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SAR Analysis
Certification Submission for Medtronic
LINQ II Implantable Cardiac Monitor (ICM) Device
(FCC: LF5BLEIMPLANT3)
(ISED: IC: 3408D-BLEIMPLANT3)

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December 12, 2018

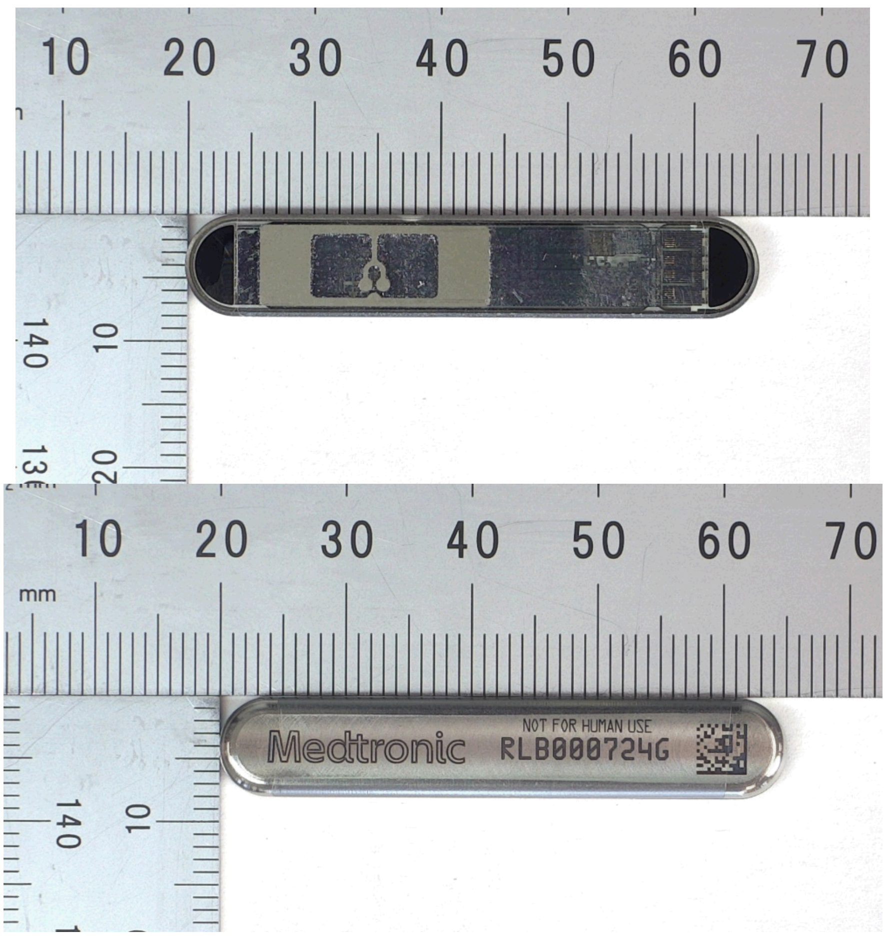


Figure 1 Medtronic LINQ II Implantable Cardiac Monitor (ICM) Device

Document Change History:

Date	Revision	Change Description
2-19-2019	1.0	Initial Release
3-13-2019	2.0	Editorial changes to report Summary

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 LINQ II device (see Figure 1).

LINQII (Medtronic implantable device) uses Bluetooth Low Energy (BTLE) as the only distance telemetry protocol, and contains a BTLE transceiver module, which has a fixed RF output power 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, and RSS-102:2015, 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. 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).
3. This SAR analysis model assumes a relatively deep implant location (2cm) for LINQ II (as a subcutaneous implant device) 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 about 3.9 dB below the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093 and RSS-102:2015.

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 LINQ II 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 ground. Inside device, the RF antenna feed-point is connected to the BTLE module through a feeding network. Therefore, the actual RF output power at the antenna feed-point should be always less than the output power directly from the RF transceiver module because of the insertion loss in between. The LINQII Medtronic implantable devices use Bluetooth Low Energy (BTLE) as the only distance telemetry protocol and contain the a BTLE transceiver module with 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 applied to the antenna.**

The titanium case is welded with a sapphire substrate, where a RF antenna is located on the substrate surface, along with two electrodes. The CAD file was imported into HFSS to create the device model. The device model contains the device case, sapphire substrate, electrodes, antenna and antenna feeding trace, and as seen in Figure 2.

