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Dokumentnamn / Title		
Specific Absorption Rate (SAR) Analysis for SJM RF Bradycardia implants		
Avdelning / Dept.: UDET	Utfärdare / Originator: Andreas Kronhamn	Ersätter / Supersedes: N/A
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Utgåva / Revision	Revisionshistoria / Revisions History
A	First revision
B	Editorial changes

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 a, to the body, external transceiver.

This report covers all existing Bradycardia RF implants with the three header variants, presented here by *Accent SR RF, Accent DR RF and Anthem RF*.

This SAR computation modelling 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 2.1093. 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 three Bradycardia RF 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]
Accent SR RF	0.012	1.6	0.000047	0.08
Accent DR RF	0.012	1.6	0.000048	0.08
Anthem RF	0.013	1.6	0.000043	0.08

Table 1 Computed SAR value of Accent SR RF, Accent DR RF and Anthem RF.

4 Method

The CST Micro Wave Studio (MWS) version 2009.03 – Jan 19 2009 - 22 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 (UVW) 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 safeguard that all emitted energy was kept within the computational volume. The validity of the chosen parallelepiped is verified in figure 2 to figure 16, 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 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.

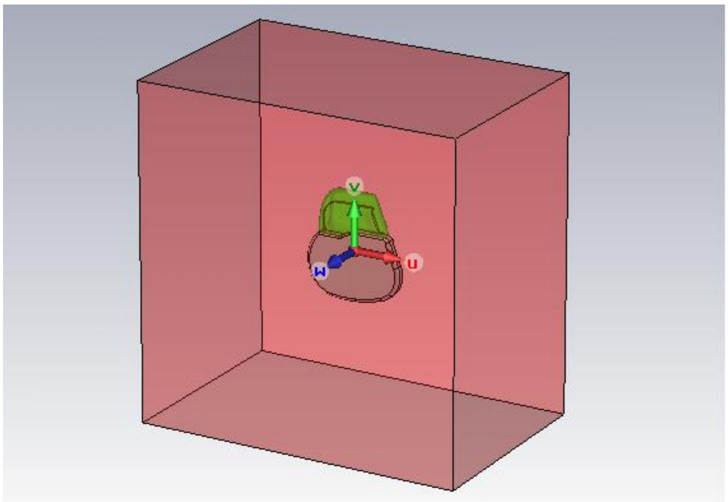

Figure 1 Device placed inside a parallelepiped of muscle. Displayed is also UVW coordinate system

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

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

4.2 Simulated object

For all three 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 three header variants. The maximum measured output power when the RF-hybrids saw different antenna impedances was 0,63mW. The maximum output power was measured with a CW (Continuous Wave) signal. 0,63mW was subsequently used as input to the SAR calculation.

The simulated impedances, as described in 4.1, for the three header variants were a subset of the antenna impedances described above and therefore is the maximum output power considered representative for the three 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, 0.51 mW (Phase 1).

Max measured power [mW]	Phase 1 power [mW]	Phase 2 power [mW]
0.63	0.8 x 0.63 = 0.51	0.5 x 0.63=0.32

Table 3 The power used during SAR calculations was 0.51mW (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 ot the header variant see table 4,5 and 6

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 – Accent SR RF

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Max 1g Avg SAR Position u;v;w[inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0.000047	0.012	0.61;0.58;0.16	0.0012	0.13	2 854 370

Table 4 Simulation results from Accent SR RF. The power that was accepted by the antenna was set to 0.51 mW.

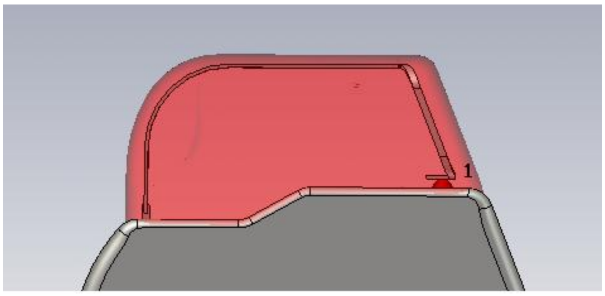

Figure 2 The header of Accent SR RF. The red triangle represents the feeder to the loop antenna.

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

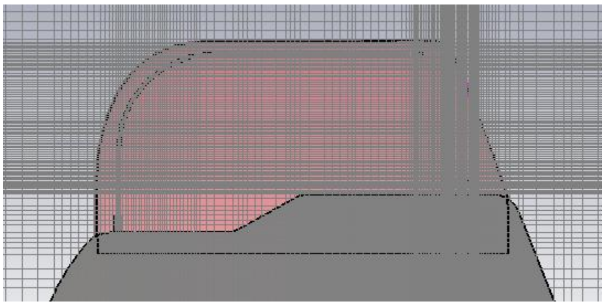

Figure 3 Mesh around the header when Accent SR RF was simulated.

