|  |  |  |  |
|---|---|---|---|
| **BIOTRONIK** | **Technical Report**<br>*Tach 35 (4120) SAR Analysis* | 3146179<br>Rev. A | Page 1 of 11 |

| Letter | Revisions | Date | Approval |
|---|---|---|---|
| A | Original | 02-23-2006 | BPS |
|  |  |  |  |

## 1 Purpose

The purpose of this report is to document the Specific Absorption Rate (SAR) computational analysis of the Biotronik Tach 35 (4120) Implantable Cardioverter Defibrillator (ICD).

## 2 Conclusion

The Tach 35 ICD, employing an ultra-low power RF transmitter, complies with the SAR regulatory limits specified in 47 CFR 95.603, §2.1093, and §1.1310. The Tach 35 maximum worst-case, time-averaged SAR is **25.417 microW/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 Tach 35 SAR is **48 dB** below the maximum allowable regulatory limit specified by the FCC.

## 3 Applicability

This report is applicable to all Tach 35 ICD’s that use the same MICS RF transmitter circuitry and antenna structure noted in this report.

## 4 Document History

| | | |
|---|---|---|
| Ver. A | 02-23-2006 | Initial Release |

## 5 References

| | |
|---|---|
| 47 CFR 95.603 | Certification Required |
| 47 CFR 2.1093 | Radio Frequency Radiation Exposure Evaluation: Portable Devices |
| 47 CFR 1.1310 | Radio Frequency Radiation Exposure Limits. |

## 6 Definitions

| | |
|---|---|
| MICS | Medical Implant Communications Service |
| Periodic Transmission | Infrequent RF signal transmission, on a periodic basis, from a transmitter to a receiver. |
| 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 | Tach 35 (4120) | 4120-00-A000723 | N/A | N/A |
| SA | Spectrum Analyzer | Hewlett-Packard | 8561E | 3804A02248 | 09-15-2005 | 09-29-2006 |
| SENSOR | Power Meter Sensor | Agilent | 8481A | MY41095529 | 05-23-2005 | 07-11-2006 |
| PM | Power Meter/Freq Counter | Agilent | 53147A | US40470964 | 08-03-2005 | 08-03-2006 |
| NET | Network Analyzer | Agilent | 8753ES | US39170321 | 05-25-2005 | 05-24-2006 |
| CALKIT | 3.5 mm Calibration Kit | Agilent | 85033D | 3423A04725 | 11-14-2005 | 11-14-2008 |
| CABLES | Cables, 50 Ohm Coax with SMA connectors | Pasternack | Assorted | N/A | N/A | N/A |

**IMP:** The Tach 35 ICD evaluated in this test report.

**SA:** A spectrum analyzer is used to monitor the RF signal emissions.

**SENSOR:** Power meter RF sensor.

**PM:** A power meter is used measure the system RF power levels.

**NET:** A network analyzer used to measure impedance at RF frequencies

**CALKIT**: Open/Short/Load calibration standards to calibrate the network analyzer.

**CABLES:** 50 Ω double-shielded cables with SMA connectors.

## 7.1 Photograph of the Tach 35 ICD

Figure 7.1.1 shows a photograph of a Biotronik Tach 35 ICD. The loop antenna is embedded in the epoxy header.

**Figure 7.1.1 Photograph of a Tach 35 Implantable Cardioverter Defibrillator (ICD).**

# 8 Tach 35 Measurement Results

## 8.1 Measurements for SAR Analysis:

**Transmitter Power:**
RF output power (Max): -3.39 dBm at 403.65 MHz, $V_{CC} = 3.0$ Volts

**Measurement of Transmitter Output Impedance:**

The Tach 35 transmitter’s output impedance was measured using a calibrated RF network analyzer. The results of the measurement are shown in Figure 8.1.1 below.

