Submittal: LF5MICSIMPLANT2

SAR Analysis

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The report is a summary of the FDTD modeling and simulations results of SAR to support the new product submittal for the Medtronic Consulta and Secura devices: LF5MICSIMPLANT2.

FCC Part 95, section 95.603(g) requires manufacturers of MICS transmitters perform a Finite Difference Time Domain (FDTD) computational modeling report showing compliance with radiofrequency radiation exposure requirements as specified in 1.1307 and 2.1093.

To show compliance with FCC rules a device model was created and put inside a human body model. The body model used was the High Fidelity Human Body Model which is provided with the Remcom XFDTD software version 5.3. For this analysis a 5 mm mesh was used. Results of the simulations showed that the highest levels of SAR are focused near the implant antenna. This knowledge was used further with a higher resolution analysis. The implant was modeled in 1mm mesh and surrounded by a homogeneous domain with electromagnetic properties of muscle tissue, which represents the worst case scenario leading to the highest local SAR levels. The information in this report is intended to show compliance of the unit with the RF exposure limits in the FCC rules.

FDTD Modeling

The Finite Difference Time Domain, or FDTD, modeling was originally developed by [Yee[1]] and has been described extensively in the literature. The method is a direct solution of the differential form of Faraday's and Ampere's laws. These differential equations are converted into difference equations using the central difference approximations. The field components are interleaved on each unit cell, so that the E and H components are half a cell apart, which is referred to as "leap-frog" scheme. In addition to being leap-frogged in space, they are also leap-frogged in time. The E field is assumed to be at time $n\Delta t$, and the H field is assumed to be at time $(n+1/2)\Delta t$.

The steps in the FDTD solution are:
1) Define model values of ε, ρ, and μ at each location
2) Assume initial conditions (usually that all fields and the sources are zero)
3) For each time step, n
   a) Specify fields at source
   b) Calculate E(n) for all locations
   c) Calculate H(n+1/2) for all locations
4) Stop when the solution has converged. For transient fields, this means all the fields have died away to zero. For sinusoidal fields, this means that all the fields have converged to a steady-state sinusoidal value.

FDTD has become the preferred method for bio-electromagnetic calculations at radio frequencies. It is efficient for modeling large-scale heterogeneous penetrable objects — like the human body. FDTD allows the use of many dielectric constants, allowing definition of different types of tissue and organs within the body.

FDTD has numerous other advantages for more advanced modeling. It is very accurate and fairly easy to use. It operates with a regular, orthogonal grid, with the wave frequencies of the modeling dependent on the dimensions of the grid. In the case of MICS modeling, a 5 mm grid of six million cells allowed creation of a model effective up to 1 gigahertz. Newly available high performance absorbing boundary conditions allow good computations throughout the body without the distortions that occurred in earlier models as a result of reflections from the outer radiation boundaries of the model.

FDTD provides an explicit time advance, with no systems of equations to solve. It can be applied to a wide variety of materials, such as the range of tissues in the human body. It allows for arbitrary incident fields, and is useful for far- and near-field exposure conditions including coupled sources.

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[1] **Yee, K.S.**, Numerical solution of initial boundary value problems involving Maxwell's equations in isotropic media, *IEEE Trans. Ant. Prop.*,14(3), 302, 1966

The Visible Human Model

The human body model used for these analyses is the High Fidelity Human Body Model which is provided with the Remcom XFDTD software. MICS modeling started with a human body model obtained from REMCOM, Inc. This model was created from "frozen man" slices from the Visible Human Project, obtained via the Internet and meshed using custom software. The software used for the analyses is Remcom XFDTD version 5.3

The bio-electromagnetic human body model is a digitized version of a real human body. A donated cadaver was frozen and sliced in 5 mm slices. Each slice was identified for parameters such as muscle, fat, and bone. The results were digitized to create a total numerical model, using a 5 mm cell, for a total of about six million cells. Twelve different types of tissue were identified. Constitutive parameters were assigned based on the original data, and checked and corrected using interactive editing.

