CVRx IPG Model 2101 SAR Report

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1. Introduction

This SAR computation modeling is performed to show compliance to radio frequency exposure limits as defined in 47 CFR Part 1, section 1.1307 and in 47 CFR Part 2, section 2.1093. The usage of the equipment is uncontrolled, therefore the limit for partial-body SAR is 1.6 W/kg, as averaged over any 1 g cubical tissue volume. The whole-body limit for average SAR is 0.08 W/kg.

2. Scope

This report scope illustrates compliance as required in 47 CFR Part 95, section 95.603(f) for the CVRx IPG Model 2101 SAR Report.

3. Summary

The maximum SAR values were computed and listed in Table 1.

Whole-body average SAR	4.9e-5 W/kg
Partial-body maximum 1g average SAR	0.035 W/kg

Table 1 Computed SAR levels summary

4. Method and Simulation Parameters

XFdtd version 7.2.0.4, developed by Remcom, Inc. (1), was used for the simulations. The software uses the Finite Difference Time-Domain (FDTD) method for electromagnetic calculation, as described in (2).

4.1. Model and Material Details

A CAD model of the parts relevant to antenna operation of the implanted device was imported into XFdtd as shown in Figure 1. The device was situated within a biological flat phantom that was 445.788 mm long (in the y-direction), 297.192 mm wide (in the x-direction), and 150 mm in depth (z-direction), as shown in Figure 2. The dimensions of the flat phantom were set based on specifications as defined in section D.9.2 (Experimental Body Phantom) of (3).



Figure 1 Device CAD file as displayed in XFdtd

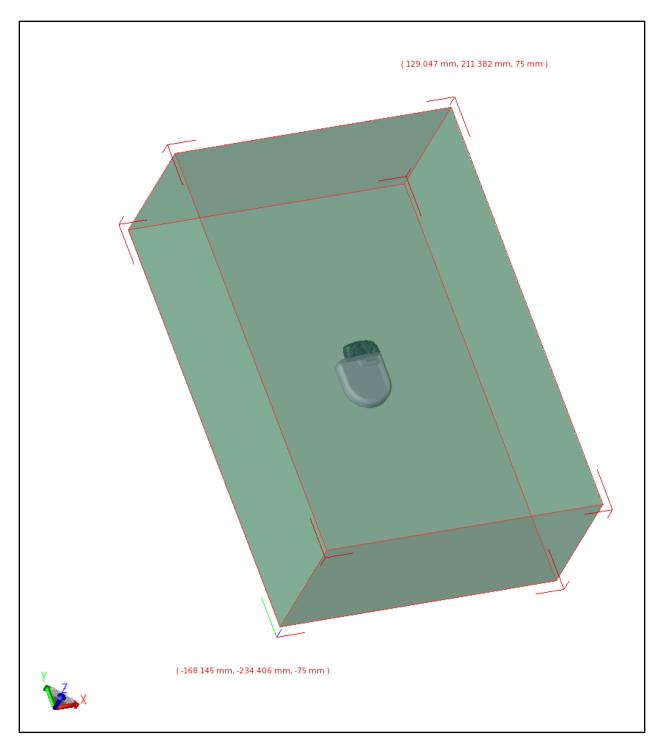


Figure 2 Device placed in flat phantom with XYZ coordinate axis shown

In order to provide a worst-case SAR analysis (with no losses in the conducting elements as would be seen in a real metal conductor), Perfect Electrical Conductor (PEC) was used on all conductive parts of the device. All dielectric materials were modeled as lossless. The flat phantom was modeled using electrical parameters as described in Appendix C of (4). Since the device is intended to be implanted into a human torso, the tissue dielectric properties for the

body were used. Since the chart in (4) lists properties for specified frequencies, a linear interpolation was performed to generate property values for the target frequency of 403.5 MHz. The dielectric material parameters used are listed in Table 2.

