Type of document / Tipo di documento / Type de document **Technical Note**			
Project ***SyndeliRF V2***	*Department:* ***ASIC***	*Original stored in:* ***Meylan***	*Department Internal Ref:*

Title: **SAR SIMULATION REPORT**	*Filed in Intraprod on :* *By:*

Abstract:
This document deals with the SAR simulations results performed on the 4 different headers of SyndeliRF V2 ICDs (CRTD SonR / CRTD / DR / VR).

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HISTORY / STORIA / HISTORIQUE

Rev.	Change	Reason for Change	Release date
A	/	Document creation	Dec. 20th, 2012

TABLE OF CONTENT / INDICE / TABLE DES MATIERES

1. INTRODUCTION

SORIN CRM company has developed a wireless communication system using the MICS frequency band. That wireless system will speed up the implantation phase, the appointments at hospital and will allow the patient at home to be monitored remotely. The system has two products:

- an ICD with DF4 connector.
- an external product (either a Home Monitor or a programmer).

Because of the RF function, the ICD has to comply with different RF standards and in particular with SAR.

2. ABREVIATIONS

SAR : **S**pecific **A**bsorption **R**ate.
ICD : **I**mplantable **C**ardioverter **D**efibrillator.
EMR : **E**lectro**M**agnetic **R**adiation.
MICS : **M**edical **I**mplant **C**ommunication **S**ervice.
IEEE : **I**nstitute of **E**lectrical and **E**lectronics **E**ngineers.
ICNIRP : **I**nternational **C**ommittee for **N**on-**I**onising **R**adiation **P**rotection.
ANSI : **A**merican **N**ational **S**tandards **I**nstitute.
FDTD : **F**inite **D**ifference **T**ime **D**omain.
FIT : **F**inite **I**ntegration **T**echnique.
CST : **C**omputer **S**imulation **T**echnology.
CST MWS : CST **M**icro**W**ave **S**tudio.
PEC : **P**erfect **E**lectrical **C**onductor.
CW : **C**ontinuous **W**ave.
GPU : **G**raphics **P**rocessing **U**nit.

3. SAR DEFINITION

SAR is the time derivative of the incremental energy (*dW*) absorbed by (dissipated in) an incremental mass (*dm*) contained in a volume element (*dV*) of a given density (ρ), as illustrated in :

$$SAR = \frac{d}{dt}\left(\frac{dW}{dm}\right) = \frac{d}{dt}\left(\frac{dW}{\rho\, dV}\right)$$

also illustrated as (for a typically averaged over a pre-defined mass) :

$$SAR = \frac{P}{\rho} = \frac{\sigma E^2}{2\rho} = \frac{J^2}{\rho\sigma}$$

SAR is expressed in units of watts per kilogram (W/kg).

with :
P = Power loss density.
E = Electrical Field module.
J = Current density.
σ *= Electrical conductivity of the medium.*
ρ *= Density of the medium.*

4. REFERENCE STANDARDS

• The **ICNIRP** sets guidelines for limiting exposure to EMR. These guidelines are generally accepted around the world ; however, some countries such as the USA and Canada have more conservative SAR limits. There is also a distinction between “occupational workers” and “non-occupational workers”.

• The **IEEE 1528** regulates measurement methods for practical assessment of compliance. Moreover, a simulation standard IEEE 1528.X is in development with the following subjects to be addressed :

→ 1528.1 : requirements for hexahedral time domain codes (end 2007).
→ 1528.2 : application to cars with passenger/bystander (~ 2008).
→ 1528.3 : application to mobile phones near head (~ 2008).
→ 1528.4 : requirements for tetrahedral frequency domain codes.

• The **ENV50166** (for Europe) gives the SAR limits.

• The **IEEE ANSI C95.1 and C95.3** (for the USA) gives the SAR limits. There is a distinction between “controlled environment” and “uncontrolled environment”.

5. SAR LIMITS

5.1. GENERAL : ICNIRP LEVELS

SAR Limits	Occupational Workers	Non-occupational workers
Whole Body	0.4 W/kg	0.08 W/kg
Localised Exposure: *Head and Trunk	10 W/kg	2 W/kg
*Hands and Feet	20 W/kg	4 W/kg

*SAR measured in a 10g cube of tissue

Table 1 : SAR levels for ICNIRP

5.2. EUROPE REGION

For Europe, the ICD should comply to the ENV50166 maximum SAR levels (for **10g** cube tissue) :

- **for Whole body : Max_SAR = 0.08W/kg**
- **for Spatial peak : Max_SAR = 2W/kg**

5.3. USA REGION

For the USA, the ICD should comply to the IEEE ANSI C95.1 maximum SAR levels (for **1g** cube tissue) :

- **for Whole body : Max_SAR = 0.08W/kg**
- **for Spatial peak : Max_SAR = 1.6W/kg**

6. METHODS FOR SAR CALCULATION

Some simulation methods are compliant for SAR compliancy verifications. In particular, the IEEE 1528.1 specifies the following :

> This standard is based in part on the extensive validation of FDTD as applied to SAR calculation that has been reported in the literature and in previous standards. In order for this basis to be valid, the meaning of FDTD in this standard must describe the FDTD implementation historically used in this extensive validation. Therefore, for application of this standard, the implementation of FDTD in the spatial region where the SAR is being calculated shall include the following characteristics:
>
> a) The electric field components are spatially located on the edges of a Cartesian coordinate system structured mesh composed of rectangular parallelepipeds.
>
> b) The magnetic field components are spatially located on the edges of a Cartesian coordinate system structured mesh composed of rectangular parallelepipeds which is offset from the electric field mesh by ½ mesh cell in each direction.
>
> c) The solution method is a finite-difference approximation to the Maxwell curl equations using central differences which are (at least globally) second order accurate and would therefore include non-uniform meshes (Monk and Suli [B104]).
>
> d) The solution method solves for both electric and magnetic fields by a fully explicit leapfrog time-stepping process.
>
> e) Gauss's laws are implicitly enforced, the fields are divergence-free, and charge is conserved.
>
> f) The time-stepping algorithm is non-dissipative in that there is no spurious decay of energy due to non-physical artifacts of the algorithm and artificial dissipation is not required for stability.
>
> Other methods and/or extensions of FDTD not included in the above definition may be applied. However, these shall provide at least the same accuracy as if the FDTD method defined above were applied. The Finite Integration Technique (FIT) in time domain can be regarded as an extension of FDTD in this context.

⇒ The FIT in time domain is IEEE 1528 compliant.

In SORIN CRM, we use the **CST MWS** software tool for simulation (***CST 2012 SP6***, 29 Sept. 2012); we use in particular the FIT in time domain for SAR calculation.

