ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

Dokumenttyp / Document Type	Dok.nr. / Doc.No.	Utg. / Rev.	Sida / Page
Report	**50042788**	**A**	1(14)

Dokumentnamn / Title	Säkerhetsklass / Classification
Specific Absorption Rate (SAR) Analysis for SJM Downsized Device 2 (DD2) implants	Intern / Internal Use

Avdelning / Dept.	Utfärdare / Originator	Ersätter / Supersedes
Electronics Development	Andreas Kronhamn	N/A

Distribueras till / Distribution List	Bilagor / Attachments
N/A	N/A

Utgåva / Revision	Revisionshistoria / Revisions History
A	Initial Revision.

Table of Contents

1 Introduction

St. Jude Medical has a wireless communication system that is operating under the MICS (Medical Implant Communication Service) standard. The intended use is for communication between Implanted Medical Devices (IMD) and, to the body, an external transceiver. The current FCCID is RIASJMRF for SJM implantable cardioverter-defibrillator.

This report covers all existing Downsized Device 2 (DD2) implants with the four header variants, presented here by Ellipse™ VR model CD1275-36 (header type VR IS1), Ellipse™ DR model CD2275-36 (header type DR IS1), Ellipse™ ST VR model CD1273-36Q (header type VR DF4) and Ellipse™ ST DR model CD2273-36Q (header type DR DF4).

This SAR computation modeling is performed to show compliance to radio frequency exposure limits as defined in, 47 CFR Part1, section 1.1307 and in 47 CFR Part2, section 2.1903. The usage of the equipment is uncontrolled and hence the limit for partial-body SAR is 1.6W/kg. The partial-body SAR is averaged over any 1g tissue volume in the shape of a cube. The Whole-body limit for average SAR is 0.08W/kg.

2 Scope

The scope of this report is to show compliance for the four DD2 implant header variants, as required in 47 CFR Part 95, section 95.603(f).

3 Summary

The computed SAR levels are well below the limits as specified in 47 CFR Part1, section 1.1307 and in 47 CFR Part2, section 2.1903.

RF implant header variants	Partial body SAR Max 1g [W/kg]	The ANSI safety limit of SAR Max 1 g [W/kg]	Whole body average SAR [W/kg]	The ANSI safety limit of whole body SAR [W/kg]
VR IS1	0.037	1.6	0.0002	0.08
DR IS1	0.038	1.6	0.0002	0.08
VR DF4	0.054	1.6	0.0002	0.08
DR DF4	0.054	1.6	0.0002	0.08

Table 1 Computed SAR value of Ellipse™ VR IS1, Ellipse™ DR IS1, Ellipse™ VR DF4 and Ellipse™ DR DF4.

4 Method

The CST Micro Wave Studio (MWS) version 2011.00 – Jan 14 2011 simulation program was used during the simulations. As described in [1] FIT is identical to pure FDTD method as defined by Yee [2]. MWS is using the Finite Integration Technique (FIT) which in the time domain can be considered as a conformal FDTD method.

MWS has in order to increase the computational accuracy and efficiency added features to the pure FDTD. During the simulations the Perfect Boundary Approximation (PBA)® and Thin Sheet Technique (TST)™ functionalities were used. The grid was implemented as non-homogeneous and non-equidistant.

4.1 Simulation volume

Cad models of relevant parts of the IMD were imported to the simulator in order to enable a correct representation of the antenna function. In order to simulate a worst case scenario the IMD was put inside muscle tissue shaped as a parallelepiped measuring 175 by 114 by 178 (XYZ) mm, see figure 1. This is judged to be a worst case scenario since an alternate placement in fat will lead to lower SAR values due to the much lower conductivity and dielectric constant of fat. The boundary condition Perfect Electrical Conductor was used. The reason for using this boundary was to safe guard that all emitted energy was kept within the computational volume. The validity of the chosen parallelepiped is verified in figure 10 to figure 17, where it is found that the energy relevant for the SAR calculation is dissipated in a distance much shorter than the distance to the boundary condition. The IMD metal parts were all modeled as lossless. This is a worst case scenario since a lossless conductor does not reduce SAR as would a real metal conductor. The dielectrical materials implemented in the simulator are viewed in table 2. The muscle electrical properties were retrieved from [3]. The electric properties were taken as mean value of transversal and parallel muscle fibers at 403 MHz. The density was chosen according to [4].The materials used in SAR calculations are all include as non dispersive.

