Axonics Modulation Technologies		**Document Number: 106-0838-001**
	Document Type: Test Report	

Revision History

Rev	**Description of Changes**	**DCO #**
A	Initial Release.	05556

Table of Contents

1 PURPOSE

Purpose of this document is to show compliance of the Axonics Charging System to the RF exposure requirements pursuant to 47 CFR 2.1093 as agreed upon by FCC via a KDB inquiry.

2 SCOPE

Scope is limited to RF exposure assessment with respect to (a) **averaged SAR levels** and (b) **whole body SAR levels** and (c) **In-situ Electric field (E-field)** for Axonics Charging Device (CD, Model: 1401, FCC ID: 2AEEGD), a portable device.

3 PRODUCT DESCRIPTION

The Axonics Charging System is used to charge Axonics Implantable Pulse Generator (IPG). The IPG is for the treatment of overactive bladder syndrome. The Charging Device is portable body-worn electronic device, which transfers energy into the IPG re-chargeable battery at a frequency of 125 kHz.

The IPG is implanted in the upper buttocks area of the patient at a maximum depth of 3 cm. To charge the IPG, the patient places the Charging Device over the patient's skin in this area, allowing patient full control over charging process.

4 SUMMARY OF RESULTS

The SAR and E-field levels for the Axonics Charging System are summarized in Table 1.

Description	Tissue description	Result
1g SAR maximum	0.2 S/m average conductivity	0.057 W/kg
10g SAR maximum	0.2 S/m average conductivity	0.033 W/kg
Whole body SAR	0.2 S/m average conductivity	3.69e-04 W/kg
In-situ E-field maximum	0.082 S/m, nerve tissue	23 V/m RMS

Table 1. Summary of SAR and E-Field values. Tissue parameters are obtained from [1].

5 METHOD OF EXPOSURE ASSESSMENT.

For EM Simulation, Axonics used CST EM Studio Low Frequency (LF) Field solver from CST Computer Simulation Technology [2] (Release Version 2019.06). The 'full-wave' mode of the solver, with tetrahedral meshing, was selected. In this solver mode, the full set of time harmonic Maxwell's equations are solved without quasi-static simplification.

For geometrical accuracy, model components for the IPG and CD were imported from CAD files. Torso was modelled as a 30cmx30cmx60cm cuboid [1] with homogeneous material with 0.2 S/m [1] conductivity and a density of 985 kg/m^3. Both quantities represent body averages. It was confirmed that there is no significant dependence of computed value of SAR on relative permittivity in the range of tissue values.

For evaluation of in-situ E-field in excitable tissue, the permittivity is chosen to represent Nerve tissue.

	Dimensions	Density	Conductivity	Relative Permittivity
Torso	30cmx30cmx60cm	985 kg/m^3	0.2 S/m	50
Nerve	30cmx30cmx60cm	1038 kg/m^3	0.082 S/m	5016

Table 2. Torso configuration.

Models were solved to a residual error of 1e-6. The background material was modelled as air. The minimum separation from the model to simulation volume boundary is 15 cm. Increasing, this separation further, at the expense of computation time, was found to not have a significant effect on the result of the simulation. In order to keep emitted energy contained in computational volume, 'Electric Field' boundary conditions are employed.

6 VALIDATION

Four validations were conducted. (1) Validation of the CST LF solver algorithms for its intended use by evaluating an analytical model. (2) Validation of EM model by measuring H-field in close vicinity of transmitter (3) Validation of transmitter coil construction by determining its inductance, and finally (4) Validation of receiver coil construction by determining its inductance. All four validations demonstrated good agreement with simulation results.

7 DISCUSSION OF RESULTS

7.1 1g and 10g SAR.

The following plots shows a section of SAR distribution in the tissue space between the CD and the IPG.