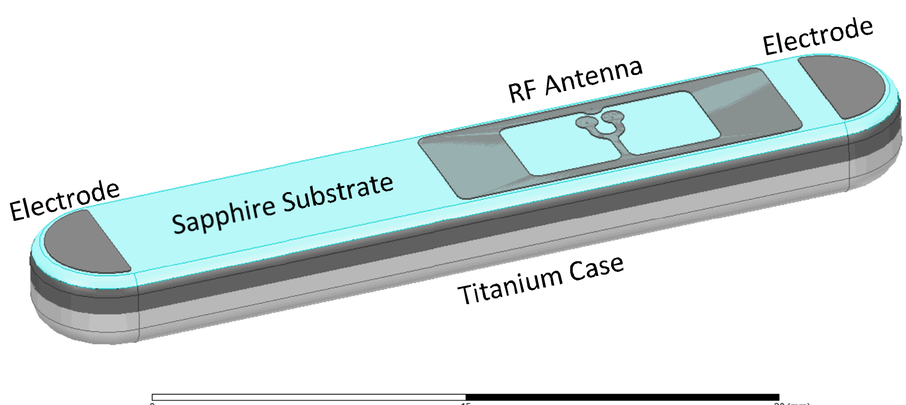


Figure 2 The Implanted Device Model in HFSS

The LINQ II devices are typically implanted within the pectoral region of the chest, 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.

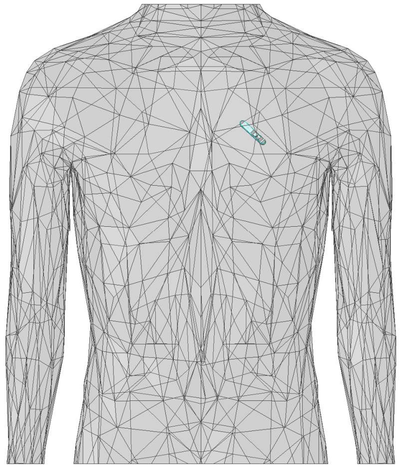
Based on this fact, **to be conservative, a human torso model including solely the muscle tissue with the LINQ II implant at the pectoral region was chosen for this model/simulation (Figure 3).** The human torso model is part of the 4 mm resolution full human body model provided by Ansys HFSS. This torso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

Medtronic LINQ II devices are usually located within the pectoral region of the chest at typically less than 1 cm deep (subcutaneous space). In this SAR analysis model, to be conservative, **the device model is located at 1.5 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.**

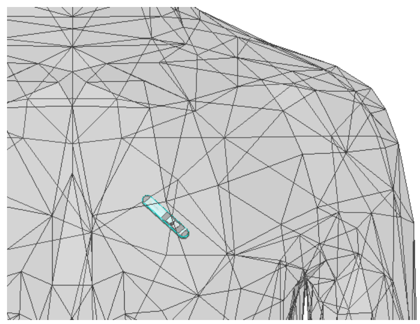
The location of the implanted device within the human body model and the zoomed-in frontal and side views are shown in Figure 3.

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

	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



(a)



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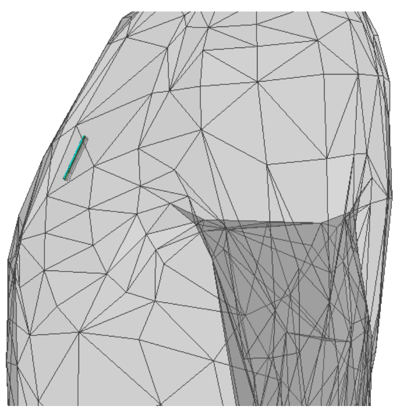


(c)

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

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.