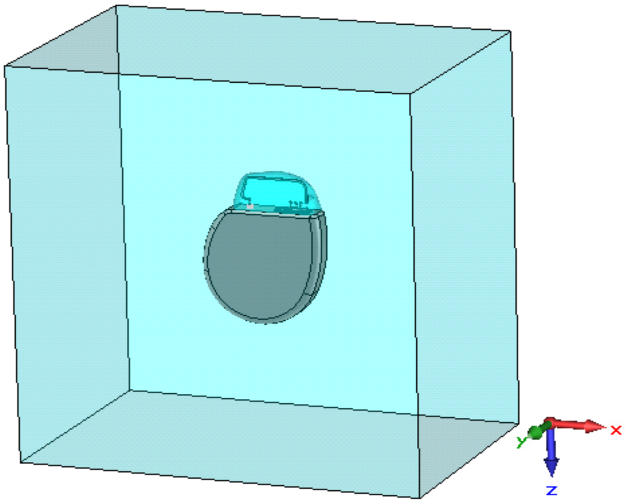

Figure 1 Device placed inside a parallelepiped of muscle. Displayed is also XYZ coordinate system

Material	Relative dielectric constant, εr	Electrical conductivity [S/m]	Tandelta Loss (δ)	Density [kg/m^3]
Epoxy	3.0	N/A	0.033	N/A
Muscle	57.9	0.82	N/A	1000

Table 2 Properties of the dielectrical materials used in the simulations.

4.2 Simulated object

For all four header variant simulations, an imported CAD model was used and hence the model used during simulations is considered representative. The loop antenna, device can, casted header, all wires in the header as well as the set screw blocks are included in the CAD model. The lead cavities were filled with epoxy. The power was fed using a discrete port between device can and antenna. This is the same place as where the antenna is connected to the RF-feedthru.

4.3 Input power and source excitation

A conservative approach was used for determining the output power to be used as input to the simulation. The determination was made trough measurements of the output power emitted from the RF-hybrid. A slide screw tuner [7] equipment was used to create several antenna impedances that have been seen during implant studies for the four header variants. The maximum measured output power when the RF-hybrids saw different antenna impedances was 1.0 mW. The maximum output power was measured with a CW (Continuous Wave) signal. 1.0 mW was subsequently used as input to the SAR calculation.

The simulated impedances for the four header variants were a subset of the antenna impedances described above and therefore are the maximum output power considered representative for the four header variants.

A typical user scenario is that during the first 20 seconds the stored IEGM (Intracardiac Electrogram) and other device data is transferred at maximum data speed to the external device. During these first 20 seconds (Phase1) the implant has a transmit on-time duty cycle of 80%. After these first 20 seconds (Phase2) the implant is transmitting almost only real time IEGM at lower data rate. During this phase the transmit on-time duty cycle is 50%. The output power used in the SAR calculations is based on the worst case duty cycle, 0.8 mW (Phase 1).

Max measured power [mW]	Phase 1 power [mW]	Phase 2 power [mW]
1	0.8 x 1.0 = 0.8	0.5 x 1.0 = 0.5

Table 3 The power used during SAR calculations was 0.8 mW (Phase 1)**.**

The source used to excite the simulation was a voltage gap between device can and antenna at the same place where the antenna is connected to the RF-feedthru. MWS calculated SAR based on the power accepted by the antenna so no antenna impedance matching was needed.

4.4 SAR calculation

The device was modeled at the middle of the frequency band since the MICS frequency band has less than 1% bandwidth and no differences in SAR is expected between high, middle and low channels. MWS calculates 1 g average SAR using a method that is compliant with IEEE Std C95.3-2002 and described below:

- compute the losses in a cell:
  Loss_x = 0.125 (sigma_1x |E_1x|^2 + ... + sigma_4x |E_4x|^2)
  Loss_cell = Loss_x + Loss_y + Loss_z

- compute the mass of each cell (conformal integration):
  Mass_cell = dx dy dz rho_cell

- find an averaging cube with a mass of 1 g (iteratively) and integrate the losses in this cube.

The described averaging procedure is therefore a 12 component averaging and also conformal to IEEE C95.3.

The whole body SAR was calculated as the power absorbed in biological tissue divided by the tissue mass.

