SAR Analysis
Certification Submission for Medtronic Evera-Brava-Viva Implantable Devices

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Figure 1: Medtronic Viva Implantable Cardiac Rhythm Disease Management Device

PURPOSE:

This report is a summary of the Finite Element Modeling (FEM) and simulation results of SAR to support the new product certification submittal for the Evera-Brava-Viva device family (see figure 1 above).

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 figure 2).

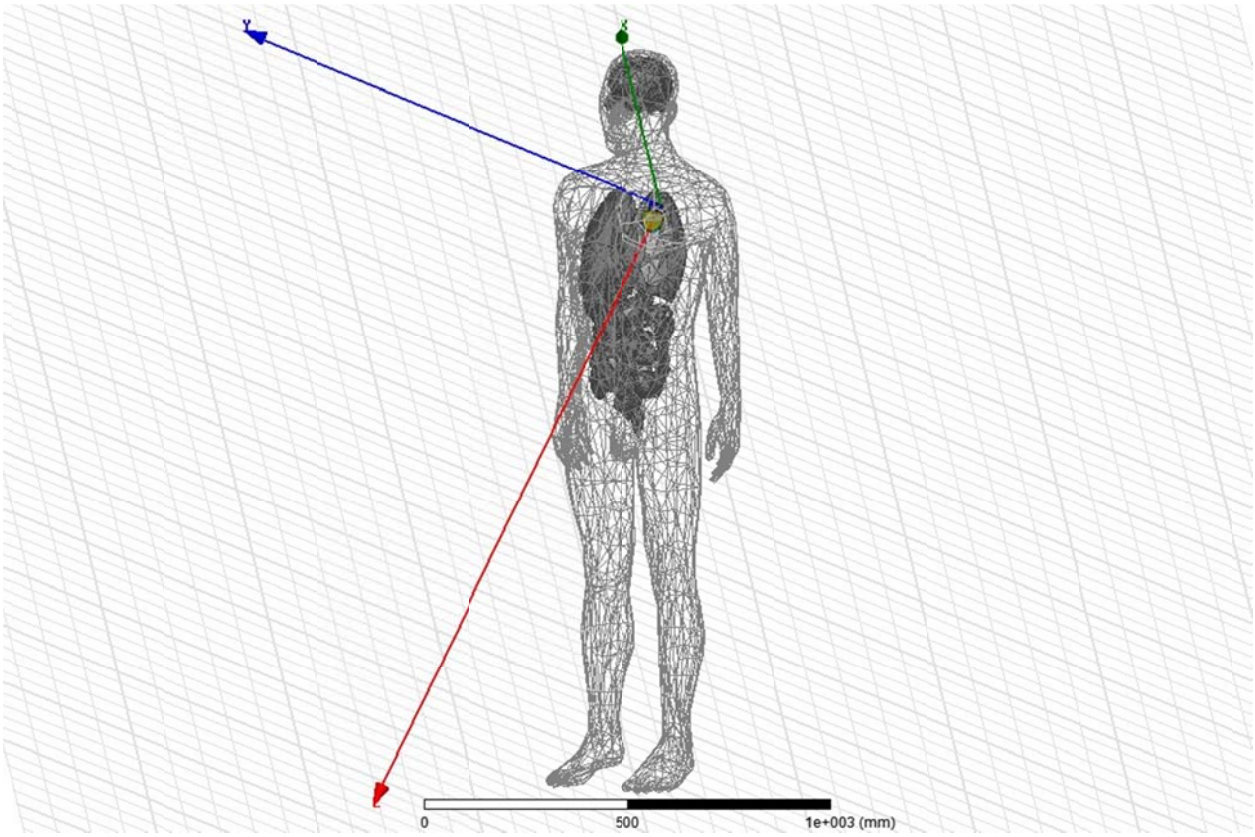

Figure 2: HFSS 4 mm Resolution Human Body Model (with implant shown)

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 14 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 for seals in the device connector header. The final device model still contains significant detail, as seen in figure 3 below.