Figure 1 shows the High Fidelity Human Body model.

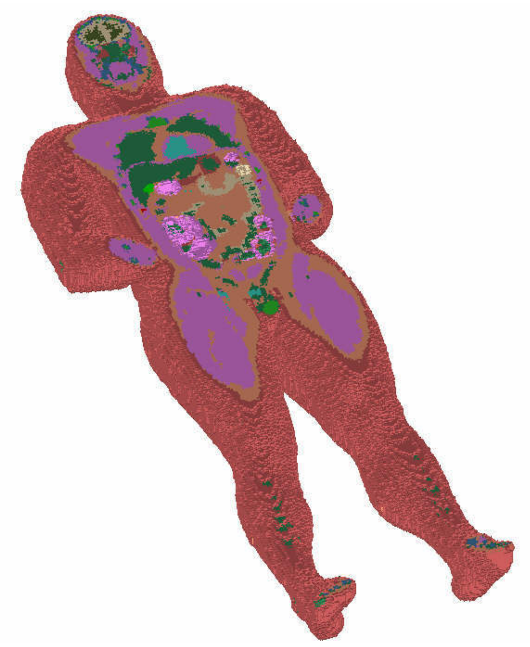

Figure 1: High Fidelity Human Body Model.

Figure 2 shows the High Fidelity Human Body Model in the chest area of the body with the MICS implant in place in the upper left quadrant, modeled at UHF.

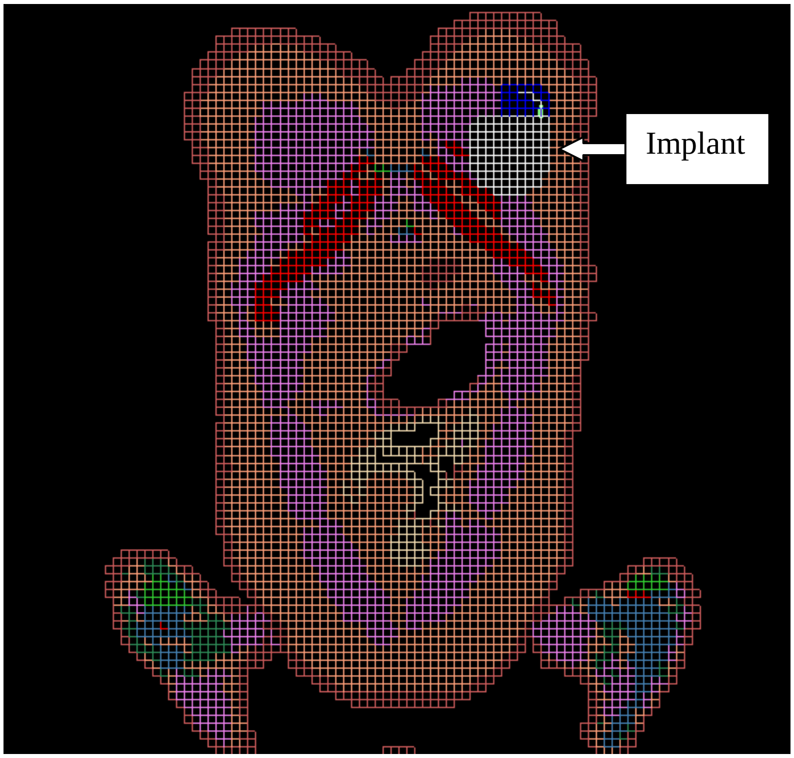

Figure 2: The MICS is visible in the upper left quadrant of the chest in this section.

For the High Fidelity Human Body Model, the depth of implant was 1 cm, typically. Detailed analyses verified 1 cm depth was sufficient to verify SAR limits are being met.

