Letter	Revisions	Date	Approval
A	Original	13-11-2008	BPS
B	Correct doc. Number on pages 2 through 9	20-11-2008	BPS
C	Updated references to FCC regulations	21-01-2010	BPS
D	Updated SAR Results	22-02-2010	BPS
E	Deleted duty-cycle averaging from SAR analysis	02-03-2010	BPS

1 Purpose

The purpose of this report is to document the Specific Absorption Rate (SAR) computational analysis of the Biotronik Primus pacemaker.

2 Conclusion

The Primus pacemaker, employing an ultra-low power RF transmitter, complies with the SAR regulatory limits specified in 47 CFR 95.1221, §2.1093, and §1.1307(b)(2).

The Primus pacemaker's maximum worst-case SAR is **2.5218e-003 W/kg**, averaged over 1 gram of tissue. The regulatory limit specified in 47 CFR 2.1093 is **1.6 Watts/kg**, averaged over 1 gram of tissue. As such, the Primus pacemaker's SAR level complies with the FCC regulatory limit with a margin of **28 dB.**

3 Applicability

This report is applicable to the Primus family of pacemakers that use the same MedRadio RF transmitter circuitry and antenna structure noted in this report.

4 Document History

Ver. A	13-11-2008	Initial Release
Ver. B	20-11-2008	Corrected doc. Number on pages 2 through 9
Ver. C	21-01-2010	Updated per FCC correspondence
Ver. D	22-02-2010	Updated SAR Results
Ver. E	02-03-2010	Removed duty-cycle averaging from SAR analysis

5 References

47 CFR 95.1221	RF Exposure
47 CFR 2.1093	Radio Frequency Radiation Exposure Evaluation: Portable Devices
47 CFR 1.1310	Radio Frequency Radiation Exposure Limits.

6 Definitions

MedRadio	Medical Device Radiocommunication Service
Periodic Transmission	Infrequent RF signal transmission, on a periodic basis, from a transmitter to a receiver.
Max-Hold	Instrument display mode that indicates and displays the maximum detected signal level.
Conducted Measurements	Electrical measurements made using hardwire connections (not antennas) to the DUT
DUT	Device Under Test

7 Test Equipment

The following equipment was used to perform the tests outlined in this report.

ITEM	DESCRIPTION	MFGR.	MODEL	SERIAL NUMBER	CALIBRATION DATE	CALIBRATION DUE DATE
IMP	Implant module (Device Under Test)	Biotronik	Primus	06082200-03-D 358212	N/A	N/A
SA	RF Spectrum Analyzer	Rohde & Schwarz	FSL 616	100288	14-05-2008	31-05-2009
SENSOR	RF Power Meter Sensor	Agilent	8481A	MY41095529	16-05-2008	31-05-2009
PM	Power Meter/Freq Counter	Agilent	53147A	US40470964	16-05-2008	31-05-2009
NET	RF Network Analyzer	Agilent	8753ES	US39170321	28-07-2008	31-07-2009
CALKIT	3.5 mm Calibration Kit	Agilent	85033D	3423A04725	14-11-2005	14-11-2008
CABLES	RF Cables, 50 Ohm Coax with SMA connectors	Pasternack	Assorted	N/A	N/A	N/A

7.1 Photograph of the Primus pacemaker

Figures 7.1.1 and 7.1.2 are photos of the Biotronik Primus pacemaker. The loop antenna, embedded near the perimeter of the epoxy header, is evident in Figure 7.1.2.

Figure 7.1.1 Front view of the Primus Pacemaker.

Figure 7.1.2 Rear view of the Primus pacemaker.

8 Primus' Specific Absorption Rate (SAR) Analysis

Biotronik pacemakers utilize an ultra-low power RF transmitter to send a patient's cardiac medical condition to a physician for evaluation. The amount of radiated power absorbed by the human body using this technology can be defined by a measure termed the Specific Absorption Rate (SAR). ANSI and the IEEE have defined the maximum SAR levels that can be safely used in these applications, and these limits are included in the FCC's regulations for the Medical Device Radiocommunication Service (MedRadio).