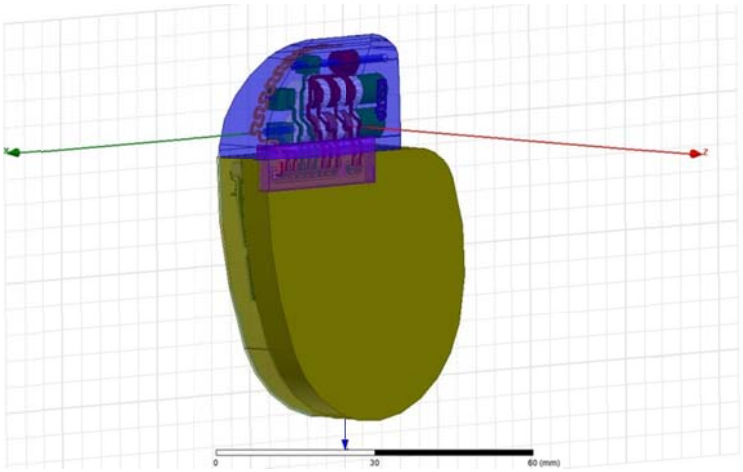

Figure 3: The Implanted Device Model

The Evera, Brava, and Viva family of Medtronic implantable devices all contain the same transceiver module, which is trimmed for the same transmitter RF power output for each device during manufacture. The maximum trimmed transmitter output power at the antenna feed-point is -0.55 dBm (maximum including manufacturing trim tolerance, with conjugate impedance matching).

There are subtle differences between the device types of the Medtronic Evera-Brava-Viva family of implanted devices. While the same RF Transceiver Module is used in all devices, slight differences in the antenna positioning within the device connector module, and slight differences in antenna length are required to accommodate the different device connector modules used to interface with different implantable therapy leads. The antenna gain and efficiency performance has been simulated between all types of antennas in this implantable device family with good agreement and with minimal differences in performance between antennas (+-1.1 dB difference amongst all types of antennas). All antennas are similar serpentine monopole antennas. As will be shown below, the margins to the SAR requirements are more than sufficient to absorb any minor antenna differences within this family of devices.

The location of the implanted device within the human body model is indicated in figure 2, with zoomed-in frontal and side views shown in figures 4 and 5 respectively. The implant is located 2 cm deep (minimum) within the pectoral region of the chest. The tissue volume of the human body model that completely surrounds the implant is muscle tissue. Cardiac rhythm device implant locations may include both pectoral and abdominal regions of 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.

As can be seen from the equation above when considering that muscle tissue has higher conductivity than fat or skin, muscle in the pectoral region is a worst-case scenario for SAR. Thus the pectoral region was chosen for this model/simulation.

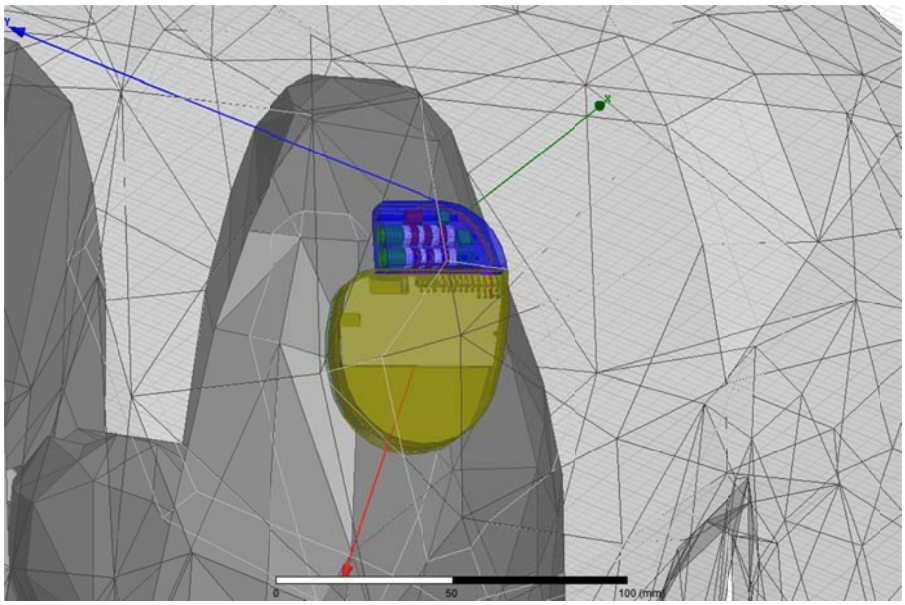

Figure 4: Implanted Device in the Human Body Model (Frontal, zoomed-in view)

