Specific Absorption Rate (SAR) Analysis Using Finite Difference Time Domain Computation for RF Transmitter Circuit Employed in Biotronik Belos "T" Implantable Cardiac Defibrillators

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Introduction

Biotronik has developed an RF communications system for use in implantable pacemakers and Implantable Cardiac Defibrillators (ICDs) 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 Belos "T" family of ICDs.

Biotronik performed this analysis on a previous implantable device designated as the BA03 DDDR pacemaker[1]. The FDTD analysis for that device was performed on February 3, 2001, and the equipment authorization for this device is listed under FCC identifier PG6BA0T. The RF circuit utilized in the Belos "T" family of ICDs is directly comparable to the BA03 pacemaker.

Summary

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

Maximum SAR	587 mW/kg
Maximum 1g average SAR	3.26 mW/kg
Average SAR	2.98 μW/kg

The ANSI C95-1-1992 limit is 1.6 W/kg. The computed value in this study of the maximum SAR in a 1 gram average is 3.26 mW/kg. The margin between the maximum attained SAR and the ANSI/IEEE specification limit is 26.9 dB (only 0.2% 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

The computational tool used for this FDTD analysis was XFDTD. The 3D import tool (available from Remcom with version 5.3) with was used to convert a 3D solid model of the ICD to a rectangular-grid FDTD computational space. Previous experience using FDTD modeling methods showed that the region of maximum SAR is concentrated very near the antenna. Thus the model used in this study was restricted to at least 2 cm of tissue around the ICD.

This SAR analysis used a relatively fine (1/3 mm) Yee cell size to realize the fine-structure in the header region, allowing modeling of the antenna and pacing connections in the header. The choice for this cell size and the decision to model only the tissue around the ICD was based on a telephone conference with Kwok Chan of the OET at the FCC (fall, 2001). As the E fields fall off very quickly a couple of cm away from the loop antenna, and the conducted power is less than 2 dBm, it was agreed that a SAR analysis with a fine cell size and limited tissue volume would suffice. The 2 dBm figure is derived from the SAR limit of 1.6 W/kg (or 1.6 mW/cc for water infused tissue) and a loop antenna area of ~1.5 square cm with an ICD thickness on the order of 1 cm. With a 1/3 mm cell size, the analysis region becomes very large when considering the model of an entire upper torso. The use of a 1/3 mm cell in this study yielded an analysis space of 27 million cells. Attempts to use a non-uniform grid with this tool have yielded nonconvergent solutions when the relative dielectric constant of the analysis space is larger than ~6, thus the analysis space was restricted to a uniform cell size.

Figure 1 shows a 3D view of the computational space.

Equipment and tools used for the analysis:

Hardware

Dell dual processor Windows 2000 Workstation, 1 Gb RAM 3 drive SCSI RAID
Hewlett-Packard 8591 Spectrum Analyzer
Hewlett Packard 8753E Vector Network Analyzer
Agilent 85070C Dielectric Probe