Material	Relative Permittivity	Conductivity	Density
PEC	0	Infinite	n/a
Header Dielectric	3.7	0	n/a
Flat Phantom	57.165	0.9338 S/m	1,000 kg/m^3

Table 2 Dielectric properties of materials used in the simulations

4.2. Gridding Parameters

The user must define the grid size according to limits determined by the highest frequency to be considered as well as the geometry of the object being simulated. At an operating frequency of 403.5 MHz, the largest cell size supported is 74 mm. This maximum size, however, was not used as it would not adequately resolve the geometry of the objects in the simulation. The maximum cell size used in this simulation was 2 mm. Since the software will support multiple cell sizes within a single project, a cell size of 0.35 mm was chosen for the cells comprising the device, and a finer cell size of 0.17 mm for the cells that make up the radiating element. Additionally, fixed points were used so that grid lines were placed along edges and other important parts of the geometry so that the size of the object was adequately represented by the cells.

The grid sizes used are summarized in Table 3. Figure 3 and Figure 4 show the grid lines of the front of the device. Figure 5 and Figure 6 show the grid lines of the side of the device.

Grid Region	Cell Size	Electrical Size (in freespace)
Base cell size	2 mm	0.00269*λ
Device cell size	0.35 mm	4.7297e-4*λ
Antenna cell size	0.17 mm	2.2973e-4*λ

