EXHIBIT S – SAR Analysis

FCC ID# PG6BA0T

Specific Absorption Rate (SAR) Analysis Using Finite Difference Time Domain Computation for RF Transmitter Circuit Employed in Biotronik Pacemakers Actros TO+ and Philos DR-T

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Introduction

Biotronik has developed an RF communications system for use in implantable pacemakers allowing for patient data regarding cardiac condition to be transmitted wirelessly to the physician for evaluation. The amount of irradiated power transmitted through the human body using this technology can be defined by a measure termed the Specific Absorption Rate (SAR). Values of SAR that can be safely used in these applications have been defined by ANSI/IEEE and are part of the FCC guidelines for medical implant communications.

Certification of medical-implant transmitters under the FCC Part 95 Medical Implant Communication Service (MICS) requires a measurement or Finite Difference Time Domain (FDTD) analysis of the SAR associated with the presence of a non-ionizing, radio frequency (RF) transmitter. This report details the SAR analysis of the unidirectional RF transmitter found in Biotronik's Philos DR-T and Actros TO+ pacemakers.

Summary

Using a commercially available FDTD program (XFDTD, Remcom Inc.), the computed SAR values determined by this analysis are:

Maximum SAR	4.54 mW/kg
Maximum 1g average SAR	1.11 mW/kg
Average SAR	427 nW/kg

The ANSI C95-1-1992 limit is 1.6 W/kg. The computed value in this study of the maximum SAR is 4.54 mW/kg. The margin between the maximum attained SAR and the ANSI/IEEE specification limit is 25.5 dB (only 0.28% of the specification limit).

These FDTD results prove that the Biotronik RF transmitter circuitry can safely be used in its intended application with respect to the energy emitted during communication.

Method of Analysis

Equipment and tools used for the analysis:

<u>Hardware</u>

Dell dual processor Windows 2000 Workstation, 1 Gb RAM 3 drive SCSI RAID
Hewlett-Packard 8591 Spectrum Analyzer
Hewlett Packard 8753E Vector Network Analyzer

<u>Software</u>

XFDTD 5.1.0.5 Bio-Pro, Calc FDTD 5.1, Remesher 5.1, HIFI Body model
Eagleware SuperStar Pro. 6.5b
MicroSim PSPICE ver 8.0

The computational tool used for this FDTD analysis was XFDTD with the hi-fidelity Visible Man model (also from Remcom). The first proposed method for analysis was to use the subgrid tool where the implant at 1 mm^3 resolution would be placed in the biomodel, which is meshed at $5mm^3$. It was found that the subgrid technique, when used with high-dielectric constant materials, does not yield a stable solution. This was verified with Remcom[1]. Because it was desirable to show the fine structure of the implant, and yet restrict the computational effort of the equipment, a mesh size of 2 mm^3 was chosen for the analysis.

Note: This 2mm mesh provides for resolution 15 times greater than the 5mm grid pattern that has been used by Biotronik competitors in similar applications for their analysis to prove compliance with the SAR limit safety standards.