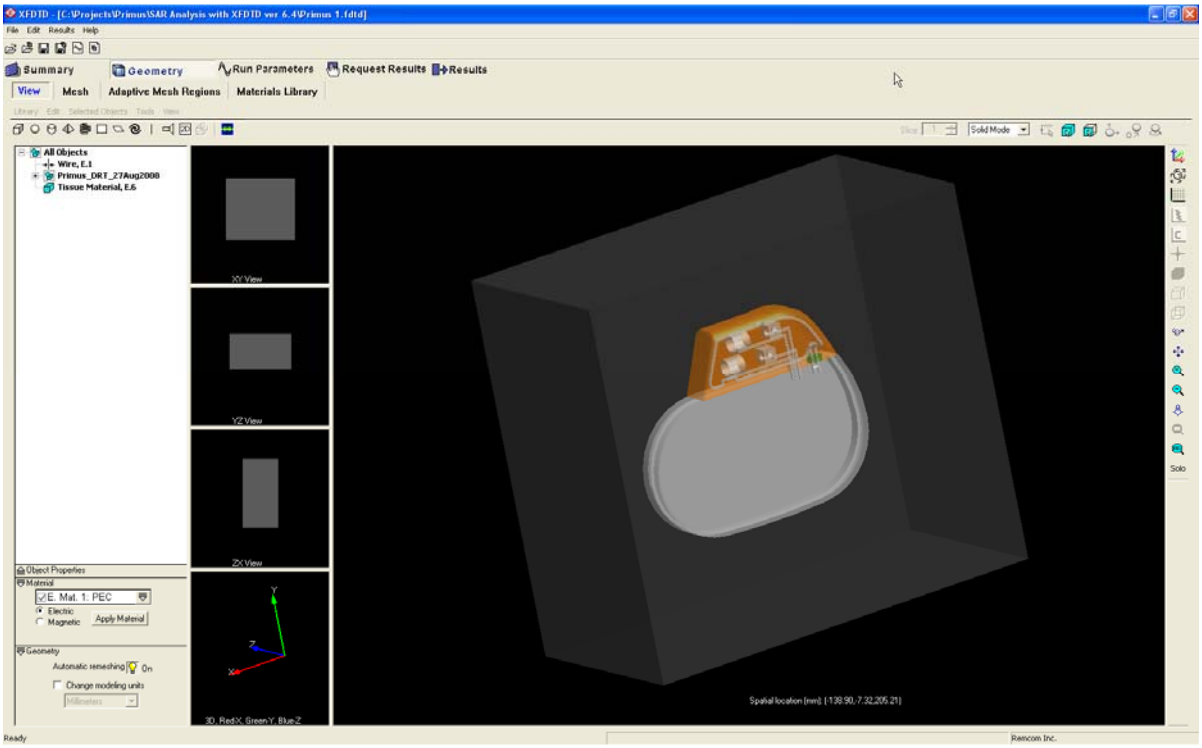
Certification of medical-implant transmitters under the FCC Part 95 MedRadio requires a measurement or Finite Difference Time Domain (FDTD) computational analysis of the SAR associated with the presence of non-ionizing radio frequency (RF) transmissions. This report details the SAR computational analysis for the ultra-low power RF transmitter employed in the Primus pacemaker.

8.1 Method of SAR Analysis

The computational software used for this FDTD analysis was Remcom XFDTD Version 6.5.14.6. This software was used to convert a Biotronik 3-dimensional CAD engineering model of the pacemaker to a 3D rectangular-grid FDTD computational space.

