ST. JUDE MEDICAL

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Dokumentnamn / Title Specific Absorption Rate (SAR) Analysis for device Current VR RF - Model 1207			
Avdelning / Dept. Ut	Utfärdare / Originator Tomas Snitting	Ersätter / Supersedes 1	
Avser / Concerns Unity	Säkerhetsklass / Classification **internal**	Bilagor / Attachments N/A	
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Utgåva / Revision	Revisionshistoria / Revisions History
001	First Revision
002	Updated error regarding model number in Section 1.

1 Introduction

St. Jude Medical has developed 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 an, to the body, external transceiver. Wireless communication will provide communication at much higher speed and longer distance as compared to the present inductive communication. The IMD is using a loop antenna mounted on the header. This report covers the *Current VR RF - Model 1207*. According to 47 CFR Part 95, section 95.603(f) a simulation shall be performed to calculate SAR values. This in order 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 of device *Current VR RF - Model 1207*, as required in 47 CFR Part 95, section 95.603(f).

3 Summary

The maximum SAR levels were computed to be:

Whole body average SAR	1,78E-6 W/kg
Maximum 1g SAR	0,16 W/kg

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

4 Method

The Micro Wave Studio (MWS) version 2006BRC1 simulation program was used during the simulations. It is developed by CST GMBH [1]. MWS is using a method called Finite Integration Theory (FIT). As described in [2] FIT is identical to the pure FDTD method as defined by Yee [3]. MWS has in order to increase 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 implanted device 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 152 by 117 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 (PEC) was used. The reason for using PEC was to safeguard that all emitted energy was kept within the computational volume. The validity of the chosen parallelepiped is verified in Figure 3, 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 PEC. This is a worst case scenario since a PEC conductor is lossless and hence does not reduce SAR as would a real metal conductor. The dielectrical materials implemented in the simulator are viewed in Table 1. The muscle electrical properties were retrieved from [4]. The electric properties were taken as mean value of transversal and parallel muscle fibers at 403 MHz. The density was chosen according to [5].The materials used in the SAR calculations are all included as non-dispersive.

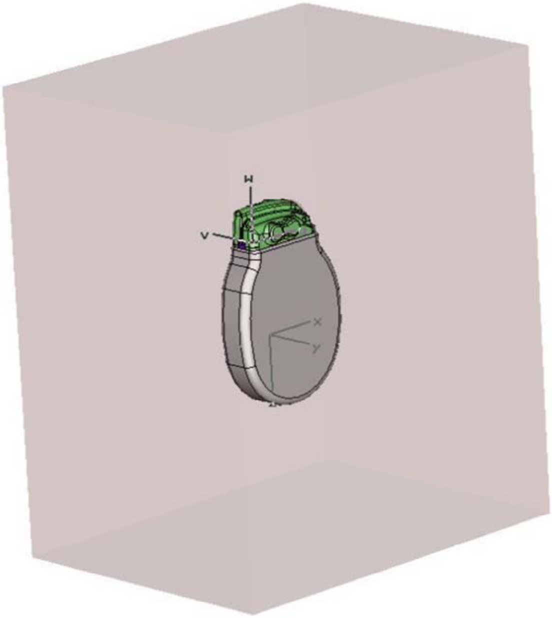

Figure 1 Device placed inside a parallelepiped of muscle. Displayed is also XYZ coordinate system

Material	Relative dielectric constant, εr	Electrical conductivity [S/m]	Density [kg/m^3]
Epoxy	3.5	0.033	N/A
Silicone	3.4	0	N/A
Muscle	57.9	0.82	1000

Table 1Properties of the dielectrical materials used in the simulations.

