On RF Telemetry for Implantable Medical Devices: A Communication Theory Perspective

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***Abstract*—Bio-engineering is one of the emerging and fast-growing fields today where medical and engineering disciplines converge. Several technologies appeared to provide an efficient treatment of diseases or human deficiencies. One of these technologies is the implantable medical devices (IMDs). These devices are supported with computing, decision-making and communication capabilities. In this paper, a survey on the RF telemetry, including the parameters that have effects on the overall system performance, such as power consumption, RF bands and security, is presented. Furthermore, this paper provides an overview of different channel models of wireless body area networks (WBANs). Then, the effects of channel behavior and challenges in channel modeling are considered. Additionally, many communications protocols which can be used to increase the data rates, including ultra-wide band techniques, infra-red transmission technique, and also body conduction techniques, are discussed.**

Index Terms*—implantable medical devices (IMDs), channel model, wake-up, body area networks, power consumption, security

I. Introduction

Implantable medical devices (IMDs) are electronic devices installed inside the human body to treat a medical condition, improve the functioning or monitor the state of certain body part, replace a missing biological structure, or provide the patient with some information, which he was not previously aware of. Nerve stimulator, cardiac pacemakers and defibrillators are some of the IMDs used nowadays. These devices are used to monitor then treat the cardiac conditions; deep-brain stimulation by neuro-stimulators in cases such as epilepsy or parkinson; drug delivery; and a variety of bio-sensors to process different bio-signals.

Several of the latest IMDs have started to work together with technologies with increased computing capabilities as well with communications, usually known as "telemetry". This provides patients more autonomy and implants with more intelligence to access data remotely.

Different medical devices are designed for humans to implant inside their bodies. These devices need to communicate with external resources for power transfer, data communication, control and management, etc. There are two types for such kind of communication: wire or wireless. The wires are the common source of surgical problems, infection, breakage, and electrical noise; while the wireless telemetry consumes a large amount of power and through the biological tissue, it have low-efficiency transmission.

Implantable devices are widely used by doctors and researchers to monitor human health and to study regular and irregular body functions. These devices can transfer important signals (e.g., Electrocardiogram (EEG), Electrocorticographic (ECoG), Intra-cortical, and Deep brain) from the implanted electrode to the external device to be analyzed or to guide treatment. Fig. 1 shows the different types of measured brain signals based upon the depth of the implantable electrode.

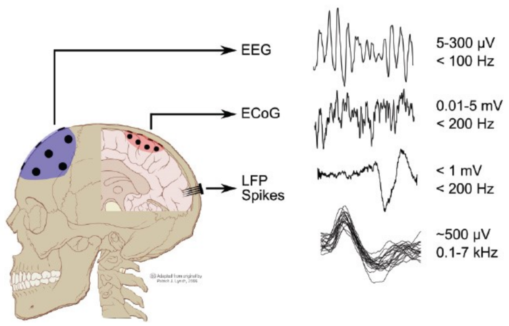

Figure 1. Different Measured Signals by several Electrode Depth [1]

This paper is organized as follows: Section II provides relevant information on wireless data links requirements and communication protocols; Section III presents the different types of IMDs, body sensors and patient data classification; the statistical data of the path loss model is discussed in Section IV; several outlines of security and privacy issues are presented in Section V; in Section VI, the challenges of short-range wireless communications are introduced; and finally, the conclusions are drawn in Section VII.

The main contribution of this paper, it gives a survey about the communications protocols of the implantable medical devices. Also, describes the statistical path loss models. And summaries the challenges in the short-range wireless communication.

II. Wireless Datalink Requirements and Communication Protocols

In the implantable system, several issues, such as size and weight, power consumption, reliability, biocompatibility, data-rate and data-latency, should be addressed [2]. Furthermore, the security and privacy of data to protect patients from jamming, especially when the device is connected with an external system through wireless communication or the Internet, should also be considered [3].

