Specific Absorption Rate (SAR) Analysis Using Finite

Difference Time Domain (FDTD) Computation

on behalf of Hi-tronics Designs, Inc.

for the Angel Medical Systems Guardian IMD Model AG101 (Implantable Medical Device)

The analysis has been performed by Remcom Inc.

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Introduction

Hi-tronics Designs, Inc. has developed an Implantable Medical Device (IMD) which has the capability of wirelessly transmitting data to/from a patient/physician. The RF communication system utilizes the MICS band (Medical Implant Communications Service). The amount of radiated power transmitted through the human body tissue using this technology may be defined by a measure known as SAR (Specific Absorption Rate). Values of SAR that can be safely used in these applications have been defined by the 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 Services (MICS) requires a measurement of Finite Difference Time Domain (FDTD) analysis of the SAR associated with the presence of a radio frequency (RF) transmitter. This report details the SAR analysis of the RF transmitter used in the Angelmed Guardian IMD.

Summary

The commercial software analysis package XFDTD, a finite difference time domain analysis of the electromagnetic fields has been used to calculate the electromagnetic fields produced by the IMD and the resulting SAR (specific absorption rate) in human body tissue. The model used an accurate representation of the IMD and the HiFi Body Mesh available with the XFDTD Software.

The results are as follows:

Maximum SAR value	674 mW/kg
Maximum 1g average SAR value	73 mW/kg
Maximum 10g average SAR value	22 mW/kg
Average SAR value in torso	18 µW/kg

The ANSI C95-1-1992 limit is 1.6 W/kg. In this study, the computed value of the maximum 1g average is 73 mW/kg. The level of computed SAR is 4.5% of the limit stated in the specification.

These FDTD results show that the Hi-tronics Designs, IMD can safely be used in its intended application with respect to the energy emitted during normal operation.

Method of Analysis

The software used for the simulation, modeling and analysis was XFDTD v6.3. A 3D CAD model of the IMD was supplied by Hi-tronics Designs, in SAT format. This is the generic format used by the modeling system within XFDTD. The material specification was obtained from Hi-tronics Designs, and the electromagnetic properties of the device were either supplied by Hi-tronics Designs, or obtained from published data. The specific values are provided in Appendix A.

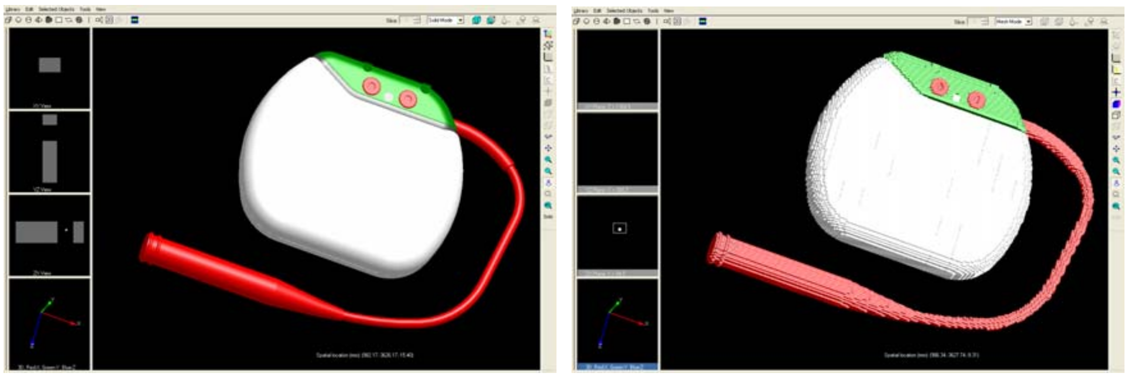

Figure 1: 3D CAD model and FDTD Mesh representation of IMD

The HiFi Body Mesh supplied with XFDTD was used to model the human tissues and body structure for this analysis. This model included frequency dependent electromagnetic properties of human tissues such that the correct values may be automatically selected to match the frequency of interest. In this case the frequency was 402.5 MHz, which is within the narrow operation frequency of the IMD (FCC MICS Band of 402 MHz to 405 MHz). The tissue material data has been developed over many years and is based on work by Dr.s Smith and Collins of the Hershey Medical Center, Pennsylivania State University.

The Human Body mesh was loaded first and the cell size set to 5mm. This matches the resolution of the tissue data within the HiFi Body Model. An initial mesh was generated to include only the Human Body. The IMD CAD model was then imported and positioned in the appropriate location (comparable to a pacemaker) within the Human Body Model. The cell size in the region of the IMD was then reduced to 0.5mm, using the built-in adaptive meshing features in XFDTD. This proved to be adequate to resolve the features of the IMD. From experience, it has become clear that the SAR is highest in the region of the antenna and so the Body Model was then limited to include only the torso to simplify computations and reduce simulation time.