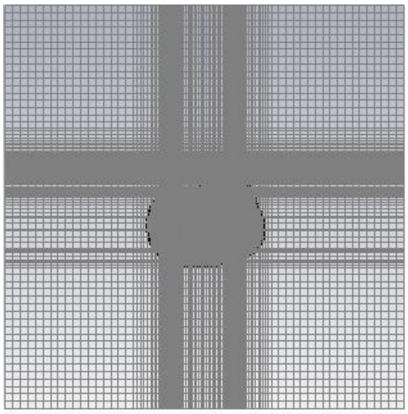

Figure 4 Mesh in the full simulation volume when Accent SR RF was simulated. The total number of meshcells were 2 854 370.

4.5.2 Header variant – Accent DR RF

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Max 1g Avg SAR Position u;v;w[inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0.000048	0.012	0.59;0.57;0.16	0.0012	0.13	3 246 045

Table 5 Simulation results from Accent DR RF. The power that was accepted by the antenna was set to 0.51 mW**.**

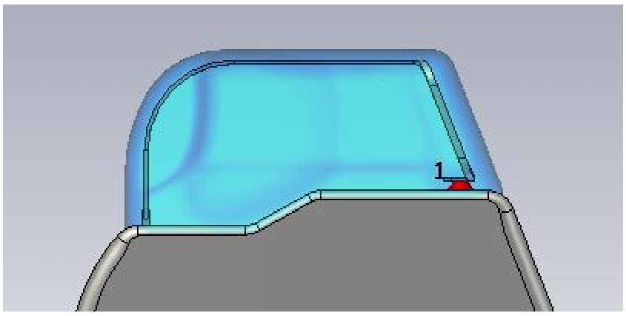

Figure 5 The header of Accent DR RF. The red triangle represents the feeder to the loop antenna.

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

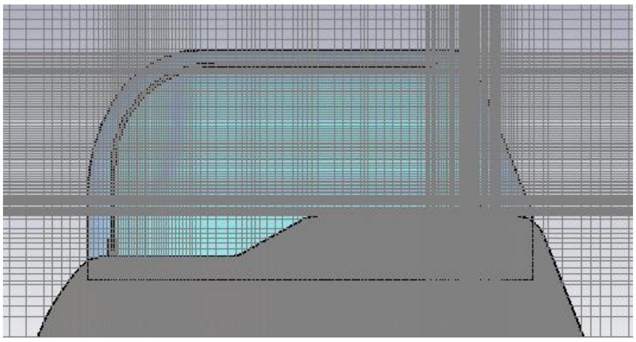

Figure 6 Mesh around the header when Accent DR RF was simulated.

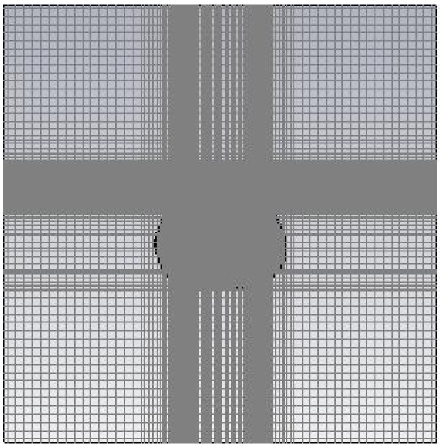

Figure 7 Mesh in the full simulation volume when Accent DR RF was simulated. The total number of meshcells were 3 246 045.

4.5.3 Header variant – Anthem RF

Whole body Avg SAR [W/kg]	Partial body SAR Max 1g [W/kg]	Max 1g Avg SAR Position u;v;w[inch]	Min mesh step [inch]	Max mesh step [inch]	Meshcells
0.000043	0.013	0.67;0.56;0.11	0.0025	0.13	3 813 642

Table 6 Simulation result from Anthem RF. The power that was accepted by the antenna was set to 0.51 mW.

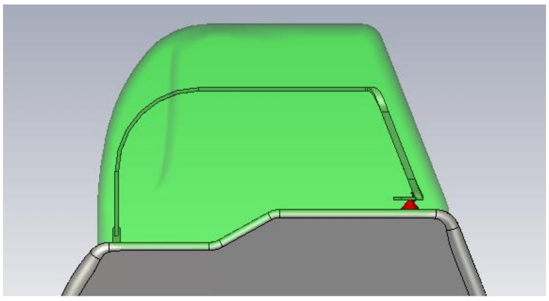

Figure 8 The header of Anthem RF. The red triangle represents the feeder to the loop antenna.