4.2 Mesh density

MWS has a powerful mesh engine that creates mesh as a function of the object that is simulated. However a lower limit can be set on the largest allowed mesh cell in the calculation. The size of the largest allowed Mesh cell was set to 3.3mm or a 20th wavelength in the muscle at the highest simulation frequency 600MHz. However it should be noted that the actual resolution of the IMD is much finer. The way the resolution of objects is performed is by defining the mesh line ratio limit which is the ratio between the largest and smallest distance between mesh lines. The mesh line ratio limit was chosen to 50. In order to prove that the simulation was performed in a stable region where additional mesh would not alter SAR, simulations also with different mesh settings was performed, see Table 2. It can here be found that refinement of mesh seems to slightly lower SAR. Impedance is stable as a function of mesh density. These findings indicate that the chosen mesh density is acceptable. A view of the mesh can be seen in figure 2.

lines/ wavelength	Mesh line ratio limit	SAR	Position x;y;z[inch]	Resistance [Ω] at 403MHZ	Reactance [Ω] at 403MHz	Meshcells
20	20	0,20	-0,67;0,25;-1,69	76	-26	288600
20	50	0,16	-0,52;0,36;-1,83	93	-25	907920
20	60	0,16	-0,47;0,27;-1,87	93	-25	1149995
30	50	0,16	-0,52;0,36;-1,83	93	-25	1534680

Table 2 Result comparison when altering mesh densities. The power that was accepted by the antenna was set to 1 mW.

