Numerical SAR analysis of SQ-RX™ Pulse Generator Model 1010 from Cameron Health

1. Abstract

This document describes the results of numerical FDTD analysis to determine the maximum 1g average SAR exposure generated by the Cameron Health SQ-RX™ Pulse Generator, Model 1010, in fulfillment of 47 CFR 2.1093 (d)(2); "… spatial peak SAR not exceeding 1.6 W/kg as averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube)."

The peak 1g average SAR has been determined to have an upper bound of 3.9 mW/kg (1.9 mW/kg simulated plus 2.0 mW/kg of combined uncertainty with 99% confidence). This value is well below the 1.6W/kg limit for uncontrolled exposure [4].

2. Summary

The specific absorption rate (SAR) of biological tissue is an important factor in determining RF safety limits. For devices radiating near and within the human body, the SAR may be computed from the tissue conductivity, σ [1/Ω–m], tissue density, ρ [kg/m^3], and magnitude of the electric field, |E| [V/m].

$$SAR = \frac{\sigma |E|^2}{\rho} \qquad (1.1)$$

The resulting SAR is a function of the antenna and device shape and material composition. In addition, the biological tissues surrounding the device have a direct impact. Numerical tools have been used to compute the electric field in the presence of these complex structures and biological tissues.

3. Numerical analysis configuration

The SAR analysis was performed using Remcom's XFDTD Bio-Pro v6.4 on an Intel quad-core processor based personal computer with 4GB of RAM. The physical model of the SQ-RX pulse generator was created by directly importing CAD files provided by Cameron Health in ACIS format. Accurate simulation of the devices radiation characteristics requires careful assignment of material and source properties. The material properties of the device were assigned according to manufactures data sheets and web material database information (§7). The source properties assigned in XFDTD have been derived from lab measurements (§4), (§5).

4. Radio Impedance Measurement

The output impedance of the transmitter was measured using a Rohde & Schwartz ZVM network analyzer[1]. A full one port calibration was made before the measurement. Application software and hardware provided by Cameron Health allowed the implant to be put into a continuous transmit mode. The transmitter impedance was measured while transmitting (Tx) in test mode. The measured impedance is shown in the table below.

Frequency = 403.5 MHz	re(Z)	im(Z)
	51.08	-69.30

Table 1 - Transmitter impedance measurement.

5. Radio Power Measurement

The transmitter output power was measured to be **-11.89 dBm** over a 1.5MHz bandwidth using a Rohde & Schwartz FSP spectrum analyzer[2]. The measurement was made using 300 kHz resolution bandwidth, 1 MHz video bandwidth and 5 mS sweep time. Trace 1 was used to monitor the peak of the signal while trace 2 was used to detect the peak of the time varying

[1] Rohde & Schwartz ZVM network analyzer with full one-port calibration. Uncertainty of reflection measurements = 0.6 dB or 4^o

[2] Rohde & Schwartz FSP spectrum analyzer. Max deviation of level measurement <0.2 dB (σ=0.07 dB)

signal using the max hold feature. Note that trace 2 was used to compute the total transmitter power and represents the maximum transmit power envelope.

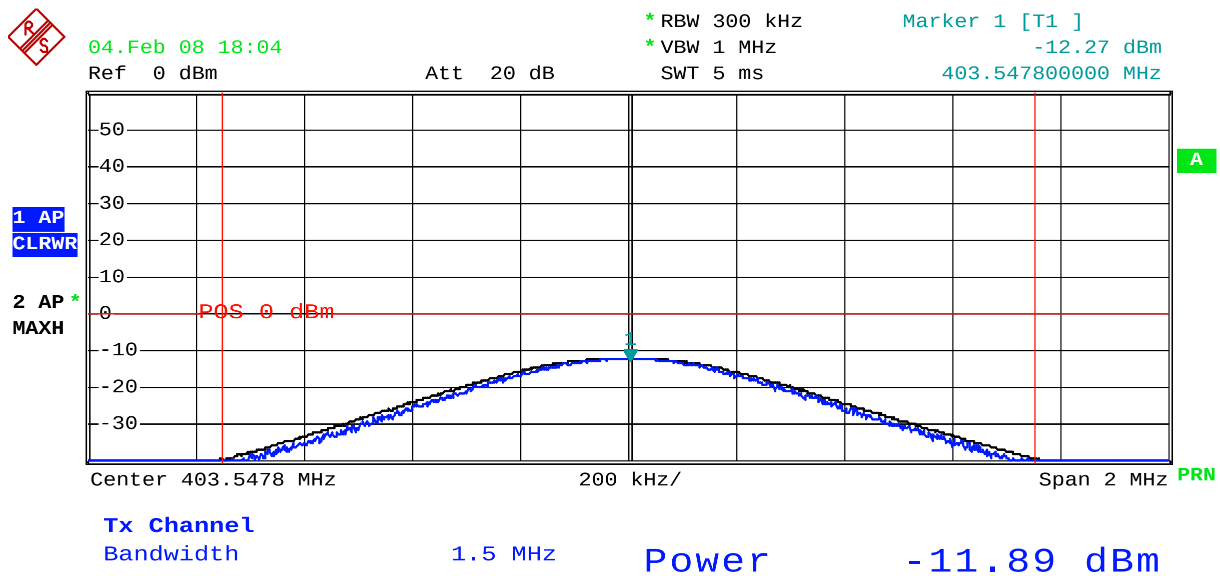


Figure 1 - Measured transmitter power

The measured output power of the transmitter was then used to compute the source amplitude in the FDTD simulation as described in the following section.

