

Transmission Power Requirements for Novel ZigBee Implants in the Gastrointestinal Tract

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Abstract—In this paper, a novel multinode wireless monitoring platform, based on ZigBee communication standard, is presented and tested *in vivo*. The transmission power levels needed to establish a reliable connection from the different gastrointestinal districts are reported and compared with safety levels from international guidelines. These findings can be useful to evaluate the effectiveness of a commercial and standardized approach to implantable and miniaturized monitoring of physiological parameters.

Index Terms—Biotelemetry, gastrointestinal (GI) tract, implantable devices, wireless monitoring, ZigBee.

I. INTRODUCTION

THANKS to the continuous development of semiconductor technologies, personal healthcare systems will become more and more miniaturized and pervasive. An increasing amount of biomedical sensors and therapeutic units will be available for the patient to be either worn or implanted. In order to minimize patient's discomfort, a wireless bidirectional data connection with an external collector is mandatory. The first main choice for a system designer is either to develop a novel communication system, with a proprietary and customized protocol, or to choose a commercial solution, taking advantage of already available standards. In the first case, the silicon area and the power consumption can be tailored and optimized for the specific application. However, considering a future perspective where several different units would be present either inside or outside the patient's body, a commercial and standardized solution would allow a simple interconnection of these devices into a medical body area network (BAN). Even if the debate is still open [1] and the state of the art about implanted systems reported much more customized solutions [2]–[4], the number of platforms based on widespread commercial standards, such as the ones from the IEEE 802.15 standard family, is constantly increasing [5]–[7].

An important example, where wireless commercial standards have never been applied yet, is related to monitoring and therapeutic systems that can be integrated into a noninvasive capsule

format to perform endoscopic functions within the gastrointestinal (GI) tract. A significative example and an exhaustive review of the state of the art in this field is reported in [8]. Wireless monitoring of physiological parameters and wireless capsule endoscopy (WCE) promise to enable a pervasive concept of healthcare, since they can greatly reduce the level of discomfort to be tolerated by patients [9].

Taking advantage of devices that are compliant with wireless communication standards would dramatically decrease the development time and would enable an easy integration into wireless networks with other devices using the same protocol.

In particular, the most suitable standard for this kind of applications is the IEEE 802.15.4 [10], approved in May 2003. It provides a worldwide standard for personal area networks (PANs) or short-distance wireless networks for low data rate solutions with long battery life and very low complexity. It defines a physical (PHY) layer and a medium access control (MAC) layer, and is the basis for the open ZigBee protocol. The typical applications are home and building automation, industrial control and monitoring systems, wireless sensor networks, remote controls, and consumer electronics. The ZigBee alliance (an association of companies such as Philips, Motorola, Atmel, Mitsubishi) in collaboration with the IEEE is defining the network, security, and application layers above the IEEE 802.15.4 PHY and MAC layers.

The main drawback of using a ZigBee compatible device for implanted telemetry is represented by the overheads included in the standardized devices, that have to meet very broad market requirements. Furthermore, the IEEE 802.15.4 standard allocates most of the communication channels (16 out of 27) in the 2.45-GHz band. This frequency range is close to the resonance frequency of water molecules. This may severely affect the transmission efficiency from an implanted device, especially if placed in districts such as stomach and colon that are completely surrounded by living tissues. In addition, the power required to establish a reliable connection with an external unit may exceed the international regulatory levels for human safety. To the best of the authors' knowledge, these issues were not yet addressed in literature before the present study.

In this paper, a ZigBee multinode wireless monitoring platform based on commercial components is presented. The performances of two nodes, introduced in different districts of the GI tract, were assessed *in vivo*. A star network was established with an external data collector, and the lowest levels of transmission power that the implant needed to establish reliable wireless connections were recorded. These values were compared with international regulatory levels for human safety and can be used as reference levels to estimate the implant battery lifetime.