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

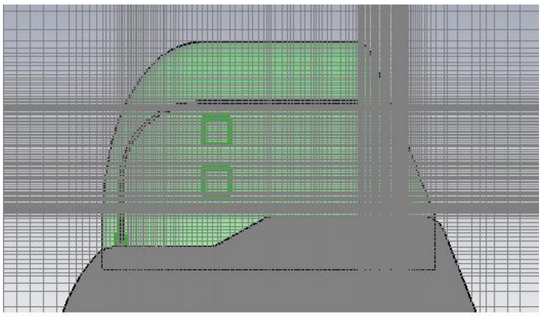

Figure 9 Mesh around the header when Anthem RF was simulated.

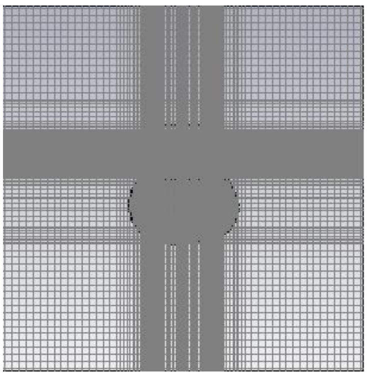

Figure 10 Mesh in the full simulation volume when Anthem RF was simulated. The total number of meshcells were 3 813 642.

5 Results

Figure 11 – 16 show the SAR distribution around the devices when the antenna is fed with 0.51mW. 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.

RF implant header variants	Partial body SAR Max 1g [W/kg]	The ANSI safety limit of partial body SAR [W/kg]	Whole body average SAR [W/kg]	The ANSI safety limit of whole body SAR [W/kg]
Accent SR RF	0.012	1.6	0.000047	0.08
Accent DR RF	0.012	1.6	0.000048	0.08
Anthem RF	0.013	1.6	0.000043	0.08

Table 7 Computed SAR value of Accent SR RF, Accent DR RF and Anthem RF.

5.1 Header variant – Accent SR RF

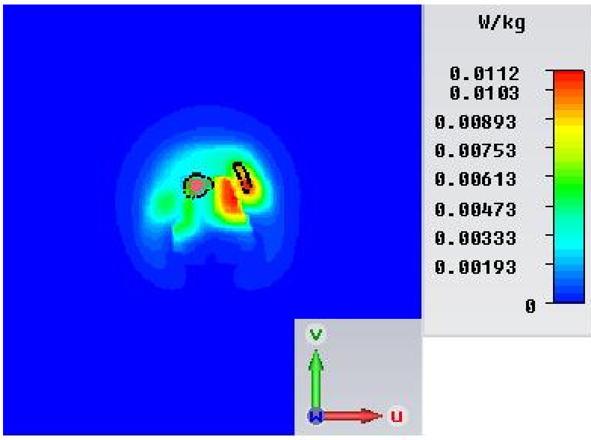

Figure 11 UV cross section of max 1g average SAR distributions, from Accent SR RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW. UV cross section of max 1g average SAR distribution is in front of the Accent SR RF.

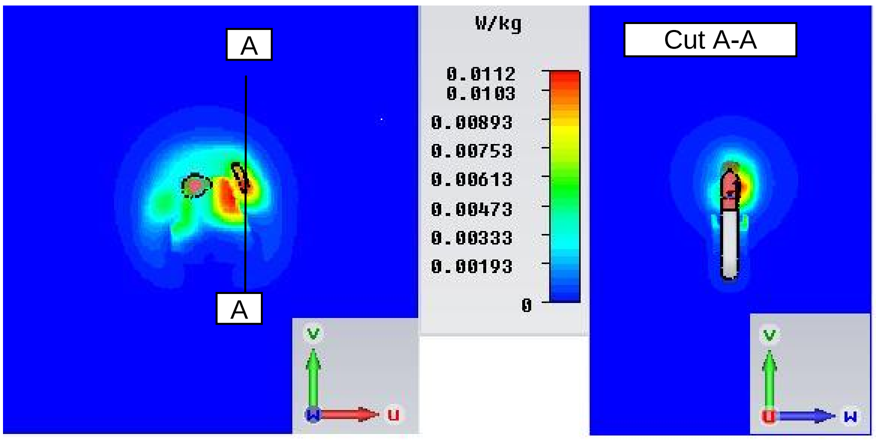

Figure 12 VW cross section of max 1g average SAR distributions, from Accent SR RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW

5.2 Header variant – Accent DR RF

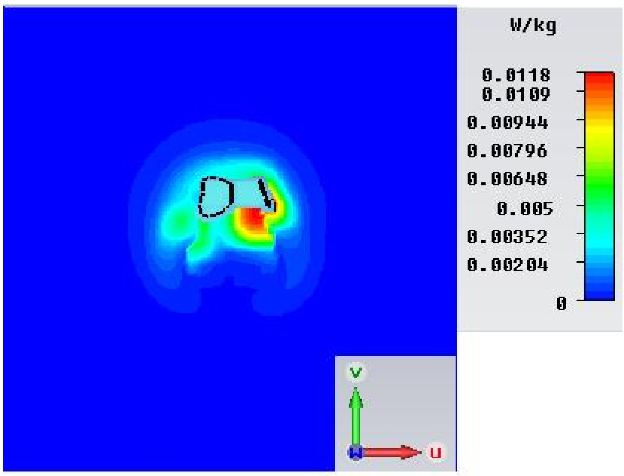

Figure 13 UV cross section of max 1g average SAR distributions, from Accent DR RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW. UV cross section of max 1g average SAR distribution is in front of the Accent SR RF.