6. Transmitter equivalent circuit calculation

FDTD simulation requires the transmitter source to be modeled as an equivalent circuit. The Thevenin equivalent is shown below

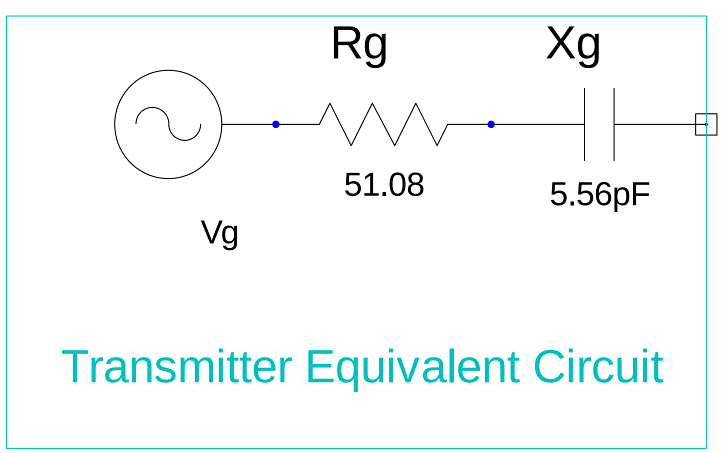


Figure 2 -Transmitter Thevenin equivalent circuit.

where the Thevenin impedance of the generator, Z_g, was measured with the network analyzer. The measured impedance,

$$Z_g = R_g - j\,X_g \tag{1.2}$$

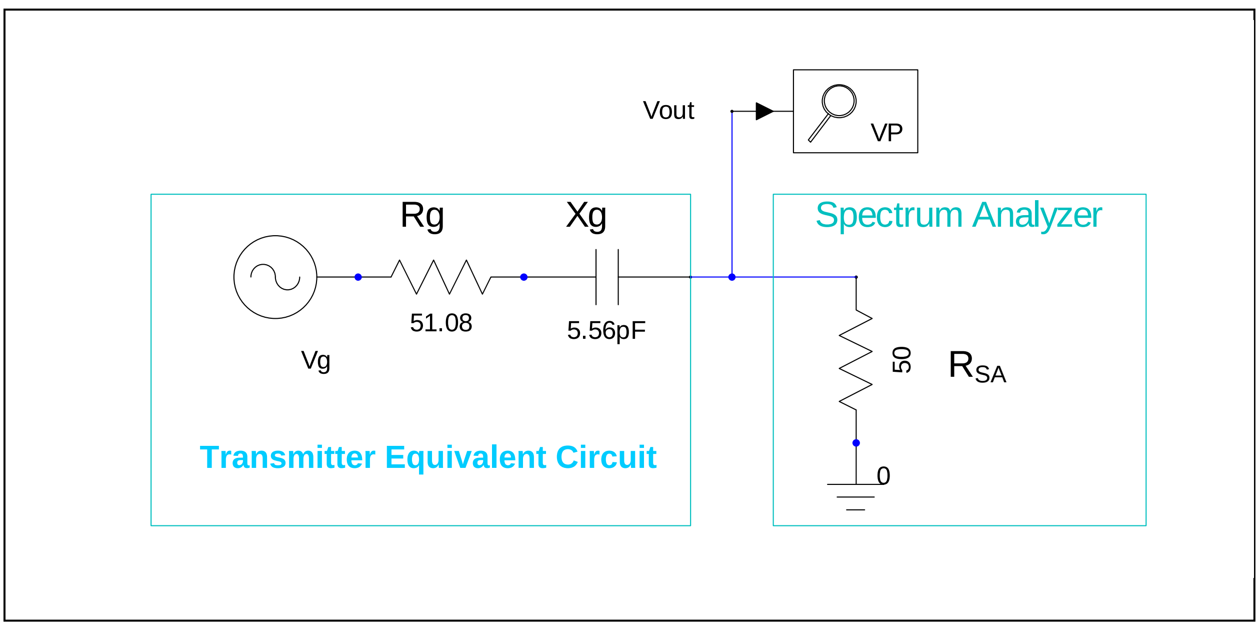
with

$$X_g = \frac{1}{\omega C} \tag{1.3}$$

has been used to calculate the capacitance value at the measurement frequency, viz.,

$$C = \frac{1}{\omega X_g} = \frac{1}{2\pi\,(403.5MHz)\,X_g} = 5.59\,\text{pF} \tag{1.4}$$

The value of the Thevenin circuit voltage was determined from the transmitter power measurement. The spectrum analyzer measures power delivered to a 50 Ω load when



connected to the output of the SQ-RX pulse generator as shown in the schematic below.

Figure 3 - Transmitter power measurement.