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II. METHODS

A. Implanted Units

The system architecture of each implantable unit is an evolution of the platform presented in [7]. In that work, the implant was $48 \times 33 \times 15 \text{ mm}^3$ before packaging, and it was implanted right under the skin. The present implantable device is $26 \times 14 \times 7 \text{ mm}^3$ before the encapsulation. This relevant miniaturization was obtained by using the CC2430 (Texas Instruments, Inc., USA) as the core component of the board. This IC embeds in a $7 \times 7 \text{ mm}^2$ package both a 8051 microcontroller (μC) and an IEEE 802.15.4 compliant transceiver. The μC has several features that may be useful for biomedical monitoring and therapeutic purposes, such as eight analog inputs with a conversion resolution up to 14 b and seven pulse width modulation (PWM) outputs that can be used to drive electromagnetic motors for actuation purposes. A built-in temperature sensor and battery measurement capabilities are two other possible inputs for the analog-to-digital converter. As regards the radio frequency part, almost all the features of the IEEE 802.15.4 standard are implemented in the hardware of the transceiver. The miniaturization road map [11] released by the IC producer foresees that the novel version of the CC2430, namely, the CC2630, will have a size of $5 \times 5 \text{ mm}^2$. This gives a robust motivation to pursue an approach based on commercial devices for biomedical miniaturized implants.

Another element that reduced the development time for the present system was the availability of several printed circuit boards providing the CC2430 and the radio frequency components already assembled together. In this work, the RC2300AT (from Radiocrafts AS, Norway) module was used. This module guarantees proper electromagnetic shielding thanks to a Faraday cage that covers the IC. A surface mount device (SMD) ceramic component acts as a quarter-wave resonant antenna. Due to the dielectric ceramic material, the antenna is shorter than a normal quarter wave antenna in air, still providing high radiation efficiency (typical 1 dBi). The radiation pattern from the implant antenna is similar to the donut-shaped radiation from a quarter wave antenna. The maximum radiation is in the plane normal to the length axis of the antenna. Proper power supply is delivered by a lithium polymer cell (LP20, Plantraco, Ltd., Canada). This battery has a capacity of 20 mAh, dimensions of $12 \times 9 \times 3.2 \text{ mm}^3$, and an output voltage of 4.1 V. Since the absolute maximum rating for the voltage supply of the CC2430 is 3.9 V, a diode (1N4148) was used to reduce the supply voltage down to a safe level.

The μC of the implantable device was programmed in C using IAR Embedded Workbench 7.2 (IAR Systems AB, Sweden). In order to measure the lowest transmission power that allowed a reliable communication between the implant and an external receiving unit, a firmware doing the following actions was conceived. Every second, the module woke up from a sleep state, where the voltage regulator to the digital core was turned off and the main crystal oscillator was not running. A temperature value was acquired from the sensor. Then, the device was programmed to send these data (1 B) to the external unit by using the lowest transmission power available for the transceiver ($2.7 \mu\text{W}$) and

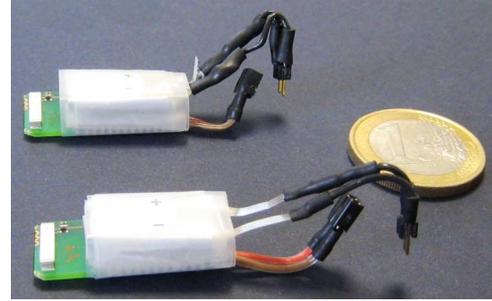


Fig. 1. Picture of the implants before the encapsulation.

requesting an acknowledgment. In case the acknowledgment was not received within 15 ms, the message was resent. This procedure was repeated for three times. If the sent message remained unacknowledged, then the transmission power level was increased and the transmission procedure was repeated. This applied until either an acknowledge was received or the maximum transmission power level (1 mW) was reached. Almost every 10 s, the transmission power was reset to the lowest level in order to restart the experiment. The selected carrier frequency was 2.405 GHz, that is one of the 16 channels in the 2.450 GHz band, as described in [10].

In order to evaluate the performances of a ZigBee star network, two implantable units were used for the experimental procedure, both loaded with the described firmware. Each unit was programmed with a different address in order to allow the receiver to discriminate the sending device. The two nodes are represented in Fig. 1 before the encapsulation.

As regards the power consumption, a rough estimation can be done considering the following basic events and the related current consumptions and time lengths.