7. CST MWS SAR CALCULATION METHOD

CST company participates in standards committee for IEEE 1528 and has already been approved by the FCC to comply with hexahedral time domain standard drafts.

For SAR calculation, CST MWS uses the following method :

- A discretization is done for calculating the mass averaged SAR (typically 1g or 10g); it uses :
  - for each point, a cube with a defined mass is found.
  - the power loss density is integrated over that cube.
  - the integral power loss is divided by the cube's mass.

- Then, to calculate the ***whole-body SAR***, the total power loss is divided by the lossy structure total mass. The method used is the IEEE C95.3 one.

8. COMPUTATIONAL RESOURCES

The calculation machine is a Windows 7 64 bits, 2xCPU Intel Xeon X5570 @2.93GHz, 48Go RAM using two Nvidia Tesla C1060 hardware accelerator (GPU). Simulation time is about :

- Electromagnetic part : 2 hours.
- SAR calculation post-process : 30 minutes for Europe case, 5 minutes for USA case.

9. GENERAL COMMON SIMULATION CONDITIONS

In that document, 4 different ICD have been simulated. Each ICD has its own CAD description but here are defined the general common elements used for simulation. It has to be noted that all CAD models of ICDs have been imported to CST MWS in order to fit, the best as possible, to the exact representation of the RF antenna function.

9.1. LEAD CONFIGURATION

We had the choice for using either "nothing" or "leads" or "lead-caps".

- The case "nothing" is not relevant since it will never be the case in a real implantation.
- The case "leads" could be interesting but suffers from the following elements :
  - leads locations are different from one implantation to another.

  - leads 3D modelisation is complexfull and requires many more computational resources due to a bigger simulation volume as well as a finer mesh.
- The case “lead-caps” seems the more adequate :
  - They are used sometimes for real implantation.
  - They are easy to model and to simulate.

⇒ Therefore, we have completed all SAR simulations with lead-caps.

9.2. TISSUE PROPERTIES

The ICD is put inside MUSCLE tissue (at the corresponding frequency). The muscle choice is judged to be a worst case scenario since an alternate placement in fat would lead to lower SAR values due to the much lower conductivity and dielectric constant of fat.

Therefore, muscle tissue properties were taken from SPEAG company which has delivered some MSL450 fluid.

⇒ Simulations are performed with the following characteristics of muscle at 403MHz :

Material	**Relative dielectric constant , εr**	**Electrical conductivity** *(S/m)*	**Density** *(kg / m3)*
Muscle	57.44	0.93	1000

Table 2 : Muscle properties

The muscle density has been chosen relative to the FCC OET Bulletin 65, supplement C.

9.3. SIMULATION VOLUME

The ICD is placed inside a **parallelepiped**, filled with muscle tissue. The parallelepiped size is : 200mm x 200mm x 120mm (XYZ).
The ICD is then placed near the middle of the parallelepiped.

9.4. BOUNDARY CONDITIONS

The “Electrical Field” boundary conditions have been used for simulations. It is verified, on simulation results, that all emitted energy is kept within the simulation volume and far apart from the volume walls. “Electrical field” boundary conditions have the advantage to speed-up simulations.

9.5. METAL PROPERTIES

The ICD metal parts were all modelled as PEC (infinite electrical conductivity). Indeed, this is a worst case scenario since a PEC does not lower SAR whereas a real metal does.

In CST MWS, the option “Simplify model” has been chosen with the two selected options :

- for *General* : “simulate surf. impedance as PEC”.
- for *Wires* : “simulate lossy metal as PEC”.

as illustrated below :

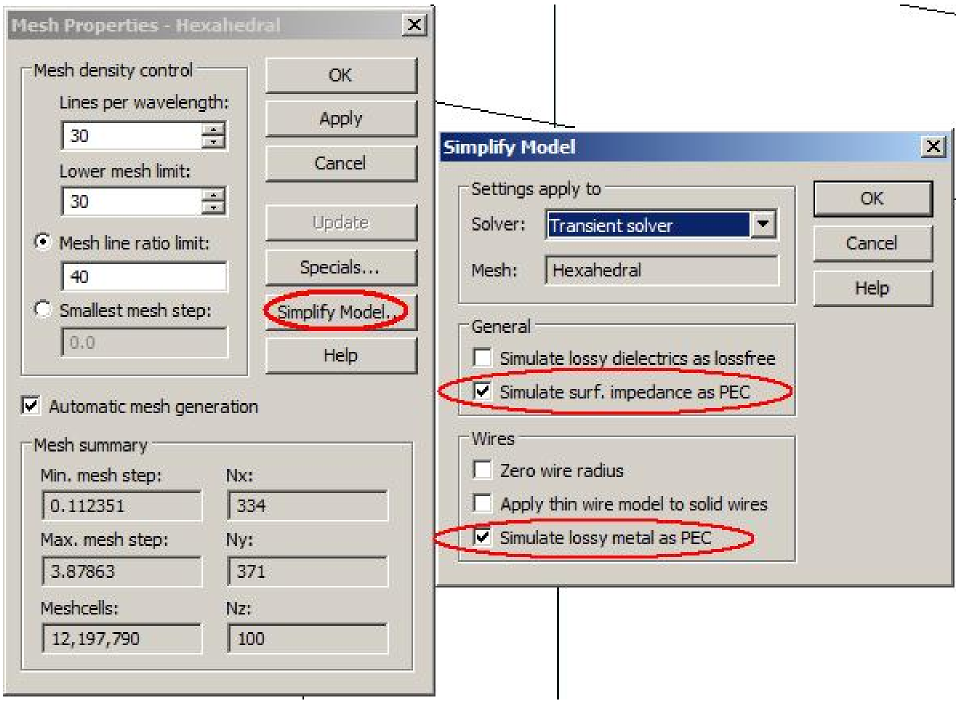


Figure 1 : PEC configuration

9.6. EXCITATION PORT

The excitation port used for simulations is a discrete port.