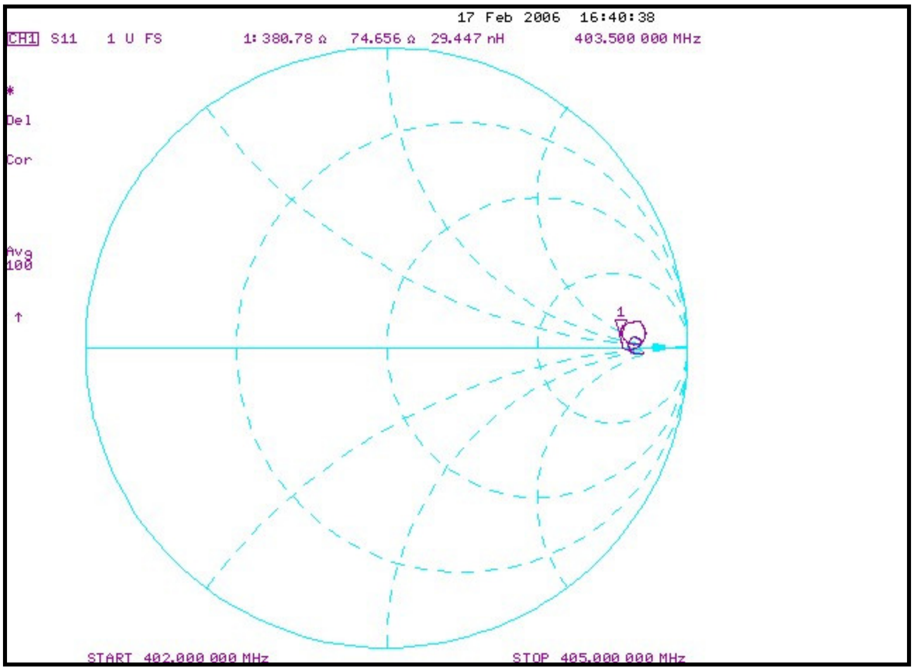


**Figure 8.1.1 Tach 35 transmitter output impedance.**

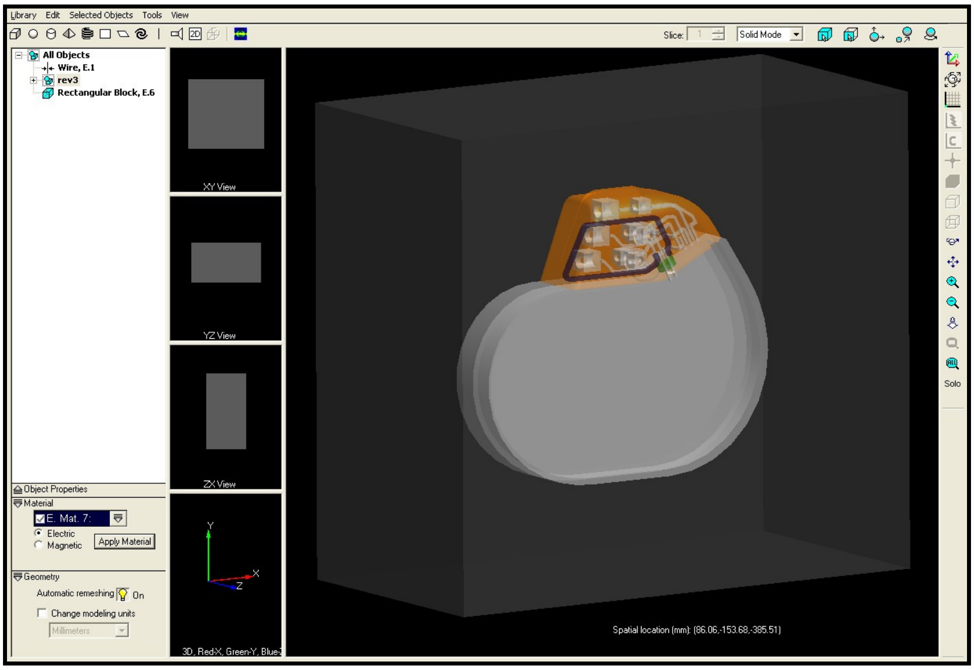
# 9 Tach 35 Specific Absorption Rate (SAR) Analysis

Biotronik Implantable Cardioverter Defibrillators (ICDs) 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 regulations for Medical Implant Communications Service (MICS).