Table 3 Summary of cell sizes used in the simulations

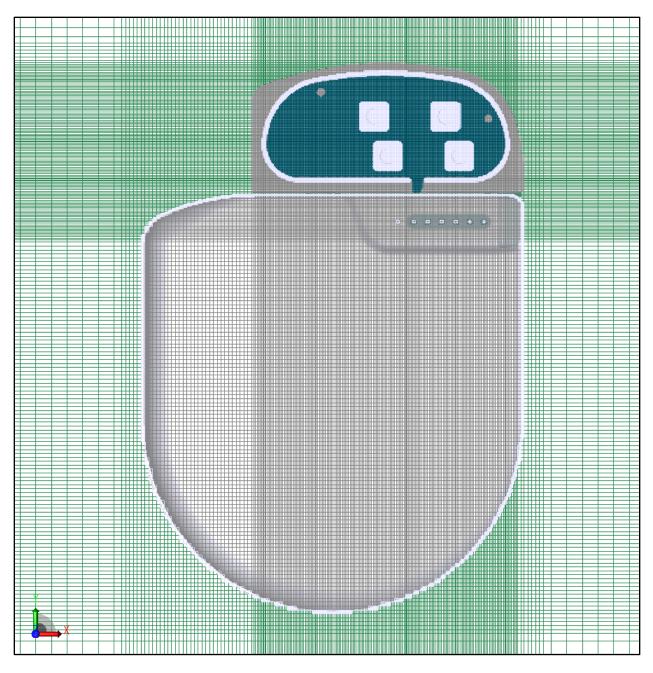


Figure 3 FDTD grid lines showing front of device

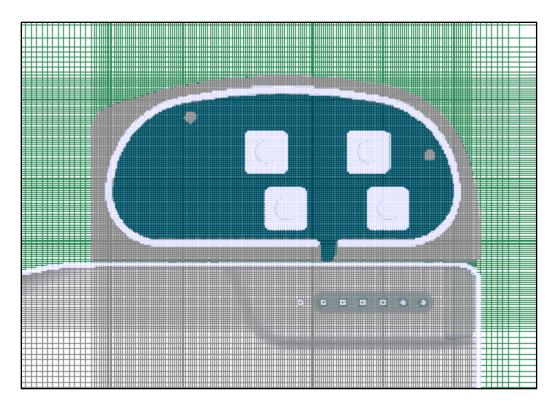


Figure 4 FDTD grid lines showing front of device, antenna closeup

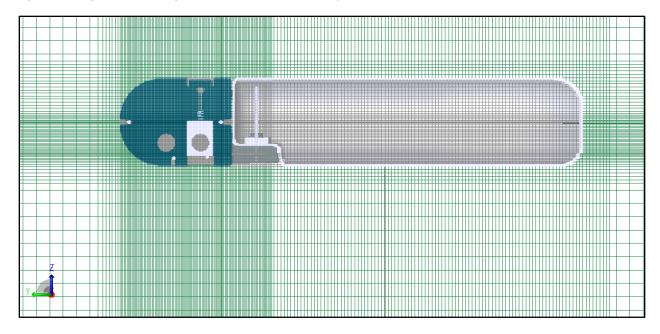


Figure 5 FDTD grid lines showing side of device

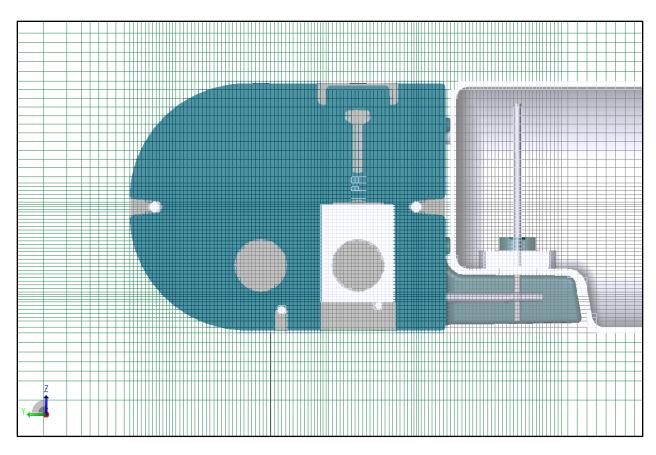


Figure 6 FDTD grid lines showing side of device, closeup of header

The base FDTD grid sizes listed above were chosen using experience and best practices for modeling such devices. The grid sizes chosen were validated by running additional simulations using sizes 0.5 and then 0.25 times the device cell sizes and verifying that the results remained the same to within a small tolerance.

4.3. Description of Simulated Device

The implantable medical device that was simulated is shown in Figure 1. The CAD model was used for the simulation and thus was representative of the device. All relevant parts of the device, including the casing, header, loop antenna, antenna leads, and other objects were included in the model.

4.4. Input Power and Source Excitation

In order to calculate the worst-case SAR values, the waveform used to excite the antenna was a 1 V peak-to-peak sinusoid (therefore 100% duty cycle) at 403.5 MHz. An initial simulation found the input impedance of the antenna (while in the device and embedded in the flat phantom material) to be $63 + j341.7 \,\Omega$. An impedance-matching network was then used to feed the device. The components comprising the voltage source and matching network were fed between the leads to the loop antenna, as shown in Figure 7. This matching circuit was used solely for the

purpose of ensuring that a meaningful amount of energy was introduced into the simulation space for later scaling. After the simulation was completed, the available power was scaled within the software to 1 mW (0 dBm), with the SAR values automatically scaled accordingly. This scaled power represents the maximum amount of power that could be delivered to the antenna assuming a perfect impedance match.

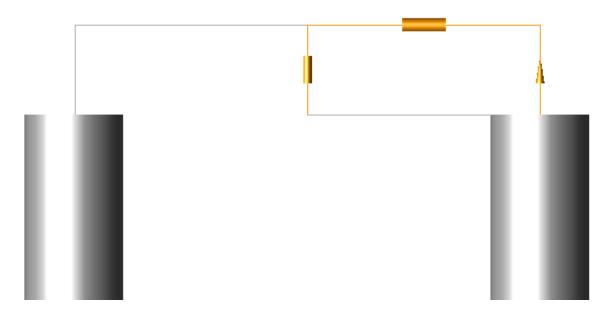


Figure 7 Voltage source (green cone) and matching network (green cylinders) used to feed the device

5. Wost-Case SAR Analysis / Results

The device was modeled in the middle of the frequency band since there was little expected difference between the upper and lower bounds. The software calculates whole body SAR and partial-body SAR using the method compliant with (3).

The worst-case average SAR values were calculated and found to be 4.9e-5 W/kg for whole-body averaged SAR and 0.035 W/kg for partial-body 1g averaged SAR, also shown in Table 1. This worst-case analysis neglects the effects of material losses, mismatch loss, and waveform duty cycle that will further reduce the final averaged SAR.

The SAR results at half and quarter of the initial device cell sizes showed agreement to within 3% - validating the modeling choices used in the initial simulation. The results of the individual simulations are summarized in Table 4. A graphical representation of the 1g SAR results scaled to a net input power of 0 dBm is presented in Figure 8.