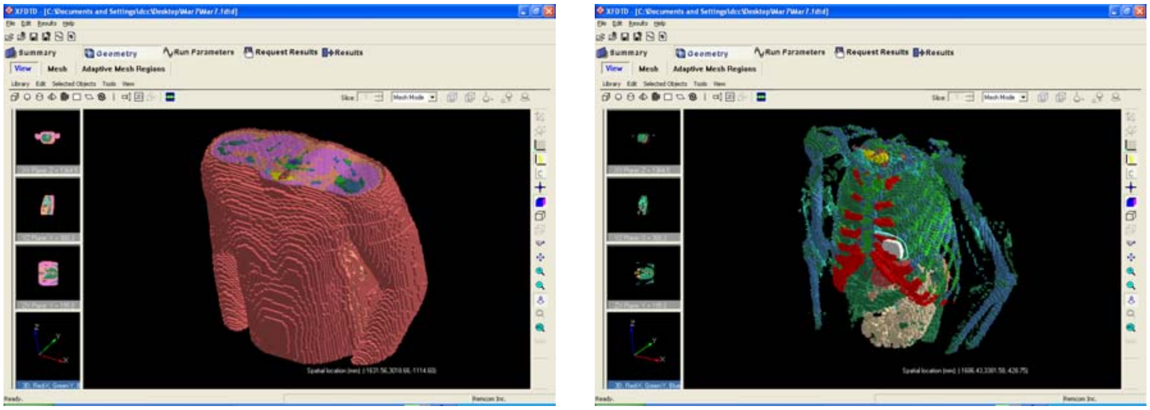

Figure 2: Torso biological tissue model (full model and selected tissues shown) With IMD in place

A single frequency analysis was carried out at 402.5 MHz.

XFDTD provides post processing features that allow SAR statistics to be calculated at a single frequency. The body tissue electromagnetic properties data have been determined by using a series of single pole Lorentz equations to fit published measured data to these equations. The equations are in the form of:

$$\varepsilon(\omega) = \varepsilon_\infty + (\varepsilon_s - \varepsilon_\infty)\frac{\omega_0^2}{\omega_0^2 + 2\,j\omega\delta - \omega^2}$$

Where ε_∞ is the infinite frequency permittivity

ε_s is the static frequency permittivity

τ_0 is the relaxation time (s)

ω is the frequency (radians/s)

In the MICS region of 402 – 405 MHz, this represents a fairly slowly changing permittivity and conductivity values. Thus it is reasonable to expect similar SAR results over the narrow band of operation of the IMD.

The SAR values are calculated from the following equation:

$$SAR = \frac{\sigma_x |E_x|^2}{2\rho_x} + \frac{\sigma_y |E_y|^2}{2\rho_y} + \frac{\sigma_z |E_z|^2}{2\rho_z}$$

where

SAR – Specific Absorption Rate (W/kg)

$\sigma_{x,y,z}$ - electrical conductivity (S/m)

$|E_{x,y,z}|$ - magnitude of electric field (V/m)

$\rho_{x,y,z}$ - material density (kg/m^3)

Results of SAR Analysis

XFDTD provides results in a tabulated format and as distributed field and SAR values in planes of the model.

Figure 3 shows a 3D view of the SAR distribution in the x-y plane where the value of 1 gm average SAR is a maximum. Figure 4 shows a more detailed view of this. The maximum value was computed as 73 mW/kg.

