SAR Analysis
Certification Submission for Medtronic Azure S SR MRI SureScan/Azure XT SR MRI SureScan and Azure S DR MRI SureScan/Azure XT DR MRI SureScan Implantable Devices

(FCC ID: LF5BLEIMPLANT)

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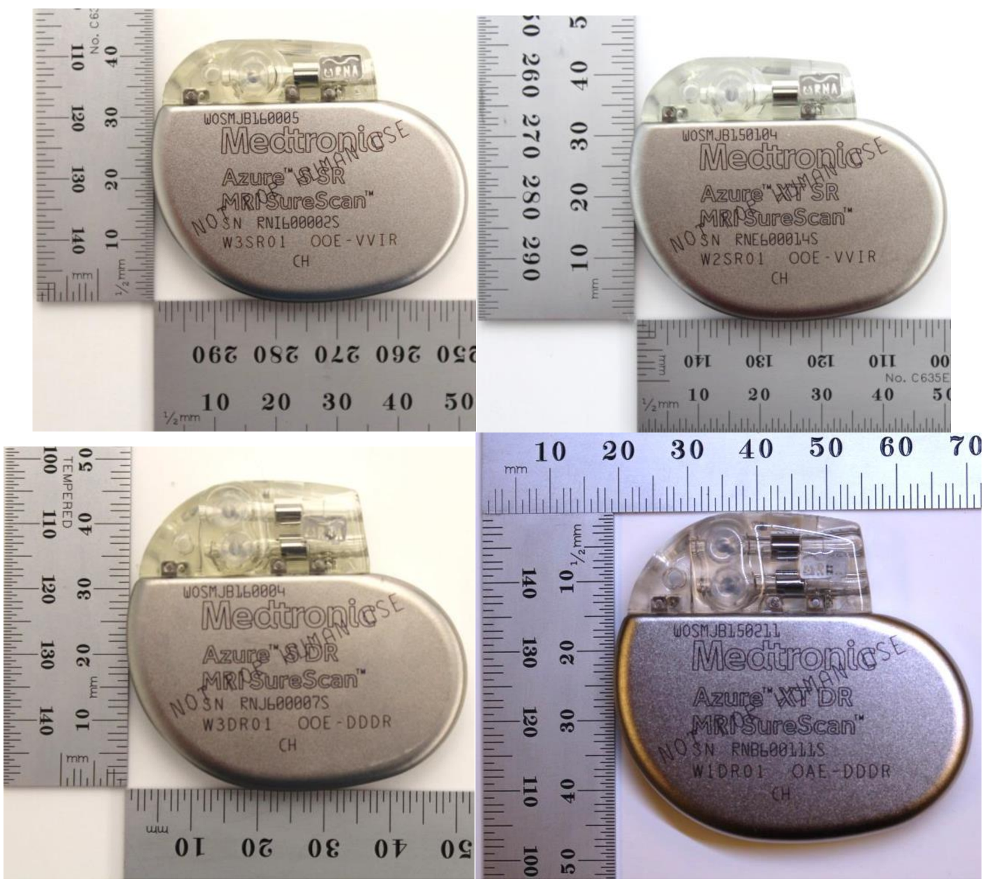
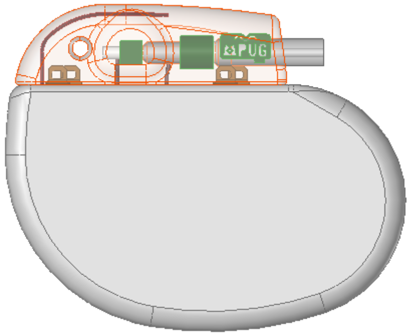
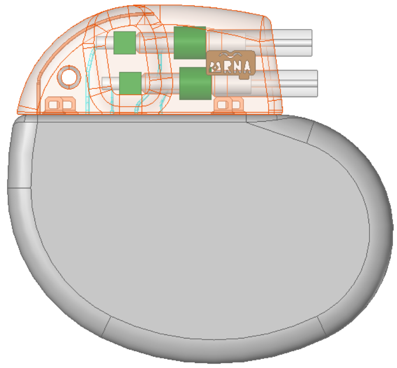






Azure S SR MRI SureScan /Azure XT SR MRI SureScan

Azure S DR MRI SureScan/Azure XT DR MRI SureScan

Figure 1 Medtronic Azure Implantable Cardiac Rhythm Disease Management Devices

(Top: Actual Devices of Azure S SR MRI SureScan and Azure XT SR MRI SureScan;

Medium: Actual Devices of Azure S DR MRI SureScan and Azure XT DR MRI SureScan;

Bottom: Computer Models of SR and DR Devices)

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 Medtronic Azure device family (see Figure 1).

Both the Azure SR and DR Medtronic implantable devices use Bluetooth Low Energy (BTLE) as the only distance telemetry protocol, and contain the same BTLE transceiver module, which has a fixed RF power output at typically 0 dBm, and up to maximum output at 2.5 dBm, according to the part specifications.

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

METHODOLOGY:

The modeling has taken a conservative approach in assumptions. These assumptions are summarized below:

1. The part has a fixed RF power output of typically 0 dBm at 37°C. Because the device is intended to be implanted in the body, the temperature is well controlled during actual use. RF power output for simulation purposes was set to 2.5 dBm based on the maximum part specification.
2. The maximum RF transmitter output power at the antenna feed-point will be less than the 2.5 dBm power output from the RF transmitter module because of the additional insertion loss in the matching circuit. To be conservative, in this SAR analysis, 2.5 dBm output power is directly applied to the antenna feed-point.
3. Because of the variability of the tissue types and geometry around the device, the tissue that results in the highest SAR was used for this simulation (parallel fiber human muscle).
4. This SAR analysis model uses a 4 cm deep implant location in the human torso model, which allows more transmitted RF power being absorbed by the surrounding tissue instead of radiated into free space, as a worst case for SAR.

The results of the simulations described in this report, based on these conservative assumptions, demonstrate that the spatial peak SAR averaged over 1 gram (cube) of tissue is more than 9 dB below the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093.

HFSS SAR Calculation Process

The computational modeling and simulations within this report were performed with Ansys HFSS™ Finite Element Modeling (FEM) program, part of Ansys Electromagnetics Suite 16.0.