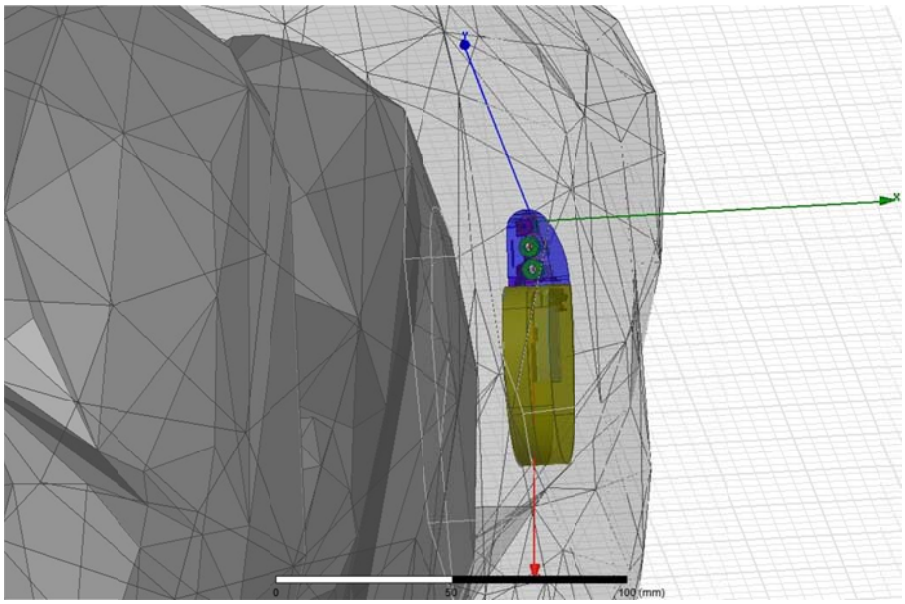

Figure 5: Implanted Device in the Human Body Model (Side, zoomed-in view)

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 0.00440 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 5% 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 showed that the highest spatial SAR levels were recorded in tissue near the implanted radio antenna. This is illustrated in figures 6 and 7 which show the whole human body model and the zoomed-in human body volume respectively with the associated field strengths due to the transmitter.

The averaged whole-body SAR due to the Medtronic MedRadio transmitter was simulated with the whole human body model to be 8.99E-6 W/Kg.

The spatial peak SAR averaged over any 1 gram (cube) of tissue was simulated with the whole human body model to be 0.103 W/Kg.

The spatial peak SAR averaged over any 10 gram (cube) of tissue was simulated with the whole human body model to be 0.0239 W/Kg.

