# SAR Analysis

# Model B35200 977005 977006

Girard Guillaume

Medtronic, Inc.
Mounds View, MN 55112
October 13, 2021

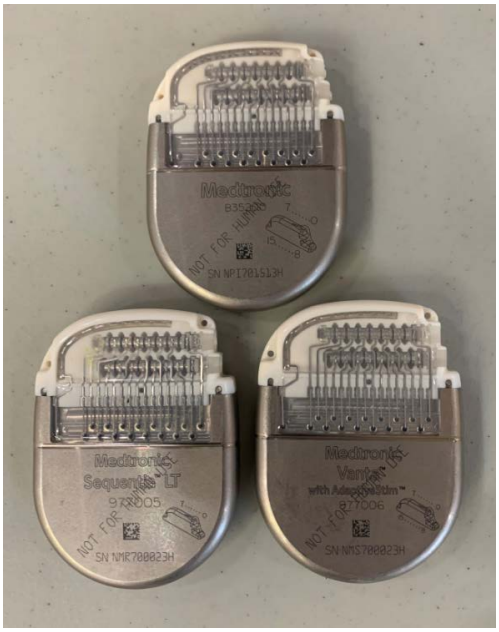


**Figure 1: Medtronic Implantable neurostimulators**

This report satisfies CFR 47, §§95.1221, and §§1.1307 and §§2.1093, which require MedRadio implanted transmitter manufacturers to show compliance with radio frequency exposure requirements using electromagnetic computational modeling.

## METHODOLOGY:

The computational modeling and simulations within this report were performed with Ansys' HFSS™ Finite Element Modeling (FEM) program, version 13.0.2. FEM modeling programs were approved for calculating SAR for implanted MedRadio transmitters as noted in FCC approval DA 11-192.

The HFSS program utilizes an Ansys provided human body model with 4mm or better of resolution (see figures 2 and 3).

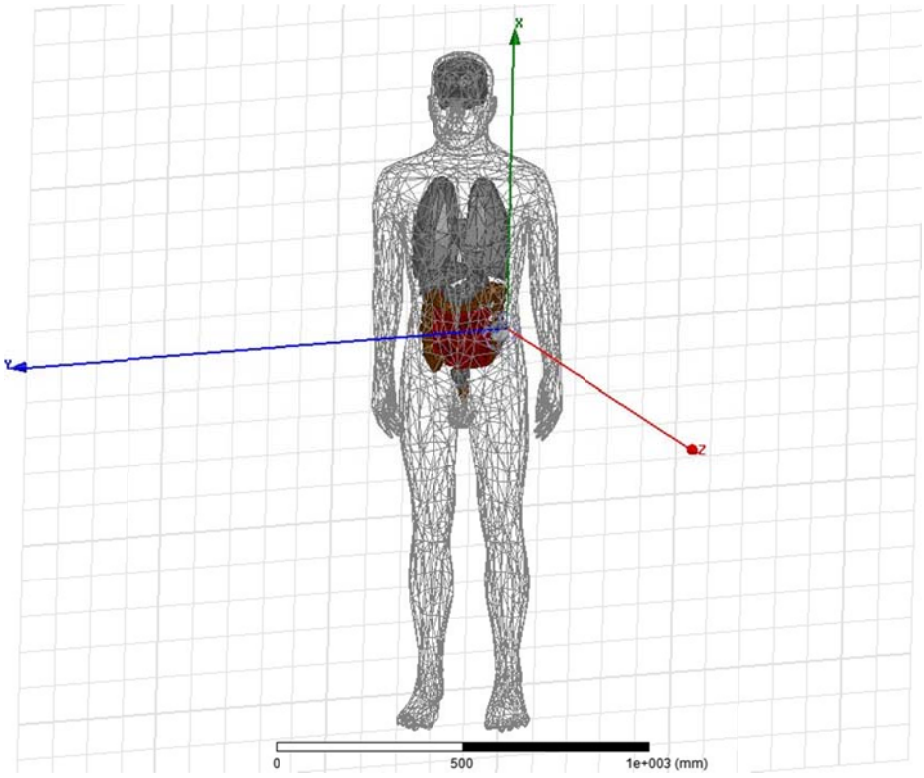


**Figure 2: HFSS 4 mm Resolution Human Body Model (with implant shown in the abdominal implant location)**

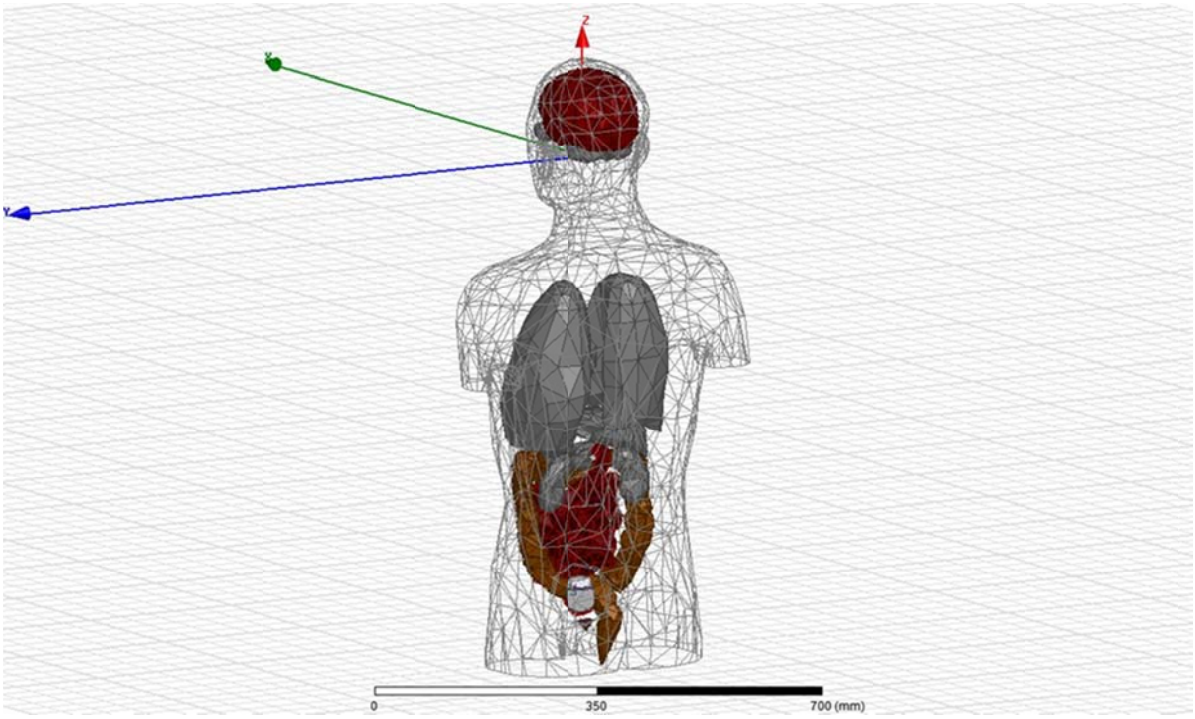


**Figure 3: HFSS 4 mm Resolution Human Body Model (with implant shown in the gluteal implant location)**

The 4mm resolution human body model contains 15 tissue types as listed in table 1. This model was used to ensure accurate modeling and to allow reasonable simulation times (simulation time for determining 1 g SAR is approximately 30 hours).