The Specific Absorption Rate (SAR) is a measure of the rate of electromagnetic energy absorbed in a lossy dielectric material. The SAR is a basic scalar field quantity that can be calculated on surfaces or within objects in HFSS. 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 = the material's conductivity. This is defined as: $\sigma_{bulk} + \omega\varepsilon_0\varepsilon_r tg\delta$

• ρ = the mass density of the dielectric material in mass/unit volume

• E = the RMS electric field in the given location

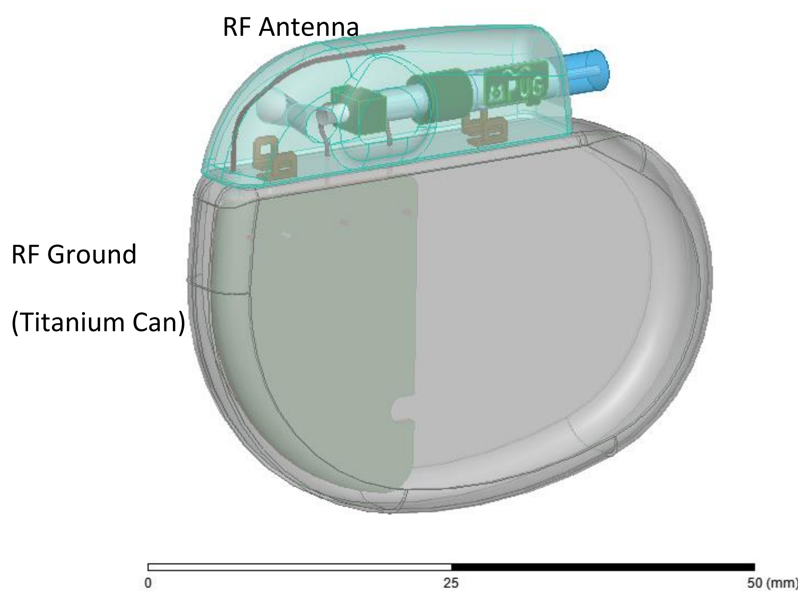
The method that Ansys HFSS is using to calculate average SAR is described in [1] (Attached appendix to this document).

Medtronic Azure Device Numerical Model

The model of the implanted devices is based on the mechanical CAD files which are used to fabricate the actual device components.

As is shown in the Figure 2, the principle of operation for the RF transmission is to drive RF power between the antenna and the welded titanium can which is grounded. Inside device, the RF antenna feed-point is connected to the BTLE module through a matching circuit. Therefore, the maximum RF output power at the antenna feed-point should be always less than the output power from the RF transceiver module because of the additional insertion loss in the matching circuit. Both the Azure SR and DR Medtronic implantable devices use Bluetooth Low Energy (BTLE) as the only distance telemetry protocol, and contain the same BTLE transceiver module, which has a fixed RF power output at typically 0 dBm, and up to maximum output at 2.5 dBm, according to the part specifications. **To be conservative, in this SAR analysis, 2.5 dBm (i.e. 1.7783 mW) output power is directly applied to the antenna feed-point.**

The welded titanium can shields any possible RF power emitted directly from the internal electronics, therefore, the internal components do not contribute to the RF radiation as well as SAR. Based on this principle of the operation, the CAD file was simplified and imported into HFSS to create the device model. The simplification is to remove all internal electronic components inside the welded titanium can. The final device model contains all objects outside the device can, such as antenna, header, titanium can, feedthrough, and etc., as seen in Figure 2.



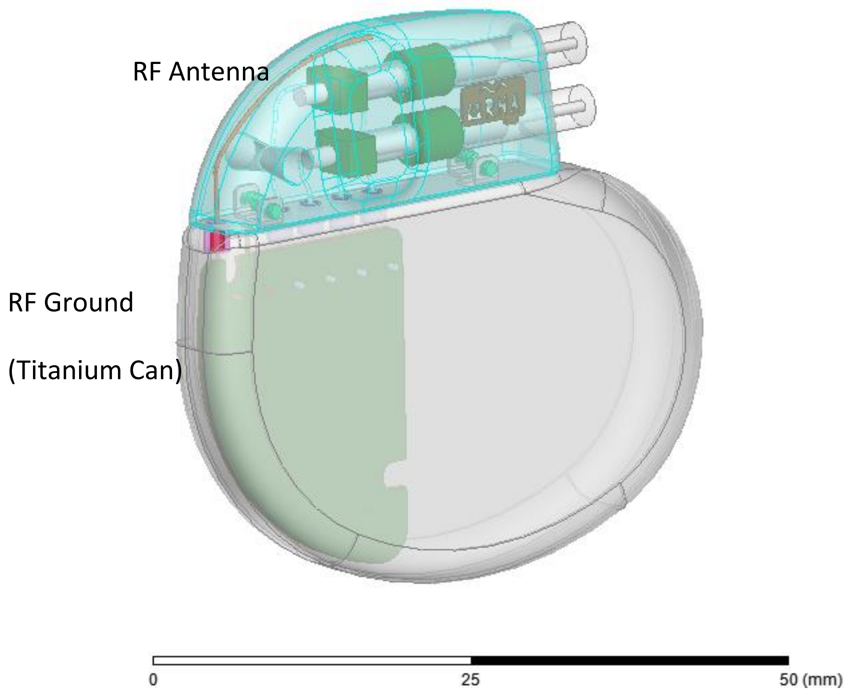


Figure 2 The Implanted Device Model in HFSS (Azure SR and DR)

Medtronic Azure Device Implant Location and Tissue Properties

The Azure devices are typically implanted within the pectoral region of the chest, or implanted in the abdominal area for some patients, and the surrounding tissues may include one or several of the following: muscle, rib, lung, fat, and skin, and the according electrical properties at Bluetooth frequency are listed in Table 1 [2]. Because of this uncertainty of the tissue types and geometry around the device, it is impossible to simulate all implant scenarios. Instead, we should identify the most conservative case, i.e. the implant condition that results in the highest SAR. As can be seen from Table 1, the muscle tissue has higher electrical conductivity than any other types of tissues, which results in more RF power absorption and peak average SAR. Therefore the muscle represents a worst-case scenario for SAR.

Based on this fact, **to be conservative, a human torso model including solely the muscle tissue with the Azure implant at the pectoral region was chosen for this model/simulation (Figure 3).** The human torso model is part of the 4 mm resolution full human body model provided by Ansys HFSS. This torso model was used to ensure accurate modeling and to allow reasonable simulation times for determining the spatial peak 1-g average SAR.

Medtronic Azure devices are usually located within the pectoral region of the chest at typically 2 cm deep, and up to 4 cm depth. In this SAR analysis model, to be conservative, **the device model is located at 4 cm deep in the human torso model, which allows more transmitted RF power being absorbed by the surrounding tissues instead of radiated into the free space, as a worst case for SAR. This can be also demonstrated by the obvious fact that the antenna radiated power reduces by increased implant depth.**

The location of the implanted device within the human body model is indicated in Figure 3, zoomed-in frontal and side views shown in Figure 4.