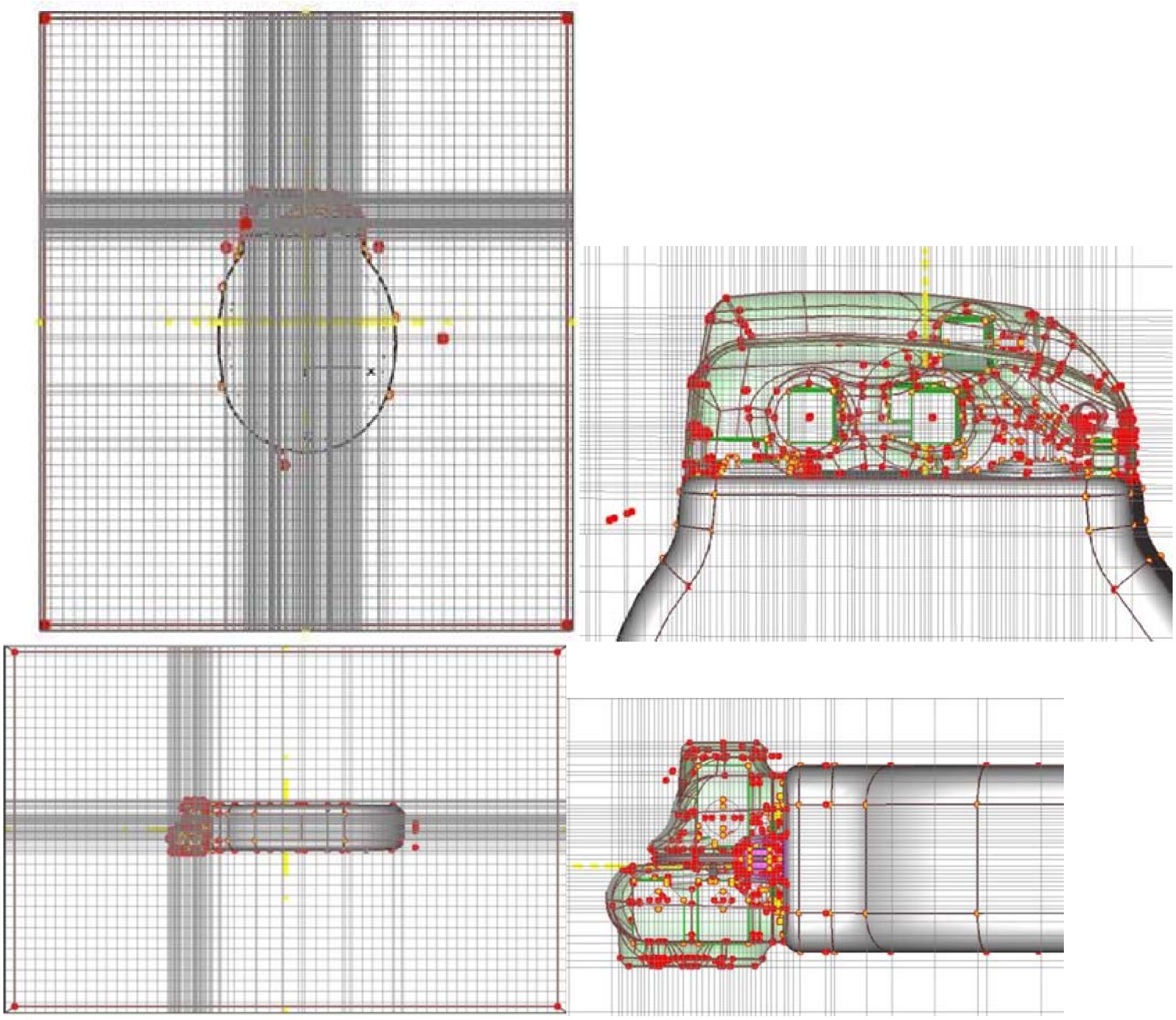

Figure 2 Views of the mesh used during the simulation. To the left up and down is the full simulation volume. To the right up and down are magnified views showing mesh around the header.

4.3 Simulated object

The IMD that was simulated is displayed in Figure 1. An imported CAD model was used and hence the model used during simulations is representative. The loop antenna, device can, casted header, all wires in the header as well as the set screw blocks is 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.

4.4 Input power and source excitation

The antenna impedance during the simulations performed as described in 4.1 was 93-j25 Ω at 403,35 MHz. Using a slide screw tuner [6] this load was presented to 3 representative devices. The maximum measured output power with a CW (Continuous Wave) signal was 0,4mW. The total spread in all 3 devices was 0,03mW.

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%. This is also a worst case duty cycle. 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%. Table 3 presents the output power used in the SAR calculations. Both Phase1 and Phase2 output powers were used during the SAR calculations.

Max measured power [mW]	Phase 1 power [mW]	Phase 2 power [mW]
0,4	0,32	0,2

Table 3 Powers used during SAR calculations.

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.

4.5 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 partial-body SAR using a method that is compliant with IEEE Std C95.3-2002. The whole body SAR was calculated as the power accepted by the antenna divided by the total mass of the modeled volume.

5 Results

Figure 3 show the SAR distribution around the device when antenna is fed with 0.32 mW. The largest energy deposition is close to the antenna feeding port and as expected the deposition is decreasing when moving away from the antenna feed. Table 4 views 1g SAR and average SAR for the average powers stated in Table 4 during the two different user scenarios.

Use case	Total SAR[w/kg]	1g SAR[w/kg]
Phase 1	1,78E-06	0,16
Phase 2	1,11E-06	0,10

Table 4 SAR values. The different phases correspond to average output powers as described in section 4.4.