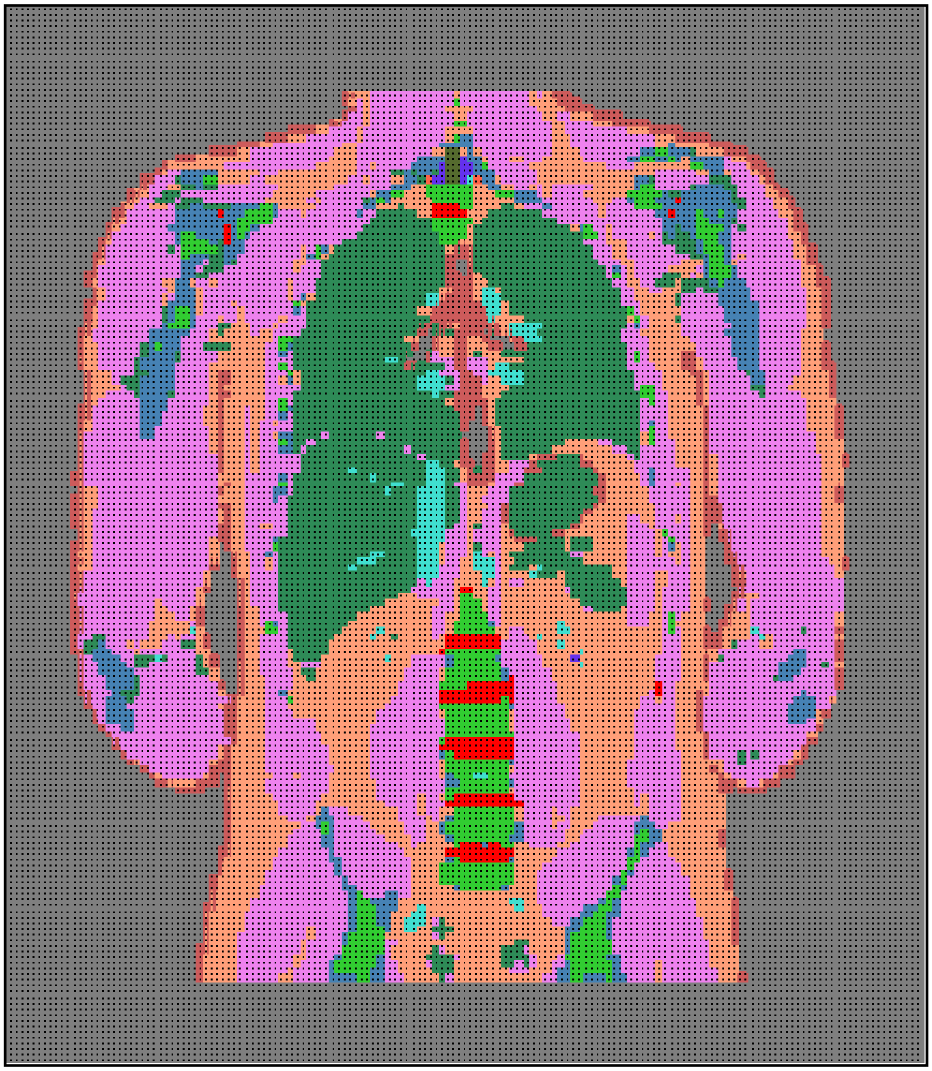

Figure 1.

Truncated Biomesh Resampled at $2mm^3$

The biomesh was resampled to a $2mm^3$ grid, and the body was truncated to include only the torso (Figure 1). Limiting analysis to the torso was deemed rational as the RF power emanates from the pacemaker located in the chest and remains concentrated within this region as proven in this analysis. While feasible, utilizing the entire human body model complicates the analysis, without providing additional insight into the irradiation properties of the pacemaker signal propagating through the tissue of concern.

Pacemaker Model

Remcom, to date, does not have a 3-D import tool and the model of the implant was restricted to the primitive geometry tools that are currently available. Figure 2 below shows the pacemaker model utilized for this analysis, which is a rectangle-box tool.

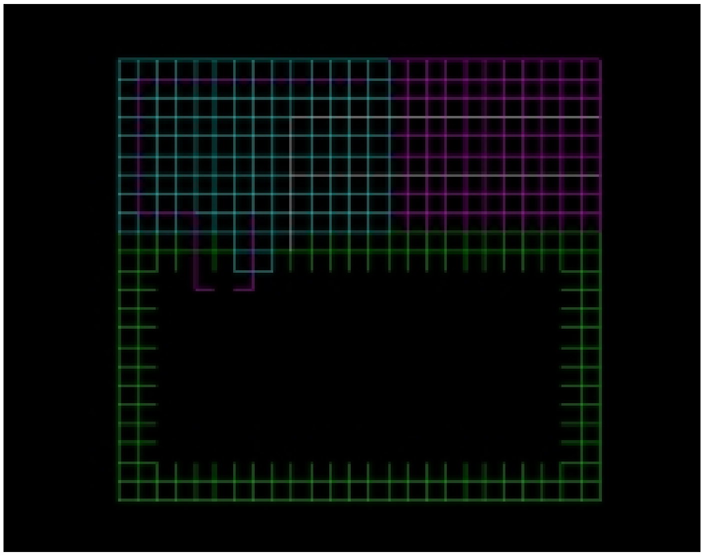

Figure 2.