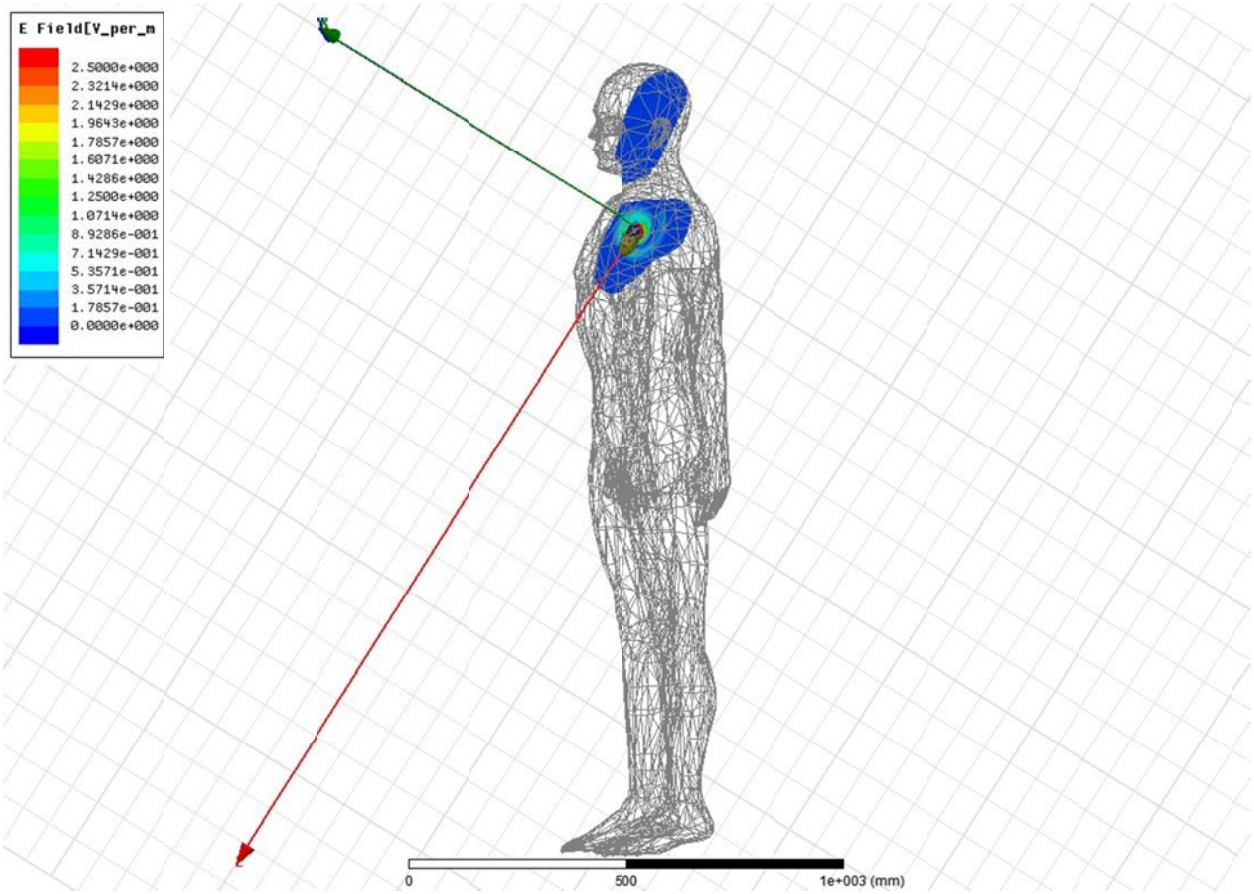

Figure 6:
HFSS 4 mm Human Body Model with Implanted Device
(simulated fields also shown)

