

BODY IMPLANT COMMUNICATION – IS IT A REALITY?

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Abstract

This paper shows how Radio Frequency (RF) communication is possible for implanted medical devices. RF links between implanted medical devices and external monitoring and programming equipment is becoming more common. However, as new RF applications are introduced the battery operating life of the implanted medical device is a concern. This paper describes a technique to prolong battery life. The testing and results of a demonstration implant within a simulated human body are also described.

1 Introduction

The need for reliable communication from implanted medical devices to external monitoring systems has been clearly established [1]. RF technology better supports longer-range wireless links between implants and communication systems, in comparison to previous systems that relied on electro-magnetic (inductive loop) technologies.

The data rate of an RF link can be considerably higher than inductive loop systems, allowing either more data to be transferred or a shorter interrogation time. Higher data rate and shorter transmission time translates into longer battery life for the implanted device. In addition, RF technology is also user-friendly, in comparison to inductive loop systems where an inductive wand needs to be accurately positioned over the implant and close to the patient.

Existing medical implants are small, have limited battery capacity and cannot be easily replaced. Size limitations mean the implanted antenna must be physically small and very compact compared to what would be used for the same frequency in air. The limited battery life and implant inaccessibility means the additional battery drain caused by the RF function must be minimal. To minimise the battery drain a wake-up function is described that leaves the RF circuit inactive most of the time.

2 Operating Frequency and Limits

The frequency assigned for implanted device RF communication is around 403 MHz and referred to as the MICS (Medical Implant Communication System) band. This has a maximum Effective Radiated Power (ERP) of 25 μ W (-16 dBm) in air. The power limit applies to an external

transmitter, such as a base-station, and to the implant but only when the signal is outside of the body in air. There are other limits that are described in the Australian Communications Authority Planning Proposal for MICS [2].

3 Battery Life

An implant will typically comprise the primary application, that could be diagnostic or therapeutic, and the RF link. Once implanted a device is not expected to be accessed for maintenance or battery replacement. Rechargeable batteries have limitations as described by Sivard et.al. [3]. Large batteries are not acceptable. This requires that the RF part of the implant have a low current drain. Even with the latest circuit design techniques, an RF transmitter or receiver will require several mA of current to operate. Such a current would quickly exhaust the battery, meaning the RF transceiver cannot be operating permanently. Typically an implant will only need to be interrogated for a short period of time separated by many hours or even weeks. This opens the possibility of having the RF transceiver switched off (sleep mode) for the majority of the time and only “woken up” when interrogation is required.

The 2.4 to 2.5 GHz ISM (Industrial Scientific and Medical) band can be used to transmit to an implant (but is not suitable to transmit from an implant) and can use a power of 100 mW (+20 dBm), dependant on country. Transmitting a wake-up signal to an implant in this band enables a receiver to be designed that does not require as much current as a receiver working in the MICS band with the limit on transmit power. Such a wake-up receiver will have relatively low current consumption, as it does not need to be as sensitive as a receiver for the MICS band. The average current consumption is further reduced if the receiver is for the most part inactive and only operating for short periods of time at pre-determined intervals. This reduces the average current of the wake-up receiver even further; typically 200 nA, if the strobe frequency is once a second, see Figure 1.

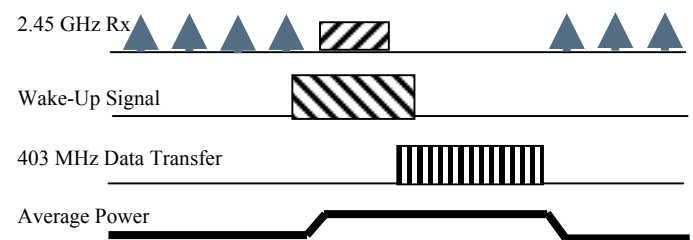


Figure 1. Sleep and Wake Up Sequence.

Once a valid wake-up signal has been received then the remainder of the implant RF circuit can be powered up as shown in Figure 2. It remains powered for the duration of the interrogation and then reverts to sleep mode and waits for a wake-up signal. The communication circuit only uses significant current when data is being transferred.

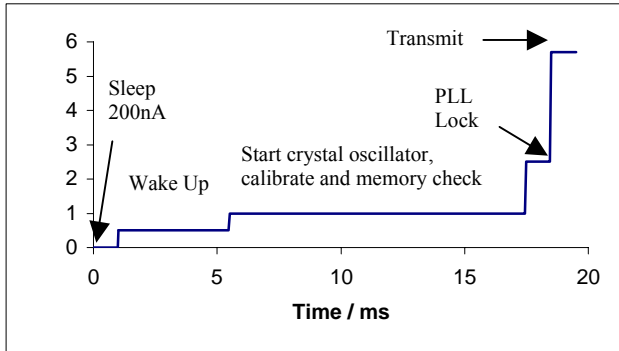


Figure 2. Typical Implant Wake Up Sequence and Current Consumption.

The time that the implant transceiver is woken up can be minimised if the data is transferred at high speed. Typically a raw data rate of 200 kb.s^{-1} to 800 kb.s^{-1} is possible.