4.5 Mesh density

MWS has a powerful mesh engine that creates mesh as a function of the object that is simulated. The adaptive mesh refinement was used when the IMDs were simulated. Adaptive meshing uses an energy based method, which check the field energy distribution inside the computational domain. Based on the data, the mesh is refined in regions with high energy density. The simulation results as the total number of meshcells, max mesh step and min mesh step for each of the header variant see table 4 – 7.

The simulation was stopped when the energy in the whole computation volume was 50 dB below initial energy. The added error due to the truncation criteria is on average 10E-5.

It is estimated that the total uncertainty in calculating SAR is below 10%.

4.5.1 Header variant – VR IS1

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Position Max SAR z;y;z [inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0,0002	0,037	0,22;0,0087;-0,13	0,0025	0,079	9 300 000

Table 4 Simulation results from Ellipse™ VR IS1. The power that was accepted by the antenna was set to 0.8 mW.

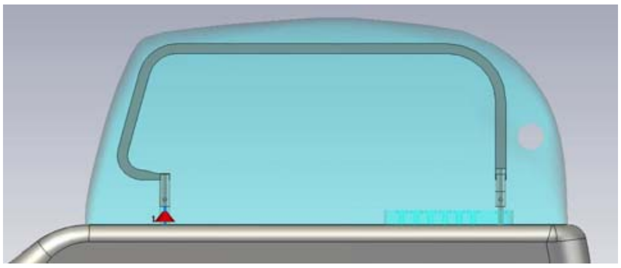

Figure 2 The header of Ellipse™ VR IS1. The red triangle represents the feeder to the loop antenna.

Note:The CAD model used in SAR computational modelling also includes all wires in the header as well as the set screw blocks.

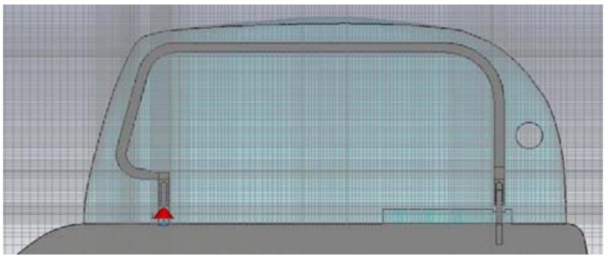

Figure 3 Mesh around the header when Ellipse™ VR IS1 was simulated. The total number of meshcells were 9,400,000.

4.5.2 Header variant – DR IS1

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Position Max SAR z;y;z [inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0,0002	0,037	0,22;0,0087;-0,13	0,0025	0,079	9 300 000

Table 5 Simulation results from Ellipse™ DR IS1. The power that was accepted by the antenna was set to 0.8 mW.

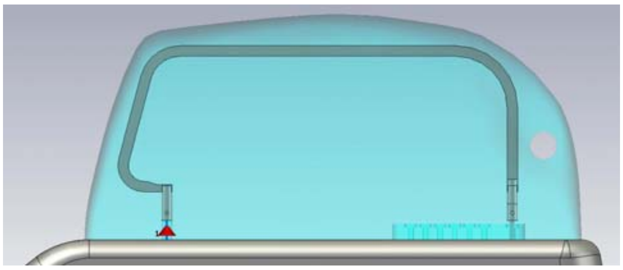

Figure 4 The header of Ellipse™ DR IS1. The red triangle represents the feeder to the loop antenna.
Note:The CAD model used in SAR computational modelling also includes all wires in the header as well as the set screw blocks

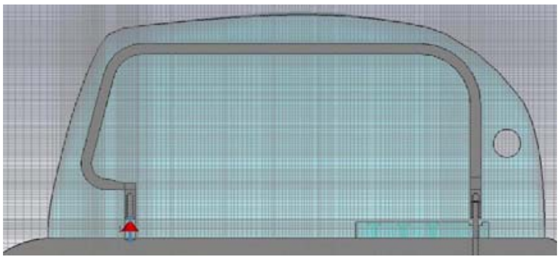

Figure 5 Mesh around the header when Ellipse™ DR IS1 was simulated. The total numbers of meshcells were 9,300,000.

4.5.3 Header variant – VR DF4

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Position Max SAR z;y;z [inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0,0002	0,054	0,073;0,21;-0,20	0,005	0,079	5 400 000

Table 6 Simulation results from Ellipse™ VR DF4. The power that was accepted by the antenna was set to 0.8 mW.

Figure 6 The header of Ellipse™ VR DF4. The red triangle represents the feeder to the loop antenna.
Note:The CAD model used in SAR computational modelling also includes all wires in the header as well as the set screw blocks.