In this section, the different requirements of data links for several neural signals such as EEG or ECG are discussed. However, it suffers from a significant lack of data rates, power consumption, size, and frequency band.

Wireless communication links in biomedical implant systems should address the following:

- **Energy**: Once the IMD is implanted, the battery can last for 8 years in case of neuro-stimulators [4] and up to *10* years in the case of pacemakers [5]. The problem in energy is when the battery is empty, it has to be replaced, which requires a surgical procedure.
- **Power Consumption**: The implantable device consumes power in the order of tens of *mW*, which must be transferred over an inductive link. While in idle mode, the power consumption could be much lower. In current implementations, the inductive link is used for transfer the data then higher data rates require a wider bandwidth (and hence lower quality factor) inductive link, leading to a reduction in power transfer. The power consumed by the implanted unit has a threshold must not exceed it which is 80 mW/cm^2 to save the tissue from damage through heating effects [6]. This power must be shared between the wireless link and the baseband stimulation/monitoring systems.
- **Storage**: The memory of the implantable device is limited because if the amount of memory is increased, this will also increase the size of the implantable and even if the device size is not important, the increase in memory will decrease the battery lifetime.
- **Fabrication Technology**: To keep fabrication costs to a minimum, it should be implemented in standard CMOS technology.
- **Frequency Band**: Several implantable medical devices have used wireless RF telemetry to avoid the complications of wired implants. The wireless RF telemetry used the band of frequencies from 5 KHz to 10.6 GHz in the process of communication, as shown in Fig. 2, according to the application requirements.

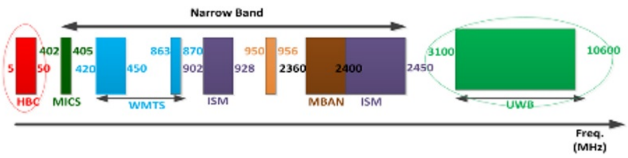

Figure 2. Frequency Bands for WBAN

Wireless medical telemetry systems include devices to measure patient's vital signs and other important health parameters, devices that transport the data via a radio link to a remote station, and finally, a device that receives and analyses the transmitted signal as shown in Fig. 3.

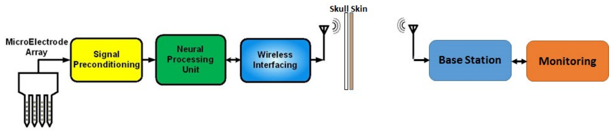

Figure 3. Wireless RF Telemetry System

Several wireless RF telemetry systems have been proposed. [7] presents a CMOS configurable wireless transceiver designed to operate at 402–405 MHz Medical Implant Communication Service (MICS) band as well as at the 420–450 MHz Industrial, Scientific, and Medical (ISM) band. Furthermore, a complete implant system has been demonstrated using this transceiver to be compliant with the newly established *IEEE 802.15.6* standard.

In [8] and [9], the authors evaluate the signal propagation in the body using the communication systems of ultra-wide band and 2.4 GHz link. [9] characterizes the UWB channel on two different subjects. For a frequency range of 1–6 GHz and for a propagation distance of 5–16 cm, a path loss model is developed. [9] studies the propagation of the frequency bands of 2360–2400 MHz, which is considered for wearable BAN nodes, and the ISM band of 2400–2483.5 MHz. This paper characterizes the path loss in-body channel scenarios showing that wireless links utilizing 2.36–2.5 GHz band are feasible for implantable medical devices.

Finally, [10] discusses the wireless power delivery schemes for the implant devices. It outlines efficient wireless power and data link schemes for the peripheral nerve recording and stimulation implants with their design requirements and safety analysis. A preliminary wireless platform achieving 100 mW for the power delivery and 4.8 kb/s for data telemetry when it has been tested in rats.