Specific Absorption Rate Modeling

The human body model can be used to evaluate the safety of the MICS implant by examining the Specific Absorption Rate (SAR) in the body. In general, the FDTD method calculates the time-domain vector E and H fields at every location inside and outside of the body. These can be converted to frequency domain fields (magnitude and phase at given frequencies). From them, values commonly of interest in bio-electromagnetic simulations can be calculated, including specific absorption rate, current density, total power absorbed, temperature rise, etc.

SAR is an important measure of the amount of power the implant is putting into the human body per kilogram of tissue. For near-field applications, such as a medical implant with telemetry transmitter, it is important to determine if the device complies with the ANSI/IEEE safety guidelines and FCC guidelines. These guidelines state that an exposure can be considered to be acceptable if it can be shown that it produces SAR's "below 0.08W/kg, as average over the whole body, and spatial peak SAR values not exceeding 1.6 W/kg, as averaged over 1 g of tissue (defined as a tissue volume in the shape of a cube)".

SAR for the MICS implant was evaluated for the Medical Implant Communication System operating at 0dBm, or power input of 1mW into the body. The SAR at a given location is given by the following formula:

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

where σ is the electrical conductivity and ρ is the mass density at the location of interest.

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Three different values must be evaluated to ensure that the implant meets safety standards:

- the maximum SAR considering total power applied to total weight
- the maximum SAR considering the same amount of power applied to 1 gram of tissue
- the maximum SAR considering the same amount of power applied to 10 grams of tissue.

5mm Model in Human Body

Results of SAR simulation in the body with 5mm mesh are shown in Figure 3. The plots present relative 1g average SAR levels in dB at the worst case slices in the High Fidelity Human Body Model with MICS implant at two locations.

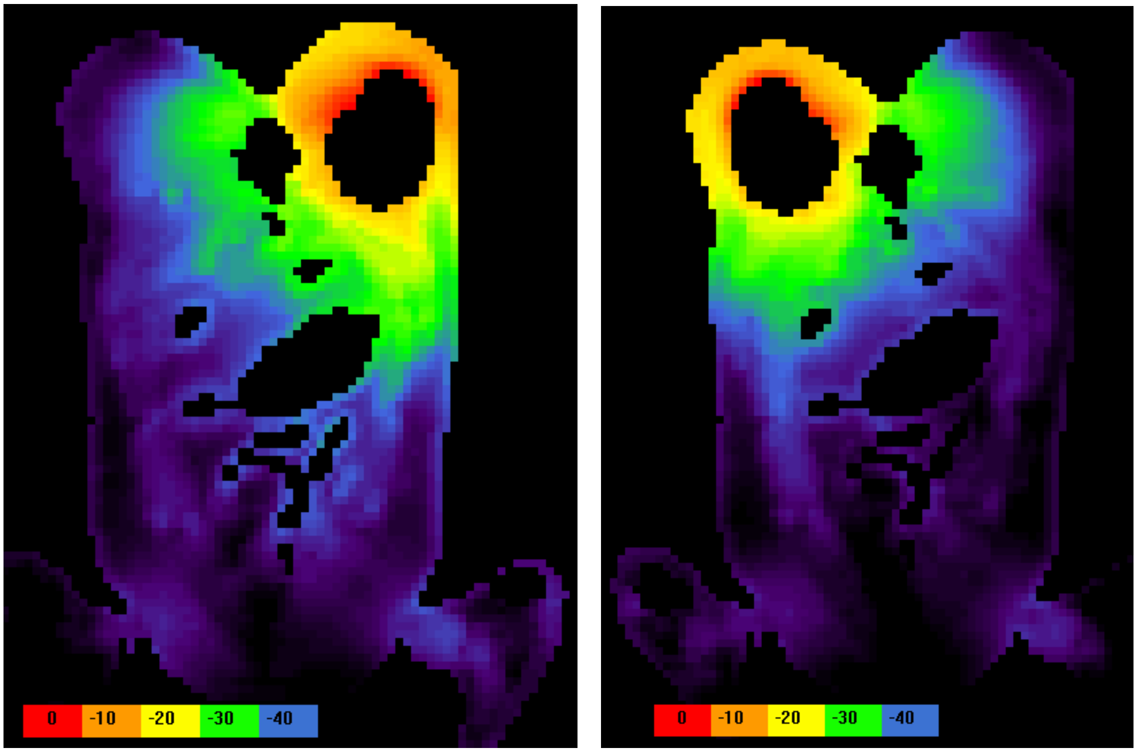
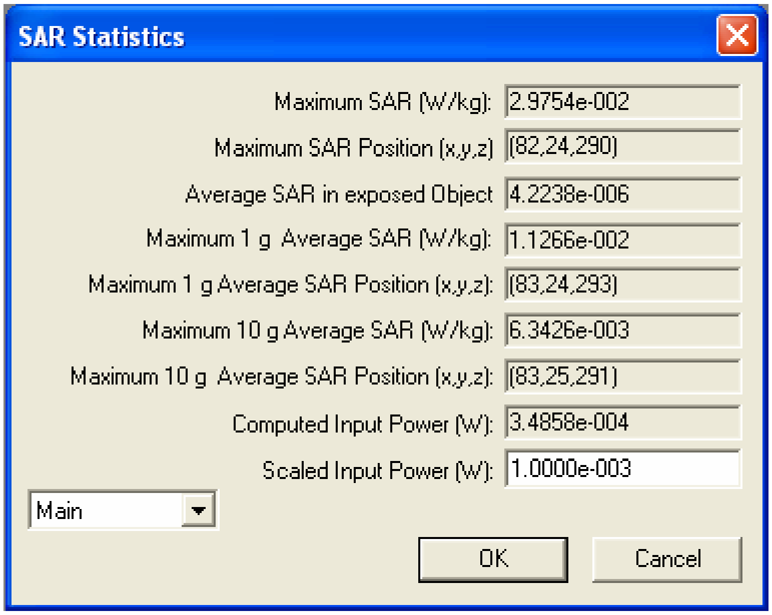