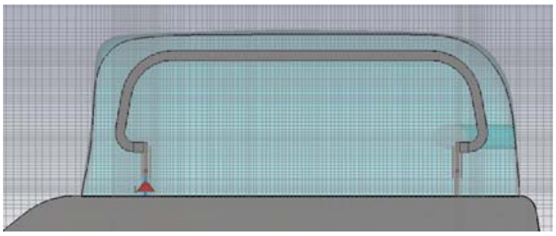

Figure 7 Mesh around the header when Ellipse™ VR DF4 was simulated. The total number of meshcells were 5,400,000.

4.5.4 Header variant – DR DF4

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Position Max SAR z;y;z [inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0,0002	0,054	0,073;0,21;-0,20	0,005	0,079	5 700 000

Table 7 Simulation results from Ellipse™ DR DF4. The power that was accepted by the antenna was set to 0.8 mW.

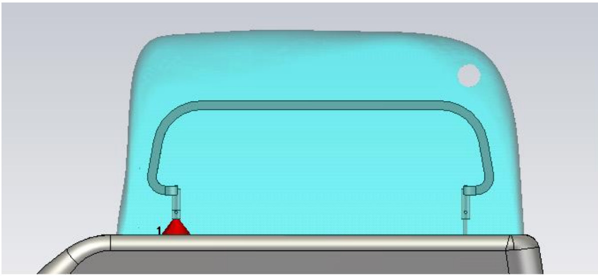

Figure 8 The header of Ellipse™ DR DF4. The red triangle represents the feeder to the loop antenna.
Note:The CAD model used in SAR computational modelling also includes all wires in the header as well as the set screw blocks.

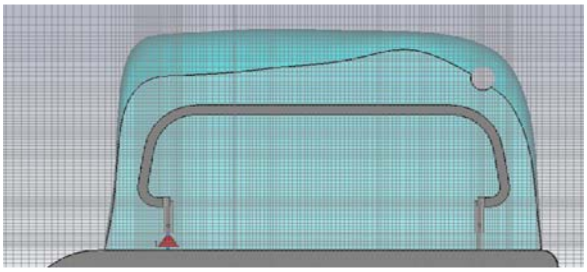

Figure 9 Mesh around the header when Ellipse™ DR DF4 was simulated. The total number of meshcells were 5,700,000.

5 Results

Figure 10 - 17 show the SAR distribution around the devices when the antenna is fed with 0.8 mW. The largest energy deposition is close to the antenna feeding port and as expected the deposition is decreasing when moving away from antenna feed.

RF implant header variants	Partial body SAR Max 1g [W/kg]	The ANSI safety limit of SAR Max 1 g [W/kg]	Whole body average SAR [W/kg]	The ANSI safety limit of whole body SAR [W/kg]
VR IS1	0.037	1.6	0.0002	0.08
DR IS1	0.038	1.6	0.0002	0.08
VR DF4	0.054	1,6	0.0002	0,08
DR DF4	0.054	1,6	0.0002	0,08

Table 8 Computed SAR value of Ellipse™ VR IS1, Ellipse™ DR IS1, Ellipse™ VR DF4 and Ellipse™ DR DF4.

5.1 Header variant – VR IS1

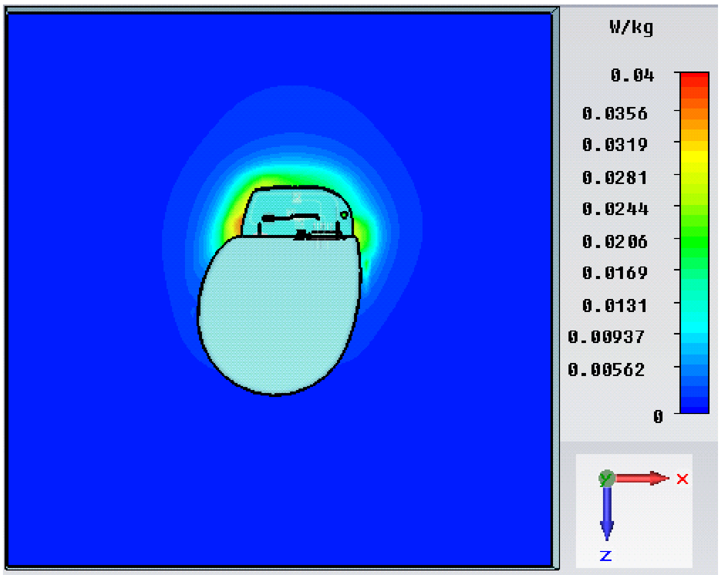

Figure 10 XZ cross section of max 1g average SAR distributions, from Ellipse™ VR IS1, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

