Esra Neufeld, Heidi Moser, Eveline Huber, Silvia Farcito, Livia Gerber, Maria Jedensjö, Isabel Hilber, Fabienne Di Gennaro, Bryn Lloyd, et al., "Development of a new generation of high-resolution anatomical models for medical device evaluation: the virtual population 3.0", *Physics in Medicine & Biology*, vol. 59, no. 18, pp. 5287, 2014.

[2] P. A. Hasgall, F. Di Gennaro, C. Baumgartner, E. Neufeld, B. Lloyd, M. C. Gosselin, D. Payne, A. Klingenböck, and N. Kuster, "IT'IS database for thermal and electromagnetic parameters of biological tissues, version 4.1", Available online: https://itis.swiss/virtual-population/tissue-properties/database/low-frequency-conductivity/ [accessed on May 31, 2024].

[3] United States Code of Federal Regulations (CFR), Title 47, Section 1.1310, "Radiofrequency radiation exposure limits", Available online: https://www.ecfr.gov/current/title-47/chapter-I/subchapter-A/part-1/subpart-I/section-1.1310 [accessed on May 31, 2024].

[4] International Commission on Non-Ionizing Radiation Protection, "Guidelines for limiting exposure to electromagnetic fields (100 kHz to 300 GHz)", *Health physics*, vol. 118, no. 5, pp. 483–524, 2020.

[5] SPEAG, "Testing compliance of WPT devices by simulations: best practice", Available online: https://speag.swiss/downloads/dasy/appnotes/ [accessed on May 31, 2024].

[6] IEC/IEEE 63184, "Assessment methods of the human exposure to electric and magnetic fields from wireless power transfer systems - models, instrumentation, measurement and numerical methods and procedures (frequency range of 1 kHz to 30 MHz)", CDV, 2023.

[7] SPEAG, "DASY8/6 Module WPT system handbook, incl. SW Module WPT 2.2", 2024.