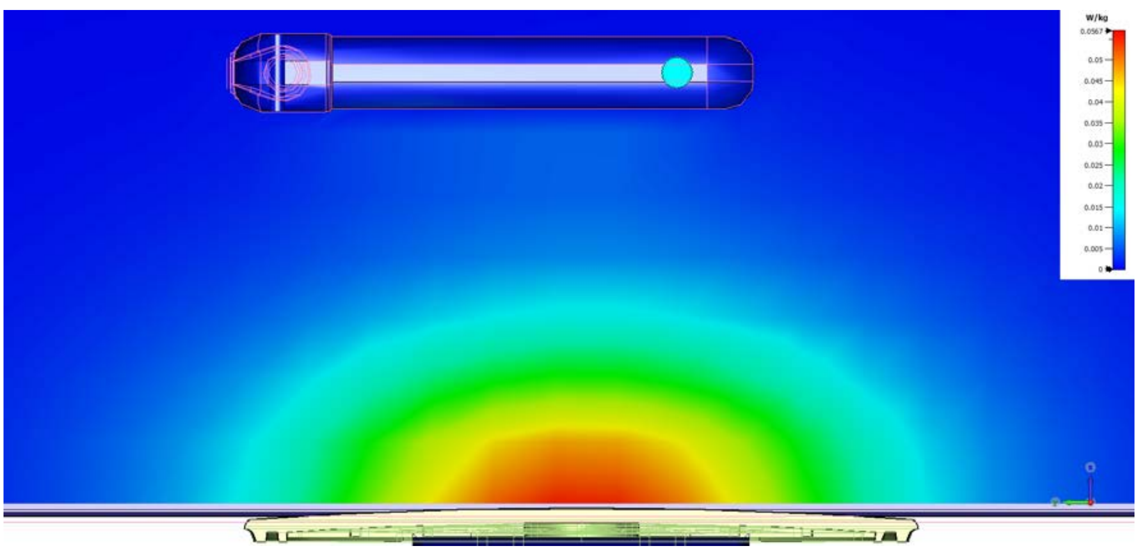

Fig 7a. SAR (1g) distribution in tissue of 0.2 S/m conductivity.

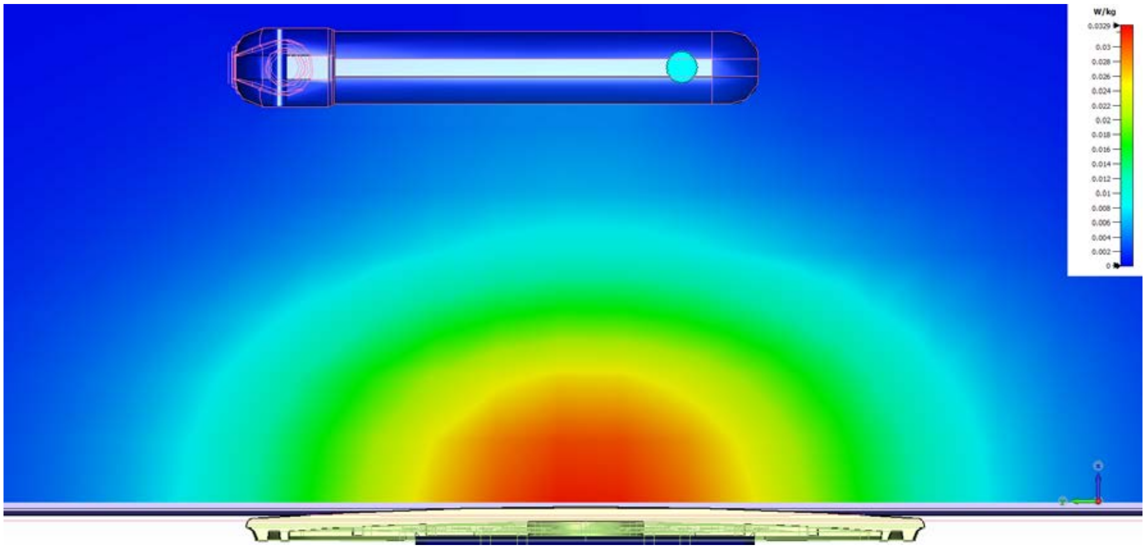

Fig 7b. SAR (10g) distribution in tissue of 0.2 S/m conductivity.

Item #	Type of SAR	Maximum SAR value
1	1g. Average.	0.057 **W/kg**
2	10g. Average.	0.033 **W/kg**
3	Whole Body SAR	3.69e-04 **W/kg**

Table 3. Summary of SAR values.

7.2 In-Situ Electric Field Strength

In-Situ Electric Field maximum is determined for nerve tissue type. The homogenous cuboid torso model was set to these tissue properties and simulation performed.

Tissue type	Effective Conductivity(S/m)	Relative permittivity	In-Situ Electric Field Strength (point-maximum) (V/m)
Nerve	0.082	5016	23 V/m RMS

Table 4. Summary of In-Situ E-field values.

8 CONCLUSION

RF Exposure simulation results for Axonics Charging Device (CD, Model: 1401) are well below the limits in 47 CFR 2.1093.

9 REFERENCES.

[1] IEC 62369-1:2008. Evaluation of human exposure to electromagnetic fields from short range devices (SRDs) in various applications over the frequency range 0 GHz to 300 GHz.

[2] CST Studio Suite, Electromagnetic Simulation Solvers, https://www.3ds.com/products-services/simulia/products/cst-studio-suite/solvers/