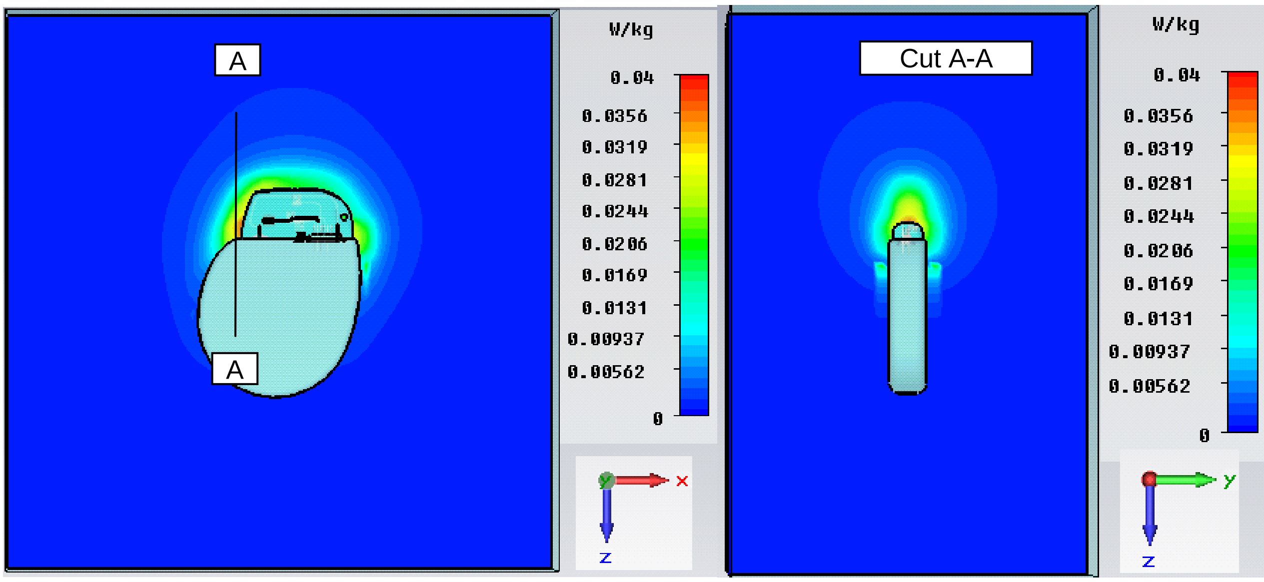

Figure 11 YZ cross section of max 1g average SAR distributions, from Ellipse™ VR IS1, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

5.2 Header variant – DR IS1

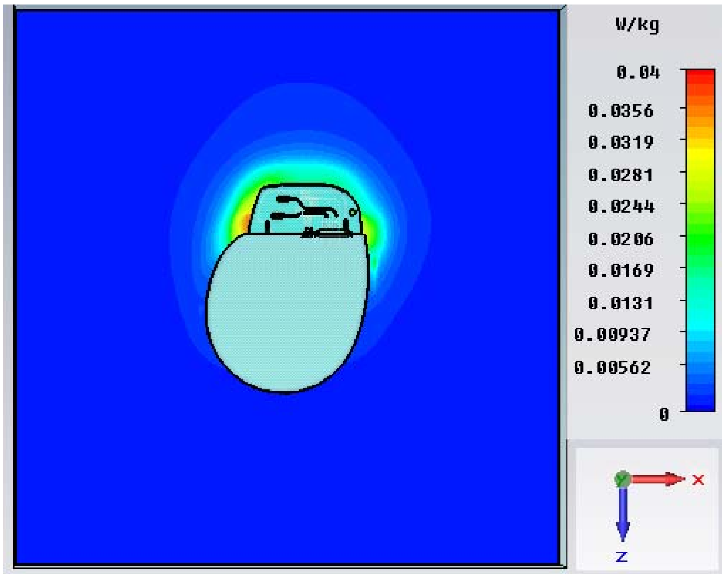

Figure 12 XZ cross section of max 1g average SAR distributions, from Ellipse™ DR IS1, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

