Implanted Medical Devices Sharing the Radar Band

Prosthetic and Diagnostic Implants Use Unconventional Communication Models

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***Abstract*—Medical applications of wireless and near-field inductive links are specific to the therapeutic application with unique constraints on power and co-site interference. The ability to share spectral regions previously reserved for radar systems, radio location, fixed and mobile communications, and amateur usage provides a critical solution to these constrained medical devices. Sharing of the 413-457 MHz band with the Medical Micropower Network (MMN) application is accomplished through a combination of mitigation measures, and its use of very low power transmission.**

Keywords-neurostimulation; microstimulator; radar; maritime mobile; aeronautical mobile; land mobile

I. Introduction

Implanted medical electronic devices are becoming more prevalent with a world-wide patient base. While cardiac pacemakers have been in use for several decades, many new applications for microelectronics and nanotechnology are enabling treatments and prosthetics that were unimagined several years ago. Cochlear implants have a world-wide patient base of over 220,000. Spinal cord stimulators for pain management are also prevalent. Microstimulators for pain suppression, neurostimulation for stroke rehabilitation and myoelectric sensing for prosthetic control are in development and various clinical trials. Retinal implant devices are available in Europe for partial alleviation of blindness. These devices are interactive with the world outside the body. Sensory replacement devices must be in continuous operation and this is generally achieved with some form of radio or induction link. The wireless linkage provides a convenient and safe means of passing power and data through the skin without the risk of infection. Just as with conventional radio links there are issues of co-site interference from other devices around the body, but there are added complexities of transferring power and the attenuation introduced by the tissues of the body. This has added to the pressure for spectral allocation for previously allocated spectral bands because of the unique transmission limitations the human body presents. As will be shown, the region in the area of 400 MHz allows useful signal transmission with modest antenna size and sufficient bandwidth for neuromodulation applications. The spectrum reserved for radar and other applications between 410-450 MHz is of course also useful for its present applications of long range radar and communication. The Medical Micropower Network (MMN) to be discussed limits its interference with the incumbent narrow-band co-channel systems by spectrally excising those signals from the receiver pass band. The reconstructed signal with interferers removed is subsequently demodulated to recover the short bursts transmitted by each implanted device. The MMN external controller monitors the available channels and can seamlessly change to an alternate channel if the current channel becomes too busy or too noisy to process. The excision also allows the MMN to maintain its own error-rate sufficiently high to avoid disruption. Additionally, as a secondary consequence of the need to conserve battery life, the low-power transmission limits the potential for interference for others users in an occupied channel.

In addition to an overview of different medical applications using wireless links, specific test results showing the compatibility of the MMN with the other formats used in this frequency domain will be presented.

II. Current Medical Applications

A. *External Medical Devices*

The number of external electronic medical devices is staggering and seemingly without bound. The devices range from cardio recording devices, insulin pumps, glucose monitors, and functional electrical stimulation (FES) devices for the treatment of the effects of stroke, spinal cord injury and other movement disorders. These devices are external to the body, generally operate autonomously, and have a limited need to communicate except to receive infrequent control signals, clinician programming, or remote data reporting. The devices are predominantly battery powered and the modest average power consumption of a Bluetooth, WiFi, Zigbee, or MedRadio (MICS) style radio link is easily supported since the usage is overall very low duty cycle. Examples of some of these devices are illustrated in Fig. 1 below.

These types of devices often have an integral controller that is immediately accessible to patient and clinician. This eliminates the need for wireless controls; conventional switches and displays are adequate, although wireless connectivity provides additional features and convenience.

B. *Implanted Sensorineural Devices*

Implanted devices, other than temporary purely diagnostic devices require external power and signaling to be transmitted