Software

XFDTD (Remcom) 5.3.0.2 Bio-Pro, Calc FDTD 5.3, Remesher 5.3, HIFI Body model

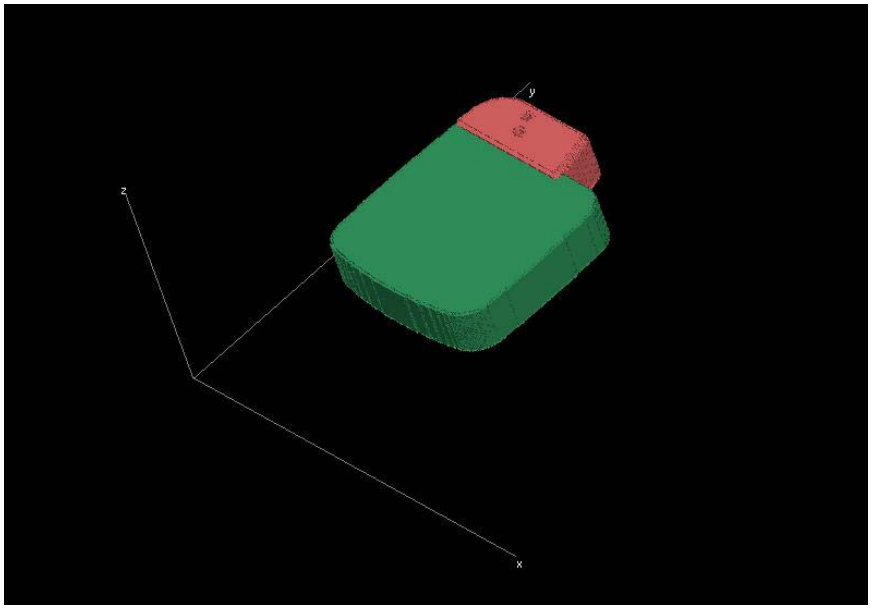


Figure 1

FDTD Model of Belos

Implantable Defibrillator Model

Figure 2 shows the model of the ICD used in the plane of the source and antenna.

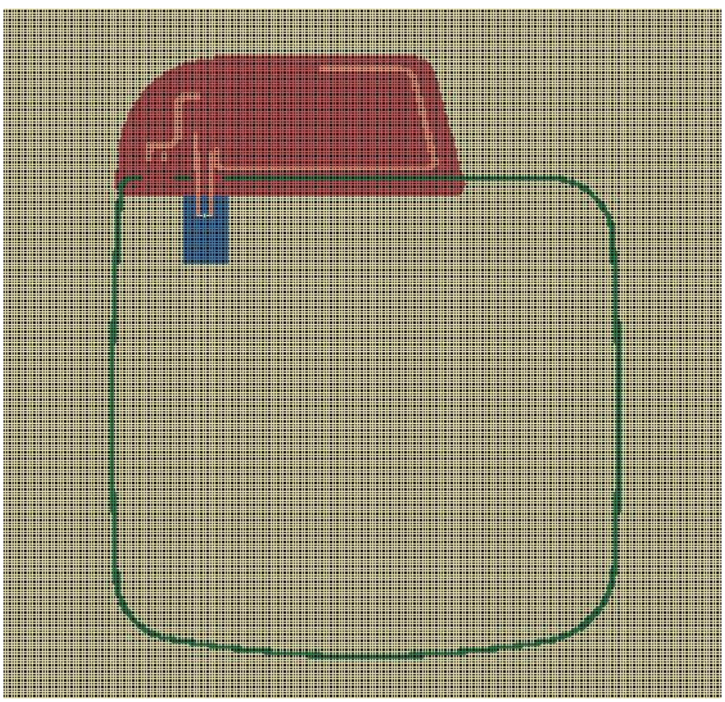
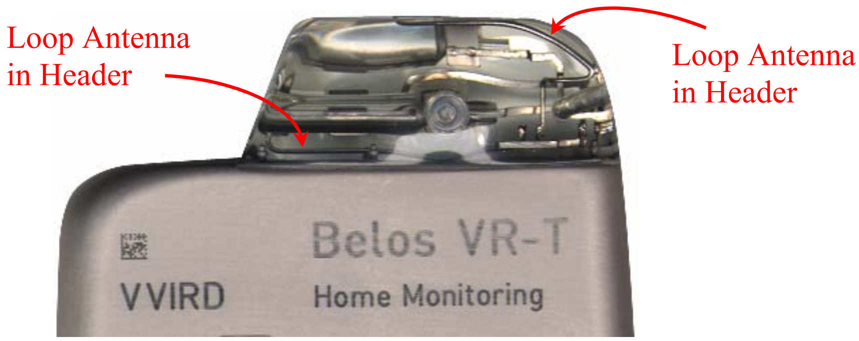


Figure 2.

Truncated Biomesh Resampled at $1/3mm^3$

The use of a small cell size allowed all elements of the structure to be realized with "non-thin" models. The epoxy-header material, shown in red , 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 of ~3 and a conductivity ~.001 S/m. The green area is the titanium case. The actual thickness of the titanium case was modeled; it is on the order of 1 mm, hence, there were ~3 cells used to model the width of the wall. The pink lines show the loop antenna and the pacing wires. The upper right corner (blue) shows an air space around the source. The electrical properties of the biological material were $\varepsilon = 54$ and $\sigma = 0.66$. As the mesh is 1/3 mm^3, Figure 2 shows that the ICD is 6.5 cm x 5.5 cm x 1.5 cm.