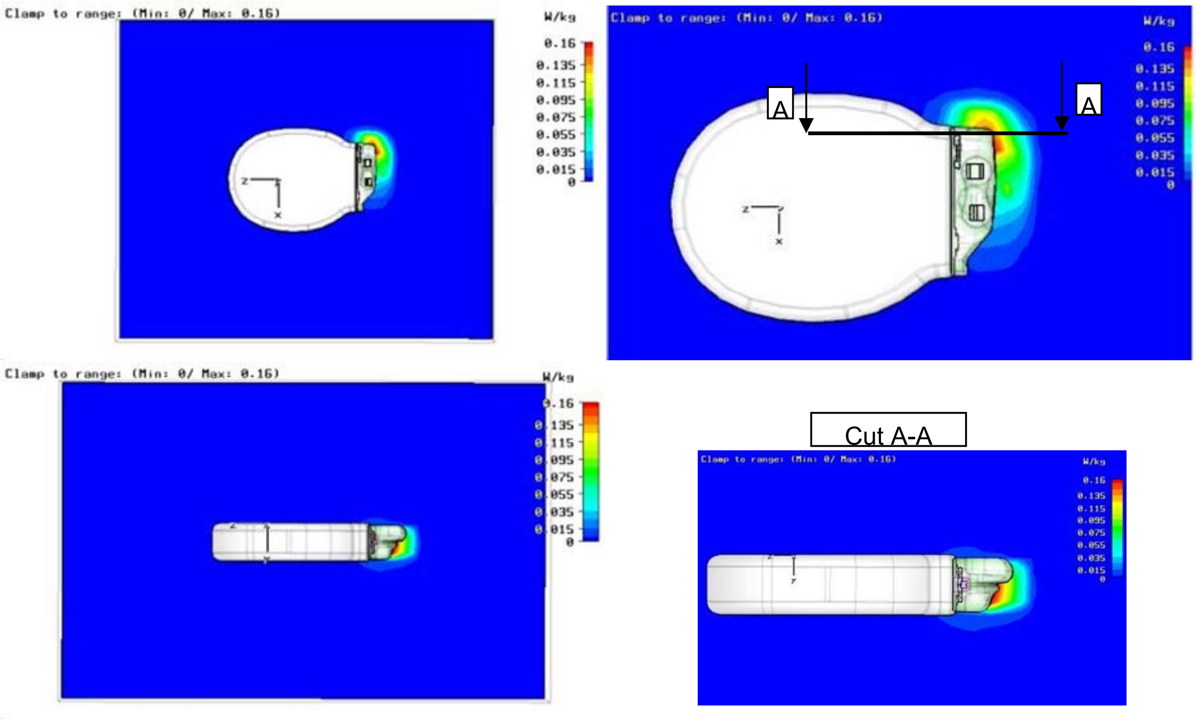

Figure 3 1g SAR distributions at or in close proximity to the place where the maximum SAR is found. To the left is shown the full simulation volume. To the right is shown magnified views.

6 Compliance

The results presented in section 5, Table 4 are below the limit for partial-body SAR and whole-body average SAR.

7 OET 65C

OET65C Appendix3 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 4GB RAM 490 precision DELL workstation with two 2.66 GHz Intel Woodcrest processors was used during the simulations. Operating system was Windows XP.

During computation 907920 mesh cells was used which gave a solver memory requirement of 341MB.

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.

Device can, header plastics, wires and blocks in the header are important to get 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.

23492 number of time steps were calculated.

7.9 Computing peak SAR from field components

See section 4.5.

7.10 One gram averaged SAR procedures

See section 4.5.

7.11 Total computational uncertainty

Since the mesh has been shown to be saturated and the truncation criteria is set to give errors on the order of 10E-5 the computational uncertainty is low. It is estimated that the total uncertainty is below 10%.

7.12 Test results for determining SAR compliance

See section 5.

8 References

1. www.cst.de

2. S. Gutschling, H. Krüger, T. Weiland: Modelling 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

3. 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

4. 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.

5. FCC OET Bulletin 65, supplement C.

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

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	50019819	**2**	1(7)

Dokumentnamn / Title Specific Absorption Rate (SAR) Analysis for device Promote RF – Model 3207			
Avdelning / Dept. Ut	Utfärdare / Originator Tomas Snitting		Ersätter / Supersedes 1
Avser / Concerns Unity		Säkerhetsklass / Classification **internal**	Bilagor / Attachments N/A
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Utgåva / Revision	Revisionshistoria / Revisions History
001	First Revision
002	Updated error regarding model number in section 1.

1 Introduction

St. Jude Medical has developed 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 an, to the body, external transceiver. Wireless communication will provide communication at much higher speed and longer distance as compared to the present inductive communication. The IMD is using a loop antenna mounted on the header. This report covers the *PromoteRF - Model 3207*. According to 47 CFR Part 95, section 95.603(f) a simulation shall be performed to calculate SAR values. This in order 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 of device *Promote RF - Model 3207* as required in 47 CFR Part 95, section 95.603(f).