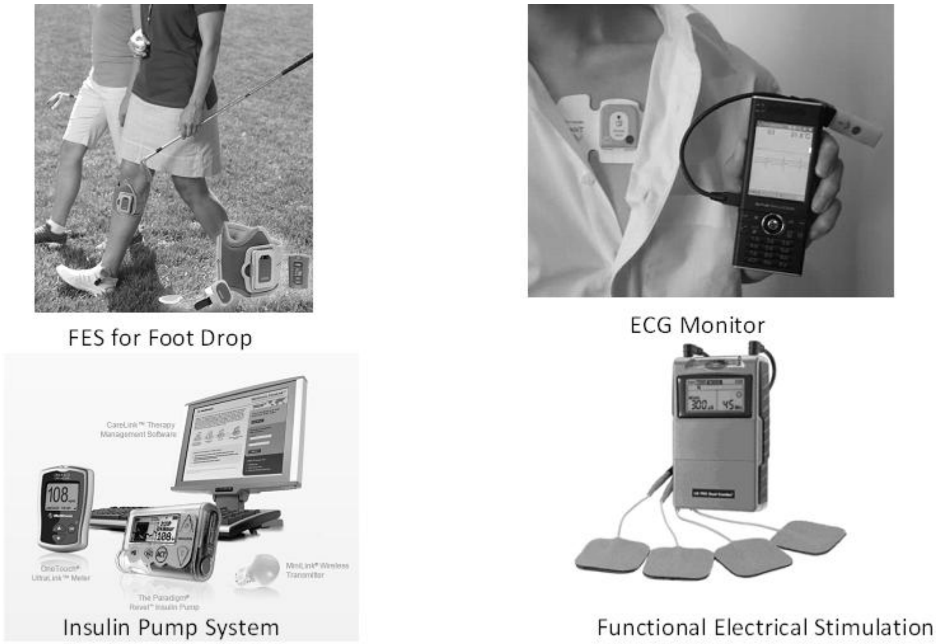

Figure 1. Examples of external medical devices.

to the device located inside the body. This is most often solved with some form of wireless channel. The development of percutaneous plugs has progressed, but the process is still developmental and presently presents risks of infection and the potential for injury.

One of the early implanted devices is the heart pacemaker. With the advances of microelectronics advanced programming capabilities were added as well as bi-directional telemetry control. Some early units utilized rechargeable batteries. The battery and electronics were contained inside a hermetic titanium enclosure, the use of low frequency magnetic induction could transfer the AC charging signal through the titanium case with moderate loss because of the rather low conductivity (and large skin depth) of the titanium. Although modern pacemakers use non-rechargeable primary batteries, the titanium case has been maintained and provides a somewhat transparent window for the communication channels as well as being a convenient hermetic enclosure. This is an example of the suitable choice of frequency for the specific application.

Devices that are currently in the market place, or just entering include cochlear implants for severe and profound deafness, retinal implants for the blind, and drug pumps for both insulin delivery and pain medication. These types of devices differ from the external applications because of the continuous data transfer that must occur and the general inefficiency of electrical sensorineural stimulation. With sensory devices, it is highly undesirable to remove the stimulation or sensing leads. Once the neuro-network and brain plasticity has accommodated the device disturbing the leads creates confusion and usually failure of the device to provide the functional therapy. For certain applications such as the cochlear implant the leads and implant package are inserted into the skull in proximity to the brain. It is desirable to create a fully implanted device with an internal rechargeable battery; however the safety aspects of having a battery in intimate contact with the brain have maintained the architecture using an inductive link external to the body that supplies the audio signals as well as the operating power for the implanted element. The implanted element and the external speech processor (that includes the battery and microphone elements) are shown in Fig. 2. Since the power is continuously transferred from the external device, the coupling link was chosen as a loosely coupled inductive link. The double-tuned network has a theoretical limit of 100% transfer, although usual component limitations, frequency multiplexing losses, and rectification losses reduce this transfer. This is distinctly different from spinal cord stimulator systems (for pain blocking) that resemble a pacemaker system. The spinal cord stimulator needs infrequent commands. A very high path loss can be tolerated to the implanted device since the communication draws on average a very low power level. The last example of the retinal implant is similar to the cochlear implant with added channels. The inductive link limits the present system to 60 channels, which are being expanded to 240 channels. This provides crude images compared to the resolution of an HD television, yet even perceiving edges is a tremendous aid to the blind.

III. The Medical Micropower Network

The medical micropower network (MMN) is a special application for wireless microstimulators and sensors. As microstimulators the devices are implanted within the muscle group, such as the arm as shown in Fig. 3. For this application it is necessary to have several devices operate in a coordinated

Figure 2. Cochlear implant and external speech processor.

fashion with direct continuous control from the patient through an unspecified sensory neural monitor system. The microstimulators are operated in a star network from a Master Controller Unit (MCU). The MCU continuously polls the implanted microstimulator devices (ISD) providing the stimulus commands and monitoring the state of health, or sensing information from the ISD's.

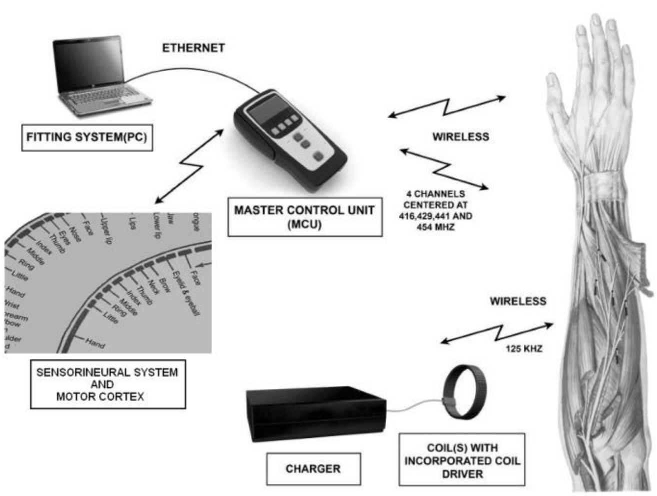

Figure 3. The MMN passes sensory information and stimulation to the ISD through the MCU.