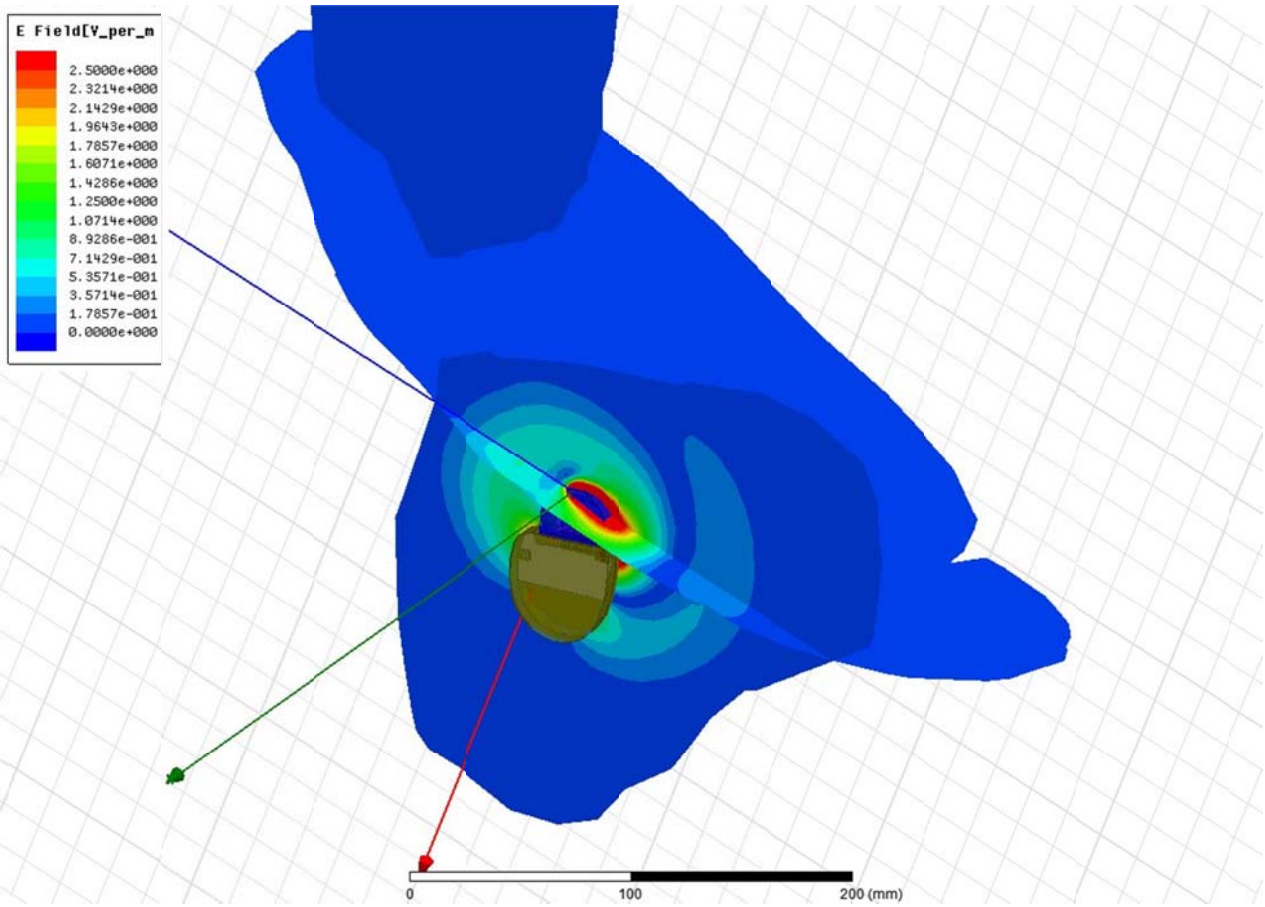

Figure 7: Zoom-In of HFSS simulation output with Implanted Device shown (4 mm Human Body Model simulated, but not shown to allow visibility of field data)

MODEL VALIDATION:

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

1) Human Body Model:

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 an 8 L muscle cube "body" model (see figures 8 and 9).
b) Device implanted in an 75 L muscle cube "body" model model (see figures 9 and 10).
c) Device implanted in a 4 mm resolution human body model (HBM) (see figures 4, 5 and 6).

Two muscle cube sizes where used: 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.