- 1) *Data acquisition*: A 14-b voltage was acquired from the temperature sensor and converted to temperature information mapped on 1 B. This operation required $T_{\text{acq}} = 620 \mu\text{s}$ and an average current consumption of $I_{\text{acq}} = 12.2 \text{ mA}$. In a general case, these values are related to the number and the kind of sensors connected to the device.
- 2) *Radio startup*: Period of time required from the initialization of the radio part to the beginning of transmission. In this case, $T_{\text{rsu}} = 440 \mu\text{s}$ and $I_{\text{rsu}} = 30 \text{ mA}$ were measured.
- 3) *Data transmission*: The time required to send the temperature reading was $T_{\text{tx}} = 580 \mu\text{s}$. This time length depends, in general, on the number of bytes that compose the transmission payload (information to be transmitted) and on the overheads required by the IEEE 802.15.4 standard (frame control, sequence number, addressing information, frame check sequences, etc.). Adding one more data byte to the transmission payload produced a transmission time $T_{\text{tx}} = 615 \mu\text{s}$. Thus, the time required for the transmission of one single byte was $35 \mu\text{s}$ without considering the overheads. The transmission time of N data bytes can be estimated by the following equation:

$$T_{\text{tx}} = 545 \mu\text{s} + N \times 35 \mu\text{s}. \quad (1)$$



Fig. 2. Implant grasped by the endoscope before insertion in the upper GI.

The current I_{tx} drained during this step is determined by the transmission power level, and experimental values are reported in Section III.

- 4) *Acknowledgment reception*: During this period, the device was settled in receiving mode in order to wait for acknowledgment. In case of a reliable communication, this message was received almost immediately, and this step lasted $T_{acr} = 920 \mu s$, draining $I_{acr} = 30 \text{ mA}$.
- 5) *Sleep*: Each cycle ended with the device powered down for $T_{sl} = 1 \text{ s}$, draining $I_{sl} = 0.9 \mu A$.

These data were evaluated experimentally, except for I_{sl} , and sometimes were found different ($\sim 10\%$) from what reported in the device specifications. These measurements were performed with a 2 GS/s digital storage oscilloscope (TPS2024, Tektronix, Inc., USA). The voltage drop across a 1Ω resistor placed in series to the positive voltage supply terminal was acquired to evaluate the current consumption of the device. Since the current consumption of the CC2430 is almost independent of small variations of input voltage, the drop over the 1Ω resistor did not affect the quality of measurements. An average over 16 acquisitions was used to improve the measurement quality. The time and current accuracies were, respectively, $\Delta T = 200 \mu s$ and $\Delta I = 4 \mu A$. The value reported for the current consumption during the power down mode was assumed from the device datasheet, since it was below the measurement resolution.

The battery lifetime can be estimated by using the following average current consumption:

$$\bar{I} = \frac{\sum_i I_i T_i}{\sum_i T_i}. \quad (2)$$

In case of a reliable communication and considering the aforementioned basic events, this equation becomes

$$\bar{I} = \frac{I_{acq} T_{acq} + I_{rsu} T_{rsu} + I_{tx} T_{tx} + I_{acr} T_{acr} + I_{sl} T_{sl}}{T_{acq} + T_{rsu} + T_{tx} + T_{acr} + T_{sl}}. \quad (3)$$

In a general case of multiple sensors acquisition, the parameters T_{acq} , I_{acq} , and T_{tx} must be updated considering the device configuration. Furthermore, T_{sl} can be modified to meet the measurement frequency requirements of the specific medical application.

Once programmed, the implants were encapsulated in three layers of elastic silicone rubber. This gave to the devices a smooth and capsule-like shape, in order to avoid damages to the inner surface of the GI tract. A picture of the final device, grasped by a gastroscope, is represented in Fig. 2.

The encapsulation took place right before the experiment, thus allowing the connection of the power supply pack to the electronic board. A better solution would be to use a magnetic



Fig. 3. Receiver station and implants ready for the experiment.

switch to start the operation of the device once packaged, but this was beyond the aim of the present work.

