In regards to your recent application referenced above we kindly request that you provide the following additional information.

1) Justification for tissue dielectric parameters used.

The dielectric fluid used in the torso model was obtained from the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" G. Hartsgrove et.al. This paper is referenced by the FCC for use in the torso model for MICS band emissions tests (95.639). The conductivity and permittivity specified in this report are typical for the implant region where a combination of muscle, fat, and lung tissue is likely to be found. Electromagnetic values for these tissue types are documented by C. Gabriel et.al., and can be found on-line at http://www.brooks.af.mil/AFRL/HED/hedr/reports/dielectric/cover.html.

2) uncertainty budget

The uncertainty analysis described below considers the error in the vector reflectometer used to measure the source impedance of the RF transmitter in the implant, the errors associated with the spectrum analyzer used to measure the output power of the implant, and the uncertainty in the spectrum analyzer measurement due to the non-ideal return loss of the spectrum analyzer and the coax connection. Each of these 3 error types will be summarized in a table and the worst-case sum of these effects will be used to modify the SAR calculation. Of interest here is the possible increase in SAR (reduction of spec margin).

Reflectometer error

An Agilent 8753ES vector network analyzer was used to measure the output impedance from the implant RF transmitter. The 8753ES was calibrated for a 1-port S11 measurement using an open, short and load. (NIST traceable Agilent 85033D 3.5 mm Calibration Kit)
Typical measurement error associated with a reflection calibration is found in the specifications for the 8753ES, and at 400 MHz for $\Gamma_S = .608 - j.254$, the uncertainty for $|\rho|$ is ± 0.01; Arg(Γ) is $\pm 1^\circ$.

Spectrum analyzer amplitude error

The amplitude error associated with an Agilent 8595E for the test conditions (-10 dBm reference level, 1 KHz resolution BW, 1 KHz video BW, 10 dB attenuation, DC coupling) are summarized in the table below:

Amplitude accuracy $\pm(.3dB + .01 \cdot (-11.57 - -20))$	$\pm .384dB$
Resolution BW switching uncertainty	$\pm .5dB$
Attenuator uncertainty $\pm .8dB\ per\ 10\,dB$	$\pm .8dB$

Return loss error

Figure 1 shows the signal flow graph for the transmitter impedance measurement.

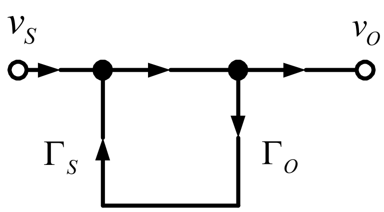

Figure 1 Signal flow graph of the transmitter connected to the spectrum analyzer

The transfer function from source to output is

$$\frac{v_S}{v_O} = \frac{1}{1 - \Gamma_S \cdot \Gamma_O}$$

The uncertainty associated with this transfer function ("Microwave Theory and Applications", Stephen Adam, Prentice-Hall pg 233) is,

$$(1 \pm |\Gamma_S| \cdot |\Gamma_O|)^2 .$$

For the nominal values of $\Gamma_S = .608 - j.254$ and $|\Gamma_O| = .1304$ (the 8595E has a VSWR of 1.3:1) the uncertainty is $(1 \pm .1304 \cdot .659)^2$, or -.780 to +.716 dB.

Figure 2 shows the equivalent circuit associated with the method used to derive the source impedance.

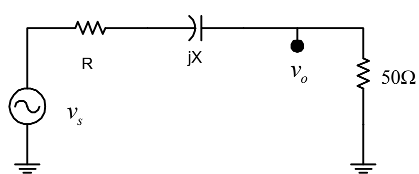

Figure 2 Determination of source voltage

Here the output load is a nominal 50Ω, (within a VSWR of 1.3:1) and the nominal source impedance is 129.64Ω in series with 3.38 pF of capacitance. The data taken from the 8753ES is shown in Figure 3.

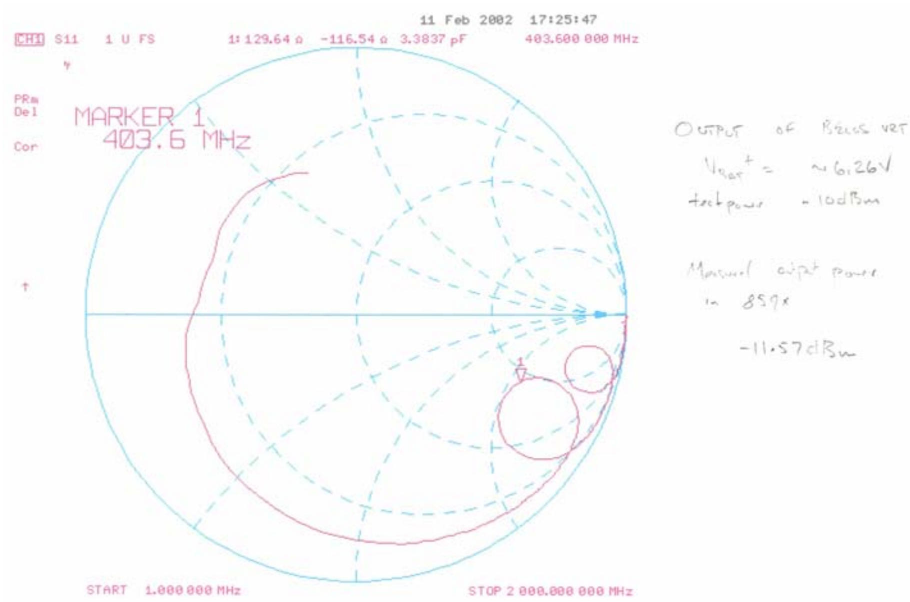

Figure 3 Transmitter reflection measurement

Referring to Figure 2, the output voltage v_S, will be maximized when the expression for v_S is maximized,

$$|v_S| = \sqrt{\frac{P_O}{50} \cdot \left((50 + R_S)^2 + X_S^2\right)} \qquad (1)$$