Certification of medical-implant transmitters under the FCC Part 95 MICS 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 Tach 35 ICD.

## 9.1 Method of SAR Analysis

The computational software used for this FDTD analysis was Remcom XFDTD Version 6.3.7.13. This software was used to convert a Biotronik 3-dimensional CAD engineering model of the ICD to a rectangular-grid FDTD computational space. A maximum uniform cell size of 0.3 mm was used in the SAR analysis. This allowed detailed modeling of the loop antenna structure in the ICD header. As the cell size is very small, it is not practical to include a model of the upper torso with the ICD. Previous experience using FDTD modeling methods has shown that the region of maximum SAR is concentrated very near the antenna structure. Thus the computational model used in this study was restricted to 2 cm of muscle tissue surrounding the ICD. As such, the computational space included in the analysis encompasses approximately 33 million cells. The region beyond the computational space was modeled with Liao-type perfectly absorbing material. Figure 9.1.1 below shows a 3D view of the SAR computational space, and the loop antenna in the Tach 35 ICD header can be clearly identified. The computational space used was 10.6 x 9.7 x 5.5 $cm^3$, or approximately 565 $cm^3$. This volume is more than sufficient for computing 1gram average SAR levels as required by the FCC.

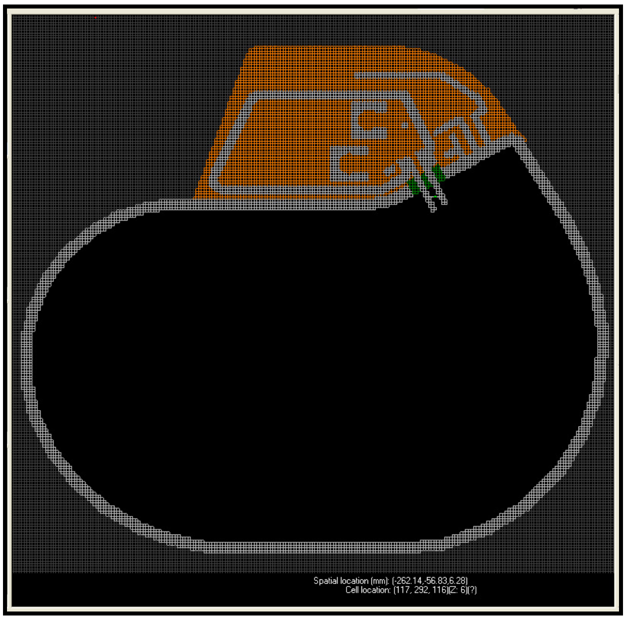


Spatial location (mm): (86.06,-153.68,-385.51)

**Figure 9.1.1 3D view of the Tach 35 ICD 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 source power and impedance used to drive the antenna were determined by the measurements outlined in Section 8.1. The material electrical properties 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 $\varepsilon_r = 62.5$ and $\sigma = 0.9$ S/m, which models the electrical properties of human tissue. The case material is titanium, and the antenna loop structure is stainless steel.

Figure 9.1.2 below shows one layer in the meshed problem space used in the Tach 35 ICD SAR analysis. The SAR computational space encompassed 227 such layers.