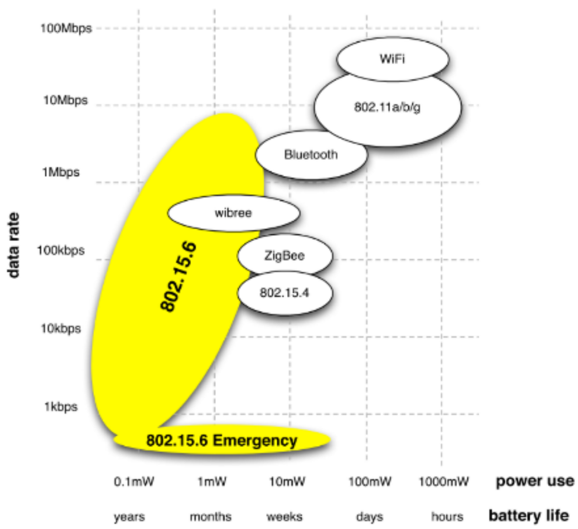

Figure 4. Technologies vs. Battery life

The relation between the battery life and data rate is dependent on the power consumption. Therefore, if it is required to conserve the battery life, then small transmission rate is used as shown in Fig. 4. It can be seen, for low data rate applications (800 kbps) over a short range (2 m), the MICS band is used, since it consumes a very-low power during the transmission and keeps a long battery life. The main disadvantage of this band is the low transmission rate and the lack of commercial products. Thus, the ISM bands have several products, which are available in the market. However, these products can be used in many devices such as smart phones, wireless Internet routers, and surveillance cameras. So, the ISM bands suffer from the interferences coming from mobile devices.

Many promising techniques can be used to increase the transmission rate. They are the following:

- Infrared Transmission
  Interference from the power carrier is the main challenge when using a separate data link. This challenge can be overcome by using infrared (IR) signaling. At 1980s, the transmission of the transcutaneous data using IR signaling has been discussed for the first time [11], and recently has been explored for high data rate (over 40 Mb/s) transmission [12] using commercial infrared transceivers. There are some challenges to be addressed before using IR signaling as an alternative solution to traditional RF techniques:
  - Power Consumption: The IR transceivers presented in [12] has *120 mW* consumed of power. The acceptable values for the power consumption should be kept in the range of *10 mW*.
  - Alignment: Alignment accuracies of 1–*2 mm* is required for the commercial IR receivers to operate properly, which are difficult to achieve with a neural prosthetic.
- Body Conduction Techniques
  The human body itself has been used as a communications channel was proposed in [13], and has been developed recently. Initial trials achieved kb/s data rates, but recently rates of 10 Mb/s with only 4.8 mW of power consumption has been demonstrated [14]. As IR signaling, the body conduction methods are insensitive to narrowband interference from the power carrier. There are several restrictions must be solved before body conduction become an choice for data transmission in the implanted devices:
  - Effect on Recording/Stimulating Electrodes: The neural recording systems generate potentials of several μV from the detected electric field, while the potentials introduced by a body conduction data link have a possibility of disrupt the neural activity being observed.
  - Electrical Contact: One point must be external to the body for neural prostheses. While previously the modeled data transfer between two points inside the body, but it must be possible to maintain the enough electrical contact between the skin surface and the external unit.

There are several communication protocols that have been used. These protocols are listed in Table I.

III. IMD Types, Body Sensors and Patient Data Classification

The IMD is defined as an electronic device which is implanted on a patient for certain purpose of treatment or to improve the function of some body part or support the user with some information. The IMD types include:

- Cardiac Implanted Devices: It's same as pacemakers. They are designed for treatment by monitoring the electrical signals of the heart and apply electrical impulses to adjust the heart pump at the desired speed [15]. The new models are equipped with pressure sensors to monitor changes which could lead to a heart failure. If there is a pressure increase, this represents a hazardous condition.
- Neuro-stimulators: These devices transmit electrical signals with low amplitude through one or more electrodes distributed within different locations inside the brain and implanted in specific area. It is also called Deep Brain Stimulation (DBS) and used to treat Parkinson, dystonia, and epilepsy.
- Drug Delivery Systems (DDS): It is implanted under the skin with a pump and a catheter. A controlled way used to supply the medication directly to the target area and the pump responsible of use a lower dose that required with oral medication [16].
- Biosensors: It have one sensor or group of sensors implanted in the body for monitor any part of it and measure some parameters to make decisions. In this IMD there is a control node (external device) exists.