For the nominal values of the source impedance and measured output power (-11.57 dBm), the nominal magnitude of the transmitter voltage is 357 mV_p.

To complete the uncertainty analysis we will apply the uncertainty of the network analyzer and the amplitude accuracy of the spectrum analyzer to the above equation. The uncertainty due to the finite return loss of the spectrum analyzer will be attributed to the power P_O of the spectrum analyzer.
The values of R_S and X_S are maximized when the uncertainty in $|\rho|$ is +.01 and Arg(Γ) is -1°. For this case R_S = 135.1Ω and X_S = -121.0Ω.
For maximizing P_O, we have,

P_O = -11.57 dBm + .384 dB +.5 dB + .8 dB + .716 dB = -9.17 dBm or 121.06 μW

Substituting all of the parameter changes to compute the worst-case uncertainty,

$$|v_S| = \sqrt{\frac{121.06\mu W}{50} \cdot \left((50 + 131.1)^2 + 121.0^2\right)} = 344.1\ mV_{RMS} = 486.63\ mV_p$$

This is an increase of $20 \cdot \log_{10}\left(\frac{486.63}{357}\right)$ or 2.691 dB. As the SAR is dependent on the square of the electric field component, and the dielectrics modeled are all isotropic and linear, the increase in the SAR is 2.7 dB.

3) Details of how antenna feed was modeled.

Figure 4 shows the sources summary from XFDTD.

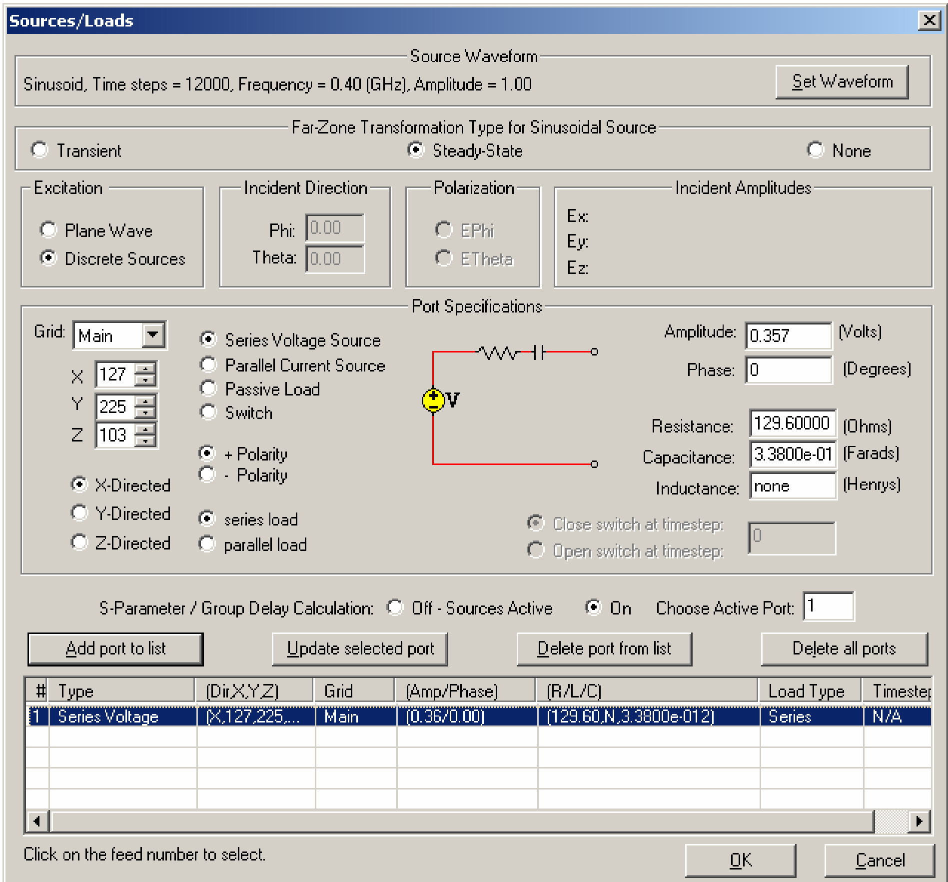

Figure 4 Details of the source used in the SAR analysis

This shows that a 357 mV_p source was placed at location (127,225,103) (x,y,z). The source impedance was a series RC network with the same element values derived from the reflection measurement shown in Figure 3. Figure 5 shows the source located in the z=103 plane of the geometry model.