| | Tissue Type | Relative Dielectric Constant | Conductivity (S/m) |
|---|---|---|---|
| 1 | Air | 1.00 | 0.00 |
| 2 | Human Bladder | 19.89 | 0.33 |
| 3 | Human Brain AVG | 49.14 | 0.69 |
| 4 | Human Cerebellum | 58.03 | 1.02 |
| 5 | Human Colon | 63.77 | 0.86 |
| 6 | Human Eyes | 69.00 | 1.53 |
| 7 | Human Gallbladder | 62.49 | 1.13 |
| 8 | Human Heart | 67.63 | 0.96 |
| 9 | Human Kidney | 68.39 | 1.09 |
| 10 | Human Liver | 52.33 | 0.65 |
| 11 | Human Muscle | 58.46 | 0.82 |
| 12 | Human Small Intestine | 75.72 | 2.04 |
| 13 | Human Spleen | 64.90 | 1.02 |
| 14 | Human Stomach | 68.10 | 1.00 |
| 15 | Human Testes | 66.61 | 1.10 |

**Table 1: HFSS 4mm Resolution Human Body Model Tissue Parameters**

The model of the implanted transmitter is based on the mechanical CAD files which are used to fabricate the device components. A modified version of this CAD file was imported into HFSS to create the device model. The HFSS program was able to process edges and curves but would not mesh complex scalloped/"true-surface" geometries. As a result, the implanted device model was slightly simplified to reduce the multi-scalloped planes along the edge of the titanium device housing/can, and to also to slightly reduce the complexity of multi-scalloped planes and minor protrusions in the device connector header. The final device model still contains significant detail, as seen in figure 4 below.

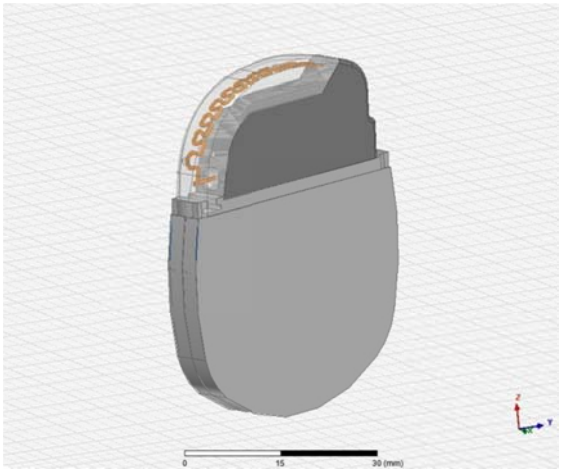

**Figure 4: The Implanted Device Model**

the implantable neuro device contains a transceiver module, which is trimmed during manufacture for a desired transmitter RF power output. The maximum trimmed transmitter output power at the antenna feed-point is -0.55 dBm (maximum including manufacturing trim tolerance, with conjugate impedance matching).

The quality of the neuro device model was tested by comparing measured results from manufactured device hardware with HFSS simulations results for devices submerged in a saline solution.
The gain and efficiency of the antenna in this implantable device have been simulated. Both agree with measured results.

The neuromodulation device is commonly implanted in two locations within the human body. Figure 2 illustrates the abdominal implant location, and figure 3 illustrates the gluteal implant location. The zoomed in frontal and side views of the abdominal and the gluteal implant locations, respectively, are shown in figures 5, 6, 7, and 8. The tissue volume of the human body model that completely surrounds the implantable device in either implant location is muscle tissue. Other location such as the subclavian are are also possible but results for the above location reflect the worst case conditions.
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 $\sigma$ is the electrical conductivity and $\rho$ is the mass density at the location of interest.

As can be seen from the equation, tissue types with higher conductivity produce a higher SAR for a given electric field strength. Neither the abdominal nor the gluteal implant locations provide an obvious worst-case scenario. Therefore SAR was modeled/simulated for both implant locations.