The common current in this circuit has been used to compute the generator voltage from the measured output power, viz.,

$$I = \frac{V_{out}}{R_{SA}} = \frac{V_g}{(R_g + R_{SA}) - jX_g} \tag{1.5}$$

$$P_{out,rms} = I^2 R_{SA} = \left[\frac{V_{g,rms}}{(R_g + R_{SA}) - jX_g}\right]^2 R_{SA} \tag{1.6}$$

$$V_{g,rms} = \sqrt{\frac{P_{out,rms}}{R_{SA}}}\left[(R_g + R_{SA}) - jX_g\right] \tag{1.7}$$

The magnitude of the generator RMS voltage is then found to be

$$\left|V_{g,rms}\right| = \sqrt{\frac{P_{out,rms}}{R_{SA}}}\sqrt{\left[(R_g + R_{SA})^2 + X_g^2\right]} \tag{1.8}$$

Finally, the generator peak voltage is obtained as

$$\left|V_{g,p}\right| = \sqrt{2}\left|V_{g,rms}\right| \tag{1.9}$$

The steps used to calculate the generator peak voltage from the measured RMS output power, resistance and capacitance are summarized in the table below. These values were used in the XFDTD simulation to define the source.

Frequency	403.5	MHz
R_{SA}	50	Ω

R	X_g	C	$P_{out,rms}$ [dBm]	$P_{out,rms}$ [Watts]	$V_{g,rms}$ (Eqn 1.8)	$V_{g,p}$ (Eqn 1.9)
51.08	-69.30	5.59 pF	-11.89	6.47E-05	0.1394	0.1972

The power delivered or "accepted" by the antenna may be computed using the Thevenin equivalent circuit developed above and the simulated antenna impedance, Z_A. The power accepted by the antenna is important because it represents the maximum power which may be radiated. As a result, the accepted power is used in the FDTD simulation to normalize the excitation and yield the correct SAR values.

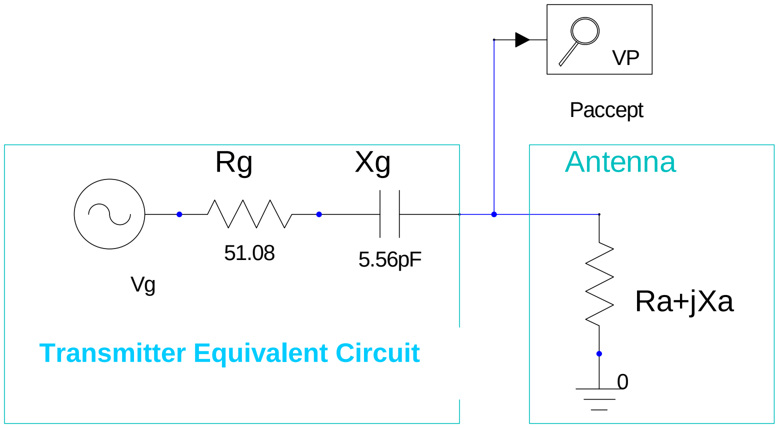


Figure 4 - Circuit for determining power accepted by the antenna.

The accepted power has been computed using the common current and the simulated antenna

$$P_{accept,rms} = \frac{1}{2}\frac{R_A\left|V_{g,peak}\right|^2}{\left(R_g+R_A\right)^2+\left(X_g+X_A\right)^2} \qquad (1.10)$$

impedance. The difference between the computed and simulated accepted power is summarized in the table below.

	Computed antenna impedance*, Z_A	$P_{accept,rms}$ Calculated (Eqn 1.10)	$P_{accept,rms}$ Simulated w/ biological losses	% Change
Coarse Grid	6.59 + j 102.3 Ω	28.92 μW	29.46 μW	1.87
Medium Grid	5.65 + j 89.89 Ω	30.17 μW	30.60 μW	1.44
Fine Grid	5.57 + j 87.33 Ω	30.64 μW	31.05 μW	1.33

***computed antenna impedance is presented in (§9)**

Table 2 - Computed vs. simulated accepted power values.

The difference between computed and simulated accepted power has been attributed to the loss in the tissue and header dielectric surrounding the antenna resulting in more power delivered from the generator.

7. Implant Model Materials

As described above, the implant geometry was directly imported from ACIS based models. The materials for each part were provided by Cameron Health as shown in the following table.

Object	Material
SQ-RX housing	TITANIUM
Antenna	PLATINUM WIRE
Header cover	THERMEDICS TECOTHANE

Table 3 – SQ-RX material assignment.

The electrical properties of the materials above were collected from data sheets and web resources. The table below summarizes the values used in the simulation.

Material Name	Permittivity	Conductivity [S/m]
TITANIUM, .0100" ±.0005" THICK, GRADE 1 PER ASTM F67	1.0	2.34×10^6
PLATINUM WIRE .025" [0.635mm]	1.0	2.21×10^6
THERMEDICS TECOTHANE TT-1075D-M, CLEAR	~3.1 – 4.4*	~0.000 - 0.006*

* Permittivity = 3.4 and Conductivity = 0.00 were used in the simulations. For worst case analysis see §10.