Figure 3: Worst case slice for two implant locations in the 5 mm model

Figure 4 summarizes the SAR statistics required for verifying the safety standards:



Maximum SAR (W/kg): 2.9754e-002
Maximum SAR Position (x,y,z) (82,24,290)
Average SAR in exposed Object 4.2238e-006
Maximum 1 g Average SAR (W/kg): 1.1266e-002
Maximum 1 g Average SAR Position (x,y,z): (83,24,293)
Maximum 10 g Average SAR (W/kg): 6.3426e-003
Maximum 10 g Average SAR Position (x,y,z): (83,25,291)
Computed Input Power (W): 3.4858e-004
Scaled Input Power (W): 1.0000e-003

Figure 4: Simulation summary of SAR results

Figure 9 illustrates the important SAR conclusions:

- The SAR average over the whole body is 4.2e-06 W/kg. This is over 42 dB below the ANSI safety standard of 0.08 W/kg.
- The maximum 1 g average SAR is 1.1e-02 W/kg. This is 21.5 dB below the ANSI safety standard of 1.6 W/kg.
- The maximum 10 g average SAR is 6.3e-3W/kg. This is 28 dB below the ANSI safety standard of 4 W/kg.

1mm Model in a Homogeneous Muscle Box

One may clearly see in Figure 3, that the maximum levels of SAR are localized near the implant antenna. Therefore, the analysis can be performed for much smaller volumes than the entire human body. This gives opportunity to significantly increase resolution of the model. We performed analysis with 1mm grid. Figure 5 depicts the antenna model with 1mm resolution. Figure 6 depicts different views of the entire implant model used in the 1mm analysis. The implant was surrounded by homogeneous volume of muscle tissue. Muscle tissue having high conductivity represents the worst case scenario, as we may expect the highest local SAR levels.