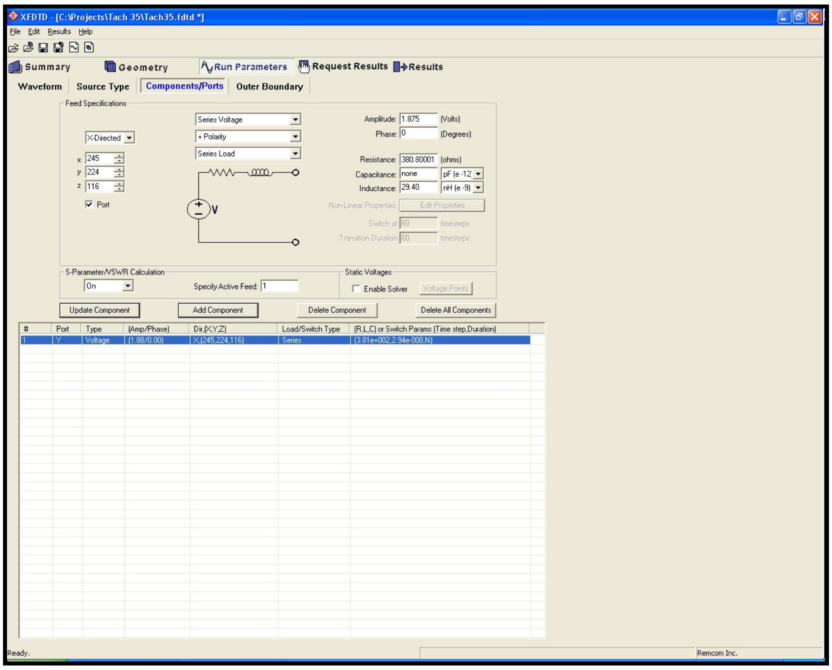
Spatial location (mm): (-262.14,-56.83,6.28)
Cell location: (117, 292, 116)(Z: 6)(?)

**Figure 9.1.2 Meshed XFDTD problem space showing the ICD case, epoxy header, and antenna**

**structure.**

The SAR analysis was performed at the center frequency of the MICS band (403.5 MHz). In the MICS 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 MICS band.

Figure 9.1.3 below shows the Thevenin equivalent circuit of the RF transmitter (source), used to drive the Tach 35 ICD loop antenna. The equivalent circuit parameters were derived using the measurement techniques described in section 8.1, and circuit analysis methods detailed in Section 9.2 below. The transmitter output impedance was modeled as a 380.8 Ohm resistor in series with a 29.4 nH inductor (equivalent to 74.66 Ohms reactance). The equivalent transmitter open-circuit output voltage was 1.875 volts peak.



XFDTD - [C:\Projects\Tach 35\Tach35.fdtd *]

X-Directed
x 245
y 224
z 116
☑ Port

Series Voltage
+ Polarity
Series Load

Amplitude: 1.875 (Volts)
Phase: 0 (Degrees)
Resistance: 380.80001 (ohms)
Capacitance: none pF (e -12)
Inductance: 29.40 nH (e -9)
Switch at 60 timesteps
Transition Duration 60 timesteps

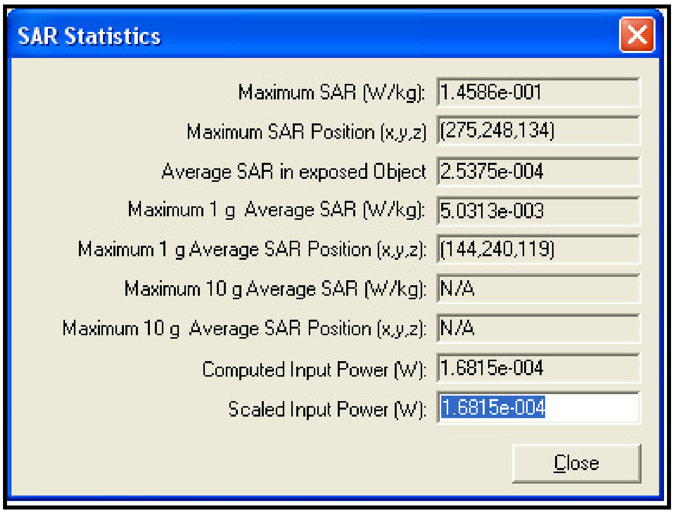
S-Parameter/VSWR Calculation: On
Specify Active Feed: 1
Static Voltages: ☐ Enable Solver

| # | Port | Type | (Amp/Phase) | Dir,(X,Y,Z) | Load/Switch Type | (R,L,C) or Switch Params (Time step,Duration) |
|---|---|---|---|---|---|---|
| 1 | Y | Voltage | (1.88/0.00) | X,(245,224,116) | Series | (3.81e+002,2.94e-008,N) |

Ready.
Remcom Inc.