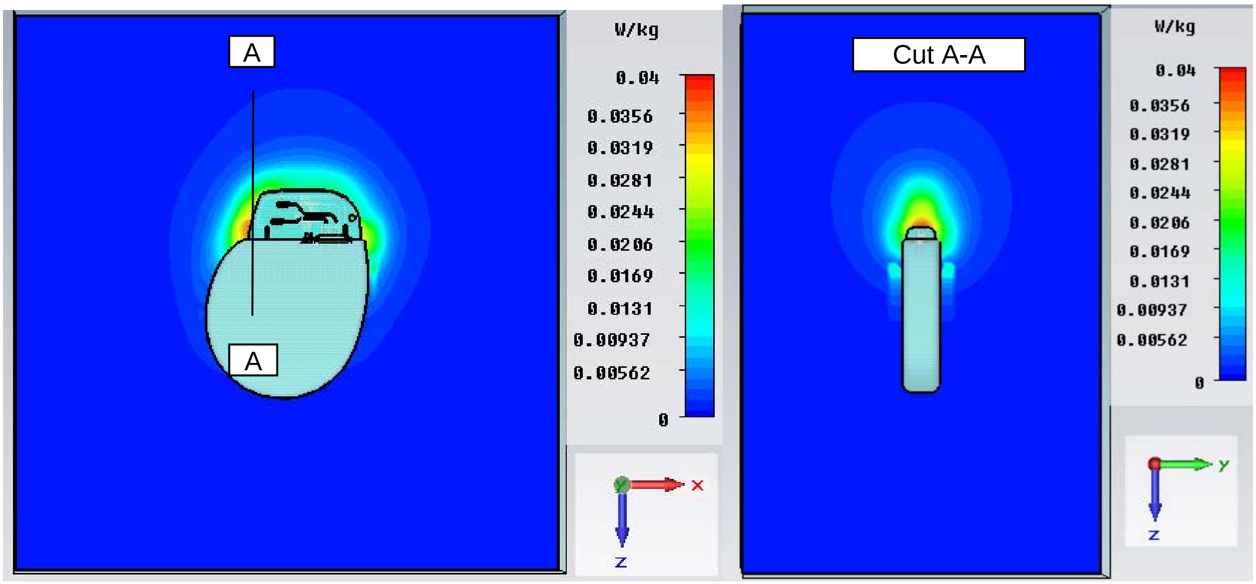

Figure 13 YZ cross section of max 1g average SAR distributions, from Ellipse™ DR IS1, at or in close proximity to the place where the maxim.

5.3 Header variant – VR DF4

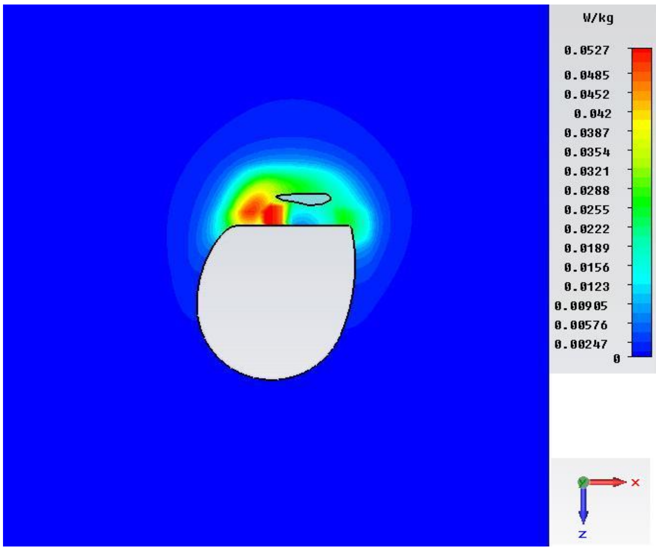

Figure 14 XZ cross section of max 1g average SAR distributions, from Ellipse™ VR DF4, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