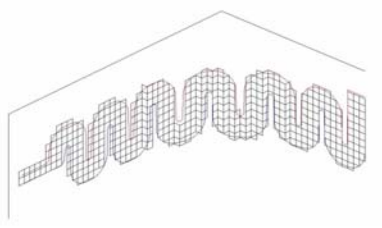


Figure 5: Antenna model

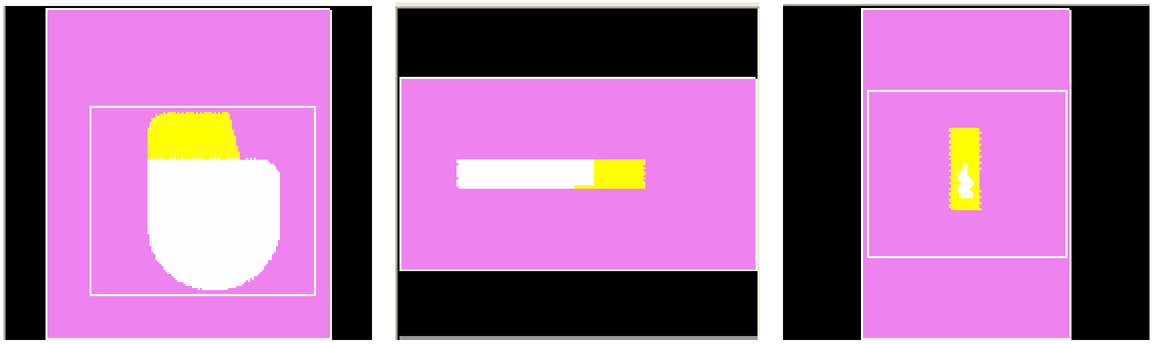


Figure 6: Views of Implant model

All simulation data is related to the implant placed in a cube of muscle tissue. The domain is surrounded by electric wall boundary. The antenna surfaces are at 4cm distance from the wall in the transverse plane and 3 cm from the wall in the normal plane. The smallest distance between the can and the wall is 2cm. Figure 7 depicts a 3D view of the FDTD model used for SAR analysis.

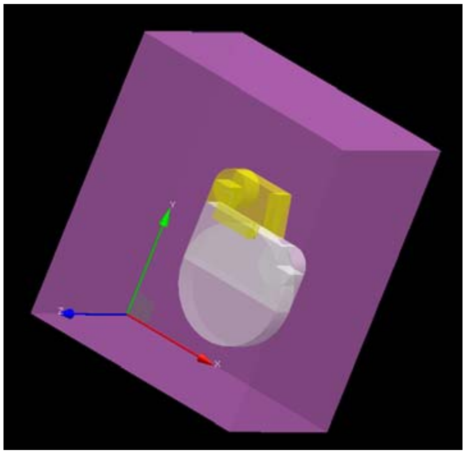


Figure 7: 3D view of SAR model

The SAR simulation result plots in Figures 8-11 show the relative SAR level for the model implant in muscle tissue.