The human response time is compatible with an update rate of about 50 Hz. The microstimulators must be physically small for insertion into the muscle. This limits the antenna size. The operating range needs to be 1-2 meters to allow for flexibility in the location of the MCU. The attenuation produced by the human tissue increases at higher frequencies as shown in Fig. 4. There is a range of compromise available in the 400 MHz region where the attainable antenna size and attenuation are more balanced.

The MMN system uses four bands (Fig. 5) of about 6 MHz width each to transmit in a half duplex format. The messages frame period is 11 msec. The modulation format is QPSK at a 5 MBPS raw data rate. Raised cosine shaping is used to minimize out of band interference. The MCU controls all timing. Fig. 6 shows the message format of the frame period. The MCU operates as the master unit in a star configuration with the ISD's, sequentially polling each unit. It is envisioned that the typical application will use between 2-12 ISD's.

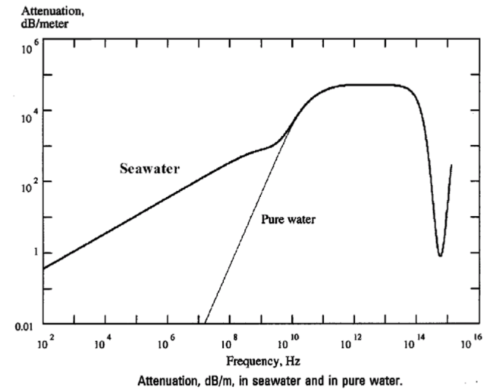

Figure 4. The attenuation of signals through the body increases with frequency while the antenna reduces in size.

MMN Channel Number (Frequency Range) (MHz)	Low Frequency Edge (MHz)	Center Frequency (MHz)	High Frequency Edge (MHz)
1 (413 – 419)	413.919	416.405	418.891
2 (426 – 432)	426.349	428.835	431.321
3 (438 – 444)	438.779	441.265	443.751
4 (451 – 457)	451.209	453.695	456.181
Guard Band 7.458 MHz		Bandwidth 4.972 MHz	

Figure 5. MMN Channels.

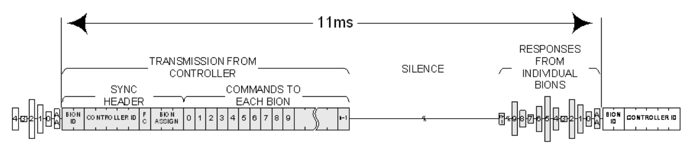

Figure 6. MMN Frame format.

A. *Interference Minimization Concepts*

To minimize the presence of the MMN to other users in the frequency band, several concepts were implemented. The transmit power is low, set at 0 dBm from the transmit elements. The implanted elements also have the additional path loss of the body attenuation that further reduces their emission. A modern digital modulation method with raised cosine shaping was chosen to reduce emissions adjacent to the MMN channels. The MMN also uses a process termed frequency excision and channel monitoring in this paper. Channels are assessed using a weighted function that factors in the number of co-channel users, ambient noise, signal levels on both ends of the link, and error corrector/detector performance. Once selected, a channel remains active until it is degraded to the extent that the error rate is likely to increase with further degradation. Under such circumstances, the master will move the system to the best available alternate channel. Channel change can be accomplished without loss of medical function. If no viable channel is available, the system will shut down by executing a pre-programmed safe shutdown sequence. The frequency excision also is a protection strategy to maintain the data integrity of the MMN system from outside interference. In the event that sufficient data error rate cannot be maintained, then a graceful shutdown algorithm is incorporated to insure that the patient does not continue to operate the system during unsafe conditions.

The physiological signals that the MMN is to replace occur at modest rates, and with the 11 msec frame rate there is sufficient overhead that dropped frames can be tolerated. The system is able to perform its designed functions with error rates in the region of 5%; thus it is inherently resistant to pulse interference such as that produced by radar transmissions, even at rather high pulse repetition rates. Occasionally during testing the MMN system would change channels when radar was detected. This is due to high pulse rate radar hitting two frames several frames apart; this very rare at pulse rates between 400 and 800 pps. There is no specific means to mitigate interference to radar systems due to the peculiar characteristics of this band which contains many more powerful uncontrolled incumbents.