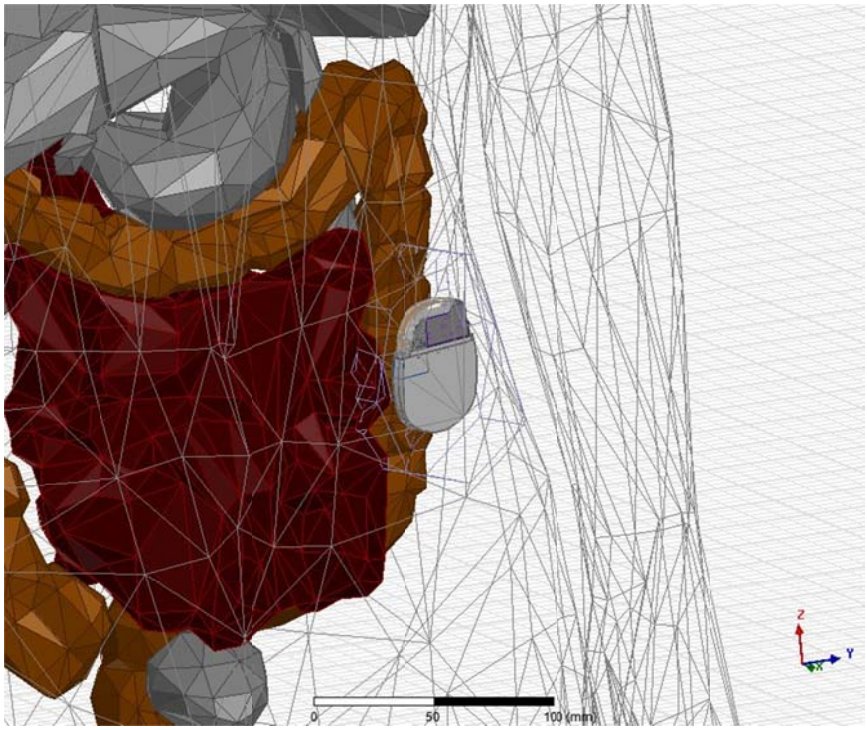


**Figure 5: Implanted Device in the Human Body Model (Frontal, zoomed-in view: abdominal location)**

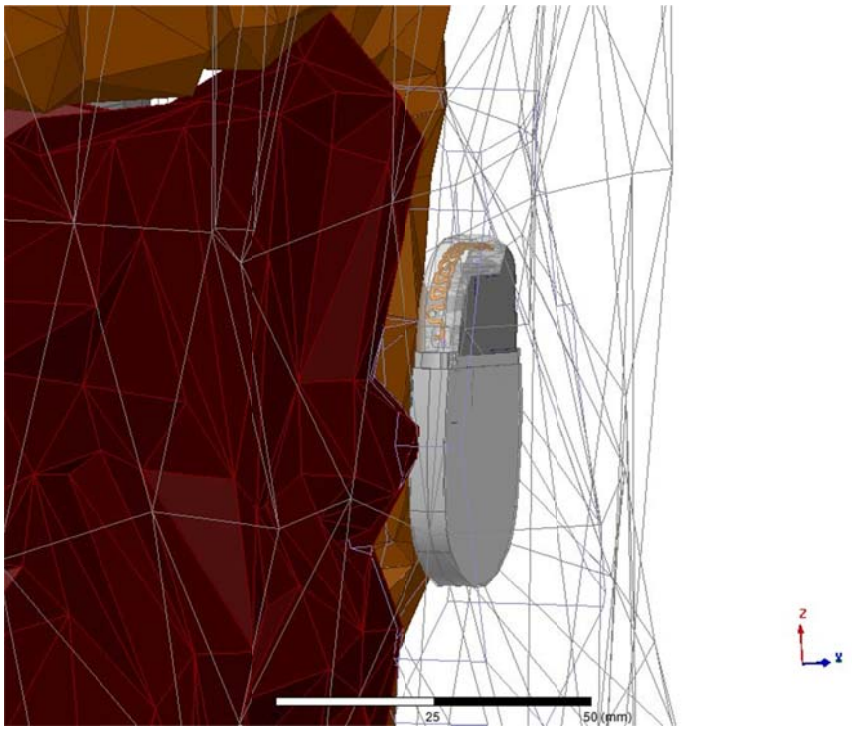


**Figure 6: Implanted Device in the Human Body Model (Side, zoomed-in view: abdominal location)**

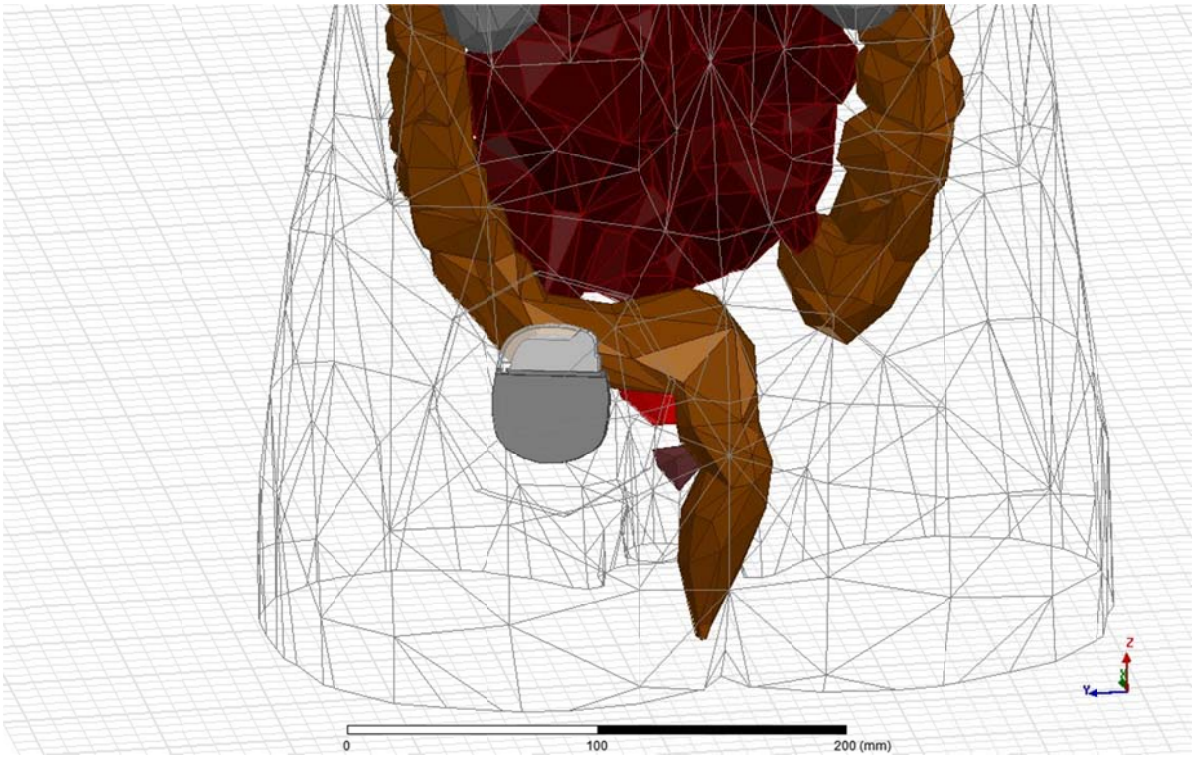


**Figure 7: Implanted Device in the Human Body Model (Rear, zoomed-in view: gluteal location)**

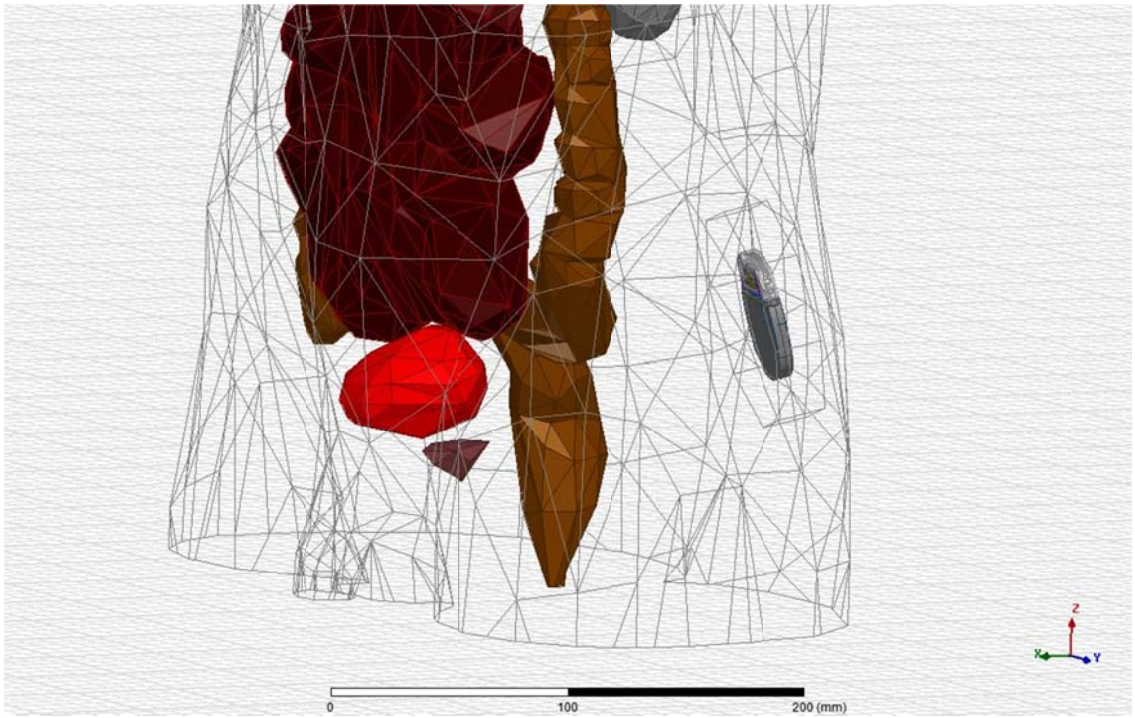


**Figure 8: Implanted Device in the Human Body Model (Side, zoomed-in view: gluteal location)**

An HFSS analysis using the 4 mm, or better, resolution Ansys supplied human body model, as illustrated, was used to determine the expected Specific Absorption Rate (SAR) when the MEDRadio transmitter is operated in-vivo. The HFSS software uses the finite element method to discretize the problem space and then calculates the electric and magnetic field vectors at each of the mesh cell vertices. The HFSS mesh resolution uses adaptive refinement which increases mesh resolution in regions with large spatial electric field gradients. In the vicinity of, and including, the implanted device, the maximum mesh resolution is 0.0152933 mm = 0.0006 inches.

The program modeling and simulation control parameters are listed below in Table 2.

| |
|---|
| 1) Solution frequency =403.5MHz (solution frequency for adaptive passes/mesh refinement) |
| 2) Maximum number of adaptive passes =15 |
| 3) Maximum refinement per pass =30% |
| 4) Solution Basis Function = First Order |
| 5) Enabled iterative solver with relative residual 0.0001 |
| 6) Expression Cache with Total_LocalSAR field calculator expression with a less than 1% change convergence condition |