Reference: http://www.allmeasures.com/

Table 4 - Material properties.

8. Muscle Box Model

The biological tissue used in the FDTD simulation was taken to be homogenous muscle with material properties defined at 403.5MHz. The frequency dependent nature of the biological tissue is sufficiently constant over the frequency of interest to allow for a steady-state sinusoidal analysis. In addition, a box of muscle tissue is used in lieu of a detailed anatomical model to reduce modeling complexity and run time. Muscle tissue is chosen as it provides the highest conductivity to density ratio of the materials presented and thus represents a worst case scenario in which to compute the SAR. It is expected that simulations of an anatomical model

Size	10 x 10 x 5 cm
Material @ 403.5 MHz	
Permittivity	57.94
Conductivity	0.82 S/m
Density	1040 kg/m^3

Source: **http://www.fcc.gov/cgi-bin/dielec.sh**

Table 5 - Biological material properties.

comprised of multiple tissue properties with lower conductivity to density ratios will result in lower computed peak 1g average SAR values.

9. Simulation setup and results

Three FDTD simulations were performed to determine the impact of mesh resolution. In all three cases adaptive meshing (3:1) was performed over the spatial extent (xyz) of the wires composing the antenna and its' feed structure. The use of an adaptive mesh allowed for at least two cells to represent the wire cross-section in the coarse grid. Absorbing boundary conditions (Berenger PML w/ 7 cells) were used in all cases. The number of allowed time steps was increased to 40,000 so as not to terminate the simulation before the convergence criteria was met.

	Coarse Grid	Medium Grid	Fine Grid
Time Step	641.9 fS	449.4 fS	321.0 fS
No. Time Steps	24,126 (converg. = -34.36 dB)	23,435 (converg. = -34.48 dB)	32,811 (converg. = -31.97 dB)
Run time	3hrs, 12m, 0s	6hrs, 13m, 9s	17hrs, 32m, 50s
Max Cell Size	[1.00,1.00,1.00] [mm]	[0.70,0.70,0.70] [mm]	[0.50,0.50,0.50] [mm]
Min Cell Size	[0.33,0.33,0.33] [mm]	[0.23,0.23,0.23] [mm]	[0.17,0.17,0.17] [mm]
Grid Size	168 x 183 x 105 cells 139.96 x 139.94 x 90.08 mm	221 x 242 x 131 cells 128.12 x 128.18 x 77.69 mm	292 x 321 x 166 cells 119.96 x 119.94 x 70.02 mm
Boundary Cond's	PML for all boundaries (7 cells)		
Est. Memory	231.37 MB	418.11 MB	796.65 MB

Table 6 - FDTD simulation configurations.

Upon completion of the simulation, the 1g average SAR was computed in a post-processing step. As discussed previously, the antenna accepted power has been computed by XFDTD and used for normalization of the SAR statistics. The output of this process for the computed accepted power and for an accepted power of 1W is presented in the table below.

	Coarse Grid		Medium Grid		Fine Grid	
Power Norm	1 W	29.46 μW	1 W	30.60 μW	1 W	31.05 μW
Peak SAR	698.37 W/kg	20.57 mW/kg	1085.3 W/kg	33.21 mW/kg	1076.1 W/kg	33.41 mW/kg
Peak SAR loc	[44,55,44]		[95,61,45]		[68,85,61]	
Peak 1g SAR	63.12 W/kg	1.86 mW/kg	54.91 W/kg	1.68 mW/kg	55.70 W/kg	1.73 mW/kg
Peak 1g SAR Loc	[41,63,38]		[50,79,45]		[63,101,54]	
Port Imped	6.56 + j 102.29		5.65 + j 89.89		5.57 + j 87.33	

Table 7 – FDTD SAR calculation results.

As can be seen in the table, the effect of increasing the resolution has a slight impact on the antenna impedance and the peak 1g averaged SAR. These variations are used in the final section to compute a 99% combined confidence interval. As further verification of the table above, screen shots from the tool are presented in the next figures.