B. Evaluations and Test Results

The MMN system has been evaluated for its impact on the existing allocated uses and in one study has shown that the MMN system produces the required separation distance (RSD) of less than 0.31 km. in the frequency band 410-420 MHz and less than 0.41 km in the frequency band 420-450 MHz with the MMN system operating out-of-doors. When the MMN is operated indoors, the distances are reduced. These predicted RSD's result from the MMN transmitters' low equivalent isotropic radiated power, duty cycle, and low antenna heights. These factors combined with the dynamic channel switching capability of the transmitter and the anticipated low number of MMN systems indicates that the MMN system should be compatible and not cause unacceptable interference with government communications and electronics systems currently in the 410-450 MHz band.

This study also concluded that the RSD for susceptibility of the MMN system to government equipment is less than 1.14 km in the 410-420 MHz band and 18.71 km in the 420-450 MHz band. However these numbers are mitigated by the frequency excision, low probability of simultaneous reception, and the forward error correction techniques used in the MMN. With these features, the MMN system can operate at substantially reduced RSD's.

In a second study the MMN system was wired to an interference simulator to evaluate the frequency excision capability and to evaluate the susceptibility of the MMN to various anticipated interference. The block figure is shown in Fig. 7.

The interference signals were synthesized from baseband files to provide the various formats with the associated data rates and modulation schemes. Twelve ISD's were connected in the test system. The test signals generated included FSK (both single and multiple simultaneous channels), analog FM, airborne radar (8 usec pulses at 2 KHz pulse repetition rate), ground radar, Enhanced Position Location Reporting System (EPLRS) (hopping 8 channels), and amateur TV. As a portion

TABLE 1. MMN SYSTEM SPECIFICATIONS.

Spurious Free Dynamic Range	68dB
Error Rate	Shall perform all functions with packet loss of up
Adjacent Channel Rejection	>40dB
Noise Bandwidth	2.486 MHz
MCU Noise Figure	11 dB
MDS at BER of 1E-3, Thermal Noise only, No Interferers	-88.7 dBm
Excision Loss Parameters	
FFT length	1024 bins
FFT bin width	4.85 KHz
# FFT Bins excised for CW intfr detected < -81dBm	7 FFT bins
# FFT Bins excised for CW intfr detected > -81dBm	9 FFT bins
SNR Loss per bin excised, worst case	0.029 dB/bin
Minimum Detectable CW Interferer	-99 dBm
Noise Floor Threshold Stepsize	6 dB
Typical Number of Interferers	10 (2dB SNR loss allowed)
Channel Change Parameters	
Channel change minimum time from command to execution	4 frames
Channel Change Trigger: Number of excised Bins	150 bins
Channel Change Trigger: Detected Interferer Narrowband Level	-60 dBm
Channel Change Trigger: Detected Integrated Noise Power	-79 dBm
Channel Change Trigger: Estimated Effective SNR	12 dB
Channel Change Trigger: Uplink Packet Errors detected on any 1 ISD	2 out of 7
Channel Change Trigger: Downlink Packet Errors detected on any 1 ISD	2 out of 50
Graceful Shutdown Parameters	
Trigger to shutdown is: At least one of the above channel change triggers occurring on all 4 channels	

of the testing the level at which the MMN dynamic channel changing activates was evaluated. The threshold for switching is generally in the range from -59 to -63 dBm.

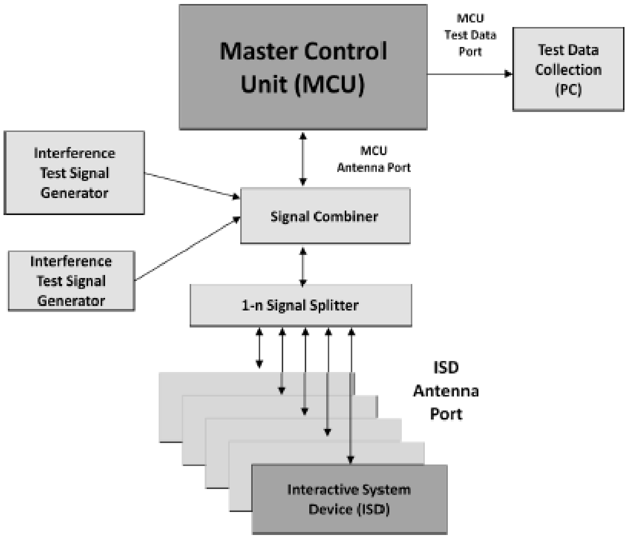

Figure 7. Test Set-Up.

The testing verified that the MMN system performs to its specifications and is able to operate in the presence of incumbent users. It can spectrally excise narrowband users and is able to change channels without suspending clinical functions. It is able to gracefully shutdown in the presence of link service-loss. It can sense incumbent users and select channels to avoid interference with them.