| 7) Frequency sweep from 402 to 405 in steps of 1.5MHz (one-time for SAR validation, and every simulation for field calculation). |

Table 2: HFSS Modeling/Simulation Control Parameters

Simulation results show that the highest spatial SAR levels were recorded in tissue near the implanted radio antenna. These are illustrated in figures 9 and 10 which show the field strengths in the whole human body model and the zoomed-in human body volume respectively due to the transmitter for the abdominal implant location. Figures 11 and 12 show similar field strengths due to the transmitter for the gluteal implant location

The averaged whole-body SAR due to the Medtronic MedRadio transmitter was simulated for an abdominal implant with the human body model to be 1.53E-5 W/Kg.

The spatial peak SAR averaged over any 1 gram (cube) of tissue was simulated for an abdominal implant with the human body model to be 0.284 W/Kg.

The spatial peak SAR averaged over any 10 gram (cube) of tissue was simulated for an abdominal implant with the human body model to be 0.0507 W/Kg.

The averaged whole-body SAR due to the Medtronic MedRadio transmitter was simulated for an gluteal implant with the human body model to be 1.53E-05 W/Kg.

The spatial peak SAR averaged over any 1 gram (cube) of tissue was simulated for an gluteal implant with the human body model to be 0.280 W/Kg.

The spatial peak SAR averaged over any 10 gram (cube) of tissue was simulated for an gluteal implant with the human body model to be 0.0503 W/Kg.

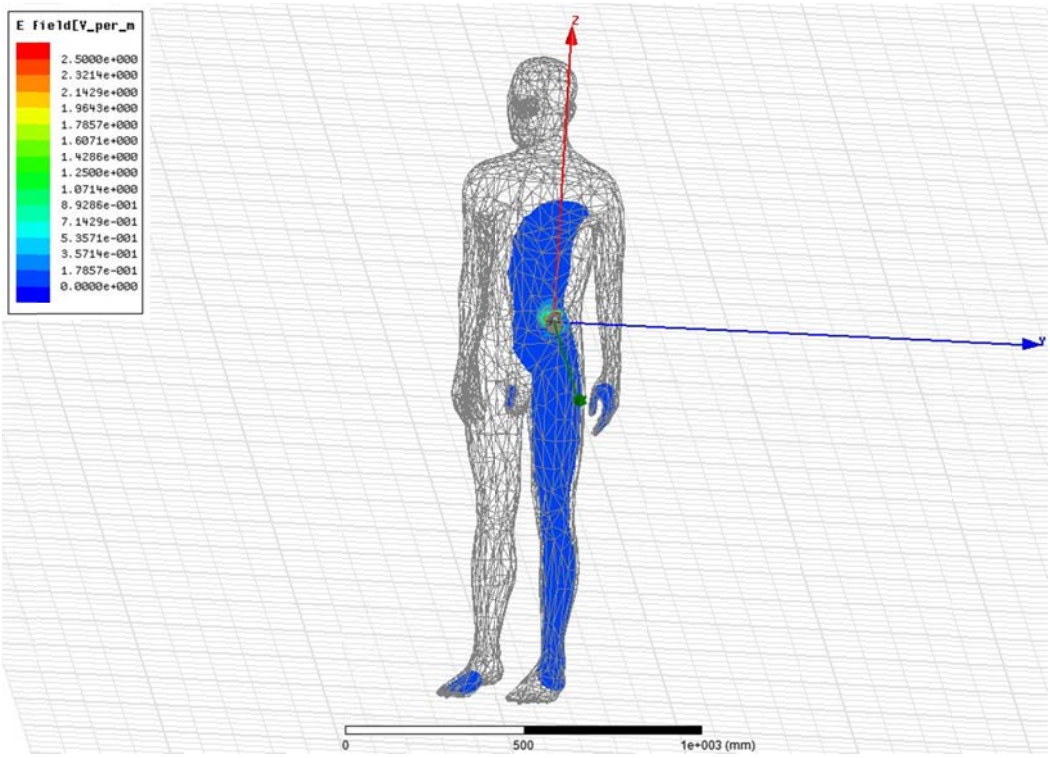


**Figure 9: HFSS 4 mm Human Body Model with Implanted Device in the Abdominal Implant Location (simulated fields also shown)**