3 Summary

The maximum SAR levels were computed to be:

Whole body average SAR	1,24E-6 W/kg
Maximum 1g SAR	0,12 W/kg

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

4 Method

The Micro Wave Studio (MWS) version 2006BRC1 simulation program was used during the simulations. It is developed by CST GMBH [1]. MWS is using a method called Finite Integration Theory (FIT). As described in [2] FIT is identical to the pure FDTD method as defined by Yee [3]. MWS has in order to increase 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 implanted device 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 152 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 (PEC) was used. The reason for using PEC was to safeguard that all emitted energy was kept within the computational volume. The validity of the chosen parallelepiped is verified in Figure 3, 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 PEC. This is a worst case scenario since a PEC conductor is lossless and hence does not reduce SAR as would a real metal conductor. The dielectrical materials implemented in the simulator are viewed in Table 1. The muscle electrical properties were retrieved from [4]. The electric properties were taken as mean value of transversal and parallel muscle fibers at 403 MHz. The density was chosen according to [5].The materials used in the SAR calculations are all included as non-dispersive.

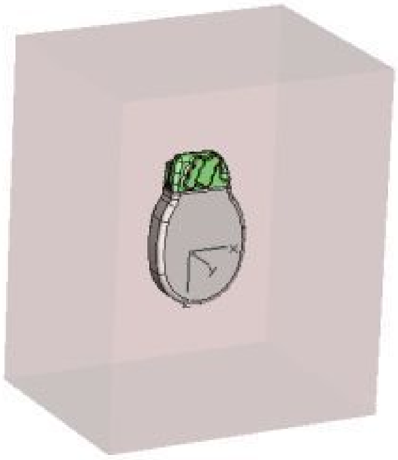

Figure 1 Device placed inside a parallelepiped of muscle. Displayed is also XYZ coordinate system

Material	Relative dielectric constant, εr	Electrical conductivity [S/m]	Density [kg/m^3]
Epoxy	3.5	0.033	N/A
Silicone	3.4	0	N/A
Muscle	57.9	0.82	1000

Table 1Properties of the dielectrical materials used in the simulations.

4.2 Mesh density

MWS has a powerful mesh engine that creates mesh as a function of the object that is simulated. However a lower limit can be set on the largest allowed mesh cell in the calculation. The size of the largest allowed Mesh cell was set to 3.3mm or a 20th wavelength in the muscle at the highest simulation frequency 600MHz. However it should be noted that the actual resolution of the IMD is much finer. The way the resolution of objects is performed is by defining the mesh line ratio limit which is the ratio between the largest and smallest distance between mesh lines. The mesh line ratio limit was chosen to 50. In order to prove that the simulation was performed in a stable region where additional mesh would not alter SAR, simulations also with different mesh settings was performed, see Table 2. It can here be found that SAR values are stable to within 0.01 W/kg. Impedance is stable as a function of mesh density. These findings indicate that the chosen mesh density is acceptable. A view of the mesh can be seen in figure 2.

lines/ wavelength	Mesh line ratio limit	SAR [W/kg]	Position x;y;z[inch]	Resistance [Ω] at 403MHZ	Reactance [Ω] at 403MHz	Meshcells
20	20	0,12	-0,67;0,29;-1,71	36	-25	305809
20	50	0,12	-0,71;0,24;-1,70	34	-24	1226841
30	50	0,12	-0,71;0,24;-1,70	34	-24	1964384
20	60	0,12	-0,71;0,31;-1,70	34	-24	1577000

Table 2 Result comparison when altering mesh densities. The power that was accepted by the antenna was set to 0.22 mW.