	Tissue Type	Relative Dielectric Constant	Conductivity (S/m)
1	Air	1.00	0.00
2	**Human Muscle (parallel fiber, i.e. worst case conductivity)**	**54.38**	**1.90**
3	Human Rib	18.51	0.82
4	Human Lung (inflated)	20.46	0.81
5	Human Lung (deflated)	48.34	1.70
6	Human Fat	5.28	0.11
7	Human Skin (wet)	37.97	1.48
8	Human Skin (dry)	42.81	1.61

Table 1 Electrical Properties (2.48 GHz) of Human Body Tissue at Pectoral Region

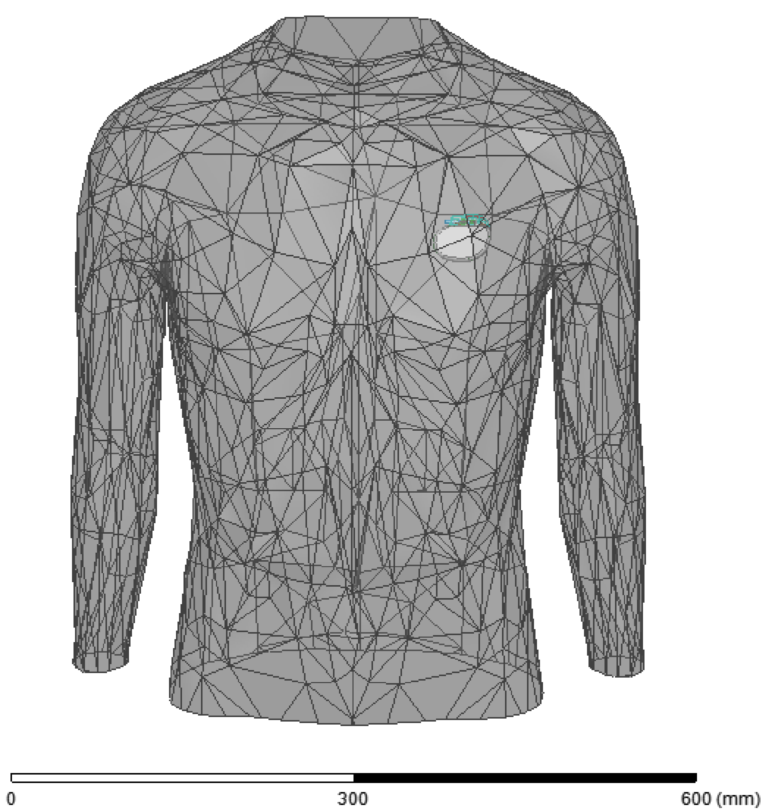


Figure 3 HFSS 4 mm Resolution Human Body Model (with implant shown)

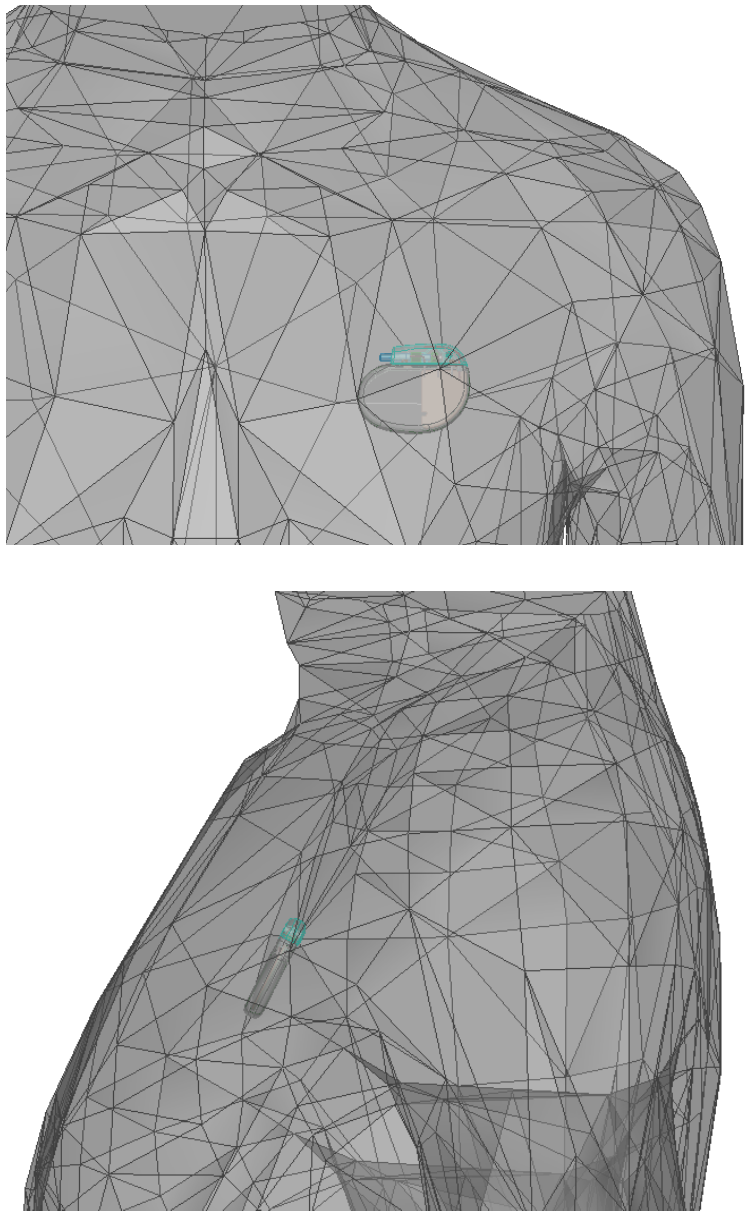


Figure 4 Implanted Device in the Human Body Model

HFSS Human Torso Model for SAR Analysis

An HFSS analysis using the 4 mm, or better, resolution Ansys supplied human body torso model, as illustrated, was used to determine the expected Specific Absorption Rate (SAR) (average in 1 g tissue) when the BTLE transmitter is operated in-vivo. We use the homogenous muscle properties in parallel fiber that represents the worst case electrical conductivity [2]. **The muscle density is specified at 1.06 g/cm^3 in this HFSS model.**

HFSS Meshing Approach and Modeling Parameters

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. The details of this adaptive mesh method can be found in a published paper by Ansys [3].

The human torso model is set in a radiation boundary, which is to simulate an open problem that allows the electromagnetic waves to radiate infinitely far into space.