However, because of the hexahedral mesh method used by the FIT time domain, it is impossible (for a reasonable mesh density) to place the discrete port at the RF module location since many mesh cells are in “stair case mode” i.e. are pieces of metal, which create some local unwanted short-circuits (see below in blue color) :

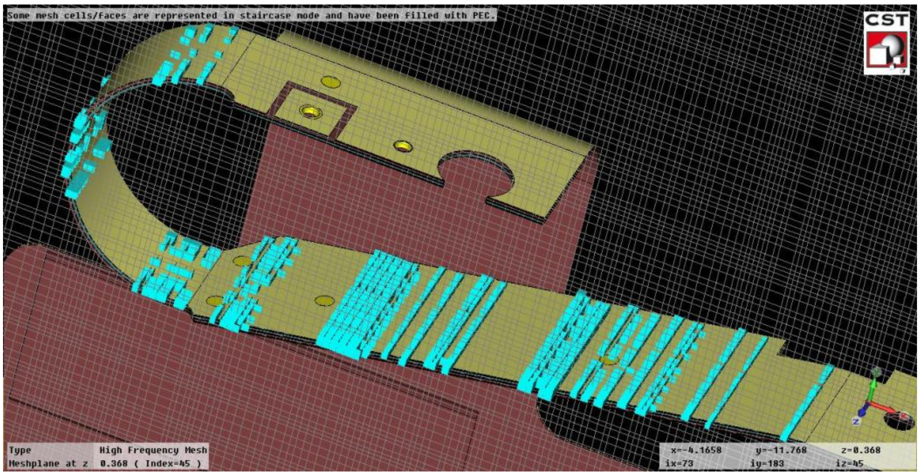


Figure 2 : Stair case cells

⇒ Therefore, the discrete port is placed at the RF feedthrough / RF flex border :

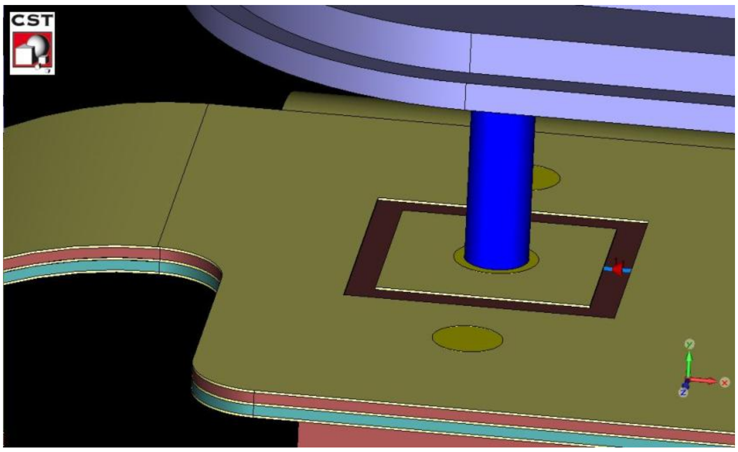


Figure 3 : Discrete excitation port

9.7. INPUT POWER

The RF module is the same for all the four defined ICD models defined. Its matching network in the MICS band has been designed and validated for the whole four models. Therefore, maximum power is transferred to the load (RF flex + RF feedthrough and antenna) when conjugate complex impedance is achieved.

- On many representative RF modules, the maximum MICS output power (with a matched load) is never greater than 0.315mW peak value (-5dBm / 50Ω).

- Also, the protocol used from data exchange mechanisms allows the ICD to transmit not full time but during a period of time.

⇒ However, to take the worst case conditions, we have run SAR simulations with the following conditions :

- **input power of 0.315mW peak value, with a discrete port placed at the RF flex / RF feedthrough border (whereas it is the maximum power at the RF module location).**
- **transmission full-time i.e. in CW mode.**

9.8. CHOICE OF FREQUENCY

The ICD has been simulated at the middle of the MICS band i.e. at **403.5MHz**.
Indeed, the MICS band has less than 1% bandwidth and so no difference in SAR results is expected between the 10 channels.

9.9. RF ANTENNA

The RF antenna is the same for the whole four models; it is a loop designed inside the header.

9.10. SAR PARAMETERS

SAR parameters are defined in two dialog boxes illustrated below :

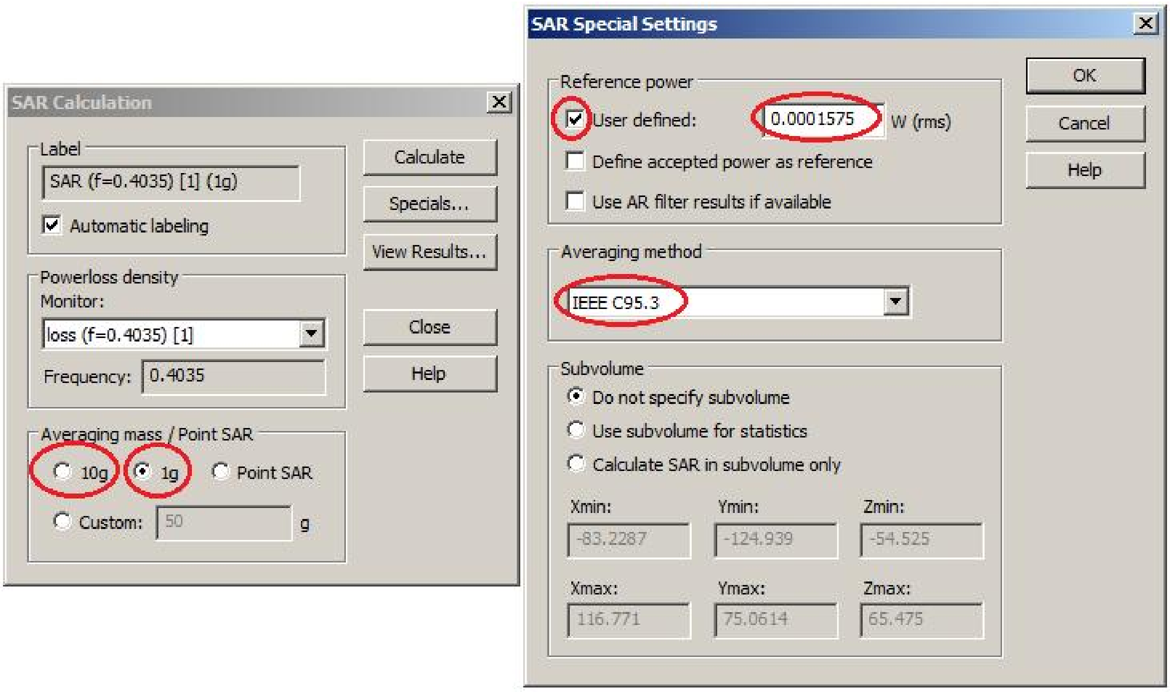


Figure 4 : SAR configuration

Once they are configured, there is a post-process calculation which gives at the end the SAR results as illustrated below :