**Figure 9.1.3** **Thevenin equivalent circuit of the Tach 35 transmitter used in the SAR analysis.**

Figure 9.1.4 shows a summary of the computed SAR analysis statistics. The result labeled Maximum SAR (W/kg) is of no real significance since its value is a function of the mesh size used in the analysis. The Remcom XFDTD software only reports it 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, the Tach 35 maximum 1 gram averaged SAR is 5.03 mW. Also, note that the SAR value computed by Remcom XFDTD assumes the ICD transmitter is operating in a continuous fashion. Since the Tach 35 ICD transmits RF energy with a very low duty-cycle, and not on a continuous basis, the time-averaged maximum SAR is considerably lower than the value stated in the SAR Statistics report.

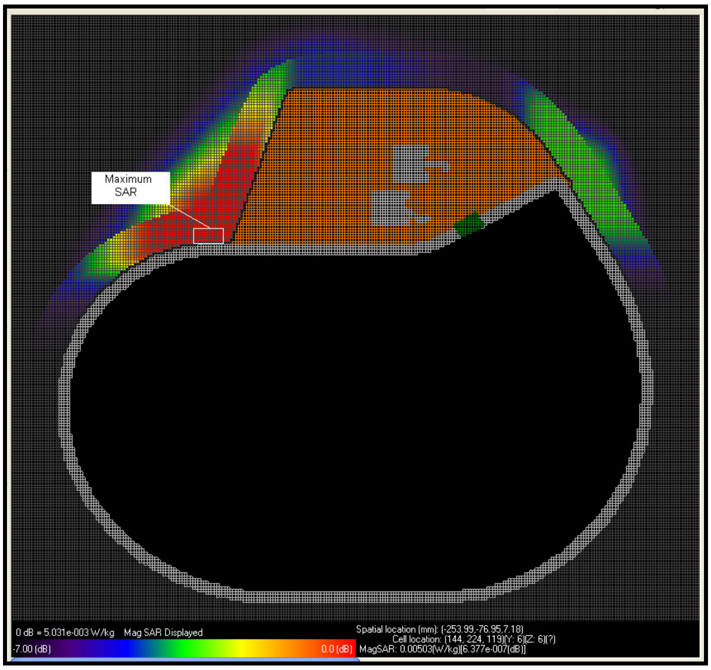


SAR Statistics

Maximum SAR (W/kg): 1.4586e-001
Maximum SAR Position (x,y,z) (275,248,134)
Average SAR in exposed Object 2.5375e-004
Maximum 1 g Average SAR (W/kg): 5.0313e-003
Maximum 1 g Average SAR Position (x,y,z): (144,240,119)
Maximum 10 g Average SAR (W/kg): N/A
Maximum 10 g Average SAR Position (x,y,z): N/A
Computed Input Power (W): 1.6815e-004
Scaled Input Power (W): 1.6815e-004

**Figure 9.1.4 FDTD Summary of SAR Statistics**

Figure 9.1.5 shows the location of the maximum 1gram averaged SAR value in the tissue material next to the Tach 35 ICD. It is apparent from the analysis that the maximum SAR exposure occurs in tissue material very close to the implant's loop antenna structure.



0 dB = 5.031e-003 W/kg Mag SAR Displayed
Spatial location (mm): (-253.99,-76.95,7.18)
Cell location: (144, 224, 119)(Y: 6)(Z: 6)(?)
MagSAR: 0.00503(W/kg)[6.377e-007(dB)]

**Figure 9.1.5 Location of maximum 1 gram averaged SAR**

Figure 9.1.6 shows another view of the SAR field exposure surrounding the Tach 35 ICD. This view shows the greatest SAR region is in tissue with close proximity to the antenna structure.

