RF Communication for Active Implant Medical Devices

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Range of applications

More than 1 000 000 pacemakers and more than 200 000 defibrillators are implanted in the world each year. Infusion pumps for diabetes and pain are more than 200 000 devices implanted per year. Neurodevices implanted for pain management, epilepsy, Parkinson and many other are growing rapidly currently more than 150 000 are implanted each year.

In 2010, 219 000 people worldwide had cochlear devices implanted. In the U.S alone some 900 000 people are believed to be deaf or near deaf. In India, there are an estimated 1 million profoundly deaf children, only about 5,000 have cochlear implants

For all these devices there is a necessity of routine monitoring for alerts and follow up which can take place at home.

First retinal implants received market approval in the USA in Feb 2013 and in Europe in Feb 2011.

Communication with Active Implantable Medical Devices AIMD

Low Power Active Medical Implants (LP-AMI), and associated Peripherals (LP AMI P) are allowed since 2012 in Europe for Active Medical Implant Communications Systems (AMICS) to operate in the band 2 483,5 MHz to 2 500 MHz.

LP-AMI using for communication ETSI standard EN301559 benefit of a high speed communications capability between patients with AIMDs and medical practitioners engaged in utilizing these AIMDs for the purposes of diagnosing and delivering therapy to individuals with various illnesses. LP-AMI and/or LP-AMI-P provide human therapeutic and diagnostic data storage and analysis capability.

The high speed communication (greater than 2Mbps) can be achieved by aggregating 2 *1MHz channels.

The access channel mechanism is based on LBT (listen before talk) and AFA (adaptive frequency agility) and 10% duty cycle.

The maximum indoor power transmission is limited to 10mW e.i.r.p.

Measurements of RF link budget for LP-AMI

The lack of literature concerning the implanted antenna inside body operating at 2,45 GHz has justified measurements on the total propagation loss of an implanted antenna.

The aim of the measurement was to estimate the additional loss on the antenna performance at 2,45 GHz when implanted in the human body. A particular attention was paid to the calculation of the combination of the near-field and far-field in order to correctly design the overall link budget for the radio link.

To evaluate the difference of link budget between the in-body to off-body configurations, the antennas radiation gain was measured. The in-body measurements were performed using the phantom model represented in Figure 3. The implant used is represented in Figure 1 and Figure 2 represents the illustration of an in-body to off-body communication link.

Finally, the measurements were also used to validate the theoretical results concerning the simulated radiation properties of implanted antennas at 2,45 GHz.

From the measurements it is determined that the antenna gain versus the mounting depth, inside the phantom can be expressed by:

$G(dB)=G_{air}\,(dB)-17{,}3-4{,}65*(e-1)$ where e is in cm and is to be higher than 1cm. This equation was derived based on measurements at 2,5 GHz.

From simulations, it is also noted that a linear decrease in dB of the antenna maximum radiation level is in the far field region. For both antennas, we have expressed the evolution of the maximum antenna gain in a horizontal plane according to the immersion depth in the phantom by the following:

$G(dB)= G_{air}\,(dB) -19{,}2 - 3{,}92*(e -1)$ (Simplified defibrillator with magnetic loop)

It is to be noted that this relation is in concordance with the attenuation law obtained considering wave propagation in a lossy media with the same dielectric properties as the phantom fluid.