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

1)	Solution frequency =2480 MHz (solution frequency for adaptive passes/mesh refinement), which is the highest frequency for BTLE (Channel 39), therefore the worst case scenario concerning the SAR
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 of Surrounding Tissue Volume Loss Density field calculator expression with a less than 2% change convergence condition

Table 2 HFSS Modeling/Simulation Control Parameters

HFSS SAR Model Accuracy

The accuracy of the HFSS SAR results is mostly limited by meshing resolution. The error approaches zero if the mesh is dense enough and if the radiation boundary is not too close. To increase the mesh resolution and reduces the mesh induced SAR errors, two enhancements were implemented in the model:

1. A local muscle seed box object surrounding the device model was created to refine the local mesh quantity around the surface of the device, where the peak SAR is expected;

2. A second adaptive mesh convergence criteria was added, and the iterations continue until the total integrated energy loss in the local muscle seed box changed by less than 2%.

The modeling accuracy of this SAR analysis is expected to be more than 98% (or less than 2% error) based on the convergence criteria.

The final mesh for the tissue around the device is plotted in Figure 5. As one can see, the highest mesh density is found around the device antenna, where the peak electric field as well as SAR is located.

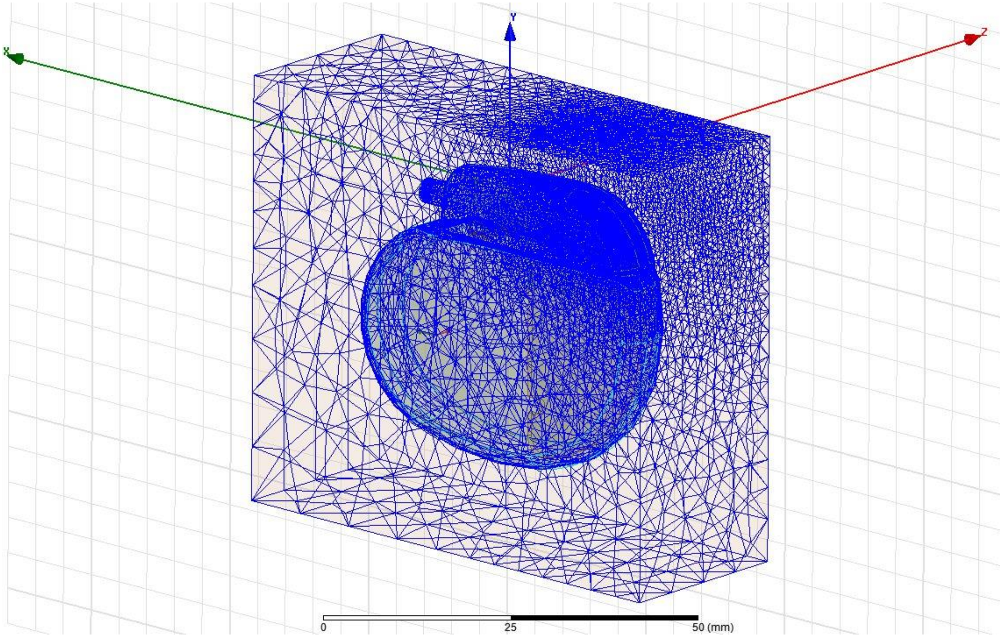


Figure 5 Final mesh plot for the Azure SR SAR Model

Total number of mesh elements: 2170038

	Num Tets	Min edge length	Max edge length	RMS edge length	Min tet vol	Max tet vol	Mean tet vol	Std Devn (vol)
Connector	653732	0.0119351	3.71036	0.325204	1.06067e-07	0.720117	0.0028779	0.0133586
Block01	1415	0.0560874	1.97196	0.995322	3.24792e-06	0.446748	0.025519	0.0464975
Block02	1013	0.137389	2.667	1.16428	0.000108462	0.853002	0.0543739	0.0753866
FT01	1764	0.0615359	1.01057	0.403684	5.56409e-06	0.00766958	0.000866193	0.000887778
FT02	1569	0.134704	1.18485	0.460746	1.63549e-05	0.00971027	0.00110292	0.00113102
Lead_Insert	2493	0.125381	2.6987	1.10208	1.59267e-06	0.213303	0.0195828	0.0254729
leads_Insert_Block	8261	0.0385397	2.54003	0.720298	3.08296e-06	0.0985778	0.0129898	0.0130887
washer01	545	0.233313	1.46969	0.568437	0.000320142	0.0645672	0.00470542	0.00653445
Washer02	307	0.229025	1.66173	0.75208	4.03946e-05	0.0827982	0.00839132	0.0125322
washer03	278	0.202888	2.03343	0.805593	0.000120645	0.104129	0.00920495	0.0155564
washer04	401	0.194403	2.02623	0.74347	0.000220753	0.068842	0.00638223	0.00845228
Matrix_ID	737	0.185943	1.83093	0.651936	6.11402e-05	0.0547799	0.00418688	0.00603024
Can	25427	0.078102	9.50179	1.6557	1.30962e-06	3.29242	0.0409699	0.139855
Ant_Wire	32148	0.026003	1.06158	0.266774	1.65626e-07	0.00271215	0.000101758	0.000141384
ferrule_ant	7537	0.0278904	0.665942	0.271494	4.72411e-07	0.00927123	0.000467967	0.000937478
air_in	249433	0.0232849	9.98732	0.72054	1.49763e-07	36.6369	0.0329645	0.429083
PCB	46992	0.0306265	1.58015	0.450739	7.61282e-07	0.134215	0.00731969	0.0163644
insulator	136659	0.00989371	0.222988	0.0618673	4.39879e-08	0.000259023	1.37094e-05	1.93228e-05
ferrule_ring	2171	0.0231955	0.402461	0.168185	6.21838e-07	0.00196075	0.000112307	0.000207351
ferrule_air	25994	0.0132686	0.312184	0.101948	1.02142e-07	0.000818933	5.34649e-05	4.50527e-05
ferrule_air_02	28867	0.0195013	0.102005	0.0520157	3.86246e-07	3.48685e-05	7.0062e-06	3.9493e-06
Ground_Pin	496	0.146741	0.841153	0.466719	1.59087e-05	0.00964706	0.001558	0.00133793
air_volume	55268	3.05477	147.158	73.6263	0.281477	210227	26600.7	32881.7
body_exterior	394932	0.666381	21.7755	11.4632	0.0112674	646.24	105.648	109.636
seed_box	491599	0.0252	12.0788	1.17763	8.33313e-07	98.5392	0.198201	1.53166

Table 3 Mesh Statistics Summary in Azure SR SAR Model

Table 3 shows the mesh size summary. It shows that there are totally 2,170,038 mesh elements for this SAR model. In the muscle seed box, which is a rectangular tissue volume shown in Figure 5, there are totally 491,599 mesh elements, and the minimum mesh edge size in the volume the device is only 0.0252 mm. Please note that the edge size of a 1-g muscle cube is about 10 mm, which is about 400 times of the minimum mesh edge size in this model. This high resolution of mesh is resulted from the 2% convergence criteria.