Table 2 HFSS Modeling/Simulation Control Parameters

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 1% change convergence condition

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 1%.

The modeling accuracy of this SAR analysis is expected to be more than 99% (or less than 1% error) based on the convergence criteria.

The final mesh for the tissue around the device is plotted in Figure 4. 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.

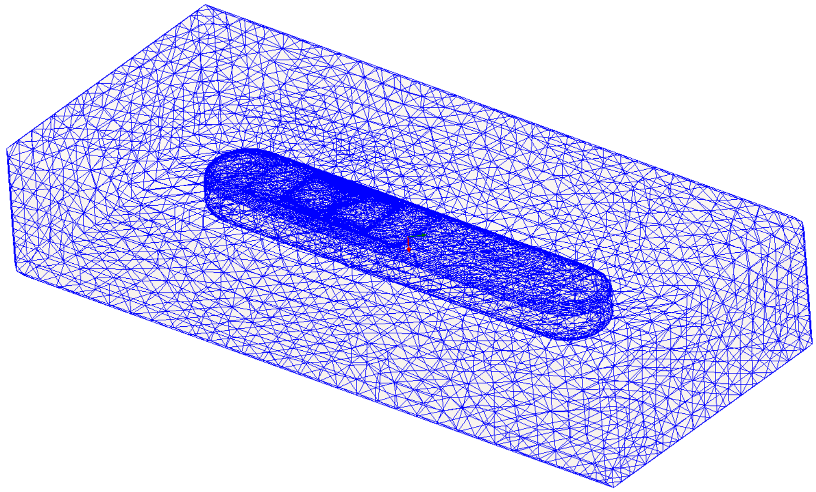


Figure 4 LINQ II Device Model Mesh Plot

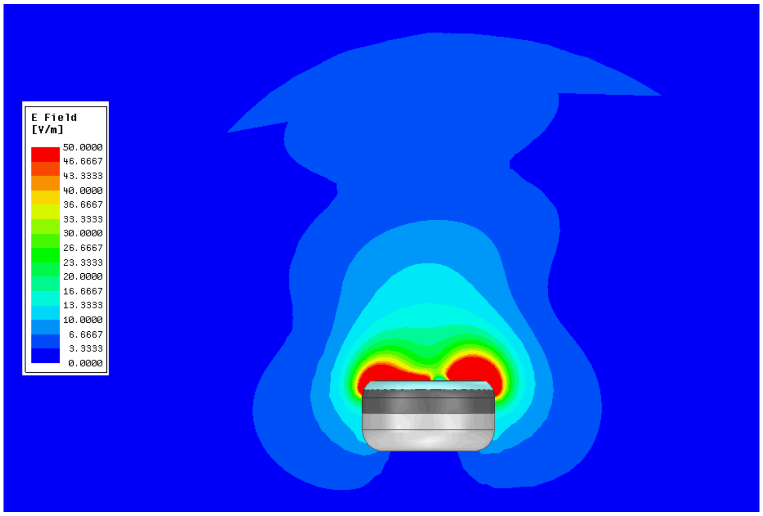
Table 3 Mesh Statistics Summary in LINQII Model