Implant Mesh 2 mm^3

The loop antenna and pacing lead wires were realized with a combination of PEC wire and thin-wire models. Thin wire models allow any FDTD algorithm to include the effects of wire diameter. The epoxy-header material, shown in light blue, used to enclose the loop antenna, was characterized for values of dielectric constant and conductivity. Using a HP8753E network analyzer and a TEM transmission line test cell, it was found the epoxy has a dielectric constant 0 ~3 and a conductivity ~.001 S/m. The green area is the titanium case. The actual thickness of the titanium case is not 4 mm as shown below; it is on the order of 1/3 mm, but FDTD modeling requires at least 1 full cell width on the wall of a hollow object to correctly model the object. The skin depth of titanium at this frequency is such that the attenuation of an EM wave is not changed with this modeled wall thickness compared to the actual case. The violet and white lines show the loop antenna and the pacing wires, respectively. The upper right corner (violet) shows an area of muscle tissue. This addition of biological tissue was included with the pacemaker to ensure that the pacemaker could be correctly merged with the biological model of Figure 1. As the mesh is 2 mm^3, Figure 2 shows that the pacemaker is 4.6 cm x 5.0 cm x 1.6 cm. Shown inside the case is a pair of violet, “L” shaped antenna wires for the source. The source cell is thus shielded by the case, as it is in the actual pacemaker, and does not effect the field distribution in the SAR calculation.

A photo of the actual pacemaker is shown on the cover of this report. In this photo, the loop antenna is easily identifiable embedded in the header of the device (around the perimeter).

Integration of Pacemaker and Torso Model

The geometry for the implant was merged with the torso and pacing leads in a typical configuration were added. The composite model (anterior view) is shown in Figure 3a; Figure 3b shows a top view. The RF transmission source can be seen inside the composite anterior view as the green "speck" inside the titanium case.

Figure 3a. Composite Mesh Showing Torso and Implant, Anterior View

Figure 3b Composite Mesh Showing Torso and Implant, Top View

Elements Developed for SAR Analysis

The computation for SAR requires a source value and a source resistance. These were obtained as follows. An FDTD model of the antenna and FCC torso[2] were used to determine the input reflection coefficient of the antenna. This data was input to a RF linear modeling tool (Eagleware), and a lumped element description, using the optimization tools in Eagleware, of the input reflection coefficient was obtained. Figure 4 shows that the lumped element model and the reflection coefficient data are in good agreement to the 4th harmonic.

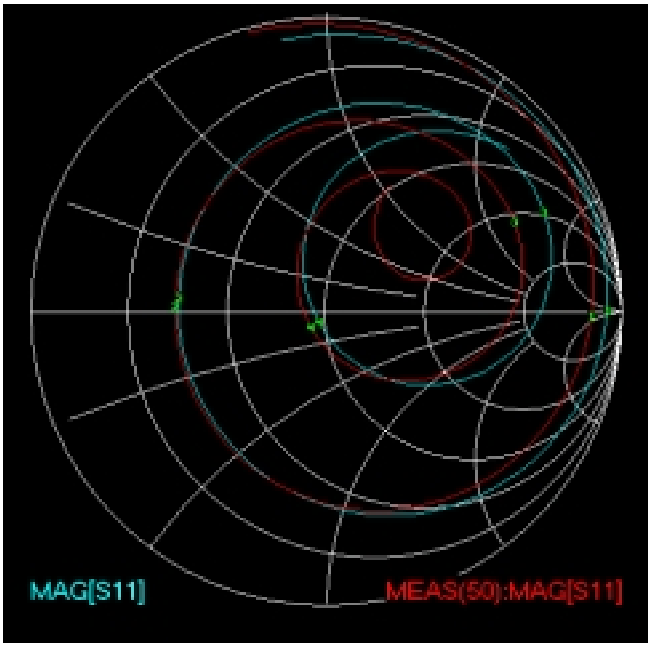

Figure 4.