Adaptive cell-size meshing was employed in the FDTD computational space to achieve accurate modeling while also maintaining a reasonable limit on the computational memory requirements. To accurately model the SAR, a maximum cell size of 0.5 mm was used; except in the region of the antenna structure where the cell size was further reduced to 0.05 mm. As the cell size is extremely small, it is not practical to include a model of the upper human torso in the analysis. However, since previous experience using XFDTD modeling has shown that the region of maximum SAR is concentrated very near the antenna structure, the region surrounding the pacemaker was modeled using a material simulating the dielectric properties of human muscle at 403.5 MHz. As such, the computational model used in this study was restricted to 2 cm of muscle tissue surrounding the implant, and this resulted in a computational analysis encompassing approximately 38.5 million cells. To eliminate reflections at the boundary of the modeled space, the region beyond the meshed volume was modeled using perfectly matched layers (PML absorbing boundary).

Figure 8.1.1 below shows a 3D view of the SAR computational space, and the loop antenna in the Primus pacemaker header can be clearly identified. The computational space used was 9.3 x 8.5 x 4.8 cm^3, or approximately 379.4 cm^3. This volume is more than sufficient for computing 1gram average SAR levels as required by the FCC.


XFDTD - [C:\Projects\Primus\SAR Analysis with XFDTD ver 6.4\Primus 1.fdtd]

All Objects
Wire, E.1
Primus_DRT_27Aug2008
Tissue Material, E.6

Material: E. Mat. 1: PEC
● Electric
○ Magnetic

Automatic remeshing On
☐ Change modeling units
Millimeters

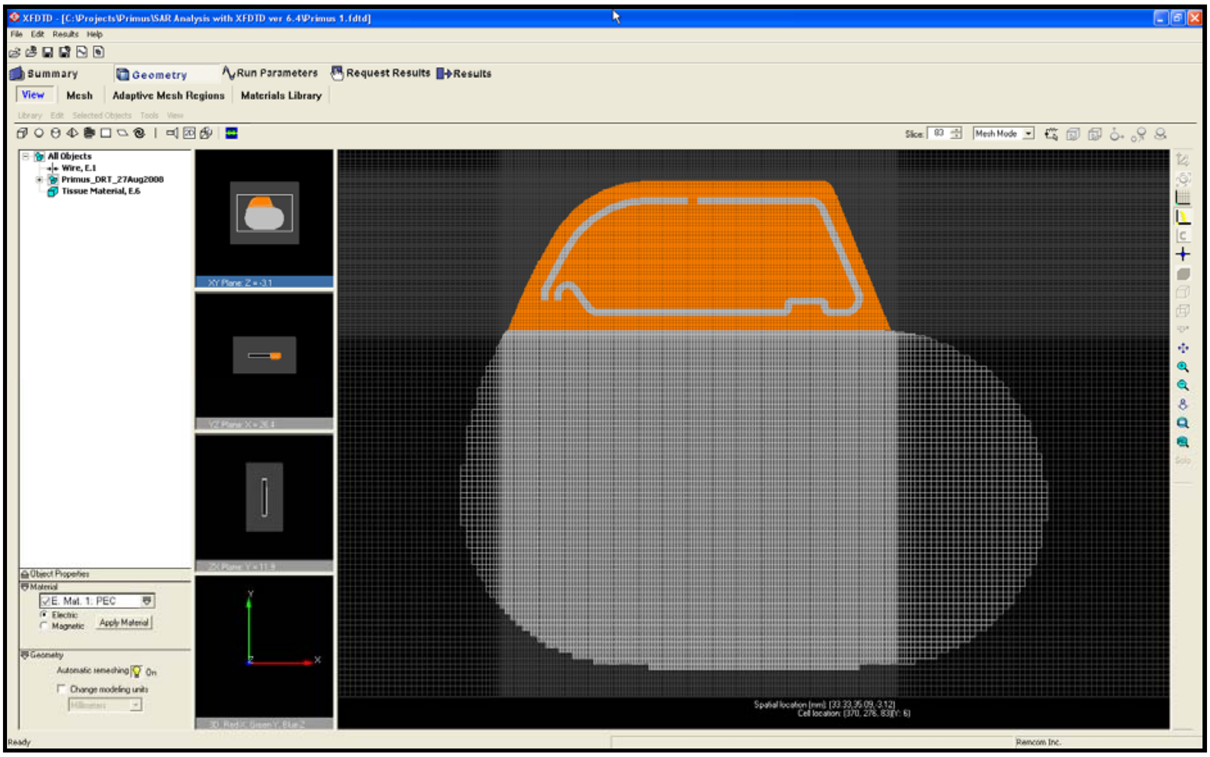
Spatial location (mm): [-138.90,-7.32,205.21]