B. External Receiver

For the present application, the main purpose of the external receiver was to display the received data, the address of the sending unit and the transmission power level that was used by the implant. In order to implement these simple functions, the CC2430DK board (Texas Instruments, Inc., USA) was used. This board can be battery operated and allows a very fast use of all the CC2430 features. Moreover, a liquid crystal display (LCD) and several switches can be used to interact with the μC . Since the external unit does not have any dimensional constraint, a 2.4 GHz Swivel antenna (Titanis, Antenova, Ltd., U.K.) was used to guarantee very high performances. In terms of total polarization, the radiation pattern of this antenna is almost uniform in all the three Cartesian planes.

The firmware code was conceived to receive the data from the two implants and to display on the LCD the received information. Pressing a digital switch allowed toggling between the data received from each of the two implants. In case no signal was received within 1.2 s, a timeout message was displayed on the LCD, while if a signal was received, but coming from an unexpected address, an error message was delivered. The transmission power level of the external receiver while sending the acknowledgment message to the implant was set to the maximum level available, e.g., 1 mW.

A picture of the external receiver with two implants is represented in Fig. 3.

III. RESULTS

The main goal of the performed *in vivo* experiments was to assess for the first time the feasibility of transmitting data with the ZigBee protocol from the GI tract of a living being. Once this was demonstrated, the minimum transmission power levels required to establish a reliable wireless data connection were recorded with the implants placed in different locations of the GI tract. These data can be used for a double aim. The first goal is to compare these levels with international safety regulations, limiting the human tissues exposure to radio frequency signals. The second objective is to give reference levels for

power consumption during data transmission that can be useful to estimate battery lifetime, since this task is one of the most energy demanding for the implant, particularly, if compared with sensor data acquisition.

For best possible omnidirectional radiation, the implantable module should be oriented to keep the antenna vertical. However, indoors reflections of the radio waves in metallic structures tend to spread the polarization; consequently, even if the orientation is not optimal, communication will still take place. Since the purpose of the present work was to investigate the wireless performances in an *in vivo* scenario, mimicking as much as possible the operative conditions, the orientation of the implant was not fixed and the implant was left free to move in terms of antenna orientation. This is because during normal wireless capsular endoscopy investigations, the capsule moves randomly (or with a loose controllability) inside the GI tract, under the effect of peristalsis. In order to have relevant results, all the acquired data were averaged on wide data sets of acquisitions.

The biotelemetric units were introduced in a 50 kg domestic pig, sedated with Ketamine injection method, in addition to Propofol and Stresnyl dosed intravenously. After intubation, anesthesia was maintained with enflurane. The experiments were performed in an authorized laboratory, with the assistance and collaboration of a specially trained medical team, in accordance to all ethical considerations and the regulatory issues related to animal experiments.

The external board was placed 2 m away from the animal, in the operating room environment. In order to assess the platform performances in a sort of “worst case” scenario, no particular care was devoted to preventing electromagnetic interferences coming from other instrumentations utilized for measuring physiological parameters such as electrocardiogram, pressure, and temperature.

For the examination in the colon, the device was inserted manually and the capsule was advanced with a rubber enema tube up to 20 cm *ab ano*. After the completion of the measurements (around 45 min), the device was retrieved manually.

For the tests in the upper GI, the transmitter was attached to an endoscopic grasper placed in the working channel of a gastroscope (EG-2940, Pentax, Japan). The implant was grasped on the opposite side of the antenna, in order to minimize the influence of the gastroscope on the wireless link. The device was inserted in the lower pharynx with the gastroscope and measurements were taken. Second set of measurements was performed in the middle part of the esophagus. The endoscope was advanced to 40 cm from the teeth. For the third experiment set in the upper GI tract, the capsule was inserted into the stomach with the gastroscope, Fig. 4, and the implant was left there transmitting. Each of these stops had a time duration of about 15 min. This was enough to have a statistically relevant number of acknowledged wireless communications.

The average values of the lowest level of transmission power required to establish successful communication are reported in Table I. The third column of this table reports the maximum values of planewave power densities emitted by the implantable unit for each different value of transmission power. These den-



Fig. 4. Endoscopic picture of the device in the pig's stomach.