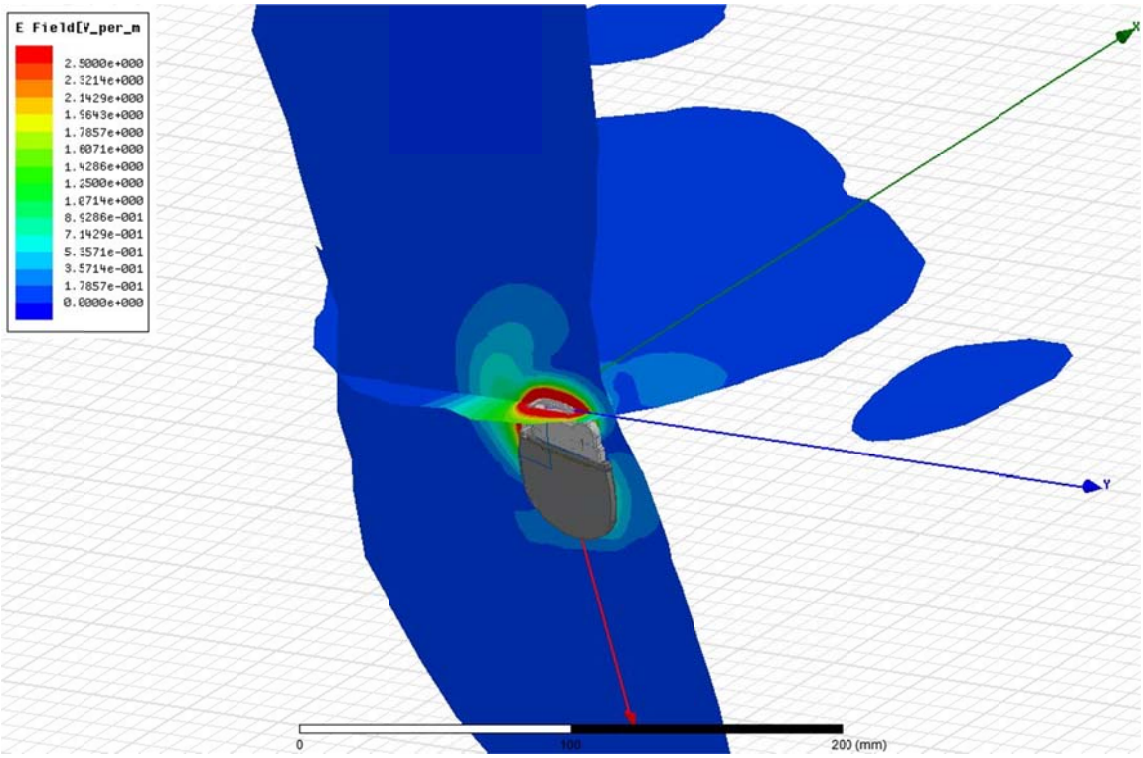


**Figure 10: Zoom-In of HFSS simulation output with Implanted Device shown in the Abdominal Implant Location (4 mm Human Body Model simulated, but not shown to allow visibility of field data)**

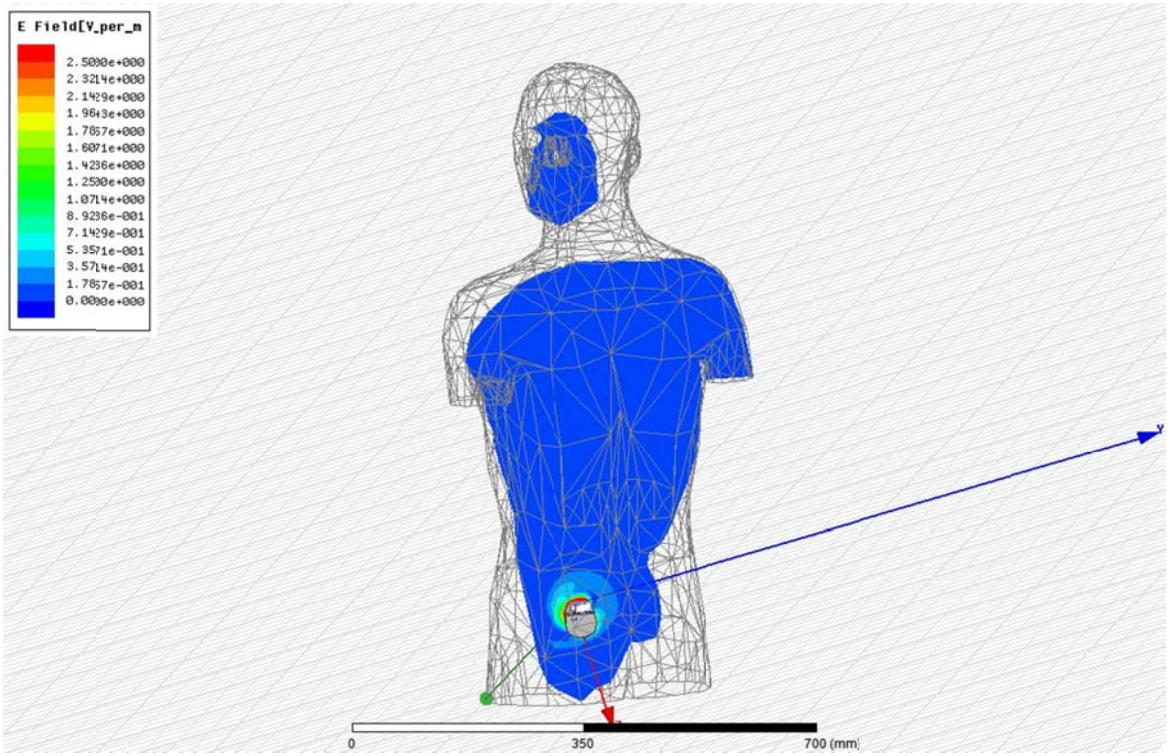


**Figure 11: HFSS 4 mm Human Body Model with Implanted Device in the Gluteal Implant Location (simulated fields also shown)**