Ready

Figure 8.1.1 **3D view of the Primus pacemaker embedded in tissue material for the SAR analysis.**

The use of a small cell size allowed all the elements of the header and antenna structure to be realized and accurately modeled with “non-thin” FDTD elements. The transmitter’s RF power and impedance, used to drive the antenna, were determined by the measurements outlined in Section 8.2. The material electrical properties used in the SAR analysis were obtained from either published data or direct measurement using a dielectric probe. Specifically, the relative dielectric constant of the header epoxy was 3.24, and the conductivity was 0.0034 S/m. The electrical properties of the biological material were $\varepsilon_r = 57.9$ and $\sigma = 0.82$ S/m, which models the electrical properties of human muscle tissue. The case material is titanium, and the antenna loop structure is stainless steel.

Figure 8.1.2 below shows one layer in the meshed problem space used in the Primus pacemaker SAR analysis. The SAR computational space encompassed 201 such layers.



XFDTD - [C:\Projects\Primus\SAR Analysis with XFDTD ver 6.4\Primus 1.fdtd]

Slice: 83

Mesh Mode

Material: E. Mat. 1: PEC

● Electric

○ Magnetic

Automatic remeshing On

☐ Change modeling units

Spatial location (mm): [33.33,35.09, 3.12]

Cell location: [370, 276, 83][Y: 6]

Figure 8.1.2 **Meshed XFDTD problem space showing the pacemaker's case, epoxy header, and antenna structure.**

The SAR analysis was performed at the center frequency of the MedRadio band (403.5 MHz). In the MedRadio band, the electrical properties of biological tissue are described by a dipolar mechanism. The dipolar region is characterized by slowly changing permittivity and conductivity, with many tissue types exhibiting a Cole-Cole behavior. Thus, it is reasonable to expect similar SAR results over the entire 402 MHz to 405 MHz MedRadio band.

8.2 Model Input Source Parameters

The Thevenin equivalent circuit of Primus' RF transmitter (source) was determined by measuring the implant transmitter's RF output power and output impedance. The output power, measured using an RF power meter, was -10.68 dBm at 403.65 MHz. The transmitter's output impedance (Zout), measured at 403.65 MHz using an RF network analyzer, was Zout = 410 +j 63 Ohms. This is equivalent to a 410 Ohm resistor in series with a 24.92 nH inductor. Using these measurements, the equivalent transmitter open-circuit output voltage was computed to be 0.859 volts peak.

The source model consists of a continuous wave (CW) signal at 403.65 MHz with an amplitude of 0.859 Volts peak, in series with a 410 Ohm resistor and a 24.92 nH inductor. Figure 8.2 shows the Thevenin equivalent circuit of this source model.

