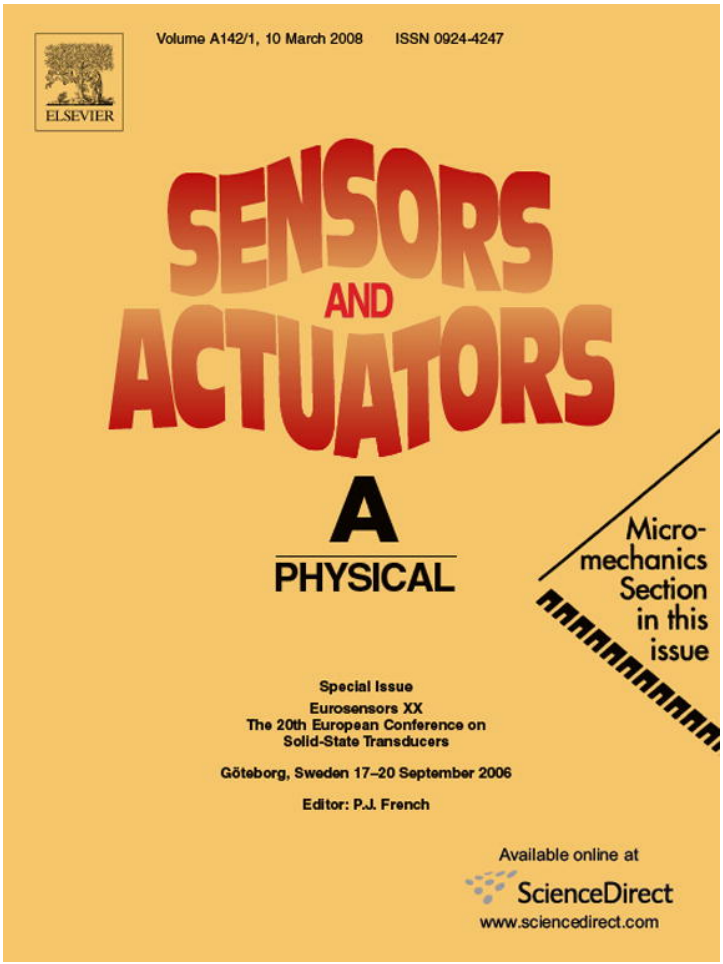

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An implantable ZigBee ready telemetric platform for *in vivo* monitoring of physiological parameters

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Abstract

This paper presents a multiple channel, bidirectional and implantable biotelemetric platform, suitable for real time *in vivo* monitoring of several physiological parameters. This system consists of an implantable unit, an external host and a user terminal. The ZigBee wireless technology, functioning as telemetric link, enables long battery lifetime and offers the opportunity to build up complex wireless networks of implantable and wearable sensors. A smart Analog Front End, that allows a real time optimization of the signals output dynamics, is also described. Different kinds of sensors, ranging from resistive to current or voltage output sensors, can be directly connected to the front end. The firmware code of the implanted unit can be reprogrammed through the telemetric link, thus enabling active interactions between the system and the end user. For the code development, particular attention was devoted to reducing power consumption: a theoretical maximum battery life of several years, suitable for chronic implants, can be achieved. In order to validate the platform, a ZigBee point to point wireless connection between the implant and the external unit was implemented. Two different sensors were used, i.e. a temperature sensor and a pressure transducer. The system performances were assessed through several *in vivo* tests. In particular, aortic and ventricular real time pressure and temperature monitoring are reported with the system implanted in farm pigs. Data acquisition was validated by comparison with medical golden standard for pressure monitoring. Finally, the lowest level of transmission power required to establish a reliable communication by using a ZigBee compliant hardware implanted under skin has been quantified as 13.33 μW during an *in vivo* experiment in an anesthetized pig. This value is fully compliant with the reference level for general public exposure to time varying electric and magnetic fields.

Keywords: ZigBee; Biotelemetry; Implantable devices; Chronic implants

1. Introduction

The range of implantable biomedical devices will increase substantially over the next 8 years, thanks to the improvements in MicroSytems Technology (MST) achieved during the last decade [1]. Percutaneous connections with leads and cables present obvious disadvantages: they limit the patient's mobility and, moreover, they can cause skin irritations or infections, thus contributing to deteriorate health conditions. Although a wireless link is not an essential requirement for physiological parameters monitoring from implanted sensors, the aforementioned issue is one of the main motivations for the trend in modern biomedical implanted systems to use wireless technology [2]. Examples of physiological data acquisition platforms with wireless links include a wide range of different biomedical applications. In [3], Coosemans and Puers obtained a continuous wireless intracavitary pressure monitoring in bladder, while other authors have assembled neural prosthetic devices [4–6]. An implantable telemetry platform for *in vivo* monitoring of several physiological parameters is proposed in [7]. This device, based on a digital microcontroller (μC), can sample and transmit up to three analog signals coming from different sensors and can be programmed in order to perform different measurement protocols. A biotelemetric system for ambulatory esophageal pH monitoring is already commercially available and its performances are well-characterized [8]. This device is attached to the mucosal wall of the esophagus and is specifically designed to diagnose gastro-esophageal reflux disease (GERD).

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Other systems aimed at monitoring pH consist of sensors placed inside a swallowable capsule that can transmit the acquired signal while traveling through the gastro-intestinal tract [9,10].

All of the above mentioned devices are custom made and each of them utilizes a different transmission frequency and protocol. This allows optimization of power consumption and minimization of dimensions, but, at the same time, limits flexibility and reconfigurability. In particular, none of these systems can be easily linked together in a wireless network of implanted sensors working in synergy with an external base station installed in the hospital or at the subject's home. Tang et al. [11] prospected a vision of the near future when single devices will be able to form a wireless sensor network comprising a large number of nodes, whose placement inside and outside the body can be either pre-determined or random, according to the application. This vision can only be achieved by using a widespread telecommunication standard for the wireless telemetric link. Standard hardware and software architectures facilitate interoperable devices that are expected to significantly influence next generation health systems. A number of these devices can be then integrated into a Wireless Body Area Network (WBAN), a new enabling technology for health monitoring [12]. In particular, the three leading contending standards for short range and low power wireless communications are Ultra Wide Band (UWB), Bluetooth and ZigBee [13]. These three solutions derive from the IEEE 802.15 Standard family and use the 2.4 GHz Industrial, Scientific and Medical (ISM) frequency band. The first one, also known as *Wi-Fi* or *wireless LAN*, has been purposely developed for very high data rates (tens of Mbps) in wireless communications, like the Radio Frequency (RF) link between two personal computers, and it is highly demanding as regards the power consumption and the overall dimensions. Since biomedical monitoring usually does not require such a high data throughput, this standard has been used for biomedical monitoring in the recent past [14], but it has been discarded as soon as more compact and power efficient solutions, even if with a lower data transmission rate, became commercially available.

Bluetooth has been primarily designed as a wireless technology for cable replacement operation, for example, among Personal Digital Assistants (PDA), mobile phones and headsets in a Personal Area Network (PAN). For such fields of application, high data rates (1 Mbps) and continuous data transfer in real time are required. This translates into quite high power consumption that limits the battery life of an implanted system for biomedical monitoring, typically to some weeks [15].

ZigBee is the name of the alliance between several electronics companies (i.e. Philips, Motorola, Atmel, Mitsubishi) established in order to develop and promote the IEEE 802.15.4 protocol [16]. The goal of this protocol is to provide a standard with ultra low