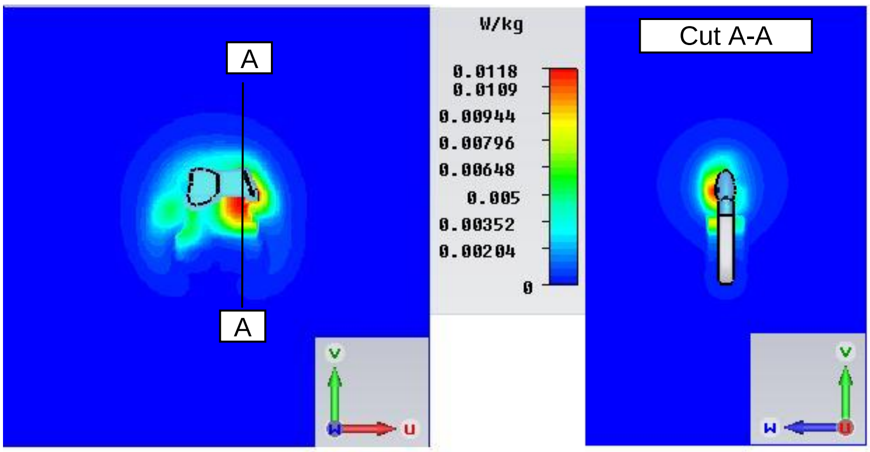

Figure 14 VW cross section of max 1g average SAR distributions, from Accent DR RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW.

5.3 Header variant – Anthem RF

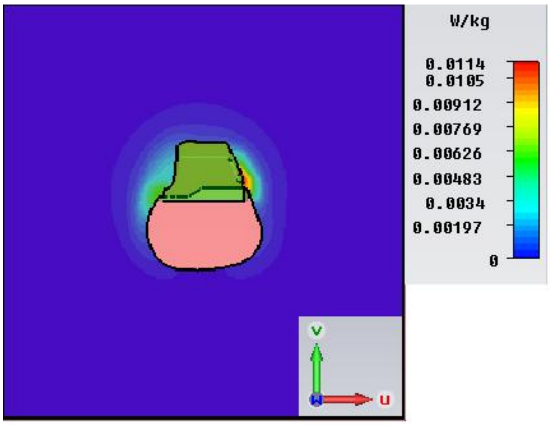

Figure 15 UV cross section of max 1g average SAR distributions, from Anthem RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW.

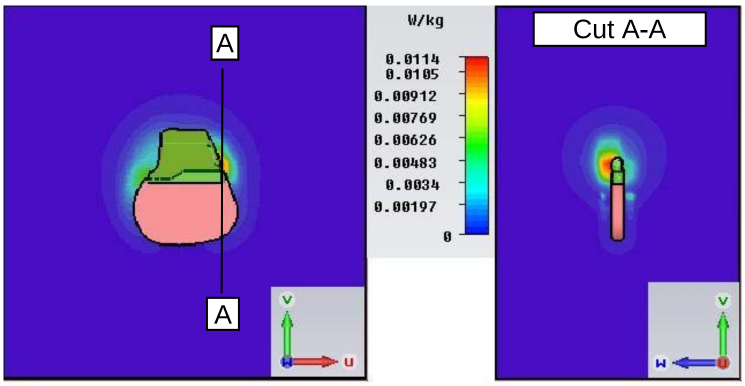

Figure 16 VW cross section of max 1g average SAR distributions, from Anthem RF, at or in close proximity to the place where the maximum SAR is found when antenna is fed with 0.51mW.

6 Compliance

The results presented in section 5 table 7 are well below the limit for partial-body SAR and whole-body average SAR.

7 OET 65C

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

RF implants header variants	Mesh cells	Solver memory [MB]
Accent SR RF	2 854 370	1070
Accent DR RF	3 246 045	1220
Anthem RF	3 813 642	1430

Table 8 Solver memory requirement of Accent SR RF, Accent DR RF and Anthem RF.

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 C95.1-1999 the human exposure standard

6. IEEE C95.3 -1999 the measurement practices standard

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