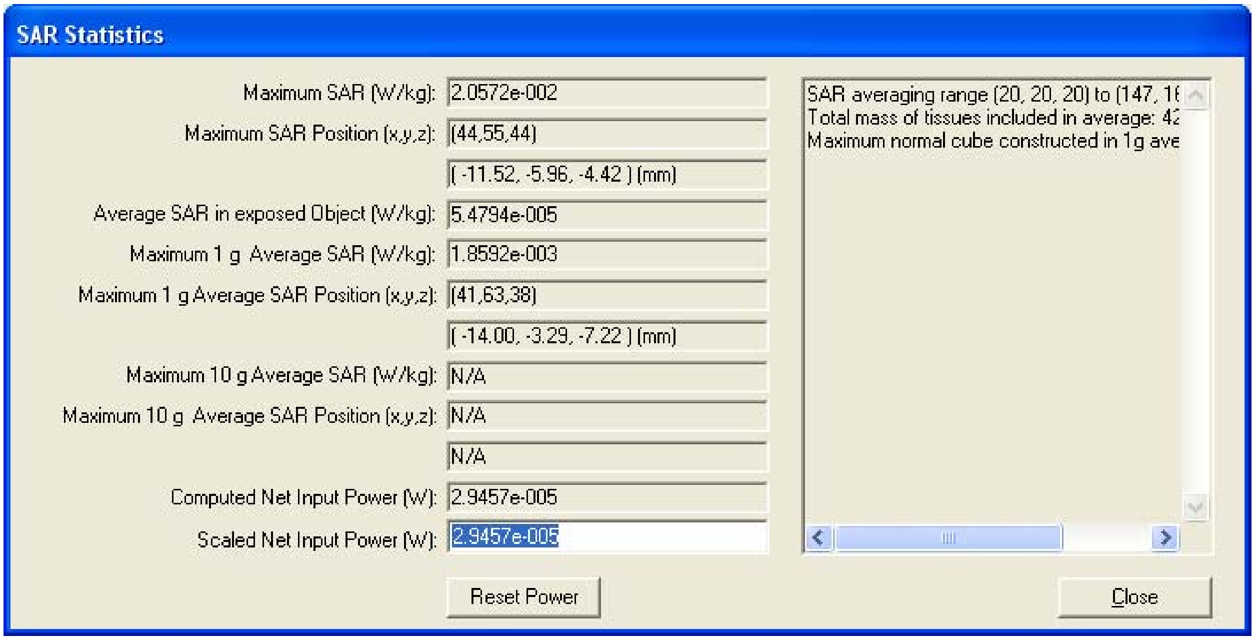


Figure 5 - Coarse grid FDTD simulation output.

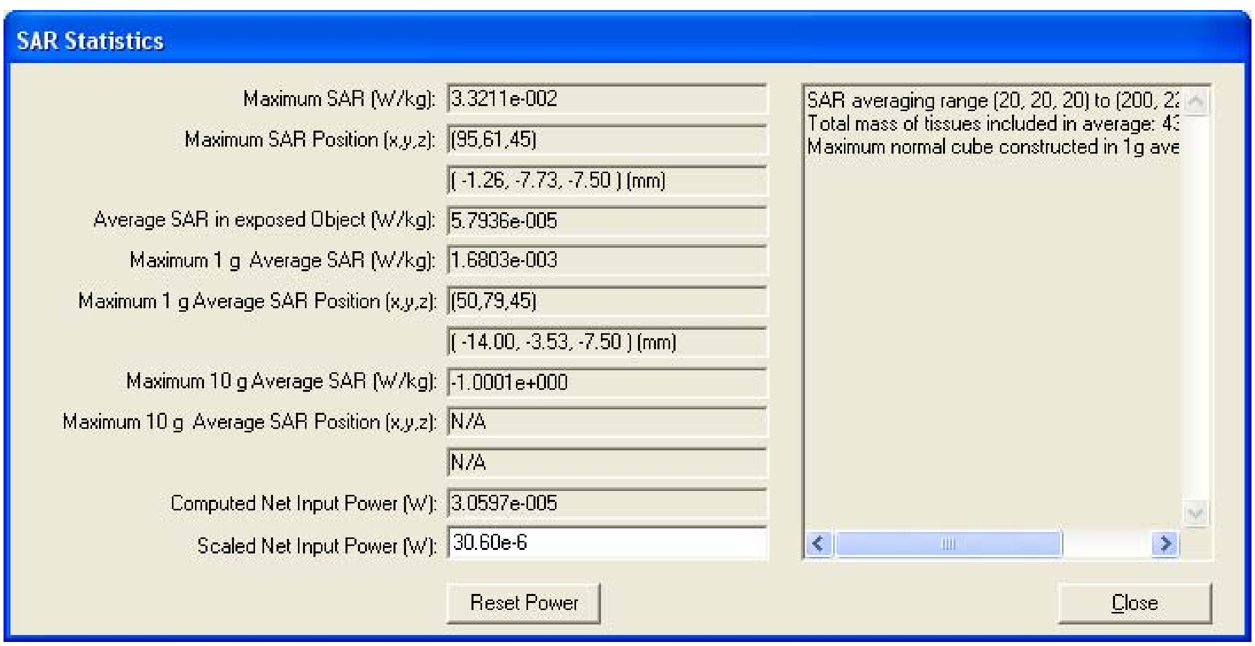


Figure 6 - Medium grid FDTD simulation output.