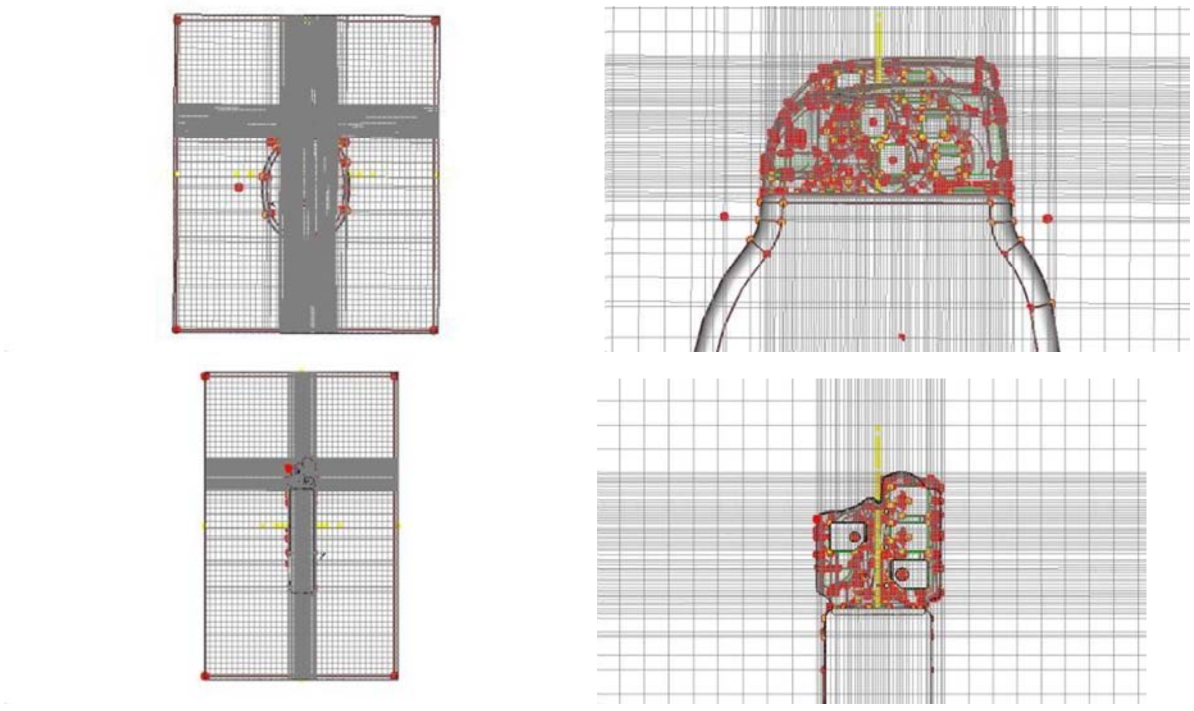

Figure 2 Views of the mesh used during the simulation. To the left up and down is the full simulation volume. To the right up and down are magnified views showing mesh around the header.

4.3 Simulated object

The IMD that was simulated is displayed in Figure 1. An imported CAD model was used and hence the model used during simulations is representative. The loop antenna, device can, casted header, all wires in the header as well as the set screw blocks is 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.

4.4 Input power and source excitation

The antenna impedance during the simulations performed as described in 4.1 was 34-j24 Ω at 403,35 MHz. Using a slide screw tuner [6] this load was presented to 3 representative devices. The maximum measured output power with a CW (Continuous Wave) signal was 0,28mW. The total spread in all 3 devices was 0,02mW.

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%. This is also a worst case duty cycle. 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%. Table 3 presents the output power used in the SAR calculations. Both Phase1 and Phase2 output powers were used during the SAR calculations.

Max measured power [mW]	Phase 1 power [mW]	Phase 2 power [mW]
0,28	0,22	0,14

Table 3 Powers used during SAR calculations.

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.

4.5 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 partial-body SAR using a method that is compliant with IEEE Std C95.3-2002. The whole body SAR was calculated as the power accepted by the antenna divided by the total mass of the modeled volume.

5 Results

Figure 3 show the SAR distribution around the device when antenna is fed with 0.22mW. The largest energy deposition is close to the antenna feeding port and as expected the deposition is decreasing when moving away from the antenna feed. Table 4 views 1g SAR and average SAR for the powers stated in Table 4 during the two different user scenarios.

Use case	Total SAR[w/kg]	1g SAR[w/kg]
Phase 1	1,24E-06	0,12
Phase 2	7,77E-07	0,08

Table 4 SAR values. The different phases correspond to average output powers as described in section 4.4.