RESULTS:

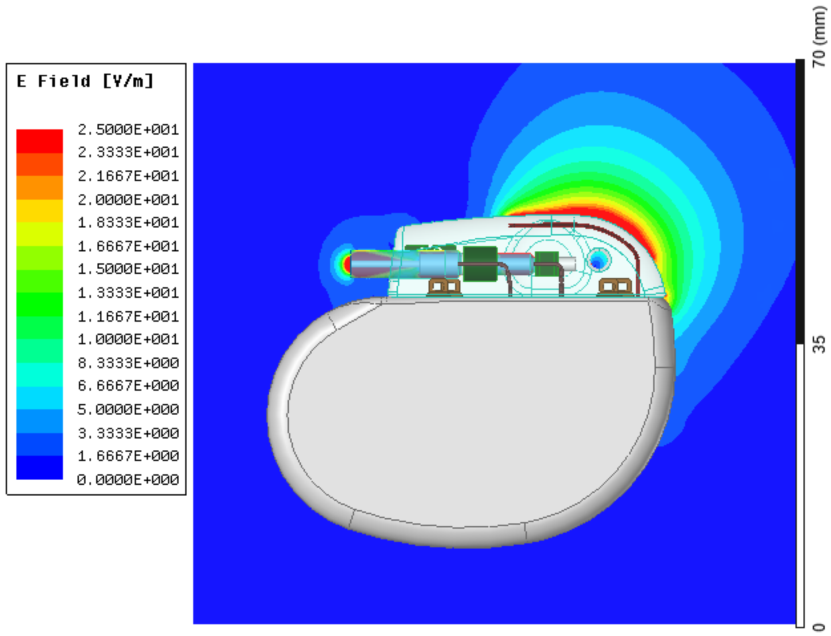


Figure 6 Zoom-In of HFSS simulated electric field in human body model cross-section with Implanted SR Device shown

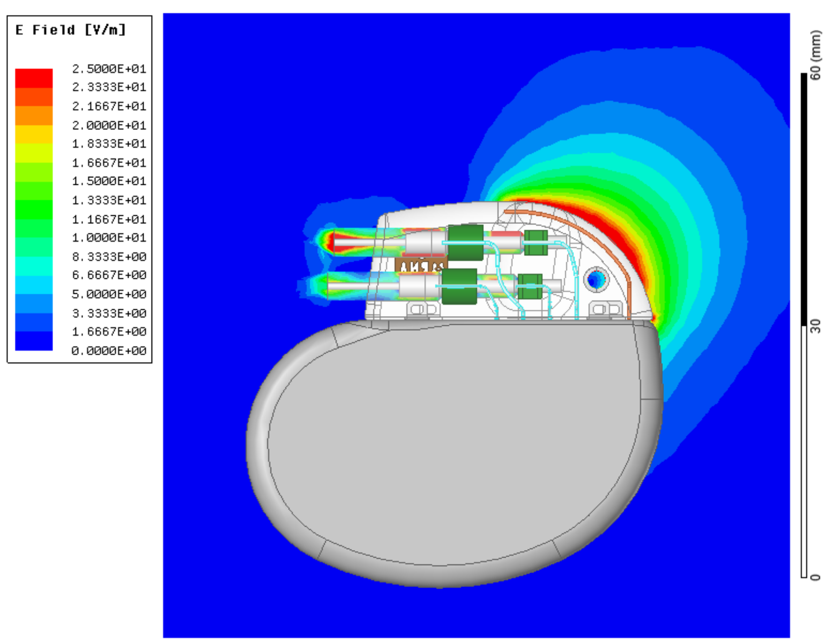


Figure 7 Zoom-In of HFSS simulated electric field in human body model cross-section with Implanted DR Device shown

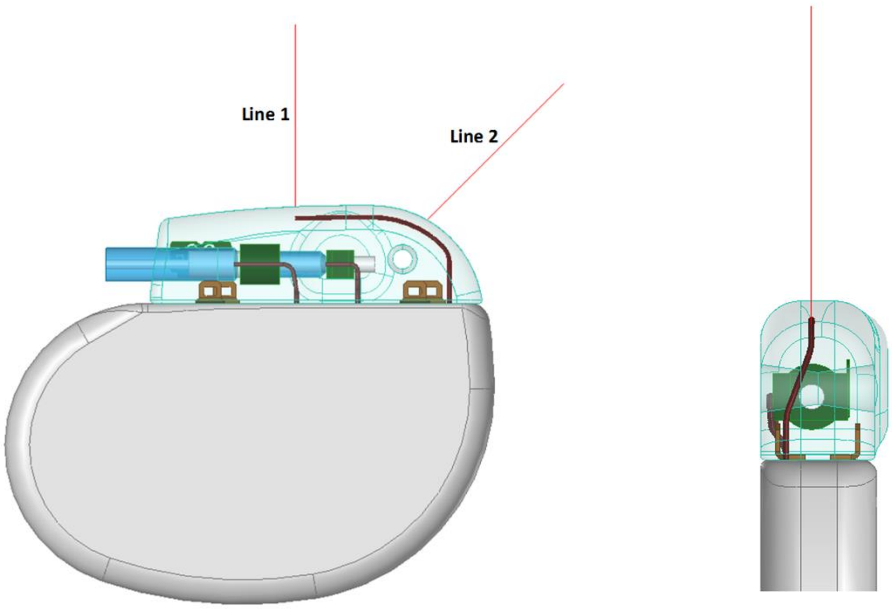


Figure 8 Location and orientation of E-field lines that start from the SR device surface