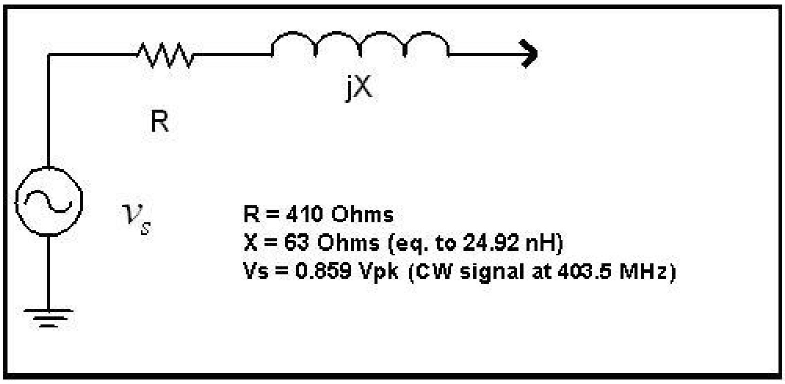
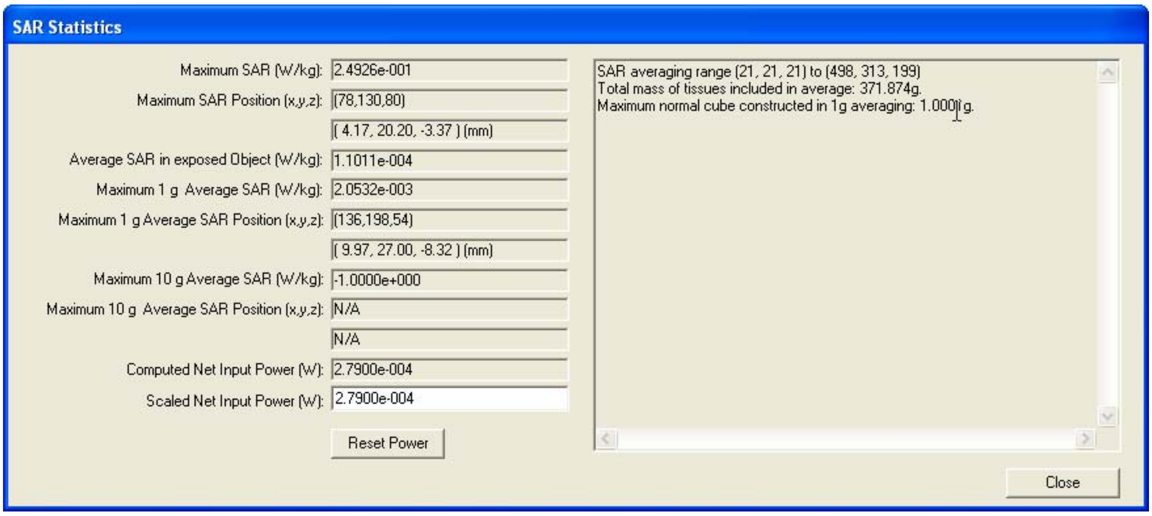


Figure 8.2 Thevenin equivalent circuit of Primus' RF transmitter that was used to model the source in the SAR analysis.

8.3 SAR Computational Analysis

Figure 8.3.1 shows a summary of the computed SAR analysis statistics. The result labeled Maximum SAR (W/kg) is of no significance since its value is a function of the mesh size used in the analysis. The Remcom XFDTD software only reports its value for reference purposes. The important result, and the one regulated by the FCC, is the result labeled "**Maximum 1 g Averaged SAR (W/kg)**". As can be seen in the SAR Statistics report, Primus' maximum 1 gram averaged SAR is 2.0532e-003 W/kg.



Maximum SAR (W/kg): 2.4926e-001
Maximum SAR Position (x,y,z): (78,130,80)
(4.17, 20.20, -3.37) (mm)
Average SAR in exposed Object (W/kg): 1.1011e-004
Maximum 1 g Average SAR (W/kg): 2.0532e-003
Maximum 1 g Average SAR Position (x,y,z): (136,198,54)
(9.97, 27.00, -8.32) (mm)
Maximum 10 g Average SAR (W/kg): -1.0000e+000
Maximum 10 g Average SAR Position (x,y,z): N/A
N/A
Computed Net Input Power (W): 2.7900e-004
Scaled Net Input Power (W): 2.7900e-004

SAR averaging range (21, 21, 21) to (498, 313, 199)
Total mass of tissues included in average: 371.874g.
Maximum normal cube constructed in 1g averaging: 1.000 g.

Figure 8.3.1 FDTD Summary of SAR Statistics

Figure 8.3.2 shows the intensity of the SAR distribution around the implant. It is readily apparent from the analysis that the maximum SAR exposure occurs in tissue material very close to the implant's loop antenna structure.