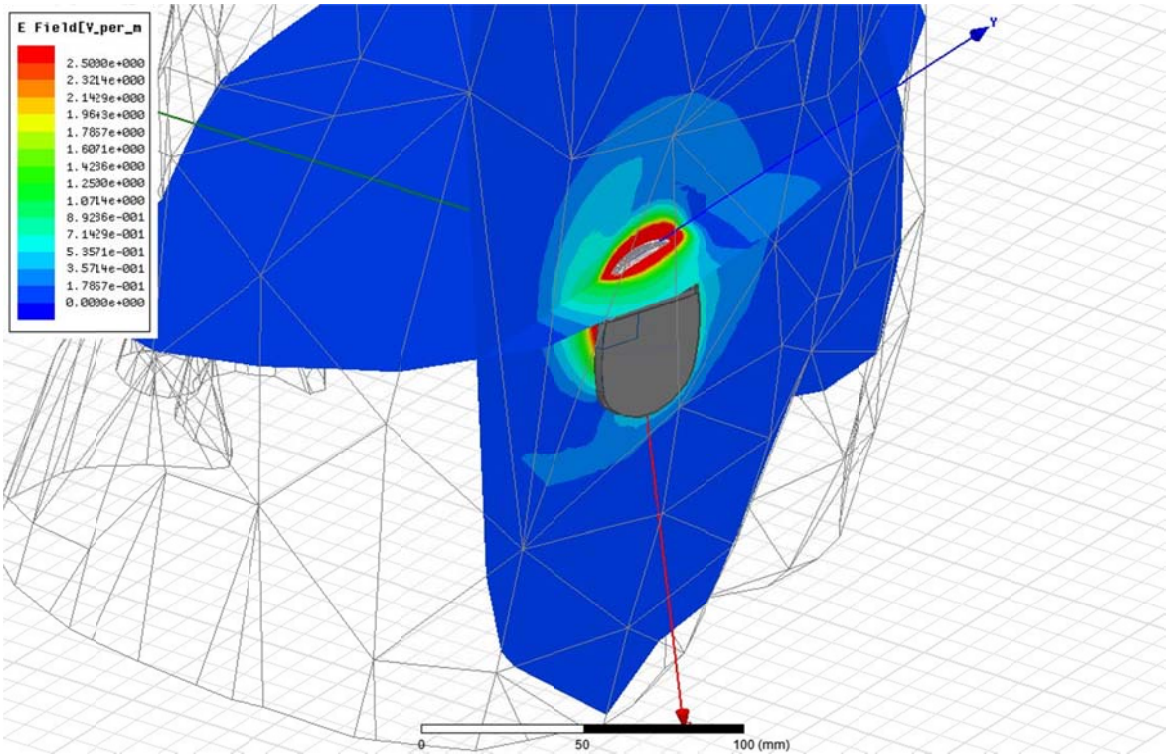


**Figure 12: Zoom-In of HFSS simulation output with Implanted Device shown in the Gluteal Implant Location (4 mm Human Body Model simulated, but not shown to allow visibility of field data)**

MODEL VALIDATION:

The models and simulation outputs were validated in several areas, and by several means:

1) Human Body Model (HBM):

While the 4 mm human body model resolution is an improvement over the previously used 5 mm resolution FDTD model, model validation was done to verify that the 4 mm human body model resolution yielded accurate SAR results. This validation consisted of comparing the simulation output for both the 1 gram spatial peak SAR, and the averaged whole "body" SAR, for the following scenarios:

a) Device implanted in a truncated 4mm resolution human body model (see figures 9 and 10).
b) Device implanted in an 8 L muscle cube "body" model (see figures 13 and 14).
c) Device implanted in an 75 L muscle cube "body" model model (see figures 15 and 16).
d) Device implanted in a 4 mm resolution human body model (HBM) (see figures 5, 6, 7, 8, 9 and 11)

A truncated human body model, consisting of the HFSS HBM with the arms removed below the shoulders and the legs being removed below the groin, was constructed in order to decrease simulation times (see figure 3). Whole Body SAR, 1g SAR, and 10g SAR were simulated for both the non-truncated, and the truncated HBM models with the implanted transmitter in the abdominal implant location. The results of these simulations are shown below in table 3.

| Phantom Type: | Whole "Body" SAR [W/kg] | Whole Body SAR (Normalized to 51.36 L, W/kg) | Average SAR 1g [W/kg] | Average SAR 10g [W/kg] |
|---|---|---|---|---|
| | | | | |
| Truncated 4mm Human Body Abdominal | 1.53E-05 | 1.53E-05 | 0.284 | 0.051 |
| Full 4mm Human Body Abdominal | 1.01E-05 | 1.53E-05 | 0.278 | 0.050 |
| | | | | |
| % Difference Full HBM to Truncated HBM | N.A. | 0.24 | 2.19 | 0.88 |

Table 3: SAR Simulation Outputs for the Truncated and Non-truncated 4mm Resolution HBM for the Abdominal Implant Location.

As shown above, the difference between the truncated and non-truncated 4mm resolution HBM SAR simulation output for the Abdominal Implant Location, for 1g SAR, 10g SAR, and Whole Body SAR is 2.19% maximum difference. This validates the use of the truncated 4mm resolution human body model in computing SAR for the Intellis implantable transmitter.

Two muscle cube sizes where used as body phantoms for simulating/computing SAR: 75 liters [40 cm x 20 cm x 93.75 cm), to simulate with similar volume to the human body model], and 8 liters (20cm x 20cm x 20cm). Using two size muscle cubes allowed the sensitivity to whole "body" model size variations to be determined, while comparing to the HBM SAR results could show SAR variation due to tissue inhomogeneity and the granularity of the 4 mm human body model.