TABLE I
REQUIRED TRANSMISSION POWER FROM DIFFERENT GI DISTRICTS

GI District	Transmission Power (μW)	Planewave Power Density (W/m^2)	I_{tx} (mA)
Lower Pharynx	533	0.009	26.4
Middle Esophagus	151	0.004	23.4
Stomach	38	0.003	22
Colon	289	0.005	24.6

sities were measured by a portable field strength meter (8053, PMM, Italy) in the closest proximity to the module antenna, having the probe oriented along the maximum radiation of the module antenna. These data can be compared with the reference levels for general public exposure to time varying electric and magnetic fields given by the International Commission on Non-ionizing Radiation Protection (ICNIRP) Guidelines [12]. The last column of Table I reports the experimental values of I_{tx} for the different transmission powers.

IV. DISCUSSION

Animal tissue strongly absorbs radio frequency power in the 2.45 GHz band [13] because this range is close to the resonance frequency of water molecules. The same hardware reported in the previous sections was able to establish a reliable wireless connection in direct line of sight (distance of separation: 2 m) with the lowest transmission power level available for the transceiver (i.e., $3.16 \mu\text{W}$). The values reported in Table I are one or two orders of magnitude higher. This is due to animal tissues absorption. The main consideration at this point must be to assess if this energy absorbed by tissues may be harmful for human beings.

At frequencies from 10 MHz to 300 GHz, heating is the major effect of absorption of electromagnetic energy, and temperature increasing of more than 1°C – 2°C can have adverse health effects such as heat exhaustion and heat stroke. Depending

on frequency, the physical quantities used to specify the basic restrictions on exposure to electromagnetic fields are current density, specific absorption rate (SAR), and power density. Reference levels of exposure are provided in [12] for comparison with measured values of physical quantities. Compliance with reference levels given in [12] will ensure compliance with basic restrictions. Established biological and health effects in the frequency range from 10 MHz to a few gigahertz are consistent with responses to a body temperature rise of more than 1 °C. Between 100 kHz and 10 GHz, basic restrictions are provided in [12] to prevent whole-body heat stress and excessive localized tissue heating. In the present work, the physical quantity that was used to assess this issue was the planewave power density. All the values listed in the third column of Table I are considerably lower than the ICNIRP reference level for general public exposure to time-varying electric and magnetic fields, fixed at 10 W/m² for a signal frequency of 2.4 GHz. Thus, the transmitter can be considered safe from the electromagnetic standpoint. However, for the introduction in the medical practice, all the steps for clinical approval must be passed anyway before this platform can be applied to humans.

The values reported in Table I point out that the stomach is the GI district where the required transmission power is lowest, while the pharynx is the most demanding. This can be explained by considering the volume immediately around the implant. Starting from volumetric considerations, it is possible to demonstrate that the inner shell that surrounds the device contributes most to the total energy absorption [14]. In case the transmitting unit is heavily surrounded by tissues and fluids, like in the lower pharynx, part of the radio signal energy is immediately absorbed in the first shell around the device, thus higher transmission power is required. In the gastric cavity, a lower amount of tissues and fluids per space unit is present around the device, thus the energy absorbed in the close surroundings is considerably lower.

Concerning power consumption, the values reported in the last column of the table can be used to predict battery lifetime. Considering the firmware presented in this paper and the battery that was used, both presented in Section II, a battery lifetime of 13 d can be obtained. This value was confirmed also by experimental evidence. Of course, the code that was implemented was functional to the presented experiment and was not conceived for long term monitoring of physiological parameters. In that case, to increase the battery lifetime, the following actions should be considered: choosing a high energy density battery and increasing T_{sl} as much as possible, in agreement with the specific application sampling requirements. Besides that, the data acquired from the sensors can be stored in a buffer and can be sent at once as soon as the buffer is full. This would minimize the overheads due to the ZigBee protocol that are added to the payload for each transmission.

V. CONCLUSION

Based on the experimental findings reported in this paper, it is possible to conclude that implantable and miniaturized monitoring of physiological parameters from the GI tract can be

achieved by using a commercial and standardized approach, such as ZigBee, for wireless data transfer. Reliable communication can be established from the different districts of the GI tract with values of transmission power that comply with international regulations. These results can be the starting point for the development of novel and miniaturized sensor networks that can be either implanted or worn by the patients and constitute a step toward the goal of pervasive healthcare and WCE.

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