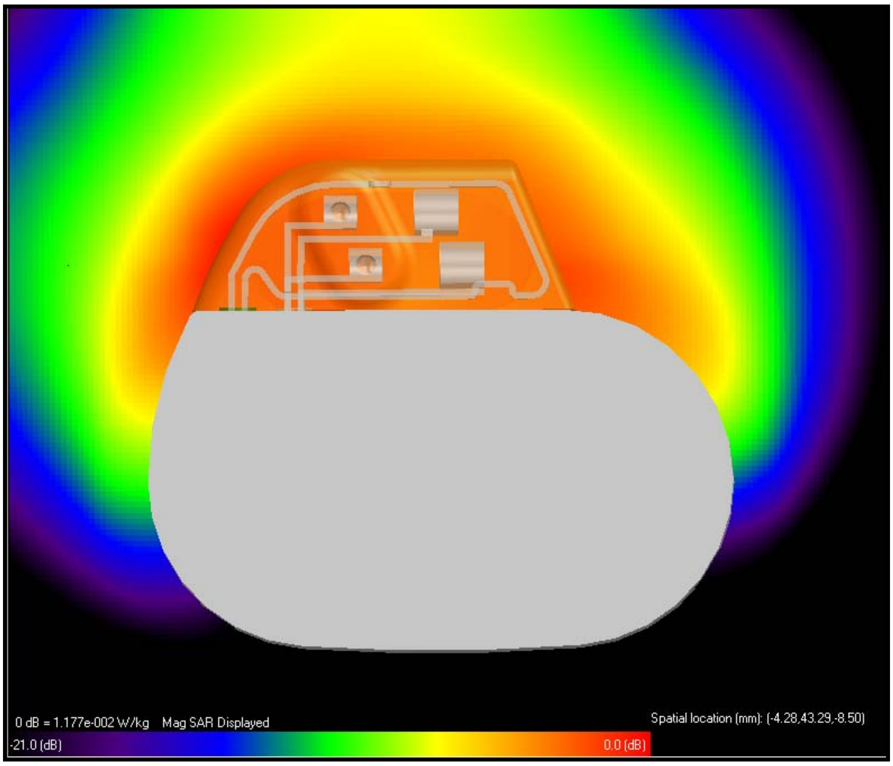


Figure 8.3.2 Intensity of the SAR distribution around the implant.

8.4 Worst-case SAR Exposure

This section details the worst-case SAR exposure analysis for the Primus pacemaker. The uncertainty analysis described below considers the effects of the errors in the network analyzer measurement used to determine the transmitter's output impedance, the amplitude accuracy of the power meter used to measure the transmitter's output power, and the uncertainty in the power meter measurement due to the non-ideal return loss of the power meter sensor/transmitter connection. Each of these 3 error types will be summarized and the worst-case sum of these effects will be used to modify the SAR exposure results. Of interest here is the possible increase in SAR exposure due to instrumentation errors.

(I) Network Analyzer Uncertainty:

The Primus transmitter output impedance was measured using an Agilent 8753ES vector network analyzer. The output impedance had a nominal reflection coefficient of $|\Gamma| = 0.787$. The 8753ES was calibrated for a 1-port S11 measurement using an open, short, and load standard from an Agilent 85033D 3.5 mm Calibration Kit.

Typical measurement error associated with a reflection calibration is found in the specifications for the Agilent 8753ES, and at 400 MHz for $|\Gamma| = 0.787$ is:

Uncertainty for $|\Gamma|$	+/- 0.011
Uncertainty for Arg(Γ)	+/- 1 degree

(II) Power Meter Amplitude Uncertainty:

The amplitude measurement uncertainty specifications for an Agilent 53147A power meter and Agilent 8481A power sensor, for the measurement conditions of –10.68 dBm in the MedRadio frequency band, are summarized in the table below:

Instrumentation Accuracy	+/- 0.02 dB
Reference Accuracy	+/- 0.03 dB
Overall Uncertainty	+/- 0.05 dB