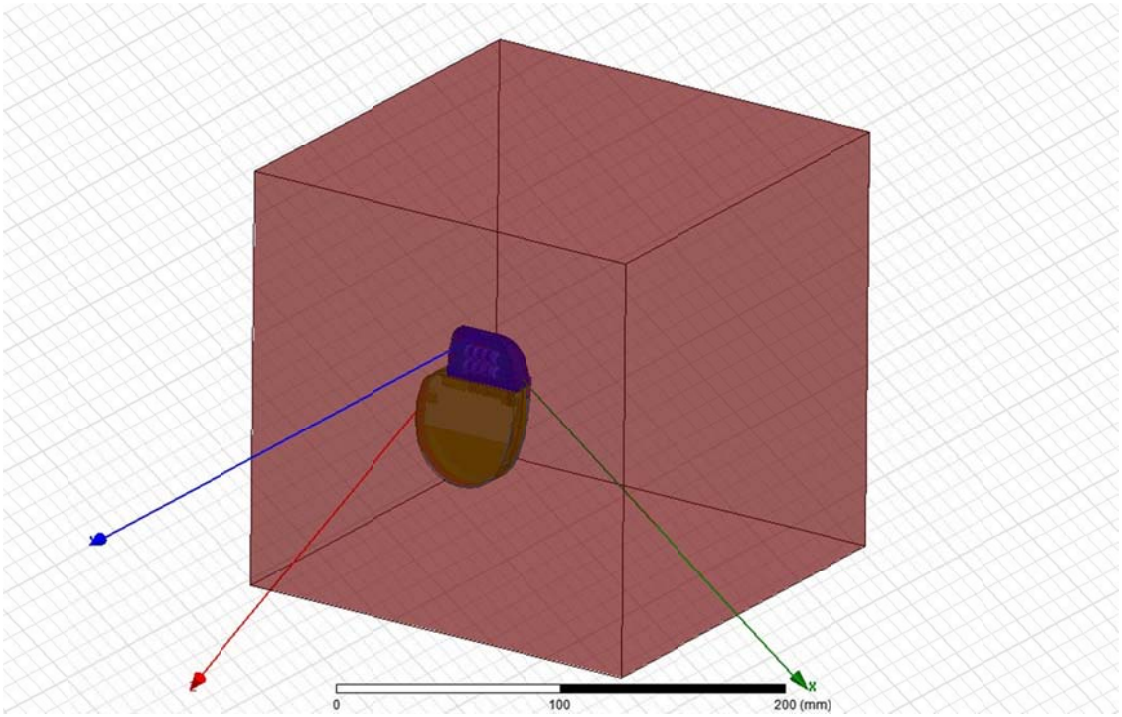

Figure 8: 8 L Phantom with Implanted Device

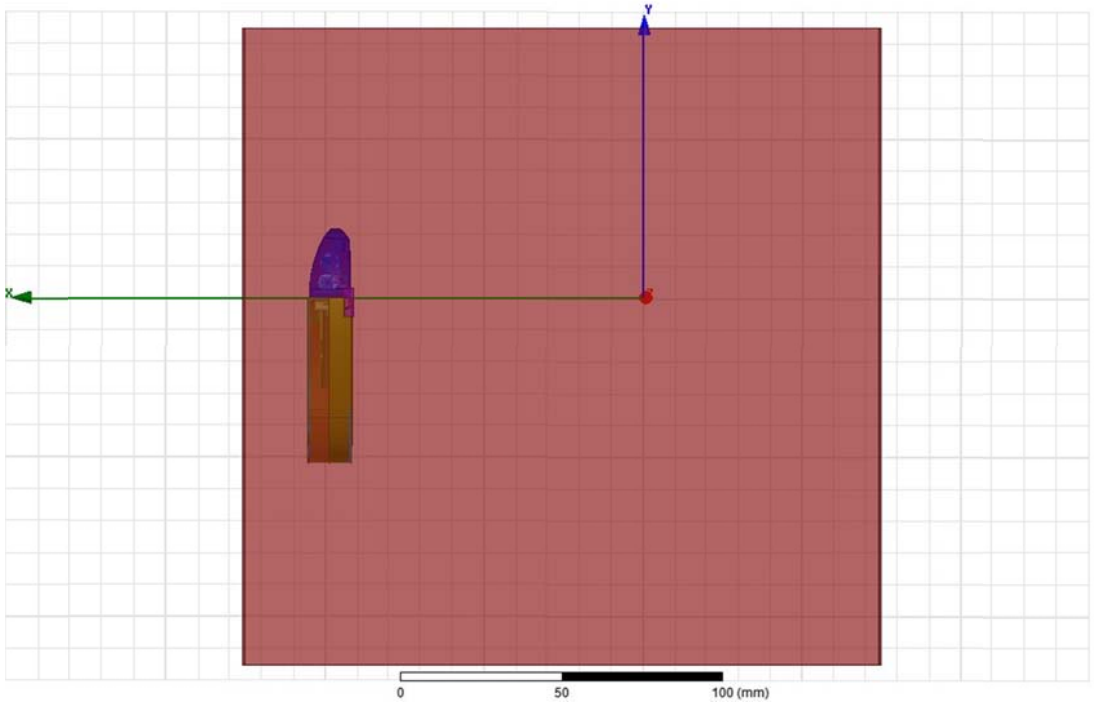

Figure 9: 8L Phantom with Implanted Device (side view)