Antenna Reflection Coefficient (red) and Lumped Element Antenna Model (blue)

The transmitter was modeled using PSpice, and this lumped element antenna model was used in the simulation. A range of resistive loads and this lumped element antenna were used to determine a Thevenin equivalent for the transmitter. These results were used as the source conditions in the XFDTD analysis. Source modeling in XFDTD is restricted to resistive loads only; the source impedance was found to be ~67 Ω, and the open circuit voltage to be 157 mV_{RMS}. A conducted measurement of the implant transmitter power into a 50 Ω load gives a value of –16 dBm at the fundamental. Using the information from the Pspice simulation to determine the available power from the transmitter,

$$P_{AVAIL} \equiv \frac{V^2{}_{OC}}{4 \cdot R_S}$$

The available power from the transmitter in the simulation is calculated to be –10.4 dBm. The calculated power delivered to a 50 Ω load would be –10.5 dBm. This shows good correlation (6 dB error) between the modeled result and the actual measured result, and furthermore it is noted that the error is conservative in that the modeled power is higher than the measured value.

SAR Analysis at 403 MHz

XFDTD provides an application to compute the SAR at a single frequency. This analysis and the biomesh model material were computed at 403.6 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[3]. Thus, it is reasonable to expect similar SAR results over the entire MICS band. Figure 5 shows the distribution of the SAR in the y plane, where the maximum value was computed. This is the maximum value in this computation and not an averaged value.

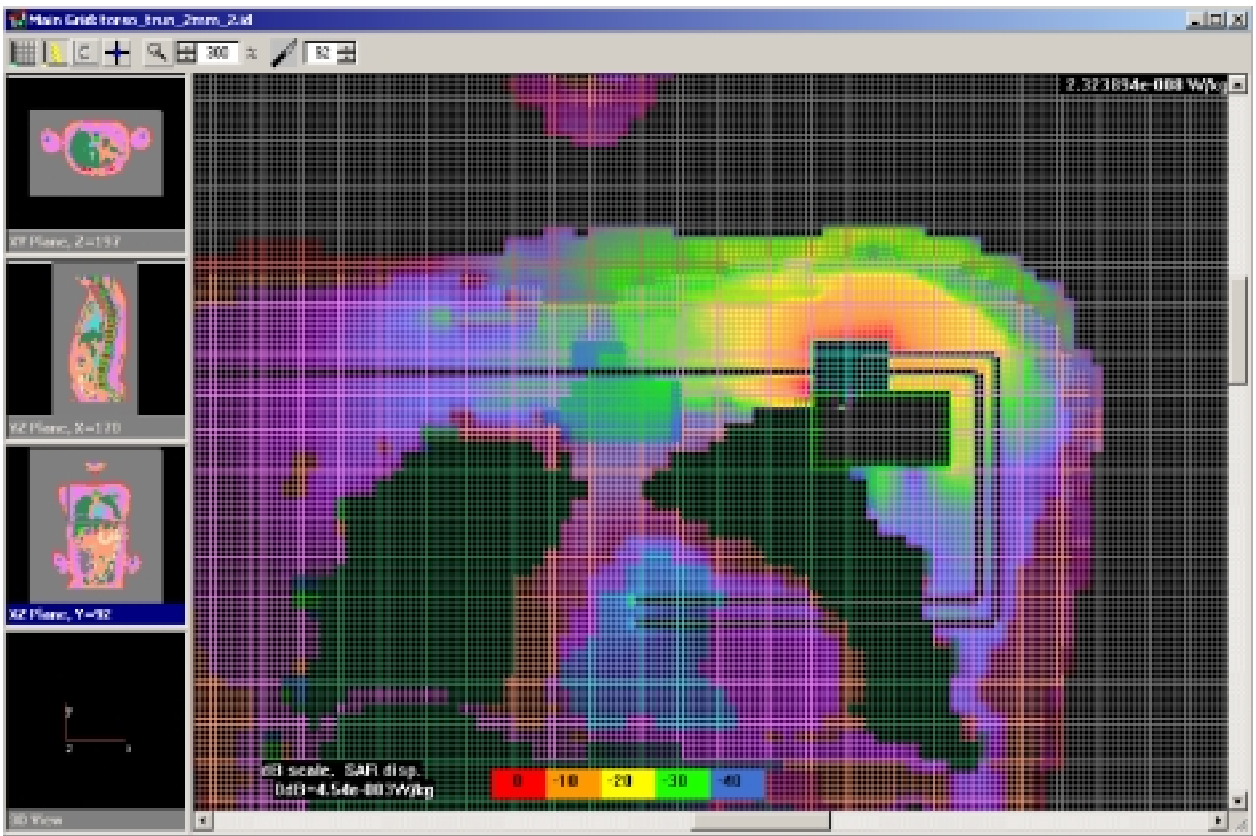

Figure 5. Plot of the maximum (unaveraged) Specific Absorption Rate (SAR)