Total number of mesh elements: 1215991

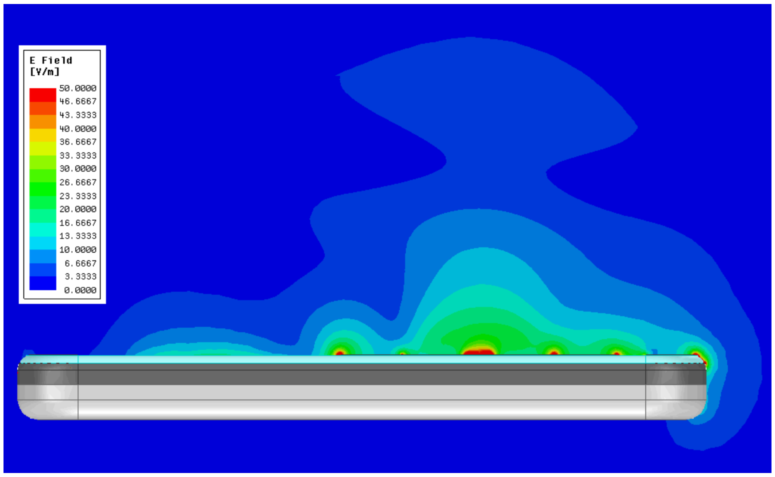
	Num Tets	RecoveredPlanarArea %	RecoveredCurvedArea %	Min elem length	Max elem length	RMS elem length	Min tet vol	Max tet vol	Mean tet vol	Std Devn (vol)
Object0	500	100	100	0.0243672	0.109969	0.0649673	6.62e-08	2.1369e-05	4.72722e-06	3.68328e-06
Object1	27	100	100	0.2132	0.464211	0.281877	2.98243e-05	0.000208333	9.70801e-05	4.82442e-05
Object2	13	100	100	0.155098	0.509902	0.397733	0.000103737	0.000416667	0.000192308	0.000104546
Object3	19	100	100	0.154299	0.300388	0.254959	5.20833e-05	0.000208333	0.000131579	5.13054e-05
Object4	54	100	100	0.111057	0.355756	0.198664	4.15565e-06	0.000108995	4.27635e-05	2.62803e-05
Object5	123	100	100	0.0397294	0.106199	0.0793559	6.91999e-07	4.66078e-05	1.60935e-05	9.19115e-06
Object6	145	100	100	0.0565914	0.127194	0.0907756	8.13802e-07	5.38854e-05	1.5198e-05	1.10736e-05
Object7	329284	100	100	0.00820343	1.68541	0.198968	4.42109e-09	0.138291	0.000477698	0.00162089
Object8	160521	100	100	0.0091007	2.4543	0.33771	7.06922e-09	0.411224	0.00251038	0.00761311
Object9	4228	100	100	0.540994	6.00587	2.46403	8.04408e-05	4.40259	0.174978	0.277289
Object10	7629	100	100	0.113413	2.918	0.748047	1.18301e-05	0.111857	0.00716083	0.0097144
Object11	456	100	100	0.218554	2.286	0.873194	7.29274e-05	0.425806	0.0171088	0.0311002
Object12	175	100	100	0.0085248	1.03856	0.69848	2.09604e-09	0.0225696	0.00335772	0.0034251
Object13	210	100	100	0.0122497	1.07859	0.623851	1.21674e-09	0.0340156	0.00279783	0.00346456
Object14	216	100	100	0.179649	0.894787	0.583539	1.40464e-05	0.0237991	0.00273074	0.00310499
Object15	232	100	100	0.202754	0.951971	0.588467	0.000146003	0.0188922	0.00253005	0.00233579
Muscle_Seed_box	351928	100	100	0.0259191	10.0892	1.98846	6.6147e-07	62.682	0.661647	1.90296
Object16	63167	100	100	0.939301	139.763	36.5499	0.0188421	134856	2802.06	7460.66
Object17	753	100	100	0.128691	1.08465	0.508804	1.14032e-05	0.00696436	0.00103628	0.000862602
Object18	12767	100	100	0.045249	0.772639	0.247784	3.31543e-06	0.00328404	0.00027119	0.000330894
Object19	184	100	100	0.128691	1.87949	1.04452	1.14032e-05	0.020517	0.00424087	0.00432203
Human_Torso	283360	100	100	1.28	21.1246	13.7272	0.0616581	654.421	146.805	99.3071

Table 3 shows the mesh size summary. It shows that there are totally 1,215,991 mesh elements for this SAR model. In the muscle seed box, which represents the nearby tissue volume (totally 234 cm^3 in volume) surrounding the device, there are totally 351,928 mesh elements, and the minimum mesh edge size in this tissue volume is only 0.026 mm. Please note that the edge size of a 1-g muscle cube is about 10 mm, which is about 384 times of the minimum mesh edge size in this model. This high resolution of mesh is resulted from the 1% convergence criteria.