A photo of the header of the ICD "T" family is shown below. In this photo, the loop antenna is easily identifiable embedded in the header of the device (around the perimeter).



Elements Developed for SAR Analysis

The computation for SAR requires a source value and a source resistance. These were obtained as follows. The output reflection coefficient of the ICD was measured with an 8753ES network analyzer. The output impedance was computed from the reflection coefficient and was found to be 129.6 –j116.5Ω. This represents a series RC source impedance, with a capacitance of 3.38 pF at 403.6 MHz. The output was measured with an 8595E spectrum analyzer, and the source voltage was determined to be 357 mV_p. These values were used for the source parameters in XFDTD.

SAR Analysis at 403 MHz

XFDTD provides an application to compute the SAR at a single frequency. 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[2]. Thus, it is reasonable to expect similar SAR results over the entire MICS band. Figure 3 shows the distribution of the SAR in the y plane, where the maximum 1 gm average value (3.26 mW/kg) was computed.

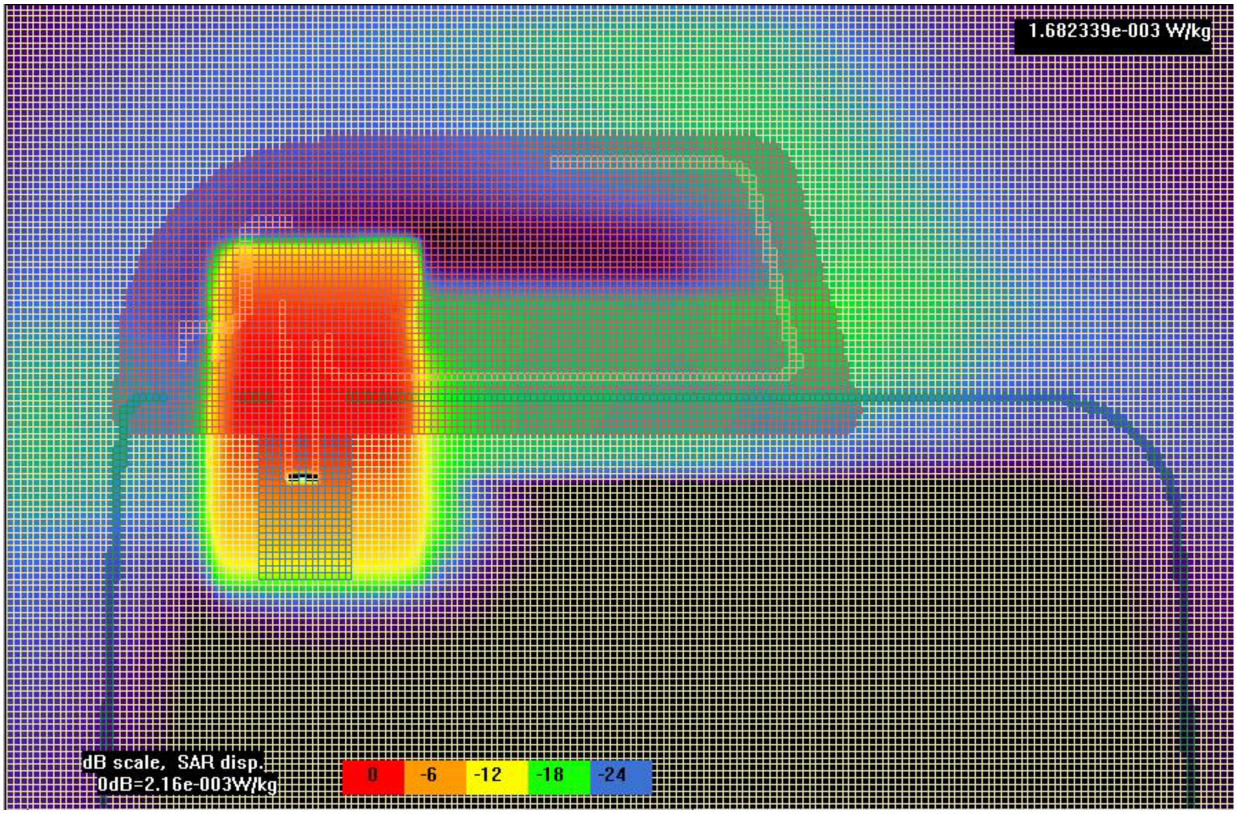


Figure 3. Plot of the Maximum 1 gm Average SAR