Summary of Results

A summary table for the SAR statistics as generated by the XFDTD program is shown in Figure 6 on the following page. Since a typical implant device is located in the subcutaneous tissue, nominally a couple of cm below the surface, a 10 g average of SAR was not computed.

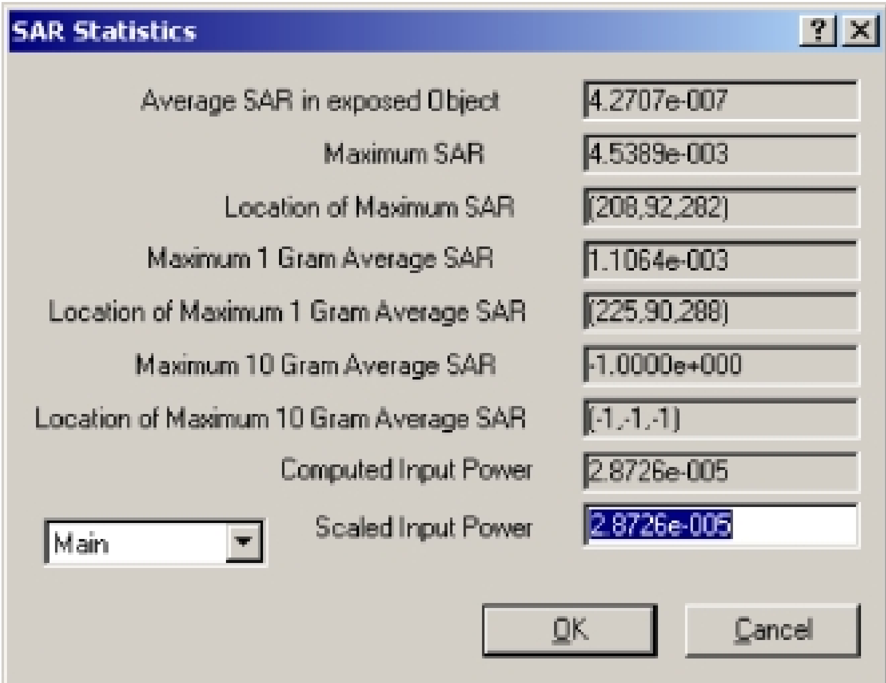

Figure 6.

Summary of SAR Statistics

The statistics summary in Figure 6 combined with the SAR plot of Figure 5 show that the location of maximum SAR is located in the area of the pacemaker antenna. The color map scale at the bottom center of Figure 5 is 10 dB per hue, so Figure 5 shows a color gradation of 40 dB. Using the pacemaker width of 5 cm as a scale notice that the SAR drops at ~20 dB in any 5 cm direction from the point of maximum SAR.

Conclusions:

As shown from this Finite Difference Time Domain analysis, the RF transmitter used by Biotronik in implantable pacemakers Philos DR-T and Actros TO+ meet the Specific Absorption Rate (SAR) standard set by ANSI/IEEE and incorporated into the FCC guidelines for medical implantable communications devices. The specific results reveal that the computed maximum SAR value for this RF circuit has a margin of 25.5 dB.

This analysis proves the safety of the implantable RF transmitter when used in its intended application, and can be compared very favorably with cellular telephone electronics, which propagate signals at SAR levels more than 350 times higher than the 4.54mWatt/kg Biotronik system. (cell phones SAR values are typically 500 to 1500mWatts/kg).

References:

1 Phone conversation with Ray Luebbers, Remcom Inc.
2. FCC torso model for MICS FCC 99-363 page 23
3. Camelia Gabriel "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies".
http://www.brooks.af.mil/AFRL/HED/hedr/reports/dielectric/cover.html