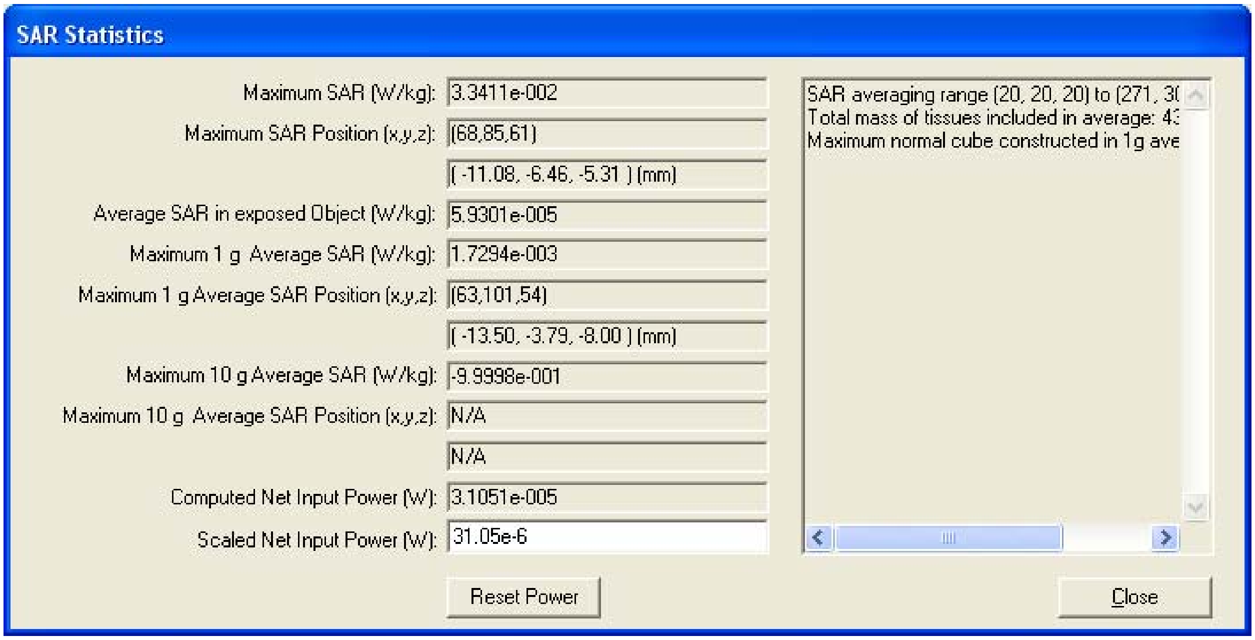


Figure 7 - Fine grid FDTD simulation output.