Biomedical Sensors (BMSs) are implantable (in-body), wearable (on-body), and/or exist away from the body of the patient (off-body) to monitor various signals in a patient body such as EEG, ECG, EMG, heartbeat, respiratory rate, temperature, blood pressure, glucose level, mental status, RUN, and WALK [17],[18]. These types of BMSs are connected wirelessly with a centralized device, that is, body area network coordinator (BANC) [16] or body area network (BAN) [19],[20] as shown in Fig. 5. Usually, patient data is classified into four classes, namely critical data packet (CP), reliability data packet (RP), delay data packet (DP), and ordinary data packet (OP).

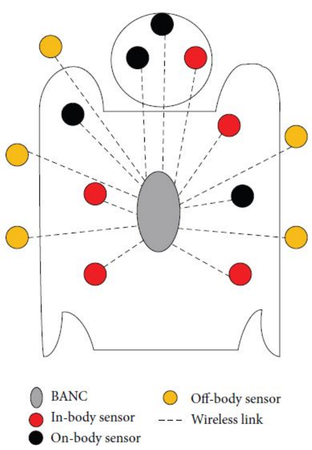

Figure 5. Wireless biomedical sensors distributed over the human body [21]

The patient data is also known as nature of data in WBAN [21]. The CP data is the most critical data, which comprises low threshold values of vital signs such as low

Table I
COMMUNICATION PROTOCOLS

Standard	Nominal TX power	Channel bandwidth	Receiver Sensitivity
Wireless Medical Telemetry System (WMTS)	10 dBm to 1.8 dB	6 MHz	—
Medical Device Radio Communication Service	- 16 dBm	3 MHz	—
Radio Frequency Identification (RFID)	—	0.5 MHz	—
802.15.6 Ultra-Wide Band (UWB)	-40 to -10 dBm	500 MHz - 7.5 GHz	-95 to -83 dBm
802.11a Wi-Fi	15 to 20 dBm	20 MHz	-57 dBm
802.11b Wi-Fi	15 to 20 dBm	22 MHz	-86 dBm
802.11n Wi-Fi	15 to 20 dBm	40 MHz	-66 dBm
802.15.1 Bluetooth Class I	0 to 10 dBm	—	—
802.15.1 Bluetooth Class II	-20 to 10 dBm	1 MHz	-70 dBm
802.15.4 (Zigbee)	–32 to 0 dBm	0.3/0.6; 2 MHz	-85 dBm

neural signal; therefore, the first slot (channel) is provided to transmit to the medical team for necessary action. The RP is the second type of critical patient data and contains high threshold values of vital signs such as high neural signal. The DP is the non-critical data; therefore, it is placed after CP data and RP data in critical data ranking category. The DP data has an audio/video streaming of a patient for physical examination. Finally, the OP is placed at the fourth position which contains routine data of the body of the patient such as temperature reading.

IV. Statistical Path Loss Model

Wireless Body Area Network (BAN) is defined as a combination of micro and advanced nano technology. It is a distinguished technology which includes a wireless network usually formed from small size ultra-low-power sensors, which are implantable, wearable or placed close to the body.

WBAN system is classified to two parts from applications point of view:

- Medical BAN
- Non-medical BAN

Medical BAN consists of wearable medical systems and implant devices to measure the health status of human body. Non-medical BAN can be regarded as consumer electronics, which can be wearable for the on-body communications.