(III) Power Sensor/DUT Mismatch Uncertainty:

The SWR (reflection coefficient) for the Agilent 8481A power sensor over the frequency range of 50 MHz to 2 GHz is shown in the table below:

Maximum SWR	1.10
Maximum Reflection Coefficient	0.048

Figure 8.3.1 shows the signal flow graph for the transmitter impedance measurement. The power transfer function from the source (Primus' transmitter) to the load (power sensor) is:

$$\frac{P_O}{P_S} = \frac{(1-|\Gamma_S|^2)(1-|\Gamma_O|^2)}{|1-\Gamma_S \cdot \Gamma_O|^2}$$

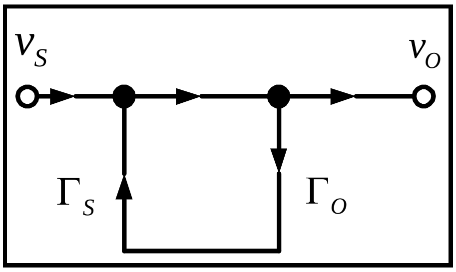


Figure 8.3.1 **Signal flow graph of the transmitter connected to the RF power meter.**

The uncertainty associated with this transfer function (*Microwave Theory and Applications*, page 233, by Stephen Adam, Prentice-Hall) is $(1 \pm |\Gamma_S| \cdot |\Gamma_O|)^2$

For the Primus transmitter, the nominal value of $\Gamma s = 0.787$, and for the Agilent 8481A power sensor, $\Gamma o = 0.048$.

The uncertainty is then: $\Delta Error_{(dB)} = 20\log_{10}(1 \pm |0.787| \cdot |0.048|)$

Hence:

Maximum Mismatch Uncertainty, $\Delta Error_{(dB)}$	+ 0.322 dB
Minimum Mismatch Uncertainty, $\Delta Error_{(dB)}$	- 0.334 dB

Figure 8.3.2 shows the equivalent circuit of the Primus RF transmitter driving a nominal 50 Ohm load (representing the Agilent 8481A power sensor). This model is used to compute the transmitter's equivalent open-circuit source voltage (v_S).

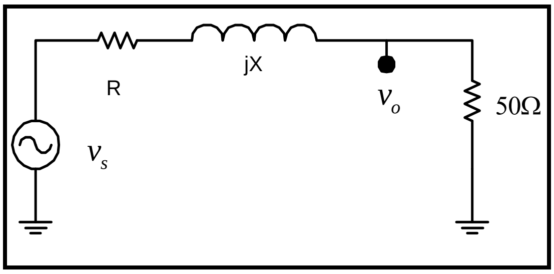


Figure 8.3.2 **Determination of equivalent source voltage**

The nominal source impedance, represented by the components R and jX, were determined using the network analyzer measurement detailed above. The transmitter's equivalent output impedance is 410 Ω resistance in series with +j63 Ω reactance (equivalent to an inductance of 24.92 nH).

Referring to Figure 8.3.2, the nominal output voltage v_S, can be computed from the expression below:

$$|v_S| = \sqrt{\frac{P_O}{50} \cdot \left((50 + R_S)^2 + X_S^2\right)}$$

For the nominal values of measured source impedance and measured output power (-10.68 dBm), the nominal magnitude of the Primus transmitter's equivalent open-circuit source voltage (v_S) is 0.859 Volts peak.

To complete the analysis, we apply the uncertainty of the power meter amplitude measurement, and the uncertainty of the network analyzer impedance measurement, to the equivalent circuit, and compute the worst-case open-circuit source voltage.

First, considering only the uncertainty in the power measurement, the worst-case maximum power can be computed by adding the overall power meter uncertainty of +0.05 dB and the worst-case mismatch uncertainty of +0.397 dB.