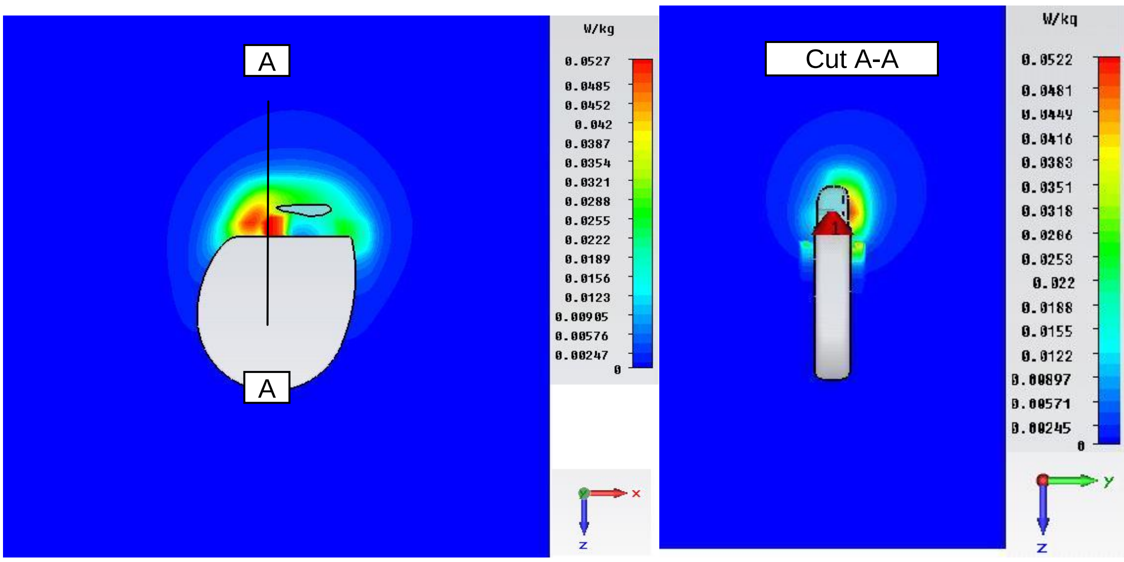

Figure 15 YZ cross section of max 1g average SAR distributions, from Ellipse™ VR DF4, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

5.4 Header variant – DR DF4

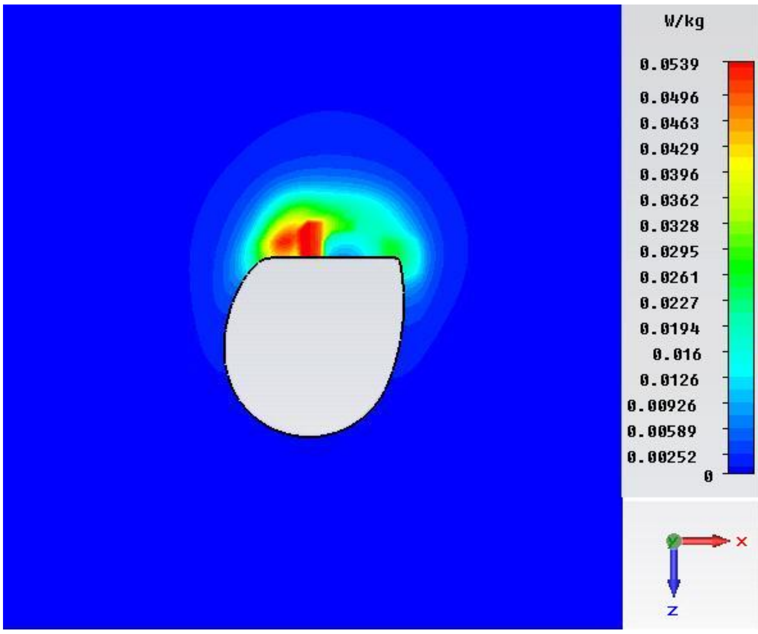

Figure 16 XZ cross section of max 1g average SAR distributions, from Ellipse™ DR DF4, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