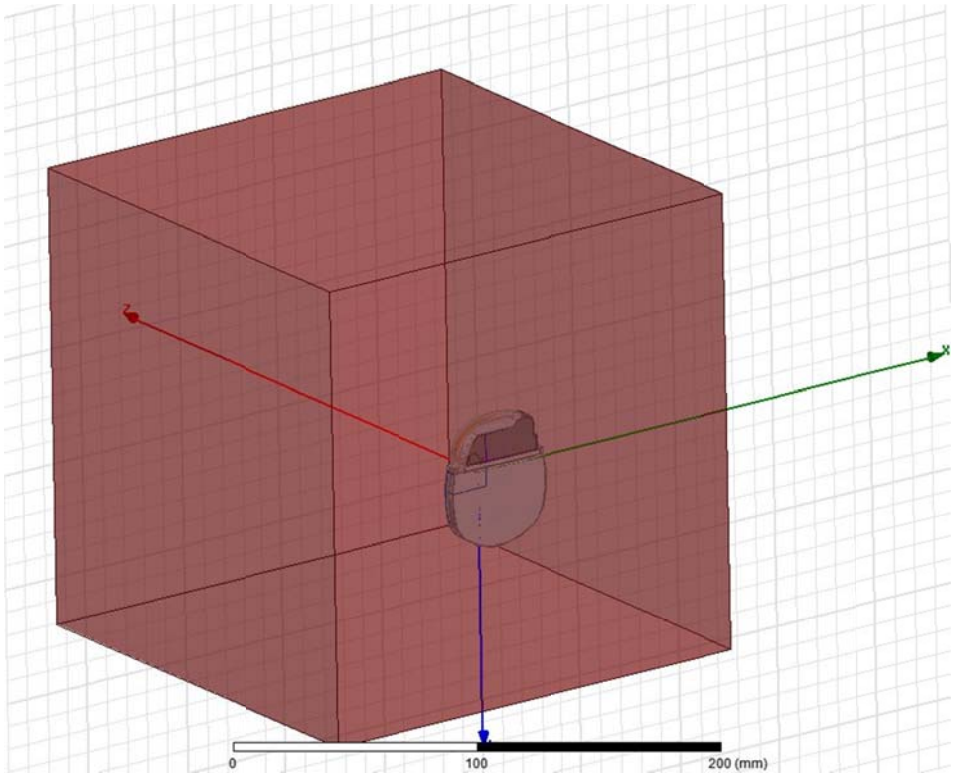


**Figure 13: 8 L Phantom with Implanted Device**

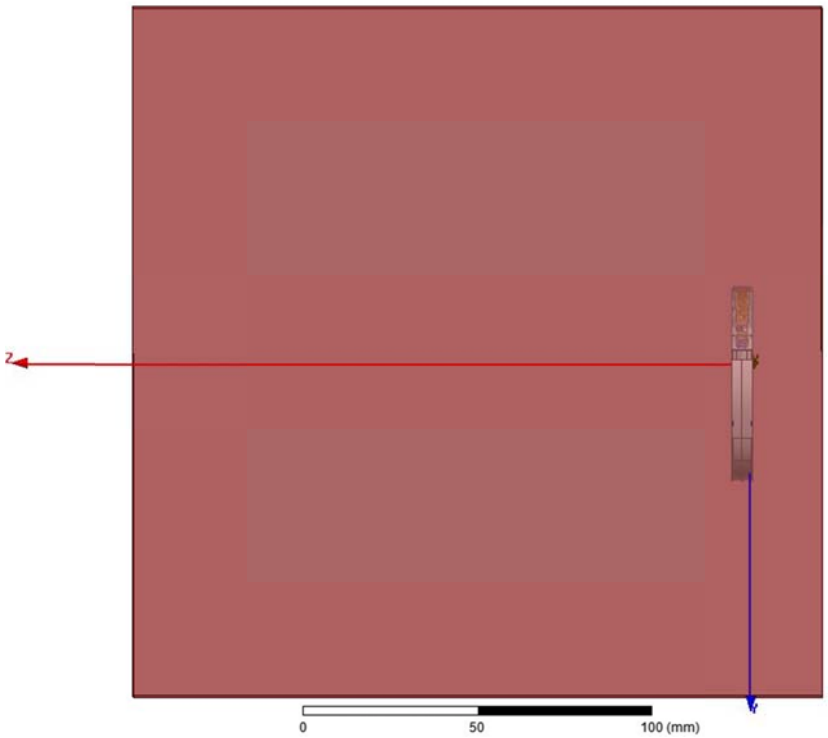


**Figure 14: 8L Phantom with Implanted Device (side view)**

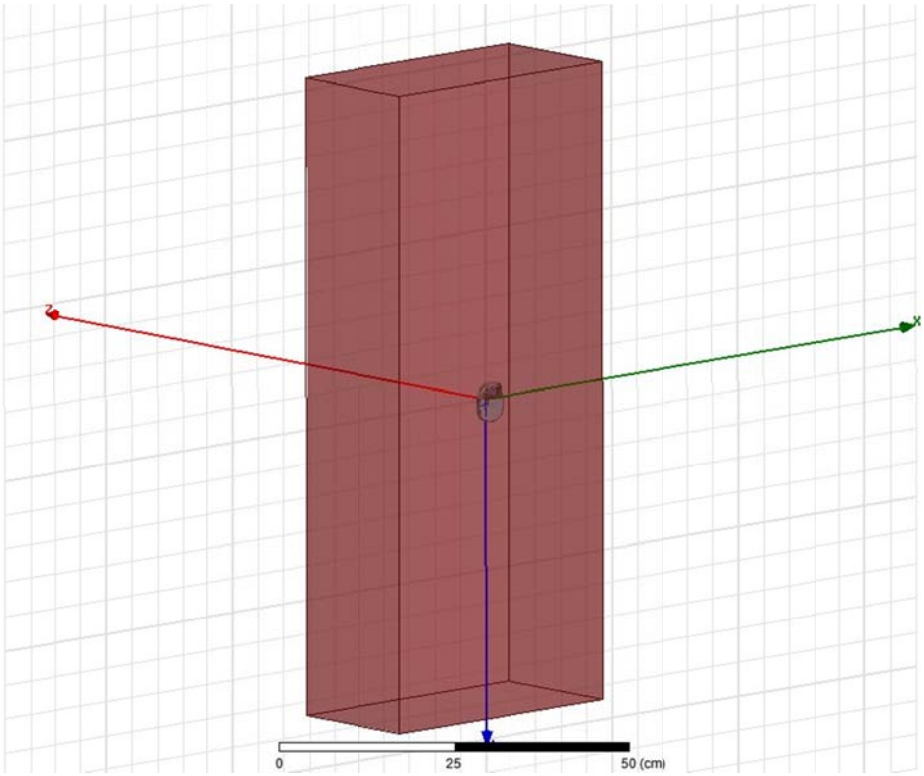


**Figure 15: 75 L Phantom with Implanted Device**

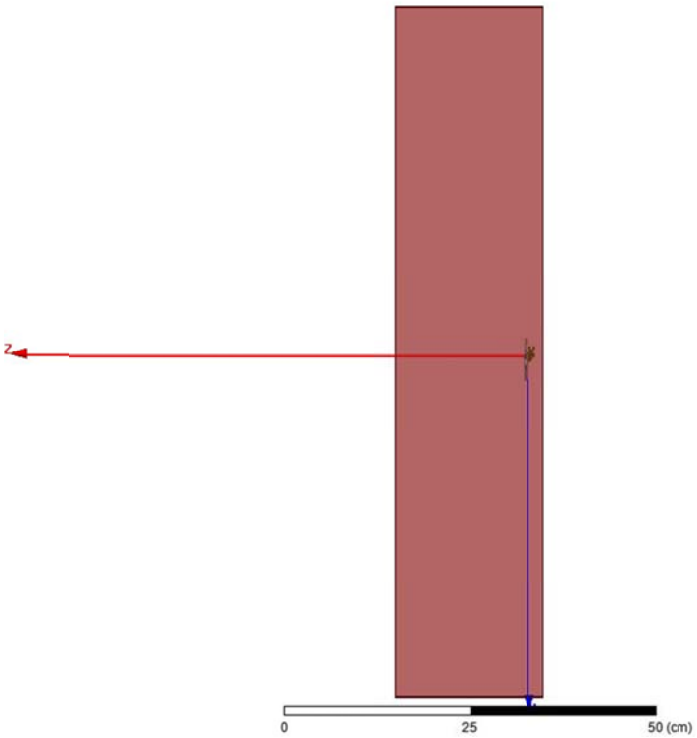


**Figure 16: 75 L Phantom with Implanted Device (side view)**

As seen in table 4, the simulated 1 gram spatial peak SAR, the 10 gram spatial peak SAR, and the averaged whole "body" SAR for both the 8 L and 75 L muscle box phantoms are all within 8.10 percent of the SAR values simulated with the 4 mm human body model. As is the case for all body phantoms simulated, the averaged whole body SAR is consistent with the total feed-point power divided by the mass of the phantom. This is consistent with the low efficiency nature of the implanted antenna, and is expected as most of the RF energy is being absorbed in the muscle tissue near the device. The similarity of spatial peak SAR averaged over 1 gram between the different body phantoms is also expected, as muscle tissue is locally surrounding the implanted transmitter for all body phantoms.