4 Demonstration System

A demonstration system was constructed that comprised a base-station, implant, antennas and controlling laptop PC. The base-station comprised a PCB with a Zarlink ZL70101 IC, a wake-up transmitter, micro-controller and other functions. The ZL70101 is the transceiver for 403 MHz with additional filtering in both transmit and receive paths. The board is controlled by the laptop through a USB interface and on board micro-controller.

The base-station has the option of using any antenna that has a nominal impedance of 50Ω . Typically a sleeve dipole is used for the 2.45 GHz wake-up transmitter and either a 0.25λ (quarter wave) monopole or half-wave dipole for 403 MHz.

The demonstration implant is shown in Figure 3. It comprises a ZL70101, micro-controller and battery. There is a Surface Acoustic Wave (SAW) filter in the 403 MHz transmit and receive path to eliminate strong adjacent channel interference. There are also sensors for battery voltage and temperature. The battery is rechargeable and there are LED indicators to show the status of the PCB. This PCB used packaged parts for ease-of-assembly and handling and was larger than necessary to enable probing during development. An implant RF function could be made much smaller if bare die were to be used.



Figure 3. Demonstration Implant PCB and Battery.

The demo implant and battery was fitted into an aluminium box that is representative of an implant. The choice of antenna for an implant is limited by the available space. Space within the implant is always limited. The antenna needs to function at both 2.45 GHz wake-up and at 403 MHz. In this example a patch antenna was attached to the box with a coax feed going through to the PCB.

The implant antenna matching circuit is split into two: one each for the 2.45 GHz and the 403 MHz. There is some degree of isolation between them. Fine-tuning of the matching is possible with variable capacitors within the ZL70101 that are optimised with an inbuilt routine.

5. Test Environment

Testing the implant operating inside a living body is difficult and only allows limited test time. The alternative is to use a Perspex body model that is filled with a liquid that mimics the electrical properties of basic body tissue. The liquid medium allows the implant to be moved with ease.

The Perspex “body” is defined in standard ETSI publication EN301 489-27 [4]; it is at least 76 cm high and has an inside diameter of 30 cm. The liquid used to simulate muscle at 100 MHz to 1 GHz comprises water, sodium chloride, sugar and Hydroxyl Ethyl Cellulose (HEC). A recipe for muscle at 1.5 to 3 GHz excludes sodium chloride. Both recipes are shown in Table 1.

Ingredient	% By Weight	
	100MHz to 1GHz	1.5GHz to 2.5GHz
Water	52.4	45.3
Sugar	45.0	54.3
Salt (NaCl)	1.5	0.0
HEC	1.1	0.4

Table 1. Body Phantom Recipes.

The Perspex body was mounted on a wood platform and filled to within 20 cm of the top. The implant was attached to a PTFE “T” such that it could be lowered into the tank to a

prescribed depth. PTFE was chosen, as it is the material least likely to distort the measurements.

The implant in its aluminium box was sealed in a nonconductive water resistant bag that was attached to the PTFE “T”.

The working environment for an implant and base-station in real life would have equipment, furniture and other surfaces that would reflect and increase or decrease the RF signals. Using such an environment for testing would result in distorted results for the operation of the RF link. The tests were therefore performed in an anechoic chamber that has its inside walls lined with absorbent material to prevent signal reflections.

6. Test Methods

Two test methods were used. One was to measure signal levels to understand the transmission medium. The second measured signal strength as detected by the implant and errors in the transmission. This showed how well the data link operates.

The measurement of signal levels was done with a standard log-periodic antenna, with known characteristics, and the signal level measured on a spectrum analyzer. From this it is possible to calculate the ERP of the base-station for 400 MHz and 2.45 GHz as well as the signal generated by the implant.

The error rate measurements used a software function that recorded the error rate to a file for future processing.

7. Test Results

7.1 Base-station

The 403 MHz output of the base-station was measured and the transmit level adjusted such that it will not exceed the 25 μ W limit. The output of the wake-up signal was measured across the band and also adjusted to be within the 100 mW limit.

7.2 RF Signal From The Implant

This was measured at 3 m and with the implant at various distances from the wall (depth) of the “body”. Both the log-periodic test antenna and the implant were measured at both orientations. “Vertical” for the implant is when the long side of the box and long side of the patch are vertical. Figure 4 shows the result where the effect of depth and polarisation on signal level are apparent. There is >10 dB difference between the best and worse results for any given depth. Also the vertical-vertical measurement shows an increase in signal level at a depth of 2 to 4 cm. This is inline with the results found by Johansson [5] where a human body posture will affect the signal strength and polarisation.