RESULTS:

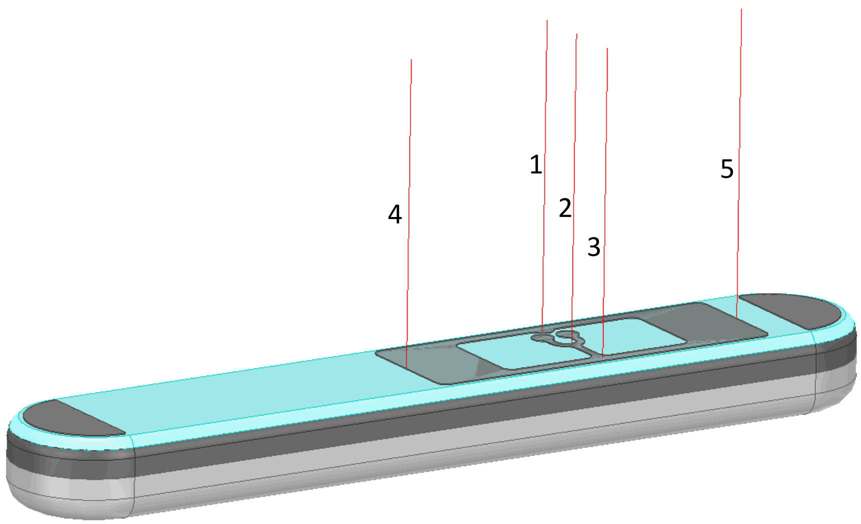


(a)

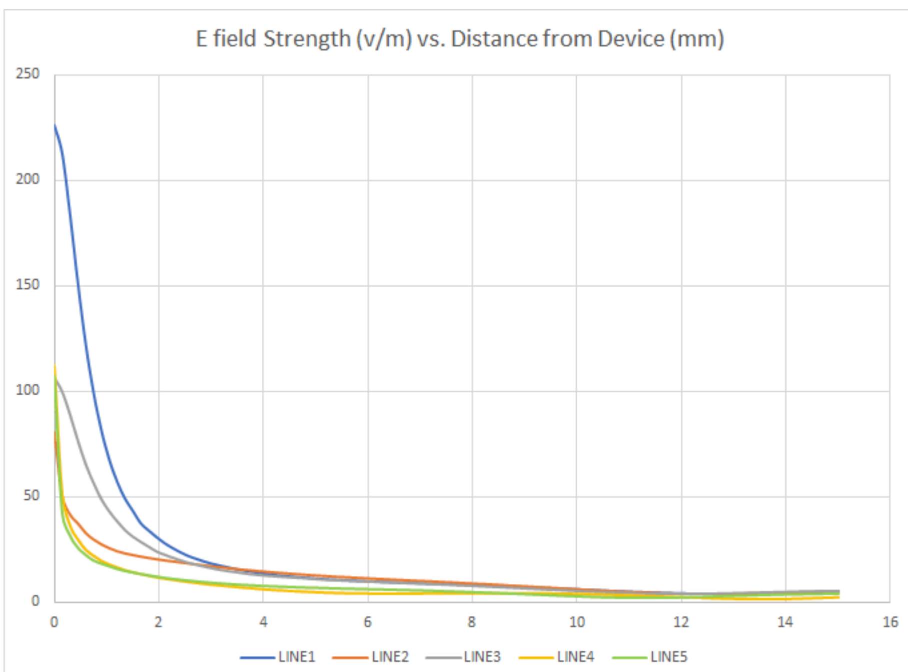


(b)

Figure 5 Zoom-In of HFSS simulated electric field distribution in cross-section with Implanted LINQ II Device shown