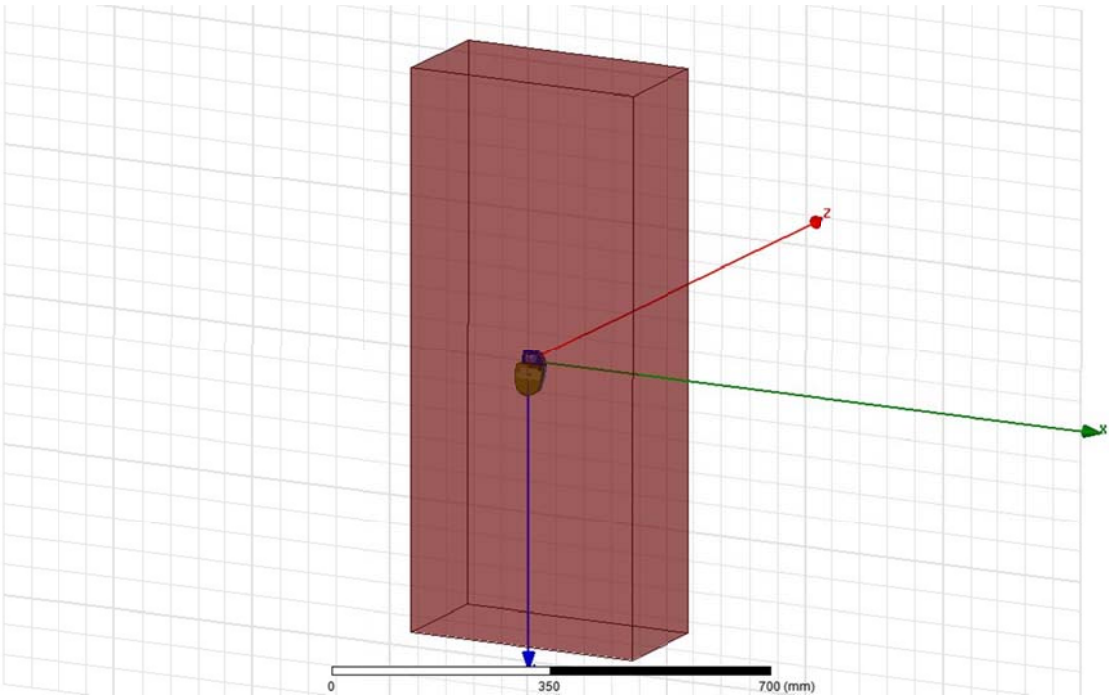

Figure 10: 75 L Phantom with Implanted Device

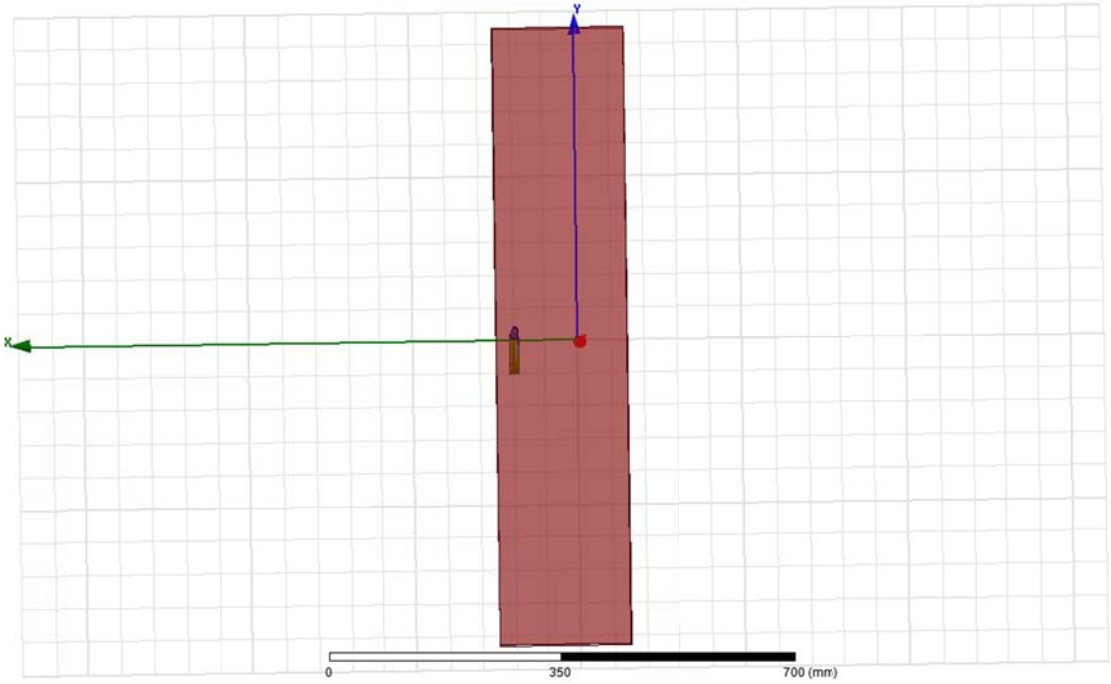

Figure 11: 75 L Phantom with Implanted Device (side view)

As seen in table 3, 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 4.2 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 ofspatial 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)	Average SAR 1 g (W/kg)	Average SAR 10 g (W/kg)
8 L Muscle Box	8.76E-05	9.87E-02	2.42E-02
75 L Muscle Box	9.37E-06	9.87E-02	2.42E-02
4 mm Human Body	8.99E-06	1.03E-01	2.39E-02
Maximum % difference from HBM	4.2	-4.0	1.3

Table 3: Simulated SAR vs. Body Phantom Type

2) Modeling Validation:

a) 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 2 different sizes . It was noted that the Average SAR in 1 g changed by 0.61% when the background was changed from 70cm x 80cm x 140cm to a volume of 110cm x 110cm x 160cm.

Air Box #1: 70cm x 80cm x 140cm: Average SAR in 1g = 0.099308693
Air Box #2: 110cm x 110cm x 160cm: Average SAR in 1g = 0.098706401

b) 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	0.098912571	9.3662E-06
Large Muscle Cube	403.5 MHz	0.098706401	9.37308E-06
Large Muscle Cube	405 MHz	0.098039843	9.35628E-06

Table 4: 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 4, simulating SAR at one frequency within the band is sufficiently accurate (within +-0.68% difference across the 3 MHz band).

c) 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 2nd 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 5%. 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 full muscle cube and phantom HBM converged muscle volume produced data that was within 4.2% of each other.

The ABC was tested in the large muscle cube using a boundary with a volume of 784 liters and 1936 liters which had results that only varied by 0.61%.