Medical BAN can be classified as:

- Wearable BAN
- Implantable BAN

The integral parts of the body area channel are transmitter and receiver. According to “IEEE 802.15.6” document (Channel Model for Body Area Network), there are three types of nodes [22]:

- Implant node: It is placed inside the human body from direct below the skin to further deep inside the tissue.
- Body Surface node: It is placed on the surface of the skin or at most 2 centimeters away.
- External (Gateway) node: It is far away from the body by a few centimeters and up to 5 meters, so this node is not in direct contact with human skin.

To design and develop an expert and stable system suitable for WBAN, it is required to study the radio propagation channel and also the channel model. There are two types of model may be generated:

- A mathematical model
- An empirical model

A mathematical model may depend on the fundamental principles of propagation of electromagnetic. It will need a detailed propagation environment description. An empirical model may be suitable for agreed set of propagation measurements and is meant to provide a suitable basis for statistical modelling of the channel. Compared with the theoretical model, a greatly simplified description of the environment will be used by the mathematical model and although network level accuracy, will not be precised at the link level [22].

Fading: In the BAN communications, fading in propagation paths can occurs due to different reasons, such as energy absorption, reflection, diffraction, and shadowing by body. Due to the environment around the body, another possible reason for fading is multipath. Fading categories are listed as the following:

- Small scale fading
- Large scale fading

Small scale fading is concerned with rapid fluctuation of the amplitude of a radio signal over a short period of time or travel distance due to small changes in the body positions or the wearable device.

Large scale fading comes due to mobility over larger areas which refers to the signal attenuation. It happens because of the variation in distance covered by signal between external node (gateway) and body because the diffraction which comes from the large surrounding objects.

Path Loss: : It is the signal attenuation as a positive quantity measured in dB and defined as the difference (in dB) between the effective transmitter power and received power. The path loss model between two different antennas is a function of the distance (d). The free space path loss in dB based on the Friis formula [19] is expressed by equation (1) as follows:

$$PL(d) = PL(d_o) + 10nlog_{10}(d/d_o) \quad (1)$$

Where PL(d_o) is the path loss at the reference distance d_o, and n is the path loss exponent.

Shadowing: Signals transmitted in a wireless channel experience random variation by giving rise to random variations of the received signal power at a given distance due to blockage from objects in the signal path. It causes variation in path loss of signal shown in equation (1). The total path loss with shadowing can be expressed by equation (2).

$$PL(d) = PL(d_o) + S \quad (2)$$

By combining equation (1) and (2), total path loss is

$$PL(d) = PL(d_o) + 10nlog_{10}(d/d_o) + S \quad (3)$$

Another paper [23] for the path loss model used 402-405 MHz range for (MICS) which is an ultra-low power, unlicensed mobile radio service, and the operating frequency is the mid-point of the MICS frequency band, 403.5 MHz.

A statistical path loss model used for a medical implantable communication system, where path loss at a distance d from the antenna at transmitter is defined as:

$$PL(d) = \frac{G_R P_T}{P_R(d_o)} \quad (4)$$

where P_T is the transmit power, P_R denotes the received power and G_R is the receiver antenna gain.

The path loss in dB at some distance d can be statistically modelled by the following equation:

$$PL(d) = PL(d_o) + 10nlog_{10}(d/d_o) + S \quad (5)$$

where d_o is the reference distance (i.e. 50 mm), and *n* is the path loss exponent i.e. free space exponent $n = 2$. The value of the path loss exponent *(n)* is expected to increase because the human body is an extremely lossy environment. *S* is the random scatter has a normal (Gaussian) distribution with zero mean and standard deviation in dB $S \sim N(0, \sigma_s^2)$ caused by different materials.