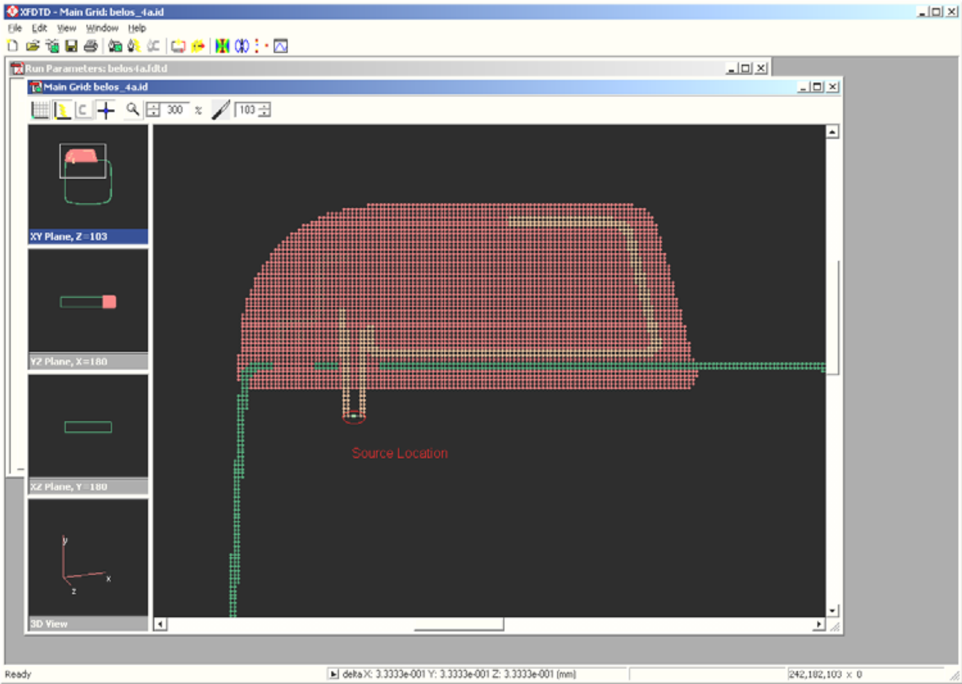

Figure 5 Location of source in model geometry

4) Clarification of loop antenna details. Photograph appears to show a cap attached to the end of the loop while modeling does not contain such a cap. Please explain.

The details of the antenna are shown in the following figures. Figure 6 shows a 3D solid model of the Belos ICD with the tissue dielectric removed in this photo for clarity.

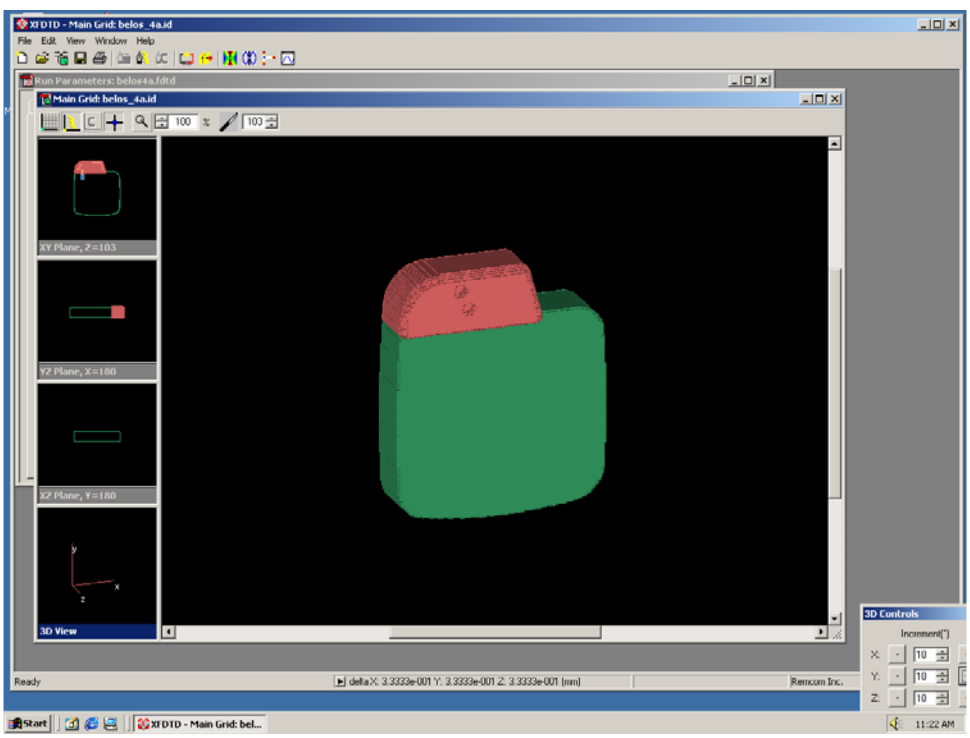

Figure 6 3D solid model of Belos ICD (tissue removed for clarity)

In Figure 6 the titanium housing is shown in green, and the epoxy header containing the loop antenna is shown in salmon. In Figure 7, the tissue and the epoxy header are removed to show the loop antenna with in a 3D rendering. Some of the pacing lead conductors that are adjacent to the loop antenna can also be seen in this figure.