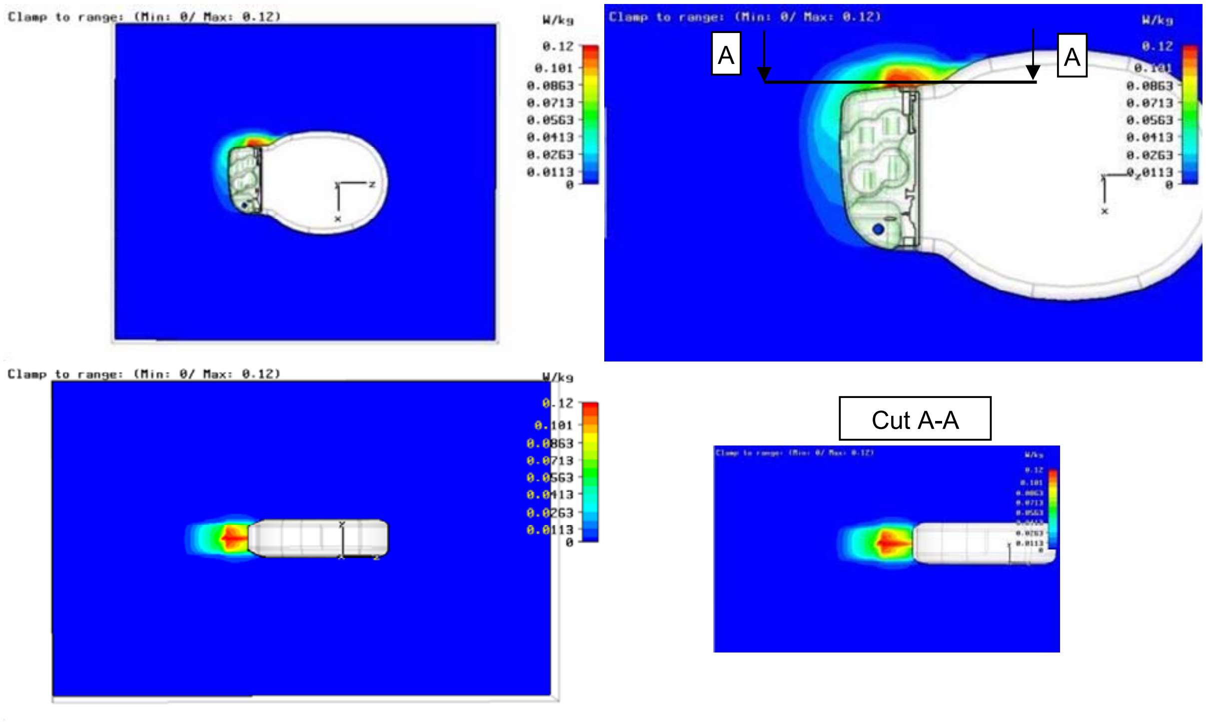

Figure 3 1g SAR distributions at or in close proximity to the place where the maximum SAR is found. To the left is shown the full simulation volume. To the right is shown magnified views.

6 Compliance

The results presented in section 5, Table 4 are below the limit for partial-body SAR and whole-body average SAR.

7 OET 65C

OET65C Appendix3 [5] 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 4GB RAM 490 precision DELL workstation with two 2.66 GHz Intel Woodcrest processors was used during the simulations. Operating system was Windows XP.

During computation 1226841 mesh cells was used which gave a solver memory requirement of 420MB.

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.

Device can, header plastics, wires and blocks in the header are important to get 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.

22512 number of time steps were calculated.

7.9 Computing peak SAR from field components

See section 4.5.

7.10 One gram averaged SAR procedures

See section 4.5.

7.11 Total computational uncertainty

Since the mesh has been shown to be saturated and the truncation criteria is set to give errors on the order of 10E-5 the computational uncertainty is low. 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. www.cst.de

2. S. Gutschling, H. Krüger, T. Weiland: Modelling 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

3. 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

4. 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.

5. FCC OET Bulletin 65, supplement C.

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