Noninvasive Medical
Technologies

NCIQ Maximum Electromagnetic Limits for Human Body Exposure

NMT E-Tag and NCIQ devices under development at NMT as of April 2007 are being designed to measure hemodynamic parameters for human patients using a proprietary noninvasive non-contact radio frequency technique. It is required to show that the NMT E-Tag and NCIQ devices will not exceed maximum safe electromagnetic limits for human body exposure. The standards for maximum electromagnetic limits for human body exposure in the United States are described and established in the ANSI/IEEE standards document, IEEE Std C95.1™-2005.

In the technique used by the NMT E-Tag and NCIQ devices a human patient will be exposed to electromagnetic radiation applied to the cardiac area of the thorax, usually over the sternum (breastbone) at a very close distance of 1.0mm to 10mm using a specially designed patch antenna, the TAP (Transducer-Antenna-Probe), through the clothes covering the thorax. The RF radiation applied is a single frequency sinusoidal signal in the 902-928 MHz ISM frequency band centered at 915 MHz. The radiation will be applied for 30 seconds for a 2 minute measurement process for a 25% duty cycle. From knowledge of the maximum possible output power of the E-Tag of NCIQ transmitter, assuming perfect lossless RF transmitter components, TAP and duplexer we have a worse case maximum output power calculated as shown

$$P_{\text{transmitter}} - P_{\text{duplexer-loss}} = P_{\text{TAP-max}}$$

$$P_{\text{TAP-max}} = +4.0 \text{ dBm} - 3.0 \text{ dBm} = +1.0 \text{ dBm} = 1.26 \text{ milliwatts}$$

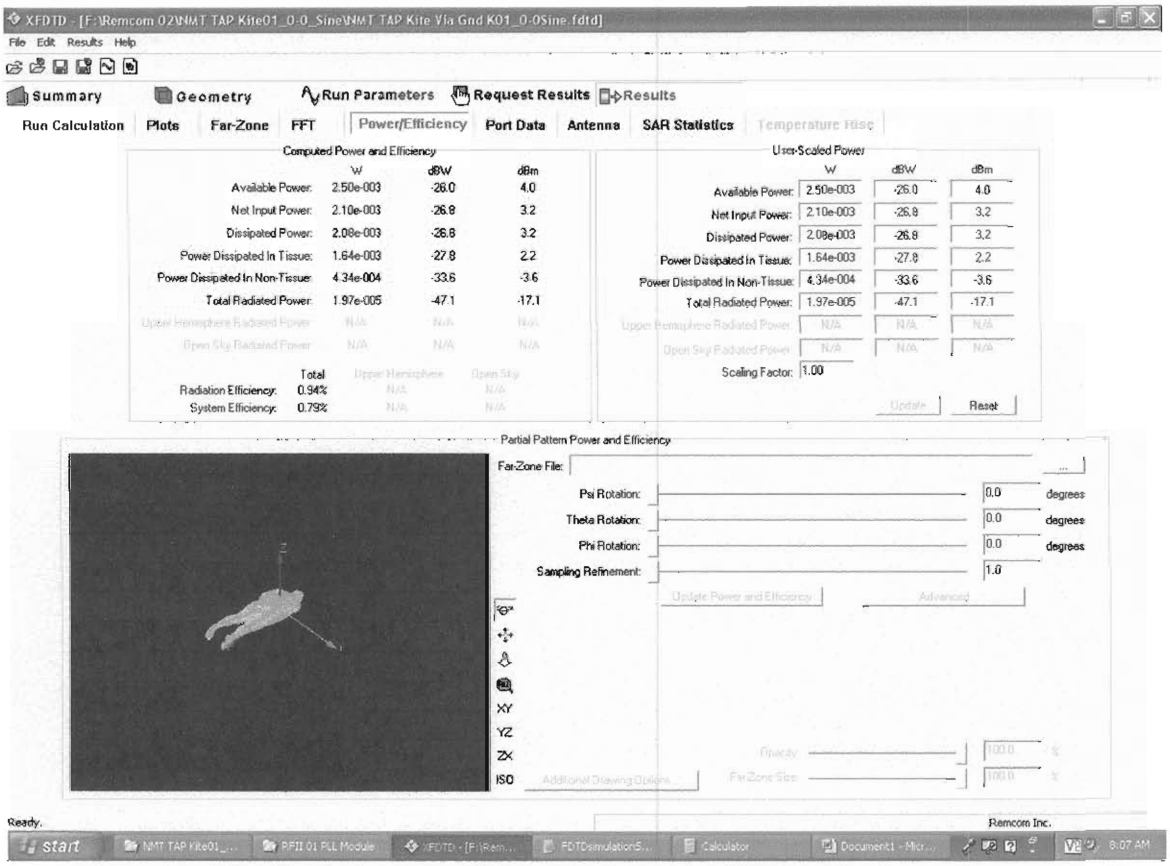
Now that the upper bounds of TAP transmitter power has been established an accurate estimate of the ratio of RF energy that is transmitted inside the body, to the interior of the thorax, with respect to the transmitter power is needed. Using a preliminary calculation on the Remcom XFDTD computer analysis suite with the Remcom human body mesh file, hifibody63.mesh, the ratio of TAP transmitter power that penetrates and is dissipated into the human body as heat is found on figure 1 on the next page. The program uses an arbitrary available power of +4.0 dBm, where we have a maximum possible available RF power level from the E-Tag transmitter of $P_{\text{TAP-max}} = +1.26$ dBm. The corresponding RF power level that is transmitted through the TAP then into the thorax from the analysis is 2.2 dBm a drop of

$$P_{\text{TAP-Thorax-Loss}} = 2.2\text{dBm} - 4.0 \text{ dBm} = -1.8 \text{ dB}.$$