Summary of Results

A summary table for the SAR statistics as generated by the XFDTD program is shown in Figure 4. 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.

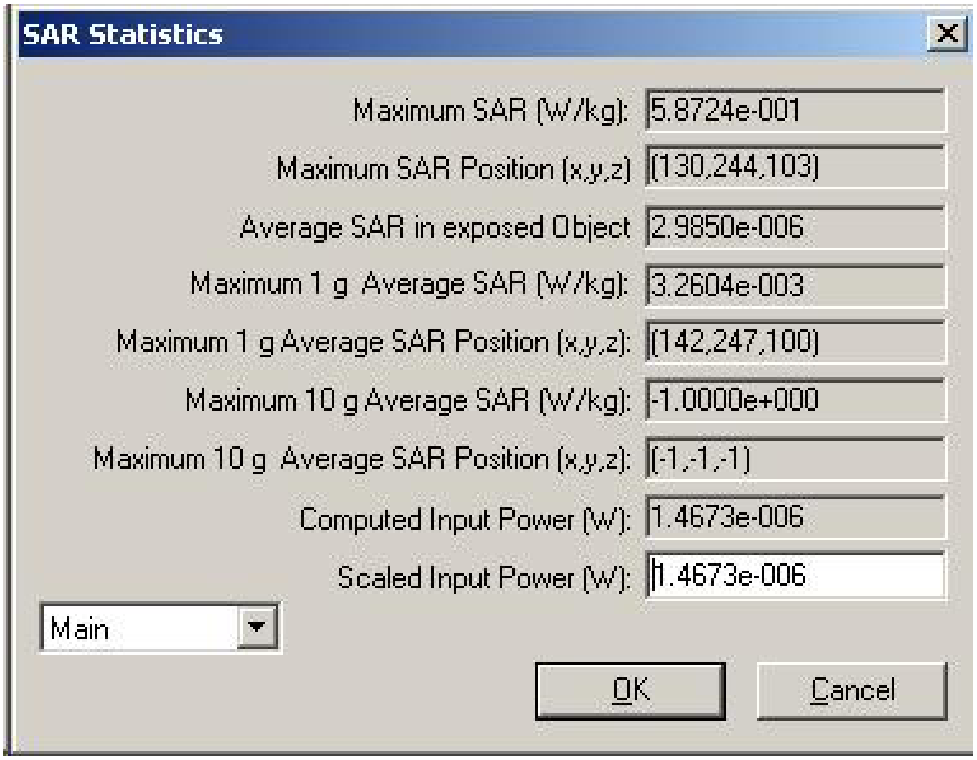


Figure 4. summary table for the SAR statistics

The statistics summary in Figure 4 combined with the SAR plot of Figure 3 show that the location of maximum SAR is located in the area of the implant antenna. The color map scale at the bottom center of Figure 3 is 6 dB per hue, so Figure 3 shows a color gradation of 24 dB. Using the Belos "T" width of 6 cm as a scale, notice that the SAR drops at ~20 dB in any 2 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 the Belos "T" ICD 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 26.9 dB.

This analysis proves the safety of the implantable RF transmitter when used in its intended application. It complies with the safety standards established by ANSI/IEEE and the Federal Communications Commission.

References:

1. Ed Wardzala, Mark Johnson "SAR Analysis Using FDTD Computation for RF Transmitter Circuit Employed in Biotronik Pacemakers Actros TO+ and Philos DR-T". Feb 3, 2001.

2. 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