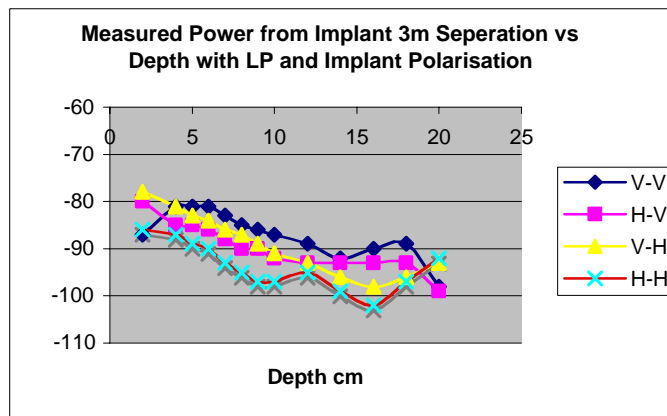


Figure 4. Measured Signal from Implant In Artificial Body vs. Depth. Four Plots For The Polarisation of the Implant and Log Periodic Respectively.

7.3 RF Signal Measured by the Base-station

The Zarlink ZL7010 IC’s built-in Receive Signal Strength Indication (RSSI) function gives a measure of the relative signal level detected. This is not an absolute measurement of signal received. This test was performed using an automatic routine that set the implant to receive and measures a Continuous Wave (CW) signal while the base-station transmitted a CW signal. This lasts for approximately 30 seconds after which the data link is re-established and the implant RSSI value is transmitted to the base-station.

This test was done with both implant and base-station antennas vertically polarised. The results of this test are shown vs. depth in Figure 5. As with Figure 4 there is an increase in signal level at depth between 3 to 4 cm. There is the expected degradation of signal strength with increasing depth.

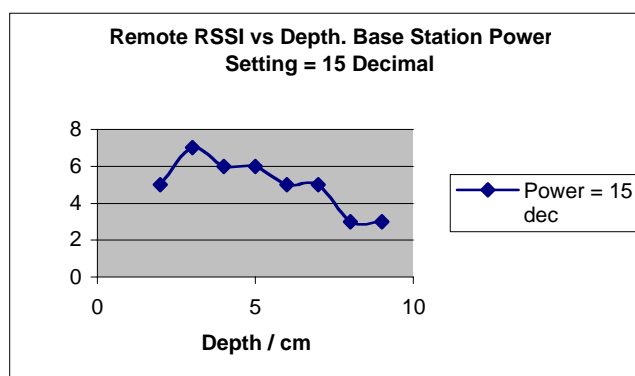


Figure 5. RSSI vs. Depth. Signal Transmitted from Base-station.

NB: the “Power Setting” refers to the base-station and was set to set the ERP to 25 μ W.

7.4 Error Rate Measurements

An indication of the quality of the link is to measure the number of times error correction is used during the transmission of 100 blocks of data. For this test the link is established with data blocks being sent between the implant and the base-station. The implant polarisation was vertical with the base-station antenna also vertical. The results are shown in Figure 6. The two types of error correction, Error Correction Code (ECC) and Cyclic Redundancy Code (CRC), can be invoked to maintain data integrity. Less error correction indicates a better link. From Figure 8 it can be seen that the error correction is lowest at depth of 2 to 4 cm that corresponds to the peak in signal level of Figure 4 and the RSSI levels of Figure 5.

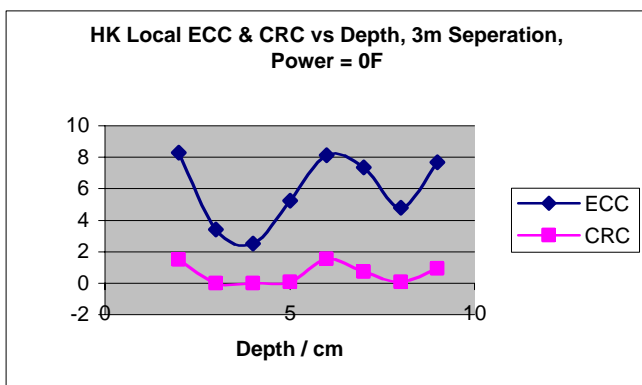


Figure 6. ECC and CRC vs. Depth.

NB: the “Power” refers to the base-station and was set to set the ERP to $25\mu\text{W}$.

8. Future Work

Subsequent to these tests a data rate indication has been added to the controlling software that will give a direct record of the quality of the link. This will be more straightforward to appreciate and will be used for future tests.

Some work has been done with other antenna types that have delivered better performance. These will also be used in future tests.

9. Conclusions

For the given patch antenna on the demonstration implant box, with the base-station operating within the regulatory limits and in a non reflective environment, the implant was woken up at a range of 3 m and maintained a data communication session. The best performance was seen at a depth of 3 cm and not close to the surface of the “skin” of the artificial body. There is a reduction in sensitivity with depth but operation was still possible to 10 cm.

These results show that the signal from a body is polarised (as expected). In a real environment there will be reflections from walls and other objects that will cause constructive and destructive interference. To maintain the link the base-station

should therefore include special and polarisation diversity. This could use multiple antennas.

The implant antenna needs to fit with the host implant, and antenna type is dictated by the application. Antenna types other than patch can be used.

The wake-up function operated over the 3 m range. The implant circuit is capable of considerable miniaturisation to fit within an implant application. Communication to an implant has been proved to be possible while maintaining the low current wake-up and sleep modes of operation.

10. Acknowledgment

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