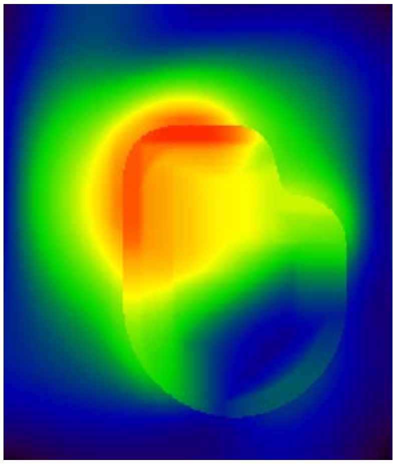


Figure 8: 1g Avg SAR distribution at front surface

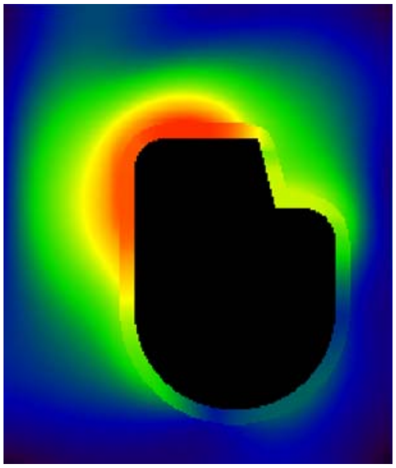


Figure 9: 1 g Avg SAR distribution at max SAR cross section

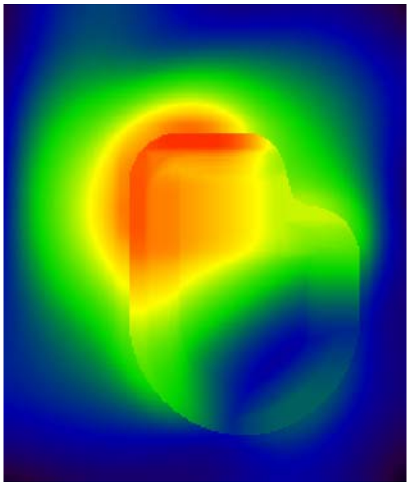


Figure 10: 1 g Avg. SAR distribution at back surface

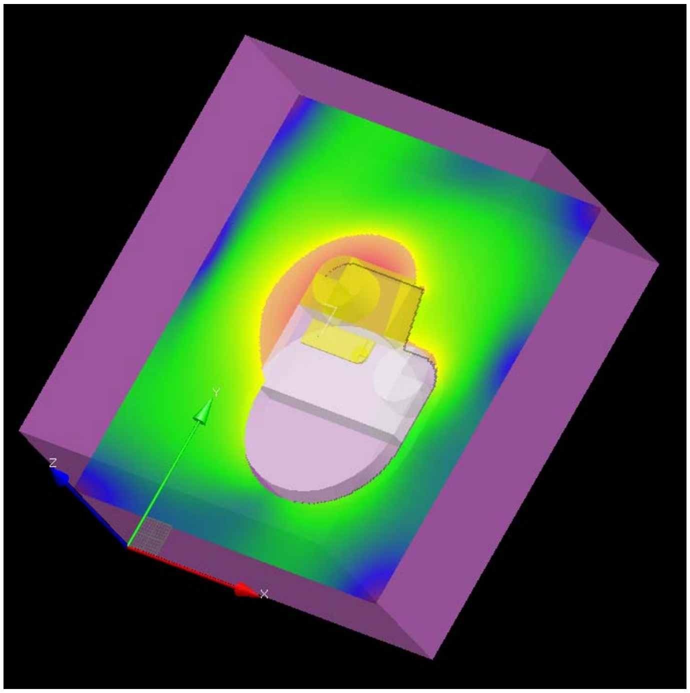


Figure 11: SAR distribution 3D view.

Implant Safety Conclusions

Based on the worst case scenario analysis of the implant inside a homogeneous muscle cube, we may draw the following important SAR conclusions:

- The SAR average in exposed object is 9.0e-4 W/kg. This is over 19dB below the ANSI safety standard of 0.08 W/kg.

  Note: This is a worst case result since the exposed object in this analysis was a cube of muscle tissue significantly smaller than the Human Body Model. Therefore if this result was averaged over an entire body the calculated SAR value would be smaller and the relative safety margin would be greater. This is justified by comparison to original SAR analysis using the Human Body Model that was accepted by FCC.

- The maximum 1 g average SAR is 7.8e-2 W/kg. This is 13dB below the ANSI safety standard of 1.6 W/kg.

Summary of FDTD Modeling Conclusions

Analysis of SAR shows an absorption rate of power into the body well within the standard guidelines for safety, demonstrating the ability of MICS to operate safely within the human body. The unit complies with the RF exposure guidelines specified in the FCC Rules.