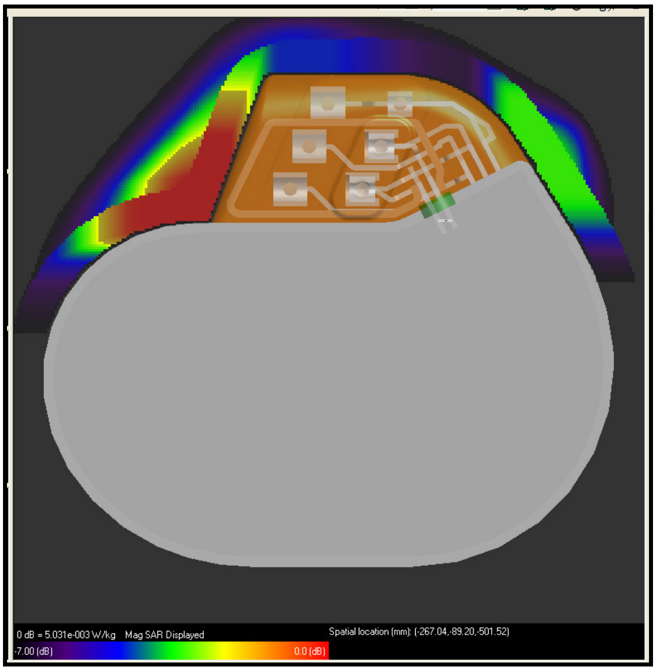


**Figure 9.1.6 SAR field around the Tach 35 ICD.**

## 9.2 Worst-case SAR Exposure

This section details the worst-case SAR exposure analysis for the Tach 35 ICD. 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 Tach 35 transmitter output impedance was measured using an Agilent 8753ES vector network analyzer. The output impedance had a nominal reflection coefficient of $|\Gamma| = 0.7757$. 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 $|\Gamma| = 0.7757$ is:

| | |
|---|---|
| Uncertainty for $|\Gamma|$ | +/- 0.011 |
| Uncertainty for Arg($\Gamma$) | +/- 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 –3.39 dBm in the MICS 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 9.2.1 shows the signal flow graph for the transmitter impedance measurement. The power transfer function from the source (Tach 35 transmitter) to the load (power sensor) is:

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

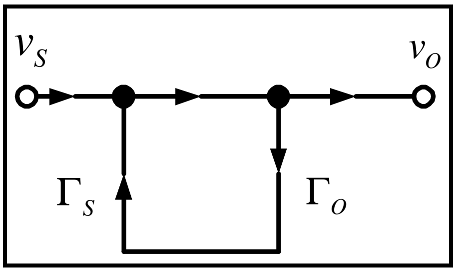


**Figure 9.2.1 Signal flow graph of the transmitter connected to the RF power meter.**

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 Tach 35 transmitter, the nominal value of $\Gamma s = 0.7757$, and for the Agilent 8481A power sensor, $\Gamma o = 0.048$.

The uncertainty is then: $\Delta Error_{(dB)} = 20 \log_{10}(1 \pm |0.7757| \cdot |0.048|)$

Hence:

| | |
|---|---|
| Maximum Mismatch Uncertainty, $\Delta Error_{(dB)}$ | + 0.318 dB |
| Minimum Mismatch Uncertainty, $\Delta Error_{(dB)}$ | - 0.330 dB |

Figure 9.2.2 shows the equivalent circuit of the Tach 35 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 ($v_S$).

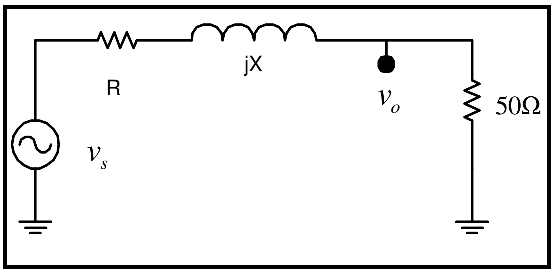


**Figure 9.2.2 Determination of equivalent source voltage**

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 380.8 Ω resistance in series with +j74.656 Ω reactance (equivalent to an inductance of 29.447 nH).

Referring to Figure 9.2.2, 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 (-3.39 dBm), the nominal magnitude of the Tach 35 transmitter's equivalent open-circuit source voltage ($v_S$) is 1.875 $V_p$.

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 +0.318 dB.