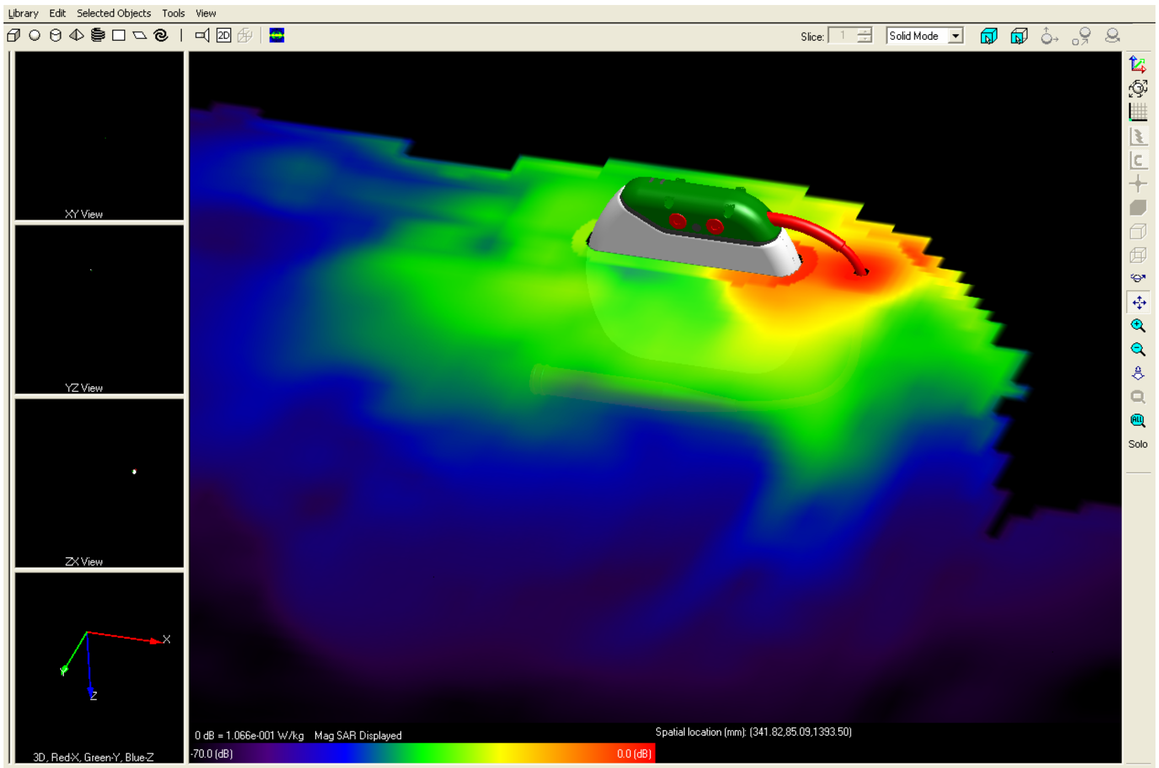

Figure 3: 3D view of the SAR distribution at the maximum value

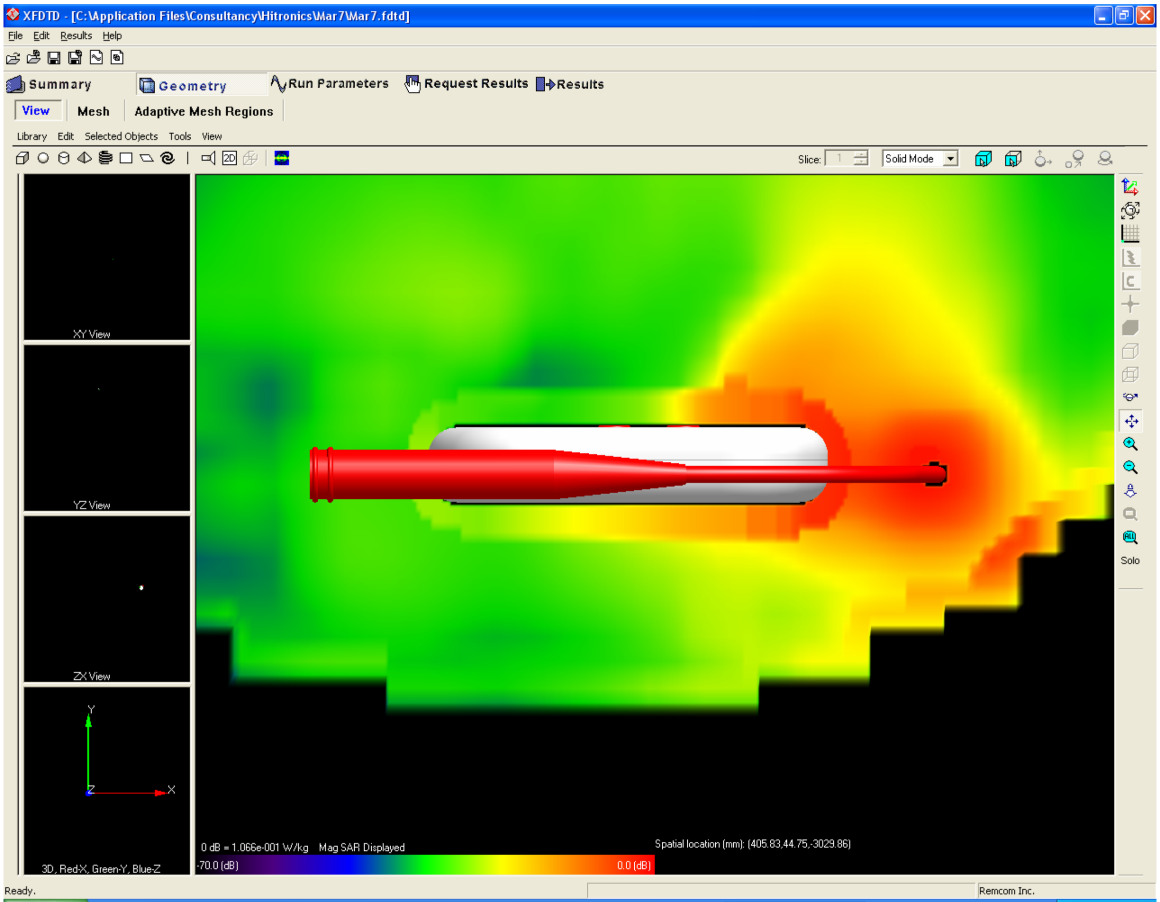

Figure 4: 2D view of the SAR distribution with and without geometry

The statistics table generated by XFDTD v6.3 is given in Figure 5.