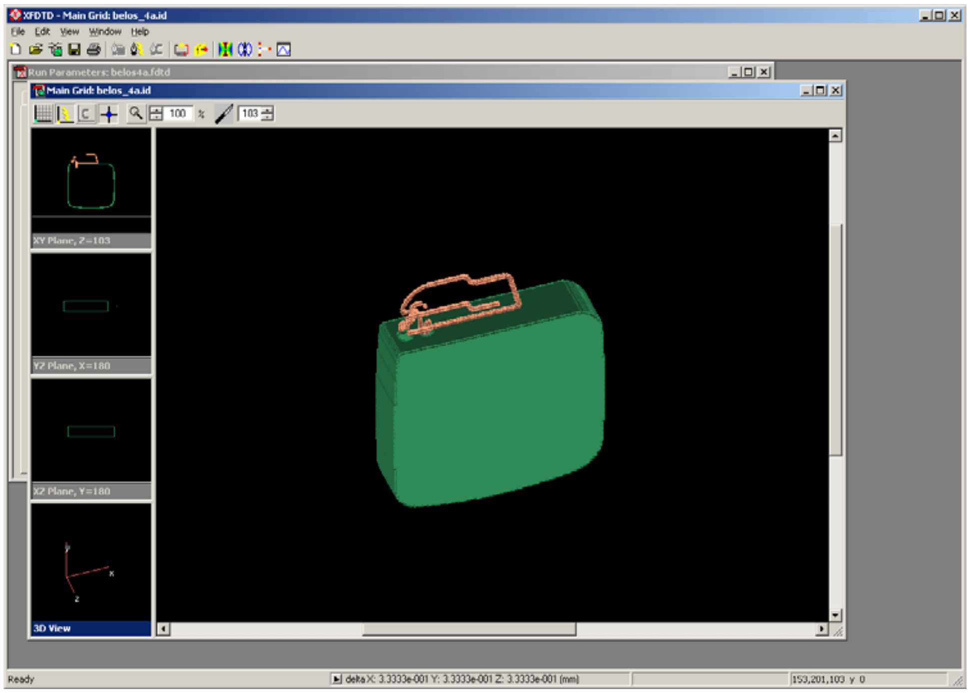

Figure 7 3D model of Belos ICD showing loop antenna (header and tissue removed for clarity)

5) Details of how the spectrum analyzer was used to measure output voltage. How was impedance preserved.

The Belos ICD was programmed to transmit a CW signal. The 8753ES vector network analyzer was calibrated through a 50Ω test coax that was de-embedded along with the network analyzer calibration. A SMA connector was soldered to the antenna pads on the hybrid, and the length of the SMA connector was removed by electrically extending the reference plane of the network analyzer. For the 0.3" length of this SMA launch, it is acceptable to treat the launch as a section of lossless coax at 400 MHz. A short placed at the antenna pads allowed the new reference plane to be established and showed that the assumption of a lossless coax model of the connector was accurate. As the Belos ICD transmitter was operational, the 8753ES test port power was varied from –30 dBm to –10 dBm and the locus of the reflection coefficient was noted on the Smith chart. The locus varied very little over this range, indicating that the output impedance of the ICD transmitter was relatively insensitive to loading in a 50Ω environment. The data was taken with a test port power of –20 dBm and the transmitter was active during this test. This details the method used to obtain the output impedance.

Figure 2 shows the equivalent circuit used to determine the transmitter source voltage. The Belos transmitter was connected to the 8595E spectrum analyzer through a SMA coupler (negligible loss at 400 MHz). The output power was measured and equation (1) was used to derive the magnitude of this source. Impedance in a 50Ω environment was thus preserved in the determination of the source impedance and also in the measurement of the output power.

6) Additional details of maximum 1 gram SAR such as location and how it was derived. The report suggests the maximum point was modeled inside the device. Please only provide computed results in the tissue.

The maximum point of a 1 gram average SAR calculation does indeed fall in the middle of the device. This is because the thickness of the device is on the order of 1 cm, and the two locations of maximum SAR fall on either side of this particular section containing the device. It is hoped that the figures below clarify this better. The following plots contain the results of the calculation using tissue only.

Figures 8 and 9 show the unaveraged SAR 1/3 mm above and below the metal case. In these photos, the epoxy header can be seen, as it is thicker than the metal case.