In [37] there are two types of tissue used and they are categorized as follows:

- Deep Tissue (20 mm of the skin)
- Near Tissue (5 mm of the skin)

Another categorization of how the path loss occurs are according to:

- Implant to Body Surface
- Implant to another Implant

It also defined two different ways to find values of PL(d_o), *n* and *S* according to the above categorizations of tissue and how path loss occurs

V. Challenges in short-range Wireless Communication

There are rapid achievements in micro-technologies and micro-systems in the past years. These paved the way to the reliable, small, and low power-consuming design of biomedical devices, which can be implanted inside the body of the patient by a surgical operation. The most important benefit from these implanted devices is that it can sense the data real-time from inside the human body, which gives a good chance for early diagnosis and treatment of diseases.

With these implanted devices, patients are enabled to participate in their own treatment by monitoring and communicating their situation to caregivers. With recent advances in very low power wireless and signal processing, WBSNs have gained popularity as a potential solution. WBSNs measure and communicate different physical signals (e.g., brain activity) with the use of a group of sensors located in the body of the patient [24].

In the most complicated scenario, powering and telemetry are used to make the implanted devices communicate with remote systems. Powering is the method of delivering energy or power to the implant from the external source to make it work. Telemetry is the electronic transmission of data between distant points, such as the transmission between the implant device and exterior system. Depending on the design, there are several values of implantable device dimensions, how much power is delivered, data transmission and error rates can be achieved. Implanted devices need a very small amount of energy in order to stimulate or sense. he implanted device would become useless and have to be substituted by surgical operation if runs out of energy.

To receive energy for the early implanted devices, it interfaces with wires through the skin which is ineffective since it increased the chances of infection and it restricted the movements of the patient. Adding a battery to the implanted device is also a prohibitive solution. The total area of the implant increases so it is of no importance to care about how small the battery might be. Moreover, in the case of rechargeable batteries, it has a limited number of recharge cycles before they become completely useless. In order to maximize the battery life, one of the suitable solutions is to use a wake up system shown in Fig. 6. It makes the implant device sleep during no signal transmission and becomes up through the wake up signal only when it needs to receive the brain signal to diagnose it in an external processing unit [24].

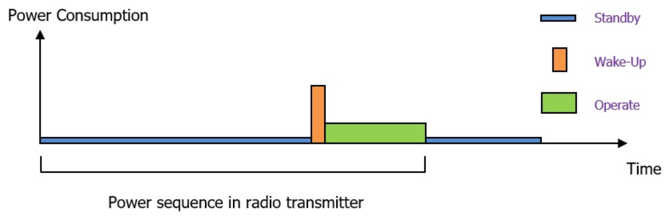

Figure 6. Power Sequence in Implantable Devices

The IMDs observe the ECoG signal by deploying high density deep electrodes inside the human brain to measure electrical activity of the neurons. Observing the activity of a great number of simultaneously measured channels is necessary for understanding the system and testing several techniques to overcome the existing problems. The increasing of the number of electrodes and channels requires a dynamic and reliable communication system to link the implantable system with the external diagnosing station. The communication system has two bidirectional (up and down) links. The uplink is used to send the diagnostic and measurable data, while the downlink is used for reconfiguring the implantable circuits.

VI. Conclusion

The quality of life for patient can be improved by IMDs and also play an important role in keeping them alive. More computing and communication capabilities are combined in the new generation of IMDs. In this paper, a survey about IMD, which is used in medical technology, is conducted. Some security issues that must be incorporated to provide the user with both security and safety guarantees are also discussed. Also an overview of the main security properties associated to the IMDs is provided. Furthermore, it's convinced that the health of the patient can be seriously threatened by a malicious adversary or some other types of attackers.

According to the problems over the different security objectives and the solutions which are proposed, it is still unclear what is the optimal choice. Saving battery life must be taken into consideration.

However, Devices must be used responsibly in order to raise security awareness. The possible threats and functioning details must be known by the users. The user should be taken into account as far as possible due to the special and delicate situation which exists nowadays. Looking even further forward, the door is open for other types of devices to improve human abilities like to the medical implants, such as perception or memory, or minimize the channel path loss. This looks certainly far ahead nowadays.

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