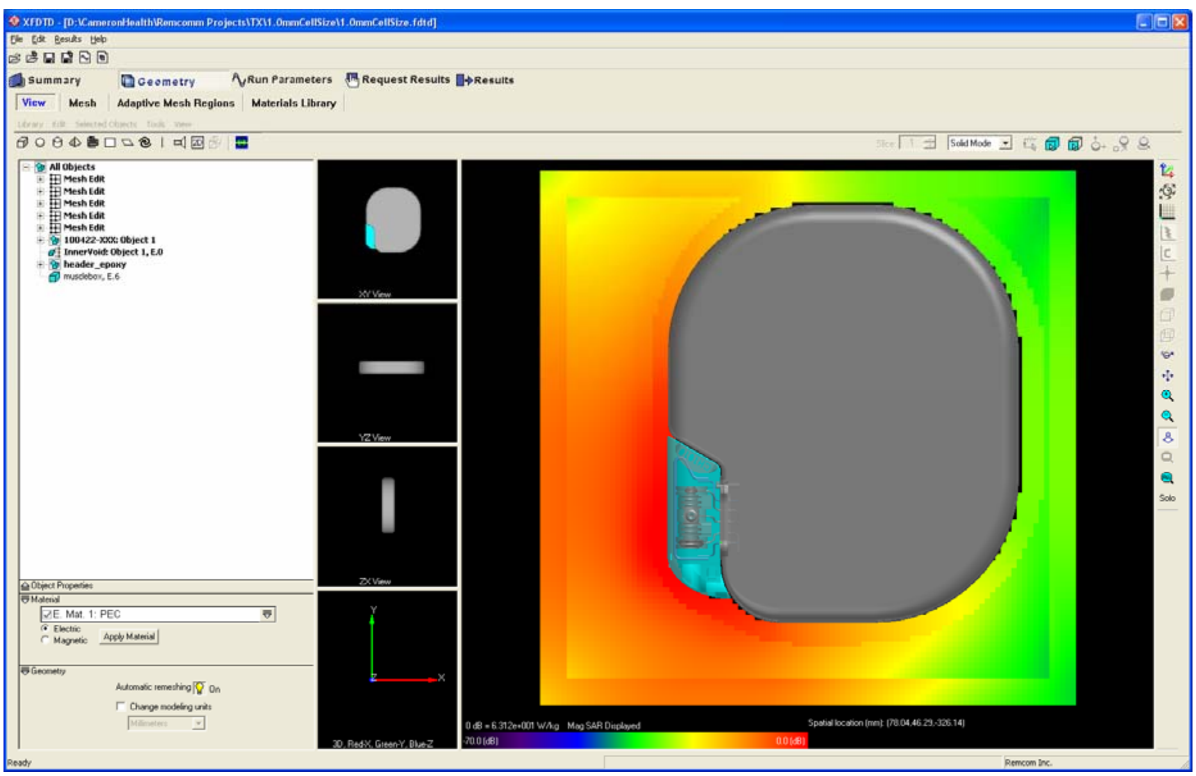


Figure 8 - Coarse grid FDTD SAR xy-plane plot

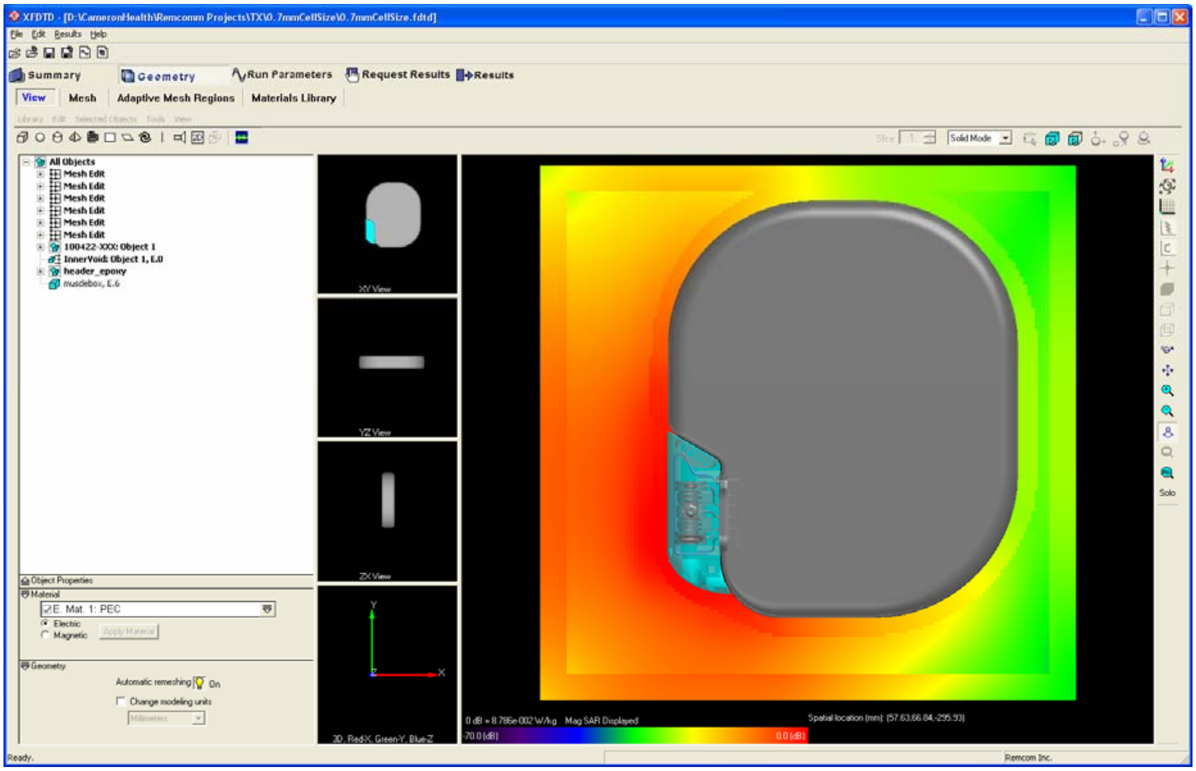


Figure 9 - Medium grid FDTD SAR xy-plane plot

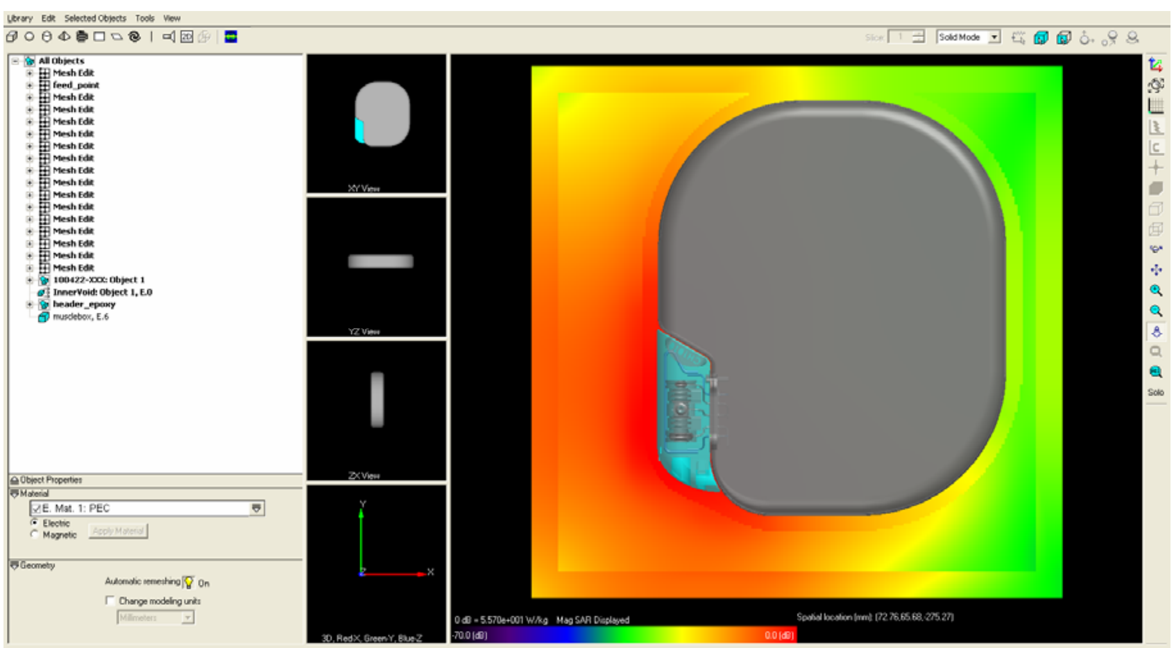


Figure 10 - Fine grid FDTD SAR xy-plane plot

10. Quantification of dielectric material variance

The material used to enclose the antenna, Tecothane, has been defined by a range of permittivity and conductivity values. The uncertainty caused by this range of values has been estimated through additional simulations. The 1g average SAR value was computed at each extreme of the specified range; resulting in an additional four simulations of the coarse grid for computational speed. The results of these simulations are presented in the table below.