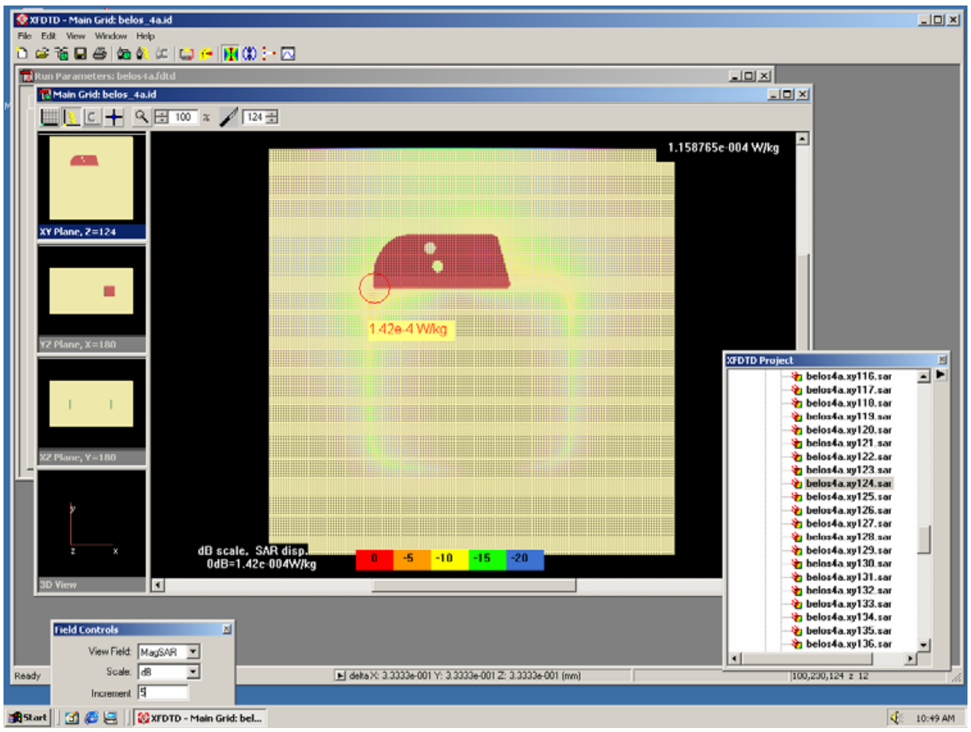

Figure 8 Unaveraged SAR at a location 1/3 mm above the metal case

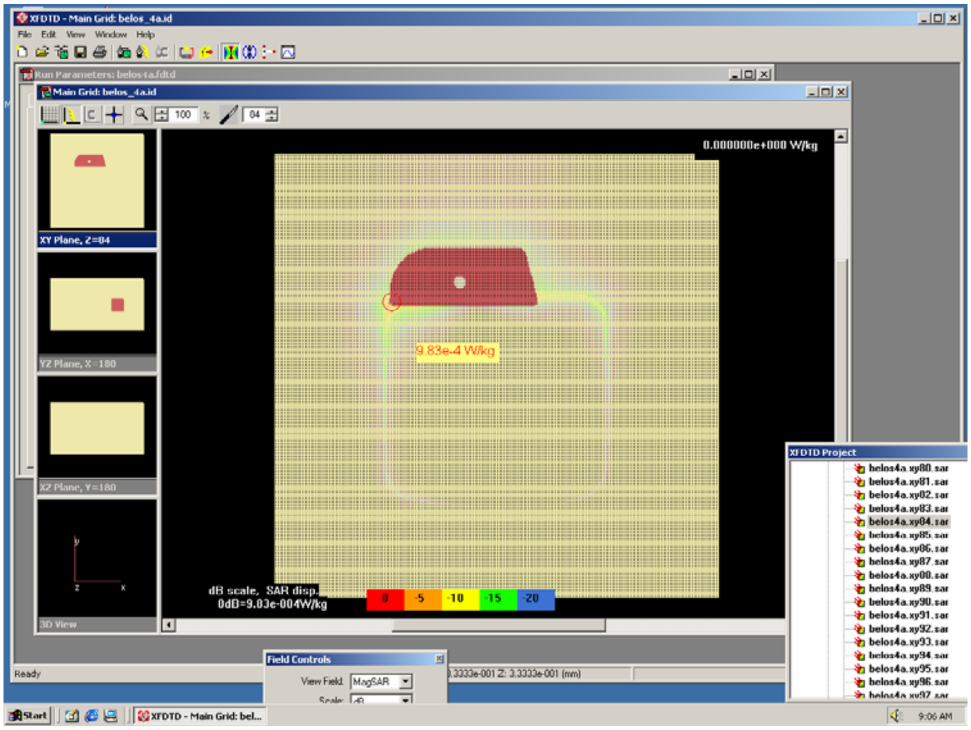

Figure 9 Unaveraged SAR at a location 1/3 mm below the metal case

For these 2 cases, the unaveraged SAR ranges between 0.1 mW/kg to 1 mW/kg.

Similarly, Figures 10 and 11 show the unaveraged SAR at a point 2 mm above and 2 mm below the device.