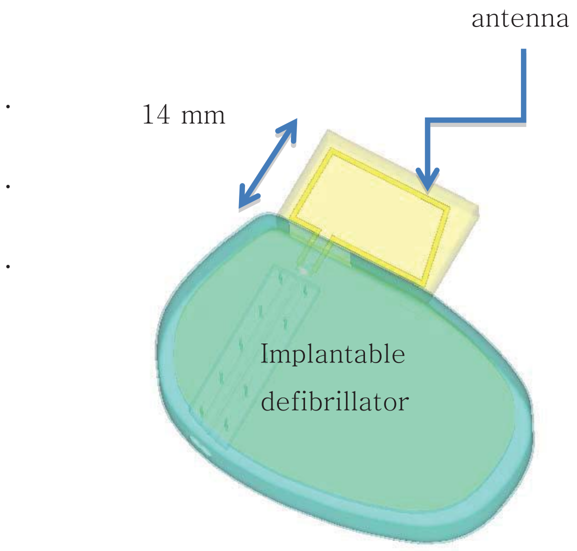

Fig. 1: Defibrillator can with header containing the loop antenna

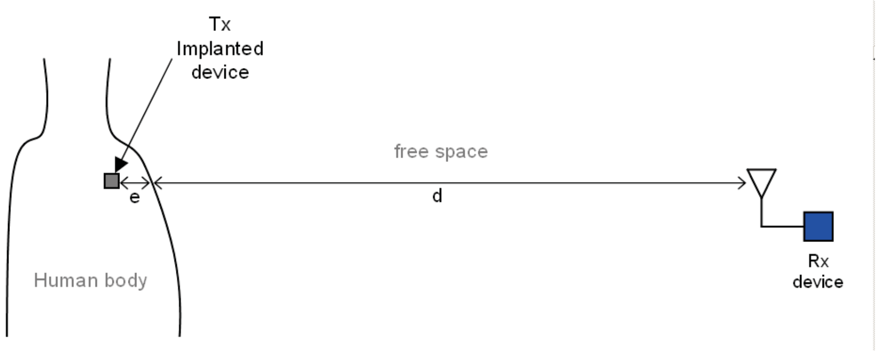

Fig. 2 Illustration of an in-body to off-body communication link

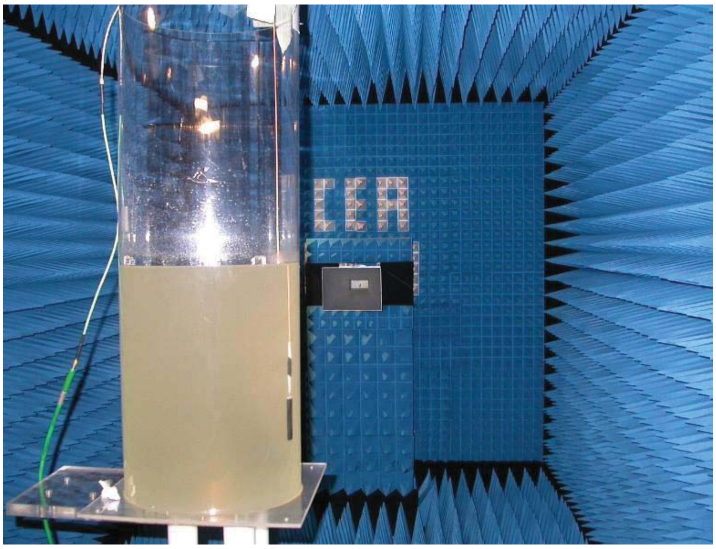

Fig. 3 Side view of the test the antenna inside the phantom

$G_{Tx,air}$		**0**								
G_{Rx}		**2**								
Free space Loss (dB)		**-40,2251 @ d=1m**			**-46,2457 @ d=2 m**			**-60,.2251 @ d=10 m**		
$L_G + m*(e-1)$ (dB)		**-19,2 @ e=1cm**	**-23,12 @ e=2 cm**	**-27,04 @ e=3cm**	**-19,2 @ e=1cm**	**-23,12 @ e=2 cm**	**-27,04 @ e=3cm**	**-19,2 @ e=1cm**	**-23,12 @ e=2 cm**	**-27,04 @ e=3cm**
P_{Tx} (dBm)	**0**	-57,42	-61,34	-65,26	-63,44	-67,36	-71,28	-77,42	-81,34	-85,26
	10	-47,42	-51,34	-55,26	-53,44	-57,36	-61,28	-67,42	-71,34	-75,26

Table 1. Summary of simulated received power in dBm according to free space propagation loss and antenna gain loss introduced by the human body at 2.5 GHz. $n = \mathbf{2}$ (LOS), $m = -\mathbf{3.92}$ and $L_G = -\mathbf{19.2}\ dB$.

SAR simulations

The measurement of the SAR makes it possible to evaluate if a system complies with the regulation limitations. For example, concerning mobile phone, 1999/519/EC Recommendation limit for an average mass of 1g is 1.6 W/Kg for a Pir = 2mW.
For a value of input power *Pir* less than 1 W, the level of maximum SAR must be

linearly weighted following the equation below:

$$MaxSAR\big|_{Pir} = \frac{Pir}{\mathbf{1}W} \cdot MaxSAR\big|_{1W}$$

The SAR levels associated to the envisaged system and the RF power level available seems to be in accordance with EC Recommendation 1999/519/EC as if *Pir* = 2 mW, then $MaxSAR_{1g}$ ~0,072 W/Kg. In other words, to reach the EC Recommendation SAR limit of 1.6 W/Kg, the antenna reference input power is to be below 45.1 mW (+16.5 dBm).

A worst case SAR simulation is made with continuous power. It should be noted that the planned implantable applications will not have continuous transmit duty cycle and is to be averaged over a six minute period.

The pictures in the figure 4 are the SAR distribution around the implant with magnetic dipole inside the human model Hugo for 3 orthogonal planes. On these pictures, one can notice that the maximum SAR is actually concentrated in the vicinity of the magnetic dipole of the simplified pacemaker. The simulation is made for an transmitter conducted power of 1 W.

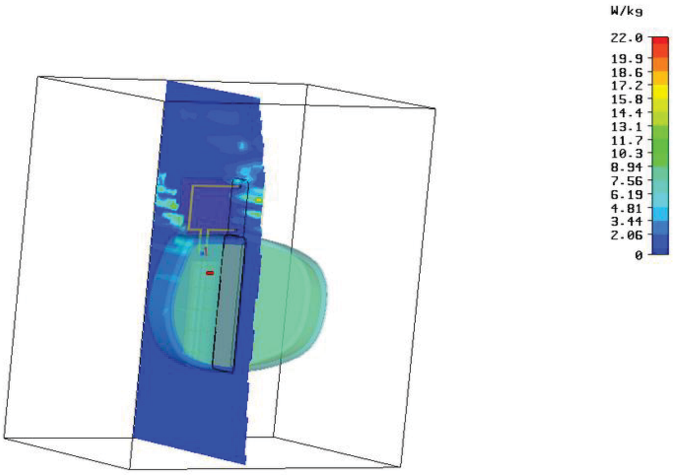

Fig. 3. SAR distribution

Conclusion:

The measurements and simulations performed in this study prove the feasibility of an implanted device to out of body device communications in the 2.483-2.5GHz band called LP-AMI standardized in ETSI EN 301559.