Coarse Simulation: Permittivity and conductivity study

	ε_r = 3.06 σ = 0.000		ε_r = 4.40 σ = 0.000		ε_r = 3.06 σ = 0.006		ε_r = 4.40 σ = 0.006	
Power Norm	1 W	25.87 μW	1 W	30.21 μW	1 W	38.87 μW	1 W	41.92 μW
Peak SAR	682.54 W/kg	17.66 mW/kg	1027.7 W/kg	31.05 mW/kg	411.18 W/kg	15.98 mW/kg	672.6 W/kg	28.19 mW/kg
Peak SAR loc	[44,54,448]		[44,55,44]		[44,55,44]		[44,55,44]	
Peak 1g SAR	64.70 W/kg	1.67 mW/kg	84.92 W/kg	2.57 mW/kg	38.9 W/kg	1.51 mW/kg	55.6 W/kg	2.33 mW/kg
Peak 1g SAR Loc	[41,63,38]		[41,63,38]		[41,63,38]		[41,63,38]	
Port Imped	5.23 + j 98.27		8.97 + j 117.13		8.58 + j 97.59		13.42 + j 115.98	

Table 8 - Dielectric variation analysis

Variation of the permittivity and conductivity has an impact on the antenna port impedance and thus the accepted power. The resulting peak 1 gram average SAR values have been used to estimate the uncertainty in the (§12).

Peak 1g SAR mW/kg		σ	
	ε_r	0.000	0.006
	3.06	**1.67**	**1.51**
	4.4	**2.57**	**2.33**

Table 9 – SAR vs. header material properties

11. Device usage and transmit duty factor

The MICS portion of the SQ-RX is intended solely for use in the physician's office or operating room. It will only operate in receive mode until awaken by a coded message from an outside transceiver. As a result, the device will not transmit the majority of its lifetime. In addition, the device uses a half-duplex communication protocol which limits the approximate transmit duty factor to 60%. The effect of duty factor has not been accounted for in this analysis; thus representing the worst case scenario.

12. Uncertainty budget

Numerous simulations with varying parameters have introduced uncertainty into the expected SAR exposure of this device. The uncertainty caused by each of the simulation variables examined as well as a combined standard uncertainty have been calculated following the methods outlined in [7].

Source of uncertainty	Eval Meth	a_+	a_-	a	K	Standard uncertainty u_i=ka (99%) [linear]
Power accepted	§4.6 (B)	31.05 μW	29.46 μW	30.26 μW*	$1/\sqrt{3}$	0.09 mW/kg
Simulation resolution (cell size)	§4.6 (B)	1.86 mW/kg	1.68 mW/kg	1.77 mW/kg*	$1/\sqrt{3}$	1.02 mW/kg
Dielectric permittivity	§4.6 (B)	2.57 mW/kg	1.67 mW/kg	2.12 mW/kg*	$1/\sqrt{3}$	1.22 mW/kg
Dielectric loss	§4.6 (B)	2.33 mW/kg	1.51 mW/kg	1.92 mW/kg*	$1/\sqrt{3}$	1.11 mW/kg
Combined standard uncertainty:					u_c	1.94 mW/kg

* $a = (a_+ + a_-) / 2$

Table 10 - Component and combined uncertainty.

The worst case scenario would be to for the SAR value to lie at the highest extreme of this uncertainty interval resulting in a total of 3.9 mW/kg (a maximum of 1.9 mW/kg simulated plus 2.0 mW/kg of combined uncertainty with 99% confidence). This value is well below the 1.6W/kg limit for uncontrolled exposure [4].

13. References:

1. “Spectrum Analyzer R&S FSP Specification”, version 1, Rohde & Schwarz, May 2001.
2. “Vector Network Analyzers ZVM, ZVK Specification”, Rohde & Schwarz.
3. 47 CFR 95.603 (f) – “…Medical implant transmitters (as defined in appendix 1 to subpart E of part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §§1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. ...”
4. 47 CFR 2.1093 (d)(2) – “Limits for General Population/Uncontrolled exposure: 0.08 W/kg as averaged over the whole-body and spatial peak SAR not exceeding 1.6 W/kg as averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube).”
5. 47 CFR 2.1093 (d)(3) – “Compliance with SAR limits can be demonstrated by either laboratory measurement techniques or by computational modeling.”
6. FCC OET 65 Supplement C
7. B.N. Taylor, C.E. Kuyatt, NIST Technical Note 1297, “Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results” 1994 Edition