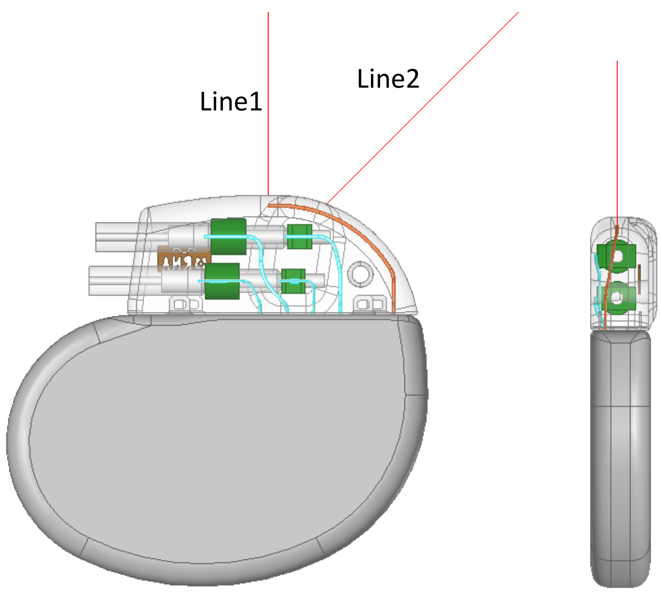
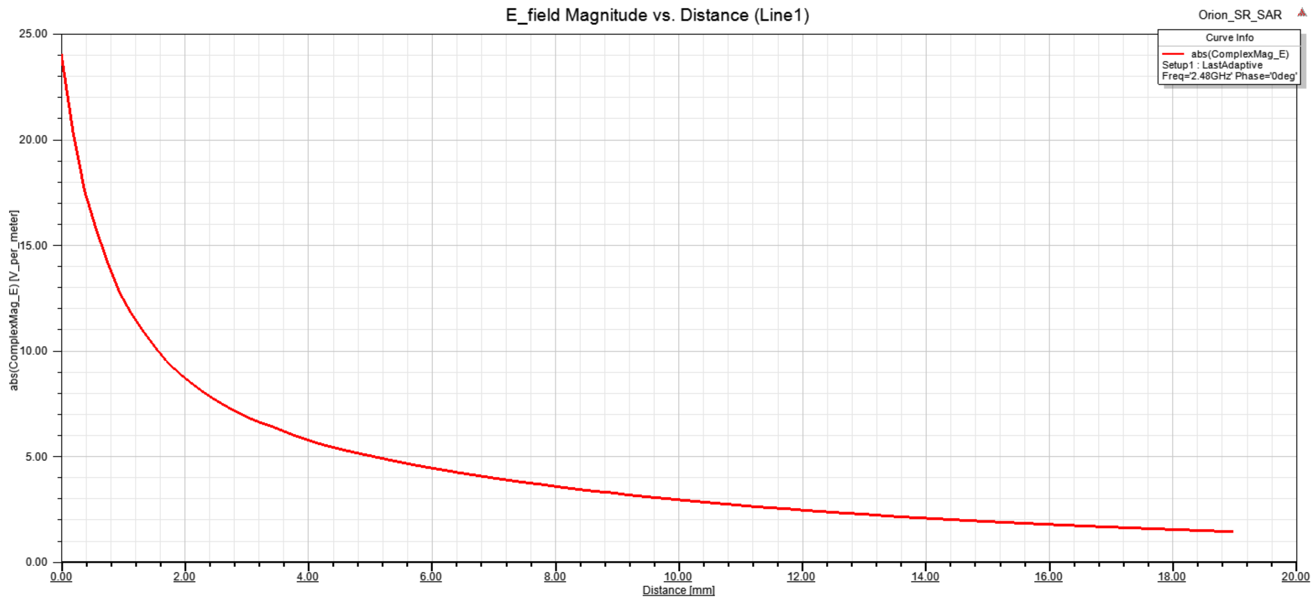
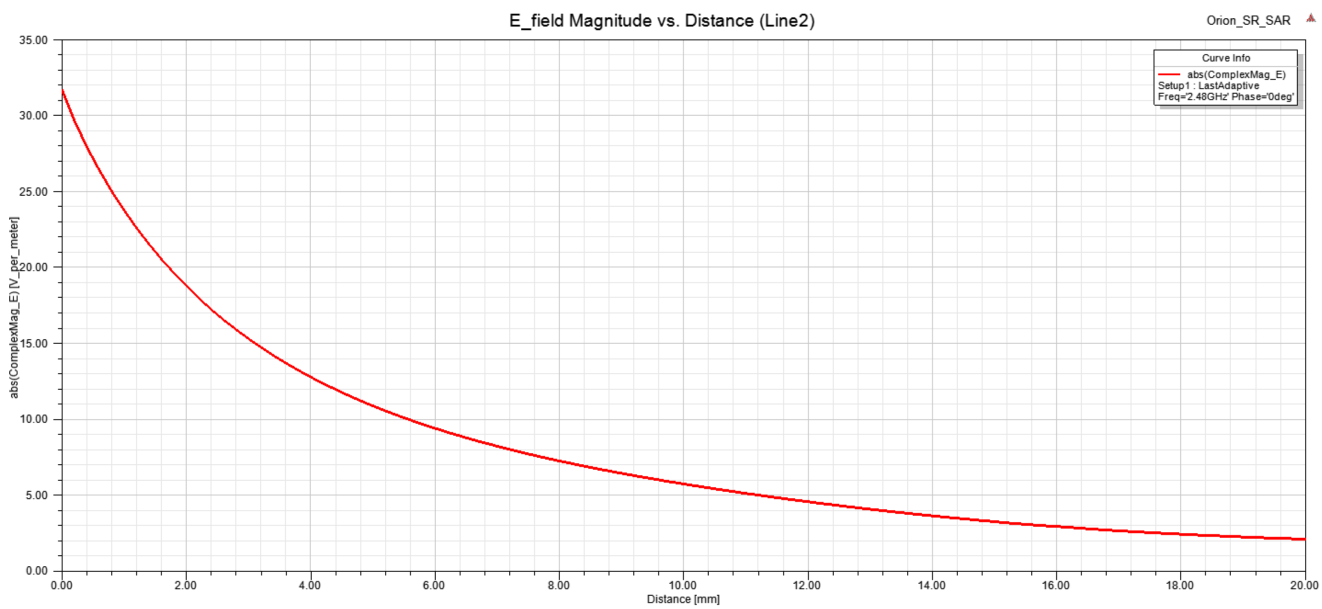


Figure 9 Location and orientation of E-field lines that start from the DR device surface