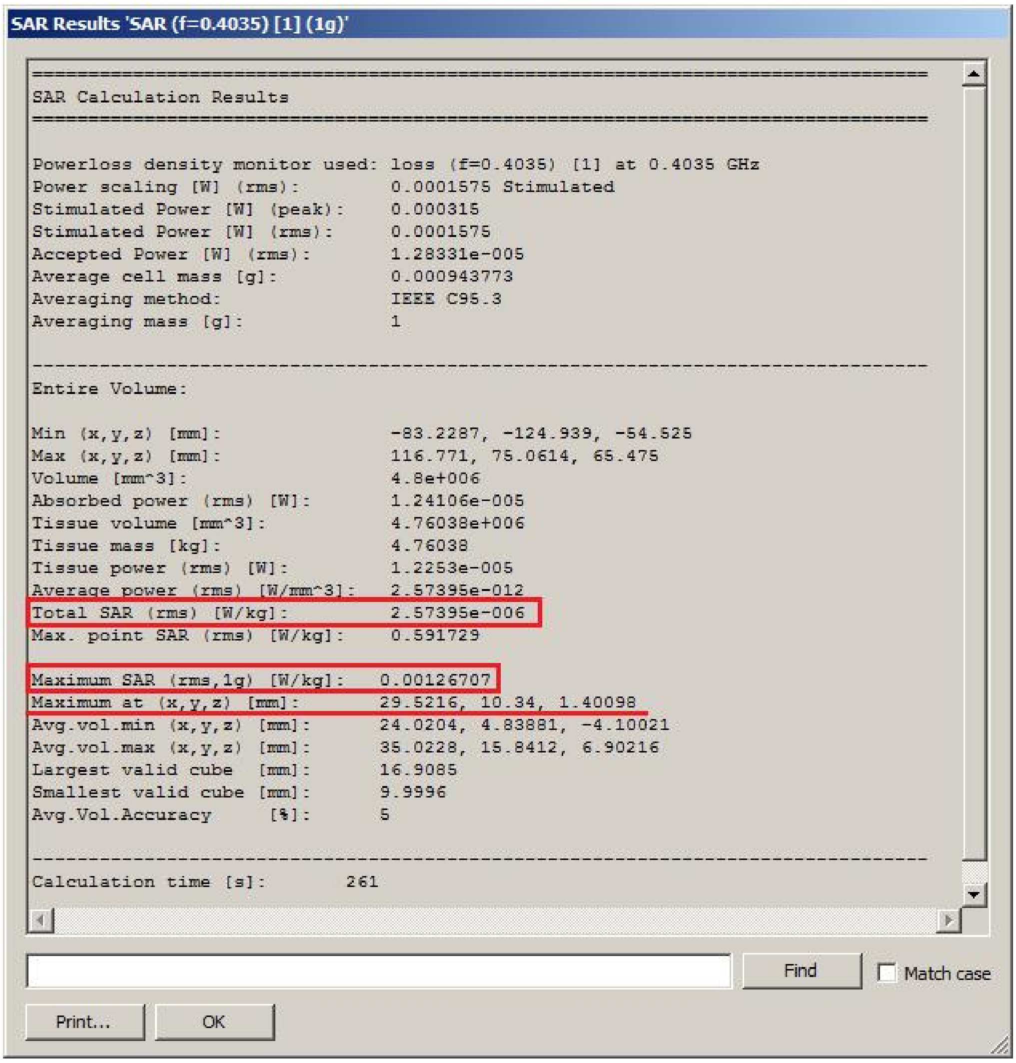


Figure 5 : SAR results

- The ***Whole Body Average SAR*** requested by standards is the parameter : "**Total SAR** ".
- The ***Spatial Peak SAR*** requested by standards is the parameter : "***Maximum SAR*** ".

9.11. MESH DENSITY

Several simulations have been performed in regards to the mesh density in order to find a minimum mesh configuration that gives stable main spot resonance and SAR results. Also, the configurations take into account the simulation time.

Thus, the following mesh configurations have been analysed (on the CRT-D SonR model) :

Line / λ	**Lower mesh limit**	**Mesh line ratio limit**	**Mesh cells**	**Main resonance** *(MHz)*	**Max 1g SAR** *(W/kg)*	**Position of Max SAR** [X; Y; Z] *(mm)*
30	**30**	**25**	**7.3M**	*385*	0.0011	[24.18 ; 10.65; 1.40]
30	**30**	**30**	**8.8M**	*387*	0.0012	[29.52 ; 10.34; 1.58]
30	**30**	**35**	**11.6M**	*388*	0.0013	[29.45 ; 10.42; 1.58]

Table 3 : Mesh configurations

Because the differences between the four models are small in terms of structures, these mesh configurations results are also valid for CRT-D, DR and VR models. As well, the behaviour of these mesh configurations is also valid for 10g cube tissue (Europe case).

We can see in *Table 3* that SAR results come stable from the values (Line / wavelength = 30; Lower Mesh Limit = 30; Mesh Line Ratio Limit = 30).

⇒ Therefore, in order to achieve fine results, the following mesh configuration has been chosen for all the SAR results in the following chapters :

- **Line /wavelength = 30.**
- **Lower Mesh Limit = 30.**
- **Mesh Line Ratio Limit = 30.**

which gives the illustrated mesh :