| Phantom Type: | Whole "Body" SAR [W/kg] | Whole Body SAR (Normalized to 51.36 L, W/kg) | Average SAR 1g [W/kg] | Average SAR 10g [W/kg] |
|---|---|---|---|---|
| | | | | |
| 8 L Muscle Box | 9.81E-05 | 1.53E-05 | 0.286 | 0.047 |
| 75 L Muscle Box | 1.05E-05 | 1.53E-05 | 0.288 | 0.049 |
| Truncated 4mm Human Body Abdominal | 1.53E-05 | 1.53E-05 | 0.284 | 0.051 |
| Truncated 4mm Human Body Gluteal | 1.53E-05 | 1.53E-05 | 0.280 | 0.050 |
| | | | | |
| Maximum % difference from HBM | N.A. | 0.37 | 2.65 | 8.10 |

**Table 4: Simulated SAR vs. Body Phantom Type**

**2)** Modeling Validation:

The validation of the modeling of the absorbing boundary conditions (ABC).

The distance to the radiation boundary (first order ABC) was validated by monitoring the spatial average SAR for the 75 liter muscle cube model using air background object volumes of 3 different sizes. It was noted that the Average SAR in 1 g changed by 0.65% when the background was changed from 70cm x 80cm x 140cm to volumes of 110cm x 80cm x 140cm and 110cm x 90cm x 160cm.

Air Box #1: 70cm x 80cm x 140cm: Average SAR in 1g = 0.28454
Air Box #2: 110cm x80cm x 140cm: Average SAR in 1g = 0.28758
Air Box #3: 110cm x90cm x 160cm: Average SAR in 1g = 0.28640

a) Sensitivity to frequency of operation.

The sensitivity to frequency over the range of 402MHz to 405MHz for Average SAR was:

| Body Phantom: | Transmitter Frequency | Average SAR 1 g (W/Kg) | Whole "Body" SAR (W/Kg) |
|---|---|---|---|
| Large Muscle Cube | 402 MHz | 1.01024E-05 | 0.283749332 |
| Large Muscle Cube | 403.5 MHz | 1.00825E-05 | 0.278258658 |
| Large Muscle Cube | 405 MHz | 1.00627E-05 | 0.272781762 |

Table 5: SAR vs. Transmitter Frequency

The bandwidth of the MedRadio Core band is only 3 MHz. This is only 0.7% fractional bandwidth. As expected, and shown in table 5, simulating SAR at one frequency within the band is sufficiently accurate (within +-1.97% difference across the 3 MHz band).

b) Accuracy of HFSS SAR Modeling:

The accuracy of the HFSS SAR results is limited by meshing resolution and absorbing boundary conditions (ABC) applied that reduce the original open region problem space into a finite region problem space. The error approaches zero if the mesh is dense enough and if the radiation boundary is not too close. To increase the mesh resolution a 2$^{nd}$ adaptive mesh convergence criteria was added with the condition that further reduces the mesh induced SAR errors by increasing the number of meshing iterations. The iterations continue until the total integrated local SAR computed in the entire local muscle cube volume changed by less than 1%.
The HBM uses the same criteria but is applied only to a localized phantom muscle volume encompassing the device to speed up computation time required. The results show that the 75L muscle cube and phantom HBM converged muscle volume produced data that was within 3.91% of each other.

The ABC was tested in the large muscle cube using a boundary with a volume of 784 liters, 1232 liters and 1584 liters which had results that only varied by 0.65%.

The total estimated error for the HFSS 1 g SAR calculations is less than 5.81%. This is the sum of the convergence/meshing error, the absorbing boundary condition error, the frequency error, and the truncated HBM error.

## CONCLUSION:

The averaged whole-body SAR due to the Medtronic MedRadio transmitter has been modeled/simulated to be 1.53E-5 W/Kg. This is 37.2 dB below the 0.08 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093.

The spatial peak SAR averaged over any 1 gram (cube) of tissue has been modeled/simulated to be 0.284 W/Kg. This is 7.6 dB below the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093.

The spatial peak SAR averaged over any 10 gram (cube) of tissue has been modeled/simulated to be 0.0507 W/Kg. This is 19.0 dB below the 4 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093 for the hands, wrists, feet and ankles.

The simulated/computed SAR compliance margins are much higher than the estimated computational error.

The Medtronic neuromodulation implantables family of MedRadio devices are therefore compliant with §§95.1221, and §§1.1307 and §§2.1093).
the FCC Rules (CFR 47,

APPENDIX A
ALTERNATE SOLUTION:

KDB 447498, 447498 D01 General RF Exposure Guidance v06 section 4.2.4 was used as the guidance.

4.2.4. Transmitters implanted in the body of a user
When the aggregate of the maximum power available at the antenna port and radiating structures of an implanted transmitter, under all operating circumstances, is ≤ 1.0 mW, SAR test exclusion may be applied. The maximum available output power requirement and worst-case operating conditions must be supported by power measurement results, based on device design and implementation requirements, and fully justified in a SAR analysis report according to KDB Publication 865664 D02, in lieu of SAR measurement or numerical simulation.

Model Number: B35200, 977005,977006
Frequency Range: 402-405 MHz
Maximum EIRP: -28.36 dBm
Maximum Conducted Output Power (Peak): -0.36dBm (402.15 MHz)*
Maximum Peak Antenna Gain: -28 dBi

*Note: based on measurements result from report no. SL18041705-MED-027-FCC-IC Rev_1.0)
Conducted Power = EIRP- Antenna Gain;
In this case, Max Conducted Power = -28.36 – (-28) = -0.36 dBm

Both the maximum EIRP and Maximum conducted output power are below required 0 dBm (1mW) SAR test exemption limit. This product qualifies for SAR test exemption.