For the E-Tag transmitter this means the upper bounds for the total power into the human body is calculated as

$$P_{\text{Thorax-max}} = P_{\text{TAP-max}} - P_{\text{TAP-Thorax-Loss}}$$

$P_{Thorax\text{-}max}$ = +1.0 dBm – 1.8 dB = -0.8 dBm = 0.83 milliwatts



In the Remcom XFDTD analysis the TAP was placed as close as possible, within a millimeter of the sternum in the thorax area of the human body mesh. This has the result of the maximum RF power delivered to the human body. The TAP design insures that the RF power delivered is localized to the cardiac region, via the sternum. Also the Remcom analysis frequency is set to the best resonant frequency of the first prototype TAP positioned against the human body thorax at the sternum, which is 862 MHz, 5.8% lower than the final target design frequency. The maximum power transfer occurs very close to the antenna resonant frequency of the TAP and the frequency difference for the preliminary analysis will not change the biological significance of the results.

In the IEEE Std C95.1™-2005 the standards are categorized by frequency. The NMT E-Tag and NCIQ devices will fall under the UHF ultra high frequency (300 MHz–3 GHz) category. At these frequencies of 300 MHz to 3.0 GHz the rules protect against adverse heat effects associated with heating, for either whole body exposure or in our case for measuring hemodynamic parameters in the thorax, localized exposure. Localized exposure for the thorax is calculated for a peak spatial average, and is not the case for extremities and pinnae. Table 6, page 24 is shown below gives the BR (Basic Restrictions) a defined term in the standards given here for convenience:

3.1.9 basic restrictions: Exposure restrictions that are based on established adverse health effects that incorporate appropriate safety factors and are expressed in terms of the *in situ* electric field (3 kHz to 5 MHz), specific absorption rate (100 kHz to 3 GHz), or incident power density (3 GHz to 300 GHz).

Note that the specific absorption rate limits have an upper bound, "Persons in controlled environments" and a lower limit of "action level". "Action level" refers to a lower level with an additional safety margin for the general public, so that a continuous long term exposure of "all individuals in the population, will be without risk of adverse effects".

Table 6—BRs for frequencies between 100 kHz and 3 GHz

		Action level[a] SAR[b] (W/kg)	Persons in controlled environments SAR[c] (W/kg)
Whole-body exposure	Whole-Body Average (WBA)	0.08	0.4
Localized exposure	Localized (peak spatial-average)	2[c]	10[c]
Localized exposure	Extremities[d] and pinnae	4[c]	20[c]

[a]BR for the general public when an RF safety program is unavailable.

[b]SAR is averaged over the appropriate averaging times as shown in Table 8 and Table 9.

[c]Averaged over any 10 g of tissue (defined as a tissue volume in the shape of a cube).*

[d]The extremities are the arms and legs distal from the elbows and knees, respectively.

The lower limit level for localized exposure is twice the "action level" SAR for whole body exposure given as 0.08 Watts/Kilogram or 80mW/Kg. Our localized SAR level is

$$SAR_{THORAX\text{-}LL} = 0.16\ W/Kg = 160\ mW/Kg$$

The SAR is to be averaged over any 10 grams of body tissue. The maximum power that could be applied to any 10 grams of body tissue and not exceed the lower level limit of exposure would be

$$SAR_{THORAX\text{-}LL}(mW/Kg)/100 = SAR_{THORAX\text{-}LL}(mW/10gm) = 1.6\ (mW/10gm)$$

The upper limit power limit that the TAP can deliver to 10 grams of body tissues is 0.83 milliwatts, which is 52% of the lower limit of localized exposure for 10 grams of body tissue 1.6 mW/10gm.

The appropriate averaging time for the SAR value of the lower limit level for localized exposure is given from Table 9, page 25, of ANSI/IEEE standards document, IEEE Std C95.1™-2005 as 30 minutes. This would imply that our estimate would hold for the case of the NMT E-Tag and NCIQ being run continuously for 30 minutes without any pause in RF power being applied to the human body. NMT's envisioned mode of operation for the E-Tag of 30 seconds "on" and 90 seconds "off" for a 25% duty cycle, provides for even a wider margin than the lower limit specifications in IEEE Std C95.1™-2005.

The IEEE Std C95.1™-2005 document does specify the importance of being under the BRs (Basic Restrictions) limits vs. the complimentary MPE (Maximum Permitted Exposure) limits in Tables 8 and 9, where 9 is the lower limit. It is stated in this paragraph above Table 8 on page 24:

"Compliance with Table 8 and Table 9 ensures compliance with the BRs on whole-body average SAR. However, lack of compliance with Table 8 and Table 9 does not necessarily imply lack of compliance with the BRs, but rather that it may be necessary to perform additional evaluations to determine whether the BRs have been met. If the BRs given above are not exceeded, the MPEs in Table 8 and Table 9 can be exceeded. Consequently, it is sufficient to demonstrate compliance with either the whole-body BRs or Table 8 and Table 9"

So from the language in IEEE Std C95.1™-2005, our estimate of maximum TAP RF power applied to the human body thorax is compliant with IEEE Std C95.1™-2005 based on the lower limits of Table 6 (BRs).

This estimate is not intended to prove compliance, but demonstrates that the initial design for NMT E-Tags and NCIQ should prove to be compliant when a rigorous SAR analysis is performed to legally prove compliance.

We can confidently estimate that for the NMT E-Tag or NCIQ, as of the design in April 2007, which is continuously on for 30 minutes, the maximum RF energy that is dissipated as heat should be 52% of the lower averaged SAR limit for 10 grams of human body tissue, and should be much lower (13%) for our current mode of operation at 25% duty cycle (30 seconds on 90 seconds off).