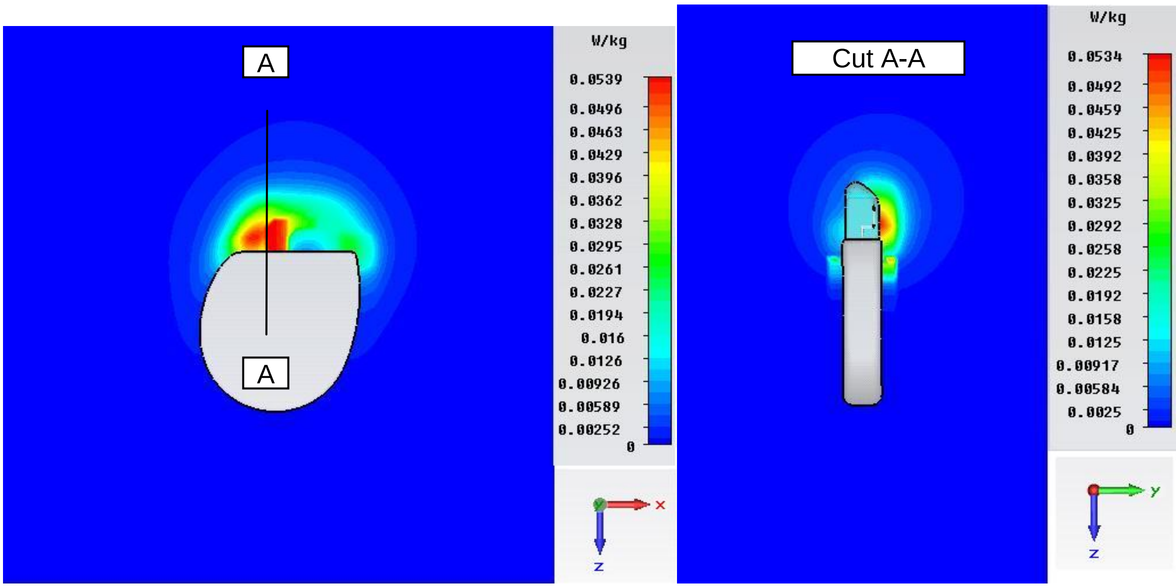

Figure 17 YZ cross section of max 1g average SAR distributions, from Ellipse™ DR DF4, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.8 mW.

6 Compliance

The results presented in section 5 table 8 are well below the limit for partial-body SAR and whole-body average SAR.

7 OET 65C

OET65C [4] defines the specific information needed to prove compliance. Below are listed either where to find information in the report or, in some cases, further clarifications.

7.1 Computational Resources

A 32GB RAM HP ProLiant BL460c with Dual 2.67 GHz Intel Xeon X5550 processors was used during the simulations. Operating system was Windows Server 2003 R2 standard x64 Edition.

RF implants header variants	Mesh cells	Solver memory [MB]	Max Timestep
VR IS1	9 400 000	4 400	400 000
DR IS1	9 300 000	4 200	370 000
VR DF4	5 400 000	3 100	200 000
DR DF4	5 700 000	3 100	210 000

Table 9 Solver memory requirement of Ellipse™ VR IS1, Ellipse™ DR IS1, Ellipse™ VR DF4 and Ellipse™ DR DF4.

7.2 FDTD algorithm implementation and validation

See section 4.

7.3 Computational parameters

See section 4.

7.4 Phantom implementation and validation

See section 4.

7.5 Tissue dielectric parameters

See section 4.

7.6 Transmitter model implementation and validation

See section 4.

Realistic simulation of device can, epoxy header, wires and blocks in the header are important to obtaining an accurate result.

7.7 Test device positioning

Device positioning is in the middle of the muscle parallelepiped.

7.8 Steady state termination procedures

The simulation was stopped when the energy in the whole computation volume was 50 dB below initial energy. The added error due to the truncation criteria is on average 10E-5.

7.9 Computing peak SAR from field components

See section 4.4.

7.10 One gram averaged SAR procedures

See section 4.4.

7.11 Total computational uncertainty

Adaptive meshing uses an energy based method, which check the field energy distribution inside the computational domain. Based on the data, the mesh is refined in regions with high energy density. The truncation criteria is set to give errors on the order of 10E-5. It is estimated that the total uncertainty in calculating SAR is below 10%.

7.12 Test results for determining SAR compliance

See section 5.

8 References

1. S. Gutschling, H. Krüger, T. Weiland: Modeling Dispersive Media Using the Finite Integration Technique. Proceedings of the 14th Annual Review of Progress in Applied Computational Electromagnetics (ACES 1998), Vol. 2, March 1998, pp. 832-837

2. K.S. Yee; Numerical Solution of initial boundary value problems involving Maxwells Equations in isotropic media; 1966; IEEE Transactions on antennas and propagation; Vol. 17; p. 585-589

3. http://www.fcc.gov/fcc-bin/dielec.sh; The tissue parameters provided here are derived from the 4-Cole-Cole Analysis in "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies" by Camelia Gabriel, Brooks Air Force Technical Report AL/OE-TR-1996-0037.

4. FCC OET Bulletin 65, supplement C.

5. IEEE C95.1-2005 the human exposure standard

6. IEEE C95.3 -2003 the measurement practices standard

7. Maury Microwave, operating instructions; Coaxial Manual Tuners.