Cell Size	1g Averaged SAR	Whole Body Average SAR
Full	0.034 W/kg	4.9e-5 W/kg
Half	0.034 W/kg	4.9e-5 W/kg
Quarter	0.035 W/kg	4.9e-5 W/kg

Table 4 Summary of SAR results

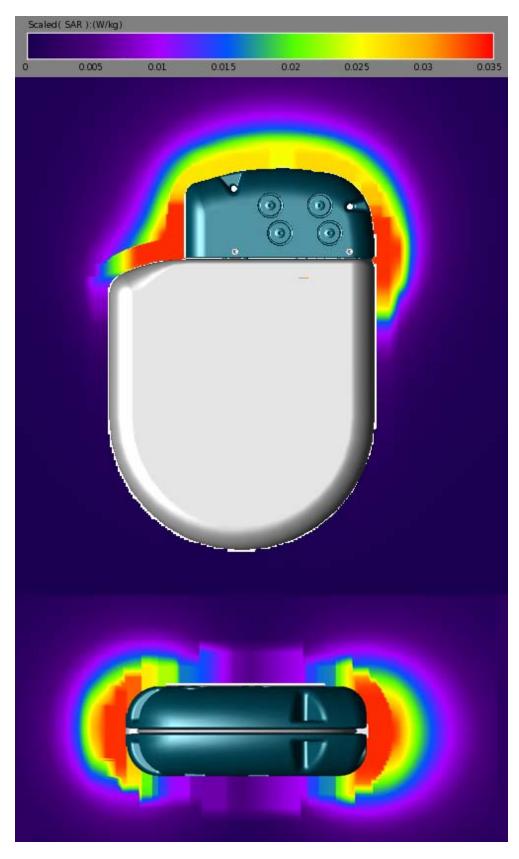


Figure 8 Graphical Display of 1g Averaged SAR Results

6. Compliance

The results shown in Section 5 are below the limit for whole-body SAR and partial-body SAR.

7. OET 65C

These sections will satisfy the OET 65C document (4). Information will be provided either in the section or referenced elsewhere in the document.

7.1. Computational Resources

System Specifications						
Processors:	(2) Intel Xeon 5660					
GPU:	(4) NVIDIA Tesla C2070					
RAM:	24 GB					
Operating System:	CentOS 5.5 x86_64					
Simulation Specifications						
	Number of	RAM	Time Step	Time Steps to		
	Cells (MCells)	Required (GB)	Duration (us)	Convergence		
Device at Full Cell Size:	34.95	2.2	3.25152e-7	113,600		
Device at Half Cell Size:	111.83	6.6	1.62874e-7	225,600		
Device at Quarter Cell Size:	484.27	27.2	8.16885e-6	449,500		

Table 5 System and Simulation Computational Resources

7.2. FDTD Algorithm Implementation and Validation

See Section 4.

7.3. Computational Parameters

See Section 4.

7.4. Phantom Implementation and Validation

See Section 4.

7.5. Tissue Dielectric Parameters

See Section 4.

7.6. Transmitter Model Implementation and Validation

See Section 4.

7.7. Test Device Positioning

Device was positioned in the middle of the flat phantom.

7.8. Steady State Termination Procedures

The simulation was terminated when the software auto-convergence detector indicated at least - 40 dB of convergence.

7.9. Computing Peak SAR from Field Components

See Section 5.

7.10. One Gram Averaged SAR Procedures

See Section 5.

7.11. Total Computational Uncertainty

It is estimated that the total uncertainty is below 10%.

7.12. Test Results for Determining SAR Compliance

See Section 5.

8. References

- 1. Remcom, Inc. [Online] www.Remcom.com.
- 2. **Kunz, K. S. and Luebbers, R. J.** *The Finite Difference Time Domain Method for Electromagnetics.* New York: CRC Press, 1993.
- 3. Committee, P1528.1 Working Group of the IEEE/ICES/TC34/SC2. IEEE P1528.1™/D1.00 Draft Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Body from Wireless Communications Devices, 30 MHz 6 GHz: General Requirements for using the Finite Difference Time Domain. 2010. (16 December 2010 revision)
- 4. FCC OET Bulletin 65, supplement C.