The total estimated error for the HFSS SAR calculations is less than 6.29 %. This is the sum of the convergence/meshing error, the absorbing boundary condition error and the frequency error.

CONCLUSION:

The averaged whole-body SAR due to the Medtronic MedRadio transmitter has been modeled/simulated to be 8.99E-6 W/Kg. This is 39.5 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 0.103 W/Kg. This is 11.9 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 0.0239 W/Kg. This is 22.2 dB below the 4 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093 for the hands, wrists, feet and ankles.

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

APPENDIX A
ALTERNATE SOLUTION:

If the impedance matched feed-point power to the antenna is limited to less than 1.6 mW, then it is physically impossible for the RF exposure limits of §§2.1093 to be violated.

The justification for this statement is based on the principal of conservation of energy and the worst-case assumption that all energy capable of being transmitted by the implanted device is absorbed by a 1 gram cube of tissue (the smallest tissue cube of interest for SAR). In this case, if the transmitter is conjugately matched to the antenna in body tissue, and outputs less than 1.6 mW in this optimally matched condition, and all the transmitted energy is absorbed in 1 gram of tissue, then less than 1.6 mW is absorbed in 1 gram of tissue. Therefore SAR requirements are inherently met in this case.

(Please see page 55 of the following presented paper:
http://www.ices-emfsafety.org/documents/Minutes/TC95_december%202002%20minutes.pdf).

MedRadio implants having a maximum matched transmitter RF output power at the feed-point of the antenna of less than 1.6 mW should be exempt from being required to perform this SAR analysis.