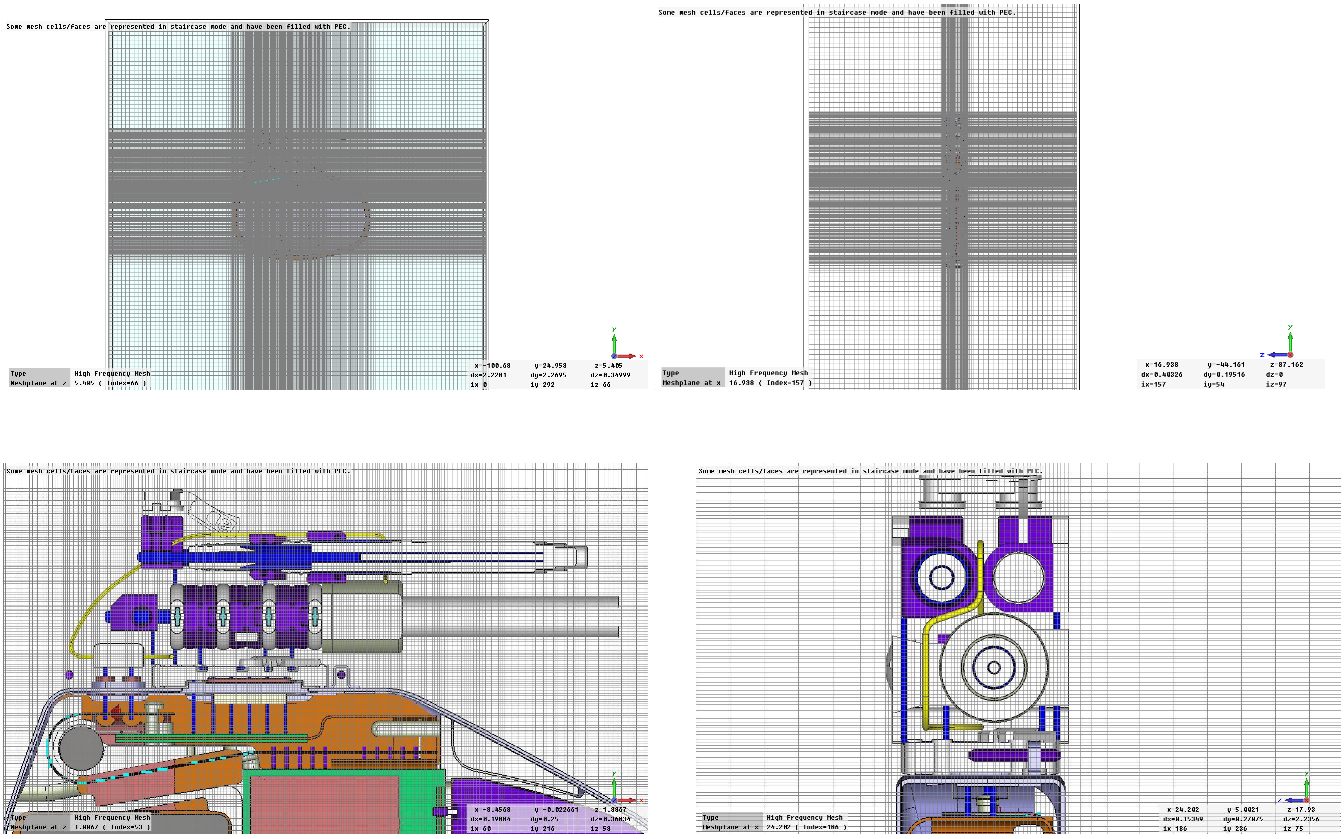


Figure 6 : Used mesh density (case CRT-D SonR model)

9.12. CONVERGENCE CRITERIA

The simulation is stopped when the energy in the whole parallelepiped is **40dB** below initial energy.

10. CRT-D SONR ICD SIMULATION

10.1. DEVICE AND SIMULATION VOLUME

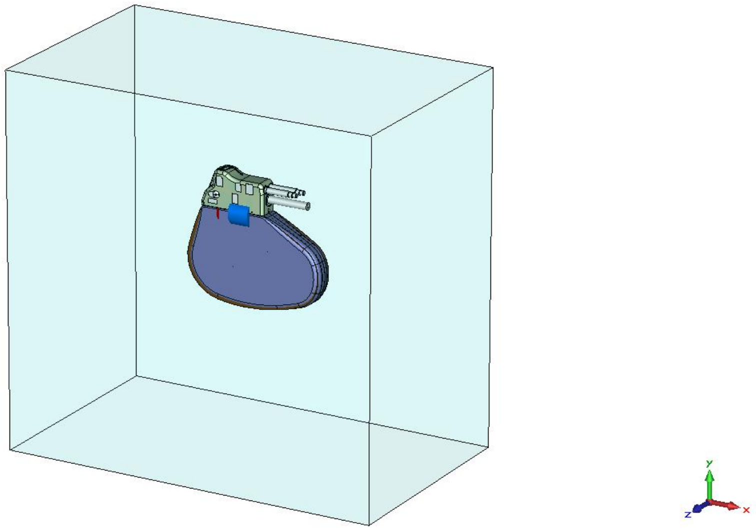


Figure 7 : CRT-D SonR model and the simulation volume

10.2. SAR SIMULATION RESULTS

10.2.1. EUROPE : 10G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.57 E-6 W/kg.
- Spatial peak SAR = 0.000402 W/kg.

with the maximum SAR level at : [24.54; 6.43; 2.07]mm.

10.2.2. USA : 1G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.57 E-6 W/kg.
- Spatial peak SAR = 0.00126 W/kg.

with the maximum SAR level at : [29.52; 10.34; 1.58]mm.

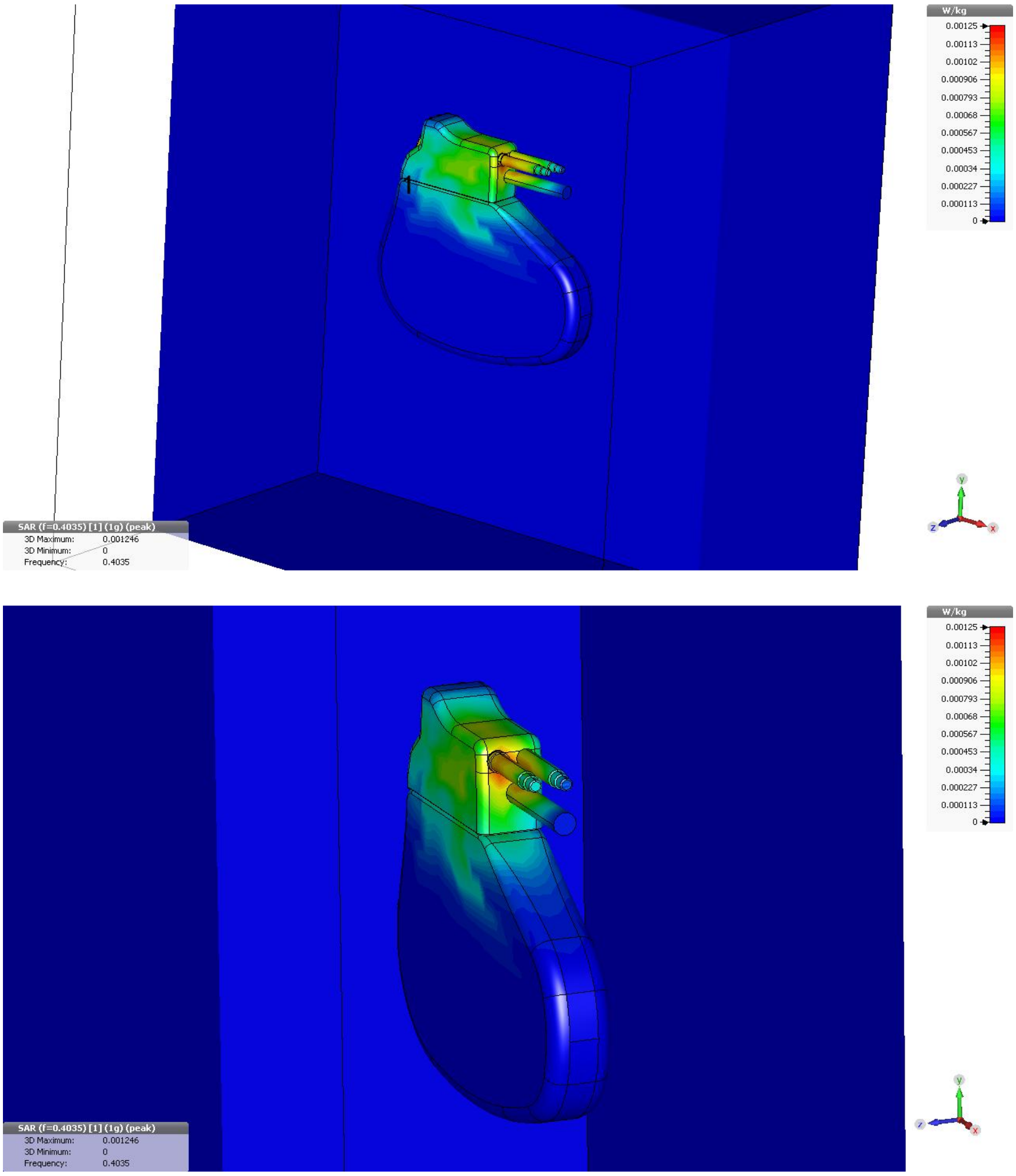


Figure 8 : SAR distribution for 1g cube tissue for CRT-D SonR model

10.3. CONCLUSIONS

SAR simulation results for CRT-D SonR model are far below the limits specified in chapter 5.

11. CRT-D ICD SIMULATION

11.1. DEVICE AND SIMULATION VOLUME

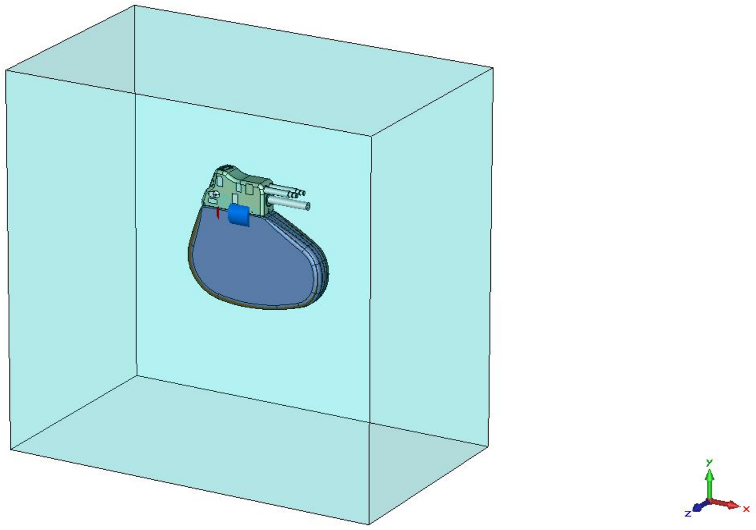


Figure 9 : CRT-D model and the simulation volume

11.2. SAR SIMULATION RESULTS

11.2.1. EUROPE : 10G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.18 E-6 W/kg.
- Spatial peak SAR = 0.00027 W/kg.

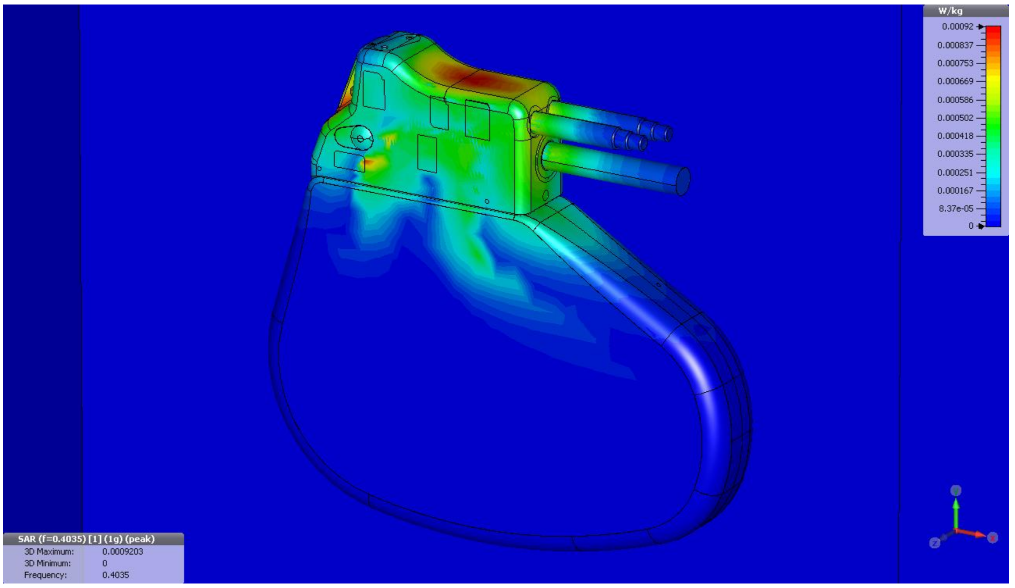
with the maximum SAR level at : [17.46; 9.91; 5.86]mm.

11.2.2. USA : 1G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.18 E-6 W/kg.
- Spatial peak SAR = 0.00093 W/kg.

with the maximum SAR level at : [13.64; 15.89; -0.635]mm.



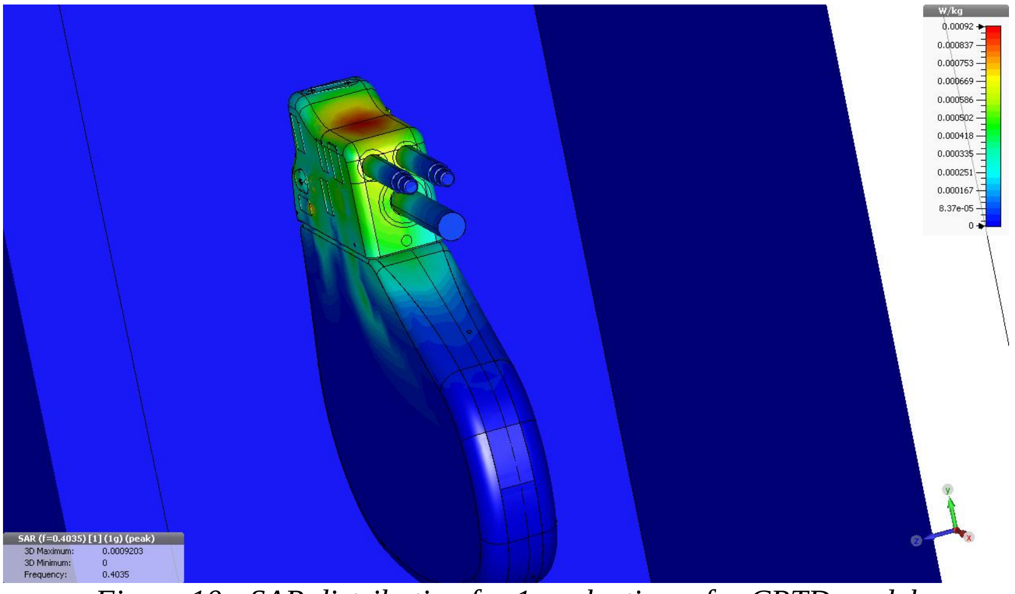


Figure 10 : SAR distribution for 1g cube tissue for CRTD model

11.3. CONCLUSIONS

SAR simulation results for CRT-D model are far below the limits specified in chapter 5.

12. DR ICD SIMULATION

12.1. DEVICE AND SIMULATION VOLUME

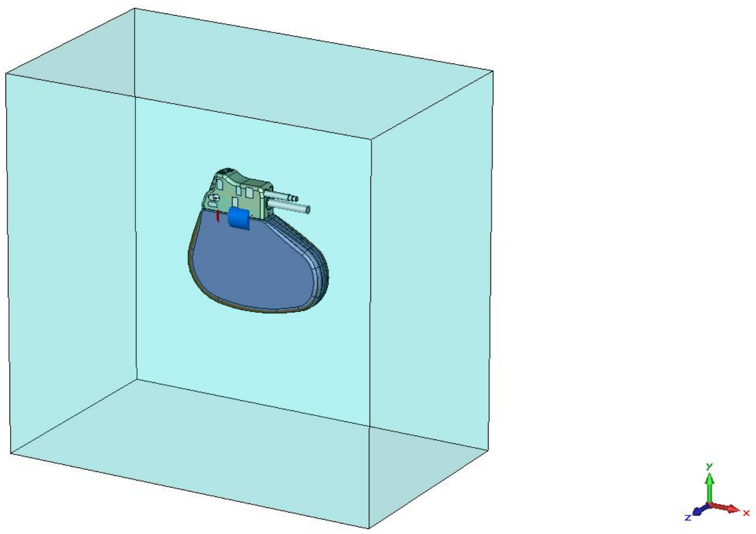


Figure 11 : DR model and the simulation volume

12.2. SAR SIMULATION RESULTS

12.2.1. EUROPE : 10G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.02 E-6 W/kg.
- Spatial peak SAR = 0.00025 W/kg.

with the maximum SAR level at : [16.23; 10.59; 5.85]mm.

12.2.2. USA : 1G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 2.02 E-6 W/kg.
- Spatial peak SAR = 0.00094 W/kg.

with the maximum SAR level at : [-8.95; 7.26; 0.025]mm.

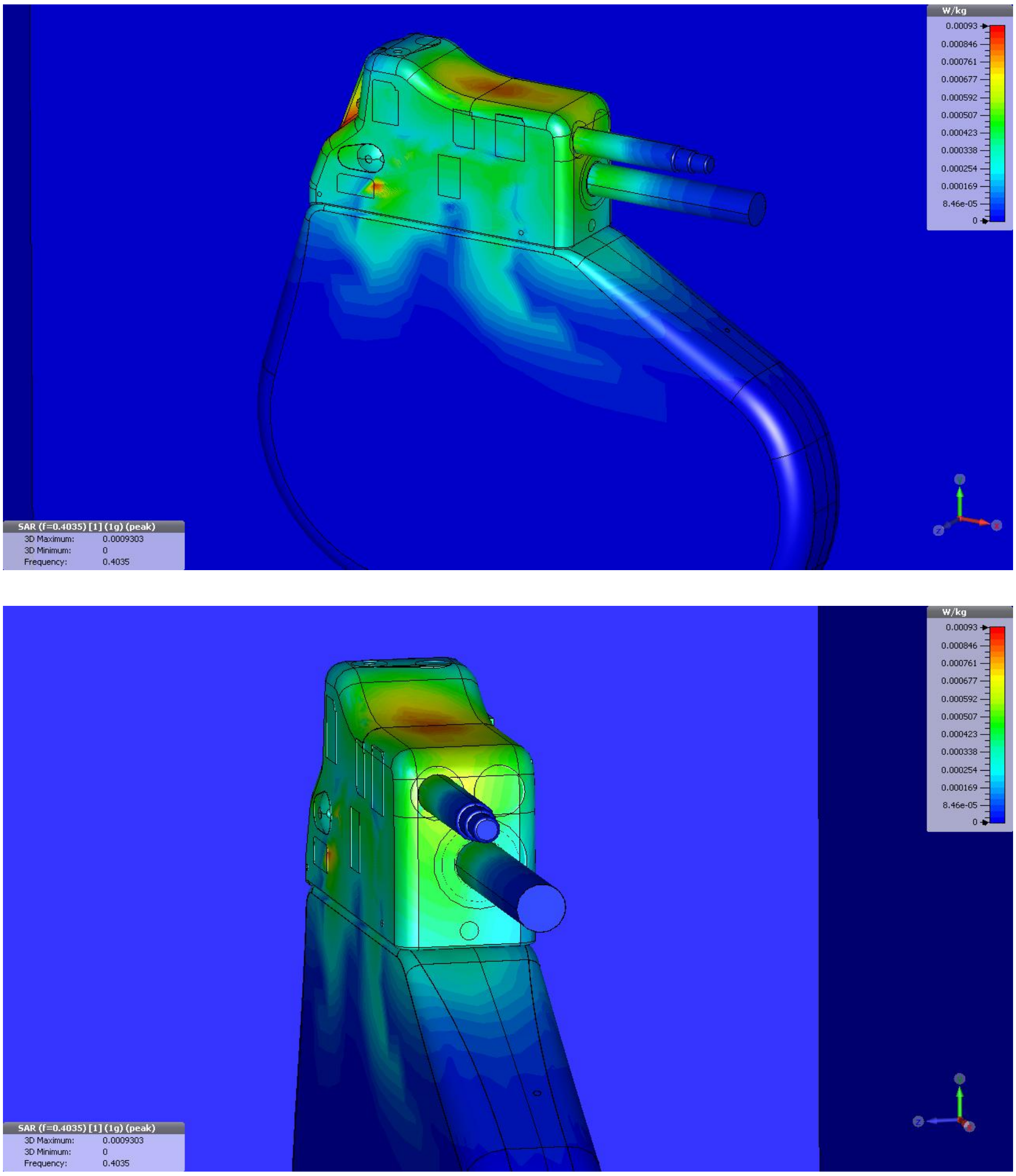


Figure 12 : SAR distribution for 1g cube tissue for DR model

12.3. CONCLUSIONS

SAR simulation results for DR model are far below the limits specified in chapter 5.

13. VR ICD SIMULATION

13.1. DEVICE AND SIMULATION VOLUME

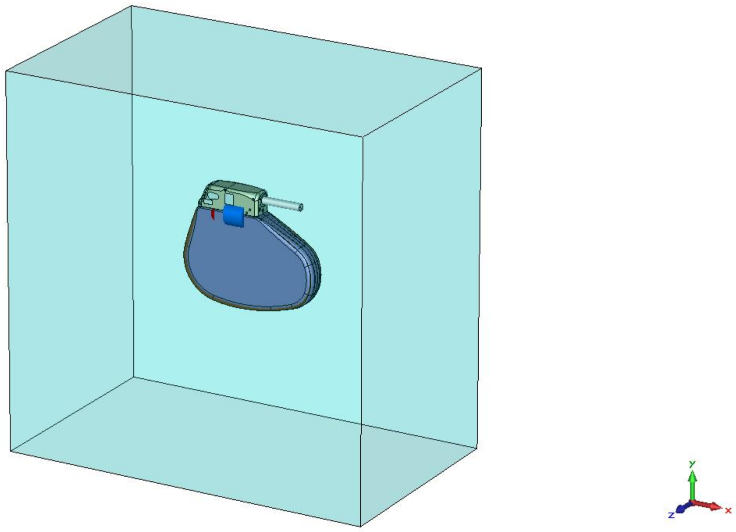


Figure 13 : VR model and the simulation volume

13.2. SAR SIMULATION RESULTS

13.2.1. EUROPE : 10G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 3.18 E-6 W/kg.
- Spatial peak SAR = 0.00084 W/kg.

with the maximum SAR level at : [-1.56; 5.79; 6.03]mm.

13.2.2. USA : 1G CUBE TISSUE

The computed SAR levels are :

- Whole Body average SAR = 3.18 E-6 W/kg.
- Spatial peak SAR = 0.0052 W/kg.

with the maximum SAR level at : [-5.25; 7.90; 1.77]mm.

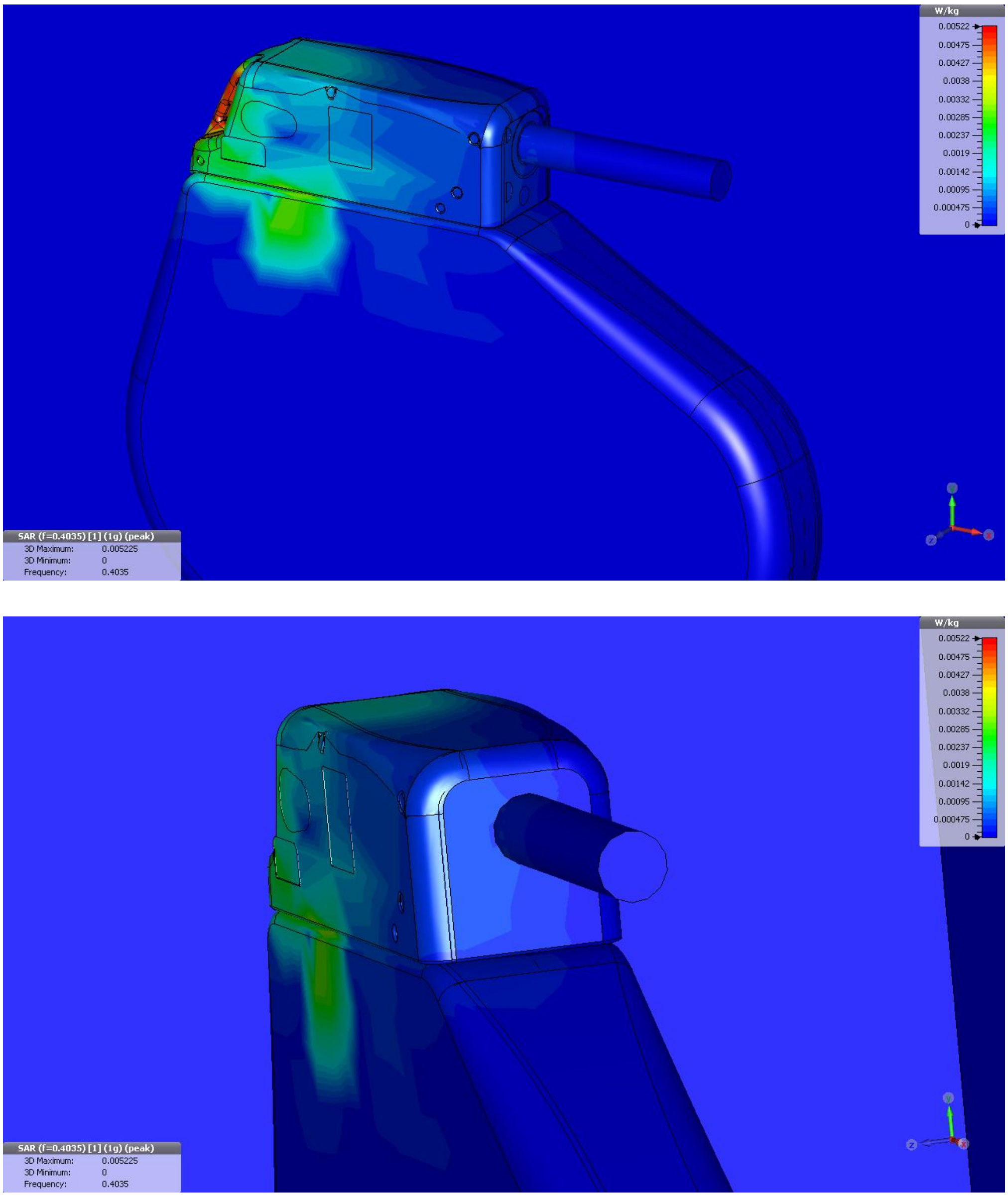


Figure 14 : SAR distribution for 1g cube tissue for VR model

13.3. CONCLUSIONS

SAR simulation results for VR model are far below the limits specified in chapter 5.

14. GLOBAL CONCLUSIONS

SAR simulation results for the four models of ICD comply with the limits specified in chapter 5.