The worst-case maximum output power is: P_O = -10.68 dBm + (0.05 + 0.322) dB
P_O = -10.68 dBm + 0.372 dB
P_O = -10.308 dBm
P_O = 93.154 µW

Next, noting that the largest equivalent open-circuit source voltage (v_S), occurs when the values of R_S and X_S are maximized; the next step is to determine when these maximums occur. Maximum values for these components occur when the uncertainty in $|\rho|$ is +0.011 and the phase angle is -1 degrees. For this case $R_S = 441.69\Omega$ and $X_S = 38.27\Omega$.

Substituting all of the parameter changes to compute the worst-case (largest) value of source voltage is:

$$|v_S| = \sqrt{\frac{93.154\ \mu\text{W}}{50} \cdot \left((50 + 441.69)^2 + 38.277^2\right)} = 0.673\ \text{V}_{\text{RMS}} = 0.952\ \text{V}_\text{p}$$

This is an increase of: $20 \cdot \log_{10}\left(\frac{0.952}{0.859}\right) = 0.893$ dB.

Since the SAR exposure is dependent on the square of the electric field component, and the dielectrics modeled are all isotropic and linear, the potential increase in the SAR is **0.893 dB.**

As shown in Figure 8.2.1, the SAR exposure was computed using Remcom's XFDTD with the nominal values of the transmitter's source impedance and source voltage. Since the worst-case SAR exposure was found to be 0.893 dB greater than the nominally computed value of 2.0532e-003 W/kg, the worst-case SAR is **2.5218e-003 W/kg** (1 gram averaged).

The 1 gram averaged SAR level of 2.5218e-003 W/kg is 28 dB below the FCC's limit.

9 SAR Summary

The following is a summary of the Primus SAR analysis reported in this document.

1. The Primus pacemaker physical model used in the analysis was derived directly from Biotronik 3-dimensional engineering CAD files.
2. The SAR analysis was performed using the Finite Difference Time Domain (FDTD) method as required by the FCC.
3. The FDTD simulation software used in the analysis was Remcom Bio-pro XFDTD version 6.5.14.6
4. The SAR analysis was performed using adaptive meshing to resolve antenna features as small as 0.05 mm. Remcom XFDTD reported this mesh size would result in accurate modeling to 59.96 GHz.
5. The analysis was performed in a volume encompassing approximately 38.5 million cells, and a time step of 192.6 fs.
6. The analysis was performed using a sinusoidal source at 403.5 MHz, the center frequency of the 402 MHz to 405 MHz MEDRADIO band.
7. The SAR analysis was performed with the pacemaker surrounded by a cube of material with electrical properties identical to human muscle tissue at 403.5 MHz ($\varepsilon r = 57.9$ and $\sigma = 0.82$ S/m). This represents the worst-case conditions for SAR exposure in the human body.
8. The simulated muscle tissue surrounding the pacemaker extended beyond the pacemaker by 2 cm. The region beyond the simulated muscle tissue was modeled as a perfectly absorbing boundary.
9. The maximum SAR exposure occurred in the immediate vicinity of the pacemaker, well within the volume of the simulated muscle tissue.
10. The dielectric properties of all the materials in the simulation were obtained from published sources.
11. The transmitter output power was measured using a calibrated Agilent RF power meter.
12. The transmitter output impedance was measured using a calibrated Agilent RF network analyzer.
13. The SAR analysis was performed using worst-case parameters for the transmitter's RF power and output impedance.
14. The SAR simulation results attained full convergence (better than –30 dB convergence threshold).
15. A full error analysis was performed on the SAR analysis. This added 0.893 dB to the computed SAR exposure.
16. The worst-case SAR is **2.5218e-003 W/kg** (1gram averaged).
17. The Primus pacemaker SAR level is below the FCC regulatory limit of 1.6 W/kg by a margin of **28 dB**.

10 Regulatory Conclusion

The worst-case SAR is **2.5218e-003 W/kg** (1gram averaged). This is below the FCC regulatory limit of 1.6 W/kg by a margin of **28 dB**.

11 Approval and Signatures

Brian Sutton March 2, 2010
ORIGINATOR/DATE

Paul Stadnik March 2, 2010
CHECKED AND APPROVED BY