The worst-case maximum output power is: $P_O$ = -3.39 dBm + (0.05 + 0.318) dB
$P_O$ = -3.39 dBm + 0.368 dB
$P_O$ = -3.022 dBm
$P_O$ = 0.499 mW

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 $R_S$ = 408.8 Ω and $X_S$ = 55.33 Ω.

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

$$|v_S| = \sqrt{\frac{0.499mW}{50} \cdot \left((50 + 408.8)^2 + 55.33^2\right)} = 1.46\ V_{RMS} = 2.065\ V_p$$

This is an increase of: $20 \cdot \log_{10}\left(\frac{2.065}{1.875}\right) = 0.838$ 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 **0.838 dB.**

As shown in Figure 9.1.3, the SAR exposure was computed using Remcom's XFDTD with the nominal values of the transmitter's source impedance and source voltage. This figure shows that a 1.875 $V_p$ source was placed at location x=245, y=224, and z=116, and the source impedance was a series-RL network of 380.8 Ohms and 29.4 nH. Since the worst-case SAR exposure was found to be 0.838 dB greater than the nominally computed value of 5.03 mW/kg, the worst-case SAR is **6.1 mW/kg** (1 gram averaged). Again, this value represents the SAR exposure assuming the Tach 35 transmitter is actively transmitting an RF signal continuously – which is not the case. Since the Tach 35 RF transmitter operates at an extremely low duty-cycle, these SAR results are adjusted appropriately as outlined in Section 9.3 below.

## 9.3 Time-Averaged SAR Exposure Calculation

In accordance with 47 CFR 2.1093 Radiofrequency Radiation Exposure Evaluation: Portable Devices, and 47 CFR1.1310 Radiofrequency Radiation Exposure Limits (Table 1B), time-averaging provisions may be used in conjunction with typical maximum duty-cycle factors to determine the maximum SAR exposure levels, if the duty-cycle is source-based. The Tach 35 ICD employs source-based duty-cycle control, and the maximum RF transmission duty-cycle is inherently limited such that RF transmissions cannot exceed 7.5 seconds duration in any 30 minute time interval. Consequently, the RF transmission maximum duty-cycle is 0.004167 or 0.4167%. Applying this maximum duty-cycle to the worst-case maximum transmitter power results in a 1 gram averaged SAR exposure level of **25.417 microWatts/kg** (0.4167% * 6.1 mW/kg). This level is **48 dB below** the regulations for maximum allowable SAR exposure levels.

## 9.4 SAR Summary

The following is a summary of the Tach 35 SAR analysis reported in this document.

1. The Tach 35 ICD 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 6.3.7.13
4. The SAR analysis was performed using a resolution of 0.3 mm to ensure all physical features were accurately modeled. Remcom XFDTD reported this mesh size would result in accurate modeling to 99.93 GHz.
5. The analysis was performed in a volume encompassing approximately 33 million cells, and a time step of 557.8 fs.
6. The analysis was performed using a sinusoidal source at 405.5 MHz, the center frequency of the 402 MHz to 405 MHz MICS band.
7. The SAR analysis was performed with the ICD surrounded by a cube of material with electrical properties identical to human muscle tissue at 403.5 MHz. This represents the worst-case conditions for SAR exposure in the human body.
8. The simulated muscle tissue surrounding the ICD extended beyond the ICD by 2 cm. The region beyond the simulated muscle tissue was modeled as an absorbing Liao-type boundary.
9. The maximum SAR exposure occurred in the immediate vicinity of the ICD, 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 0.838 dB to the computed SAR exposure.
16. Since the Tach 35 employs source-based duty-cycle control, which limits the RF transmissions to a duty-cycle of 0.4167% (averaged over a 30 minute interval), the true 1 gram averaged SAR of the Tach 35 ICD is **25.417 microWatts/kg.**
17. The Tach 35 ICD SAR level is below the FCC regulations by a margin of **48 dB**.

## 10 Approval and Signatures

Measurements performed on: **February 17, 2006**

Measurements performed by: **Brian Sutton**

**Brian Sutton February 23, 2006**
ORIGINATOR/DATE

**Paul Stadnik February 24, 2006**
CHECKED AND APPROVED BY