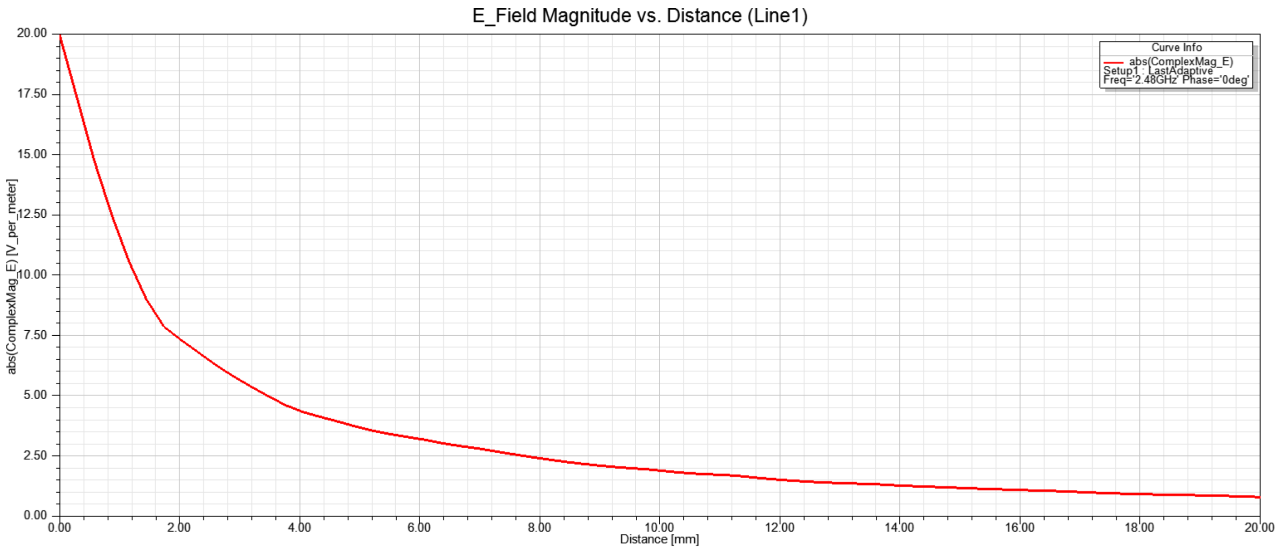


(a)

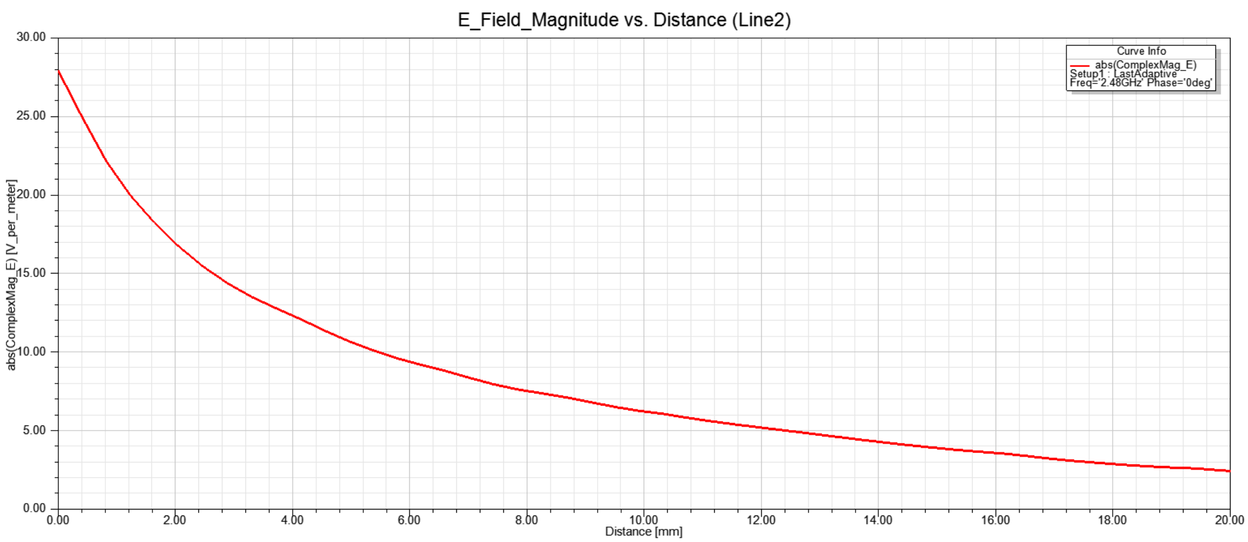


(b)

Figure 10 Simulated E-field strength versus distance from the SR device surface: (a) Line 1 (b) Line 2



(a)



(b)

Figure 11 Simulated E-field strength versus distance from the DR device surface: (a) Line 1 (b) Line 2

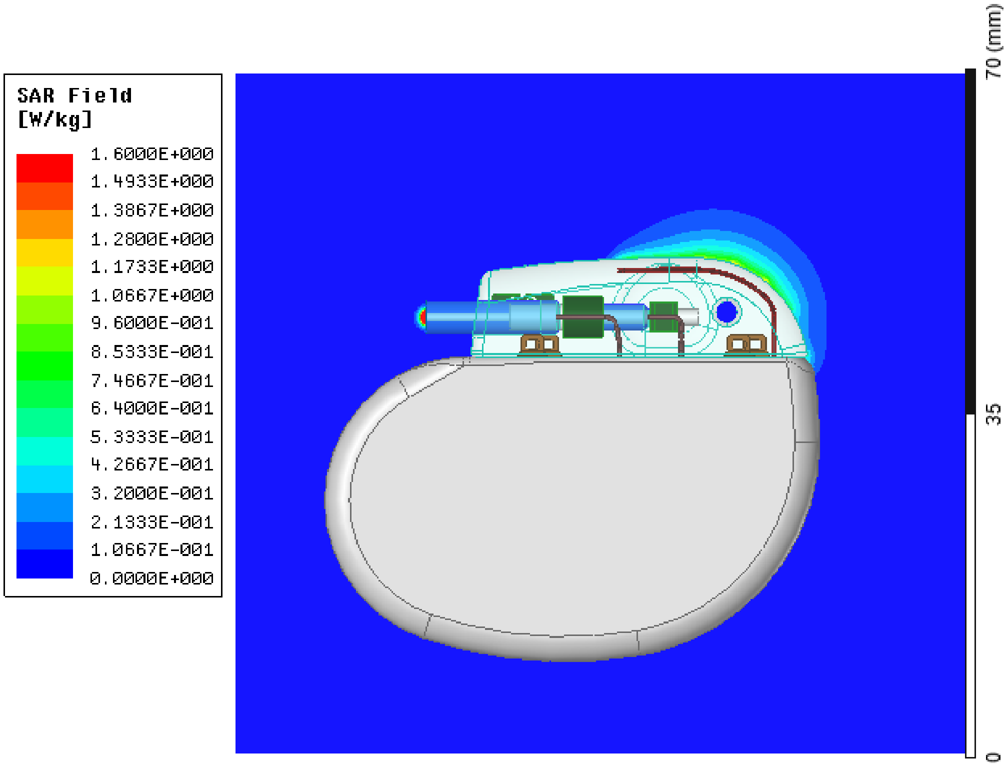


Figure 12 Zoom-In of HFSS simulated local SAR field in human body model cross-section with Implanted SR Device shown