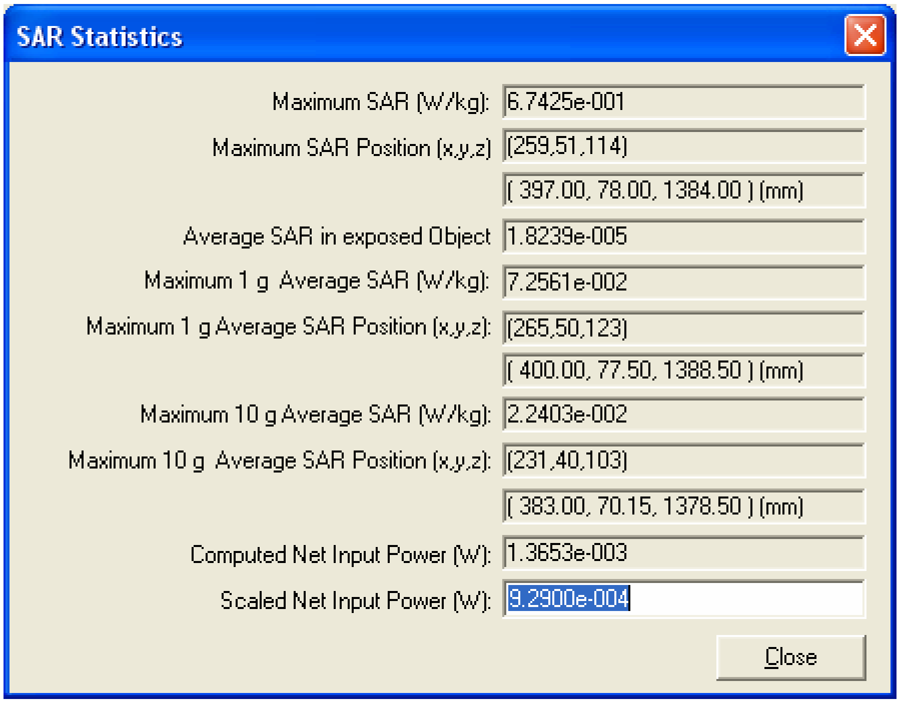

Figure 5: SAR Summary Table Generated by XFDTD

The statistics table of Figure 5 combined with the SAR distribution of Figure 4 shows that the maximum SAR value is located very close to the IMD Lead Adapter that contains the antenna and falls away within a few millimeters of the Lead Adapter/Antenna assembly.

Conclusions

The Finite Element Difference Time Domain analysis has shown that the SAR values produced by the radiated RF power of the Angelmed Guardian IMD are well below the maximum levels set by the ANSI/IEEE standards incorporated into the FCC guidelines for MICS. The results show that the computed maximum 1g average SAR value is 13.4dB below the maximum level permitted by the guidelines.

Specifications of Hardware and Software used in the analysis

For geometric modeling and post processing:

Dell dual 2.66GHz processor Windows XP Professional Workstation, 2GB RAM

For running the analysis:

Atipa 32 processor Linux cluster, Myrinet internal LAN with 1GB RAM per processor

Software:

XFDTD Bio-Pro v6.3 with adaptive meshing and HiFi Body mesh model.

Limitations

The Finite Element Difference Time Domain analysis has been based on information, data, measurements and specifications provided by Hi-tronics Designs, Inc. Remcom Inc. are not responsible for effects on the results of this analysis due to incorrect information, data measurements or specifications provided by Hi-tronics Designs, Inc.

Appendix A:

Specifications of IMD:

Peak power delivered to antenna (measurement supplied by Hi-tronics Designs,): 4dBm or 2.5mW. This is a conservative value as it is higher than the maximum obtained by measurement on a statistically significant sample of units.

RF Tx Duty cycle of device when RF operating: 37% of “on-time” which occurs during full data upload

Mean power delivered to antenna: 0.929mW

Material properties of IMD:

Header: Bionate 75D, conductivity=0 S/m, relative permittivity = 3.7, permeability=1.

All conducting parts (titanium can, header blocks, screws and antenna) were treated as PEC (perfect electrical conductors). Experience has shown that the difference between using PEC and the actual conductivity of highly conductive metallic parts is negligible.

Lead adapter insulation and other similar parts: Silicone, conductivity=0 S/m, relative permittivity = 3.2, permeability=1.