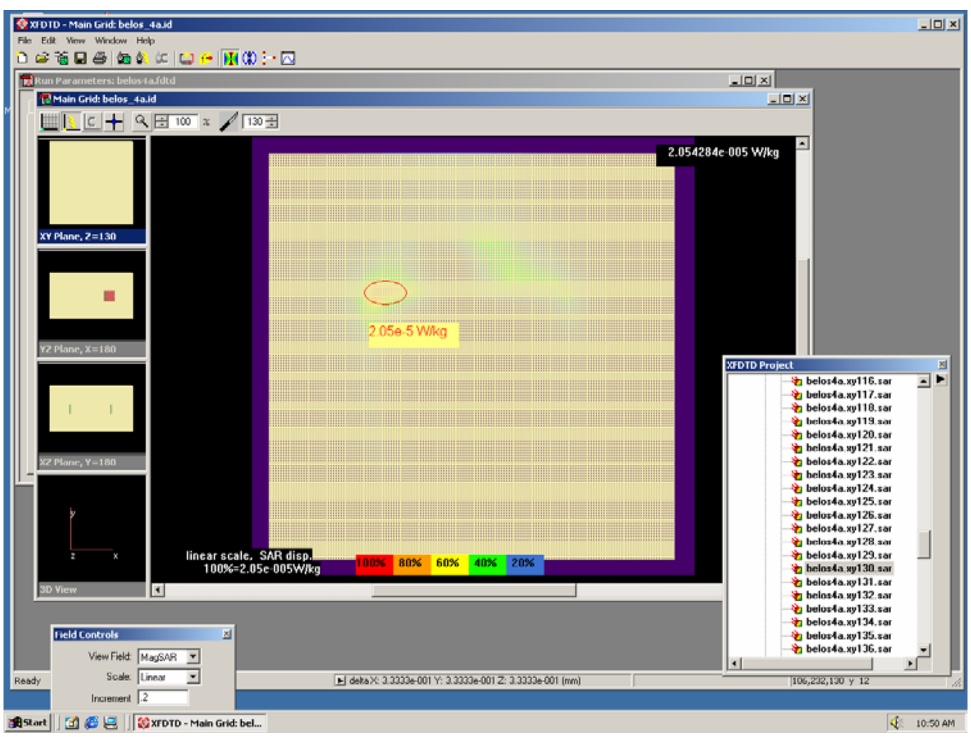

Figure 10 Unaveraged SAR at a location 2 mm above the metal case

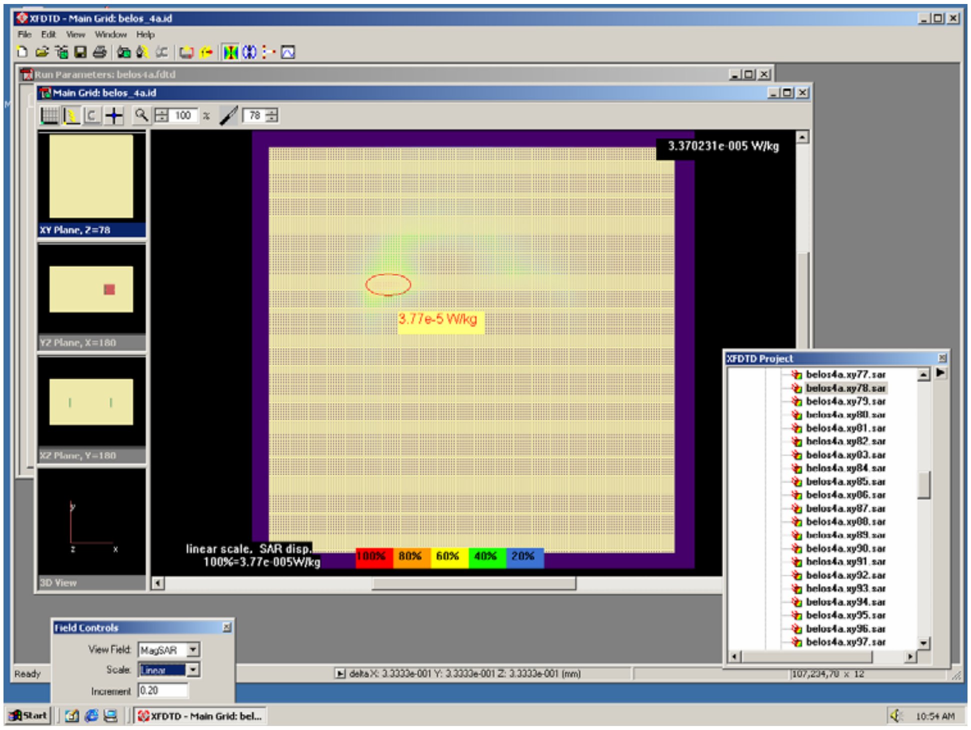

Figure 11 Unaveraged SAR at a location 2 mm below the metal case

In Figures 10 and 11 the unaveraged SAR is on the order of ~30 µW/kg.

Figures 12 through 15 show the 1 gram averages at locations 1 cm and 2 cm above and below the Belos ICD (with slight overlap on the averages below the device).