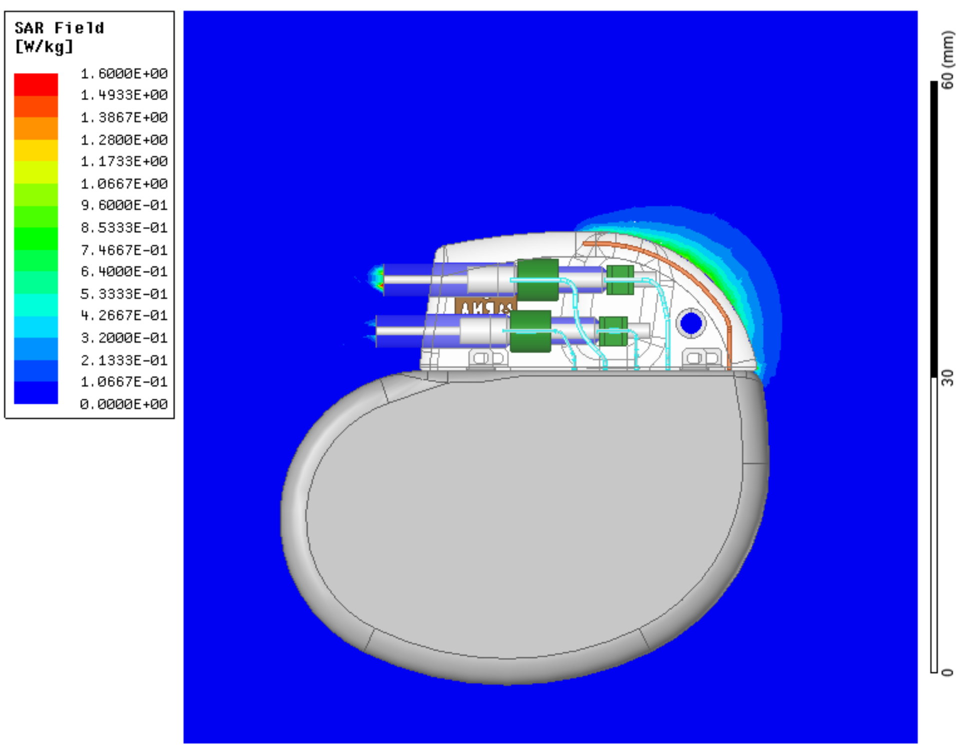


Figure 13 Zoom-In of HFSS simulated local SAR field in human body model cross-section with Implanted DR Device shown

The HFSS simulation result clearly shows that the peak electric field, i.e. the peak spatial SAR, is located in the tissue directly adjacent to the implanted RF antenna. This is illustrated in Figure 6 and 7 which shows the human torso model with the associated electric field strength due to the BTLE transmitter. The E-field strength versus distance from the device surface along EM wave propagation direction are plotted at two locations where peak E-field can be found based on Figure 6 and 7. Figure 8 and 9 shows the location and orientation of the E-field lines, and Figure 10 and 11 shows the dependence of the E-field strength versus the distance from device surface. It clearly shows that the E-field attenuates with the distance from the device. This also demonstrates the fact that for implanted devices, the peak 1-g average SAR should be determined by the tissue interface right adjacent to the device antenna in our model, but not sensitive to the device implant depth or location. Figure 12 and 13 are the simulated local SAR field plots for both SR and DR devices. It shows that the local SAR field is concentrated in a thin layer of interface tissue, and is below 1.6W/Kg in most area.

The spatial peak SAR averaged over any 1 gram (cube) of tissue was simulated with the human body torso model to be 0.1971 W/Kg for Azure SR and 0.1830 W/kg for Azure DR.

MODEL VALIDATION:

Ref [4] in attached appendix shows a report from Ansys Inc. about how HFSS complies with the accepted code validation and canonical benchmark problems prescribed in IEC 62704-1. In this attached report, to validate the accuracy of HFSS, SAR analysis simulations were run to mimic the measurement system performance check.

The above code validation and benchmarking results are based on earlier draft versions of the IEEE 1528.1 and IEC 62704-1 documents and ANSYS is currently working with the standards working group to establish procedures that are specific for finite element implementations. Due to the low SAR for these simulations, this preliminary code validation report from ANSYS should be sufficient for the two devices simulated for SAR.

The summary for the simulation results for HFSS as compared to results for FDTD are outlined in Table 4 below [4].

Freq. (MHZ)	% diff 1g average	% diff 10g average	% diff Feed Point	% diff 2cm offset
300	2.3%	1.5%	4.3%	1.9%
450	4.9%	0.3%	6.0%	2.2%
835	0.1%	0.2%	4.9%	0.2%
900	0.2%	0.4%	4.2%	0.4%
1450	0.4%	0.2%	7.0%	3.4%
1800	2.4%	1.8%	8.7%	2.5%
1900	0.6%	1.0%	6.9%	3.8%
2450	5.1%	3.6%	12.8%	0.6%
3000	0.4%	1.3%	9.4%	2.2%

Table 4 Percent difference between FDTD and HFSS simulation of SAR for a flat phantom

According to the benchmark results, the maximum difference on 1 g SAR between HFSS and FDTD at Bluetooth frequency is 5.1%. The SAR analysis shows that the Azure device 1 g peak SAR is 87.7% lower than the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093. This margin (87.7%) below the exposure limit is approximately 16 times greater than the 5.1% deviation between FEA and FDTD results shown in above report. Therefore, we believe the quoted validation report from Ansys is sufficient to support our Azure SAR submission.

CONCLUSION:

The spatial peak SAR averaged over any 1 gram (cube) of tissue has been modeled / simulated to be 0.1971 W/Kg for Azure SR and 0.1830W/kg for Azure DR. This is more than 9 dB below the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093.

The Medtronic Azure family of Bluetooth Low Energy (BTLE) devices are therefore compliant with the FCC Rules (CFR 47, §§1.1307 and §§2.1093).

REFERENCES:

[1] Appendix: "Calculating the SAR", HFSS Technical Notes, Ansys Inc. (incorporated by permission)

[2] https://transition.fcc.gov/oet/rfsafety/dielectric.html

[3] IEEE TRANSACTIONS ON MAGNETICS, VOL. 36, NO. 4, JULY 2000

[4] Appendix: Ansys HFSS Compliance with IEEE / IEC 62704-1