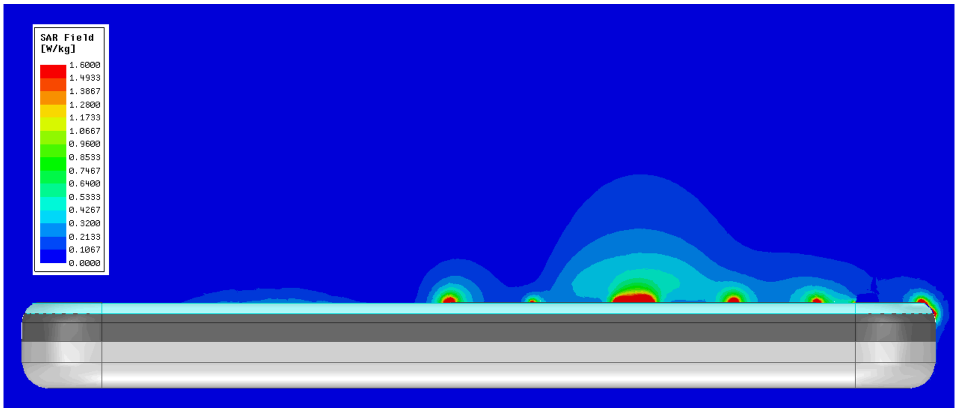


(a)

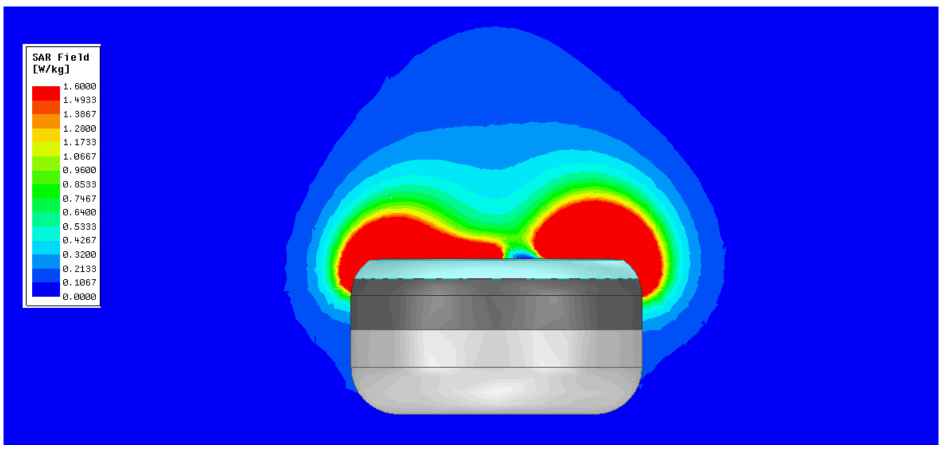


(b)

Figure 6 Simulated E-field strength versus distance from LINQ II device surface: (a) location and orientation of each E-field line (b) simulated field strength on each E-field line



(a)



(b)

Figure 7 Zoom-In of HFSS simulated local SAR field distribution in cross-section with Implanted LINQ II Device shown

The HFSS simulation result, in Figure 5, clearly shows that the peak electric field, i.e. the peak spatial SAR, is located on the tissue directly adjacent to the implanted RF antenna. The E-field strength versus distance from the device surface along EM wave propagation direction are plotted at multiple locations where peak E-field can be found based on Figure 6. Figure 6(a) shows the location and orientation of the E-field lines, and Figure 6(b) shows the dependence of the E-field strength versus the distance from device surface. It clearly shows that the E-field strength attenuates with the distance away 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 7 shows simulated local SAR field plot for LINQ II. It also indicates that the local SAR field is concentrated in a thin layer of interface tissue and is below 1.6W/Kg in most of the area.

The spatial peak SAR averaged over any 1 gram (cube) of tissue was simulated with the human body torso model to be 0.6481 W/Kg for LINQ II.

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].

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

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%

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 LINQ II 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 LINQ II SAR submission.

CONCLUSION:

The spatial peak SAR averaged over any 1 gram (cube) of tissue has been modeled / simulated to be 0.6481 W/Kg for LINQII. This is about 3.9 dB below the 1.6 W/Kg General Population/Uncontrolled exposure limit called out in §§2.1093 and RSS-102:2015.

The Medtronic LINQ II Implantable Cardiac Monitor (ICM) Bluetooth Low Energy (BTLE) radio device is therefore compliant with the FCC Rules (CFR 47, §§1.1307 and §§2.1093) and RSS-102:2015.

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