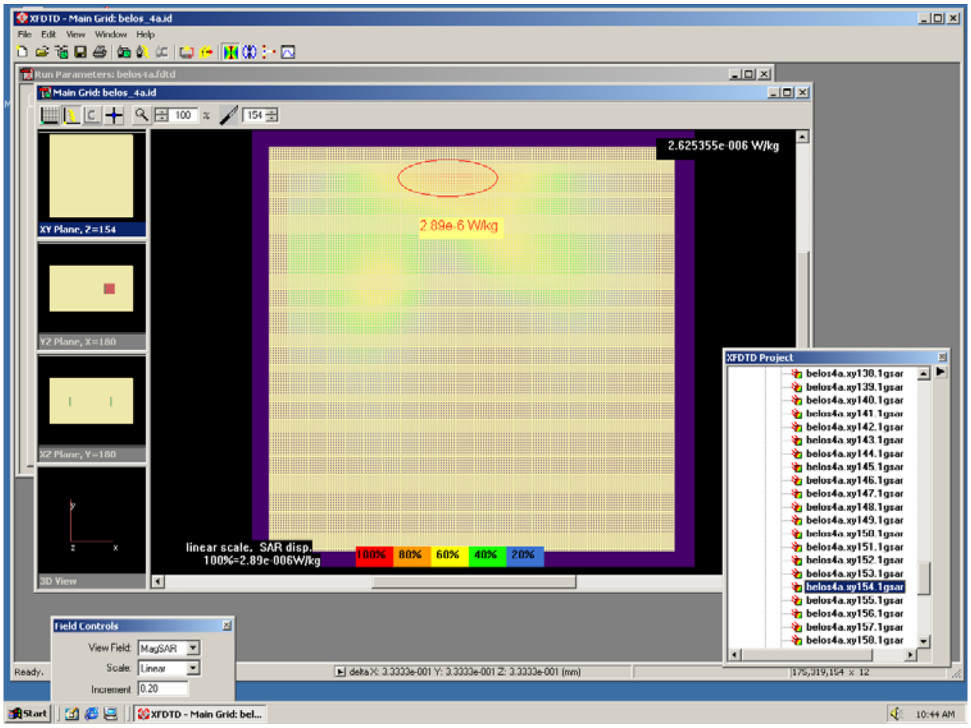

Figure 12 1 gram SAR average 10 mm above Belos

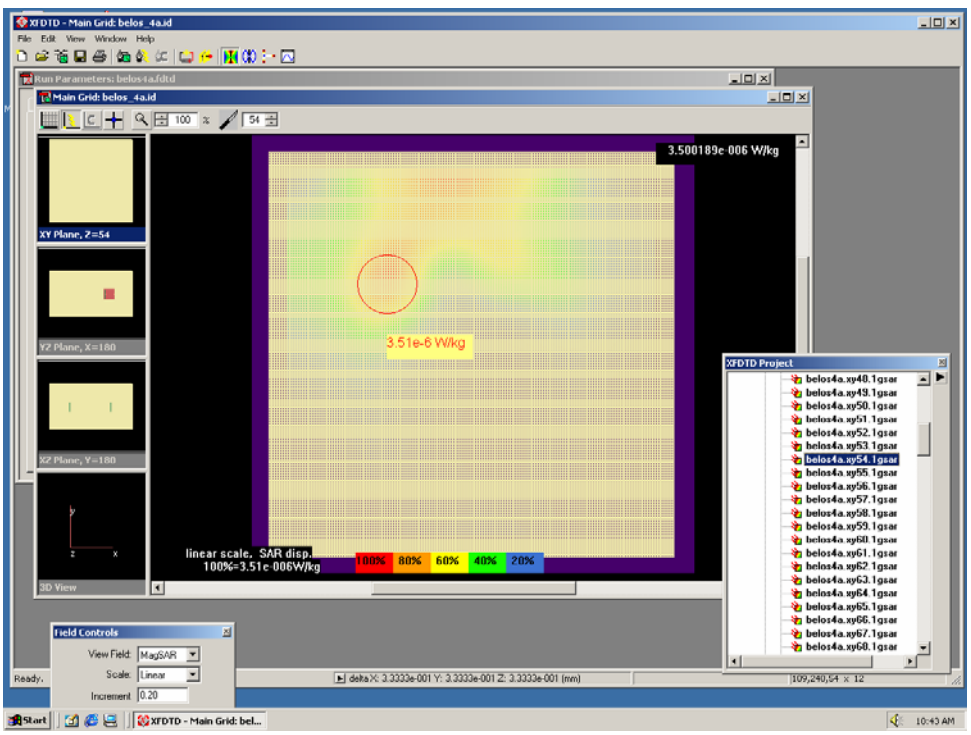

Figure 13 1 gram SAR average 10 mm below Belos

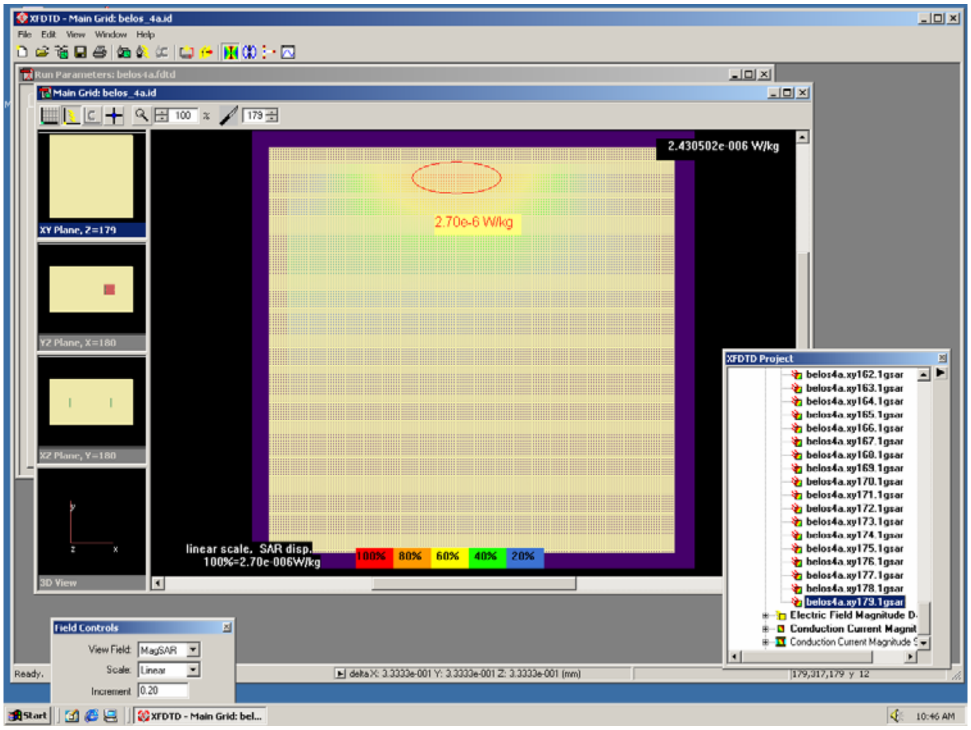

Figure 14 1 gram SAR average 20 mm above Belos

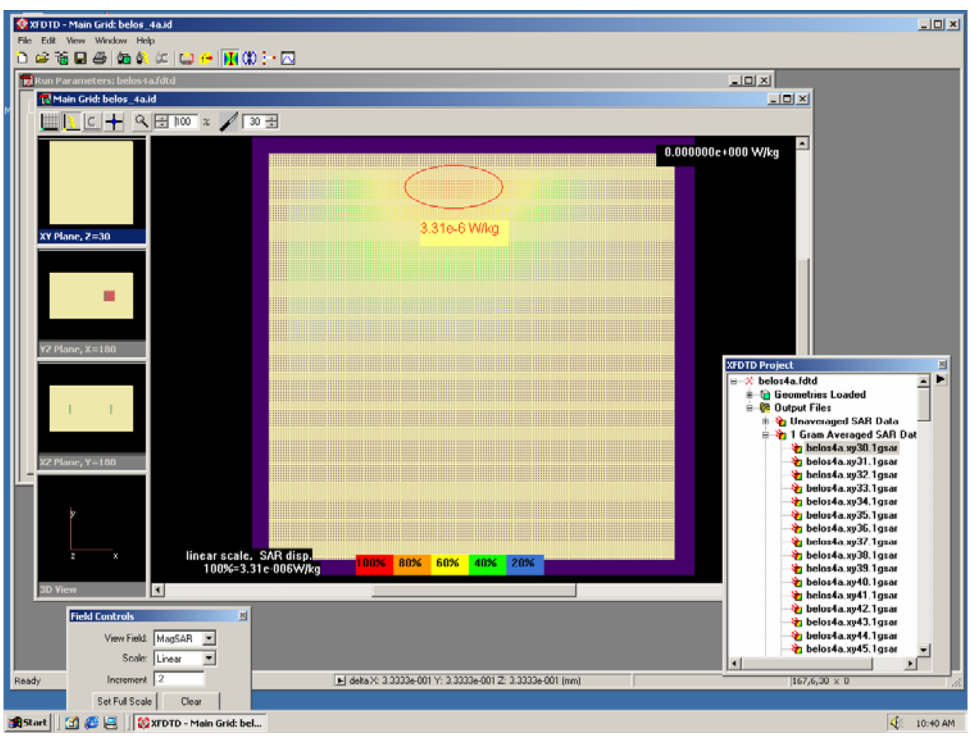

Figure 15 1 gram SAR average 20 mm below Belos

In these latter 4 figures, the 1 gram average SAR is on the order of 3μW/kg. As the header epoxy has about the same density as water infused tissue, has a finite, non-zero conductivity (σ ~ 1 mS/m) and considering that the electric field strength is very large in the vicinity of the antenna (embedded in the header), the location of the maximum 1 gram average SAR is found to exist very close to the antenna.

7) Drawing of device orientation relative to modeled body.

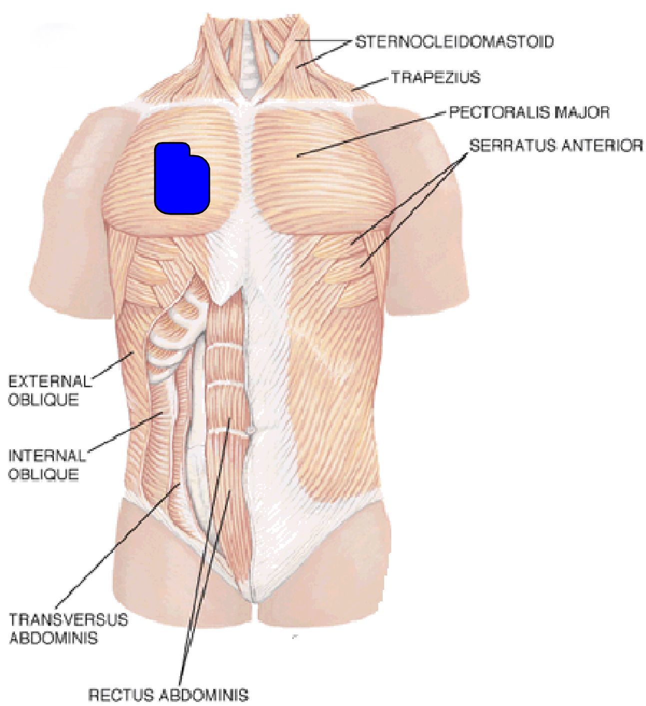

Figure 16 Location of Belos ICD relative to upper torso

Figure 16 shows the typical location of an ICD implant relative to a human torso. The implant is placed in a small distance below the subcutaneous tissue, often residing within the muscular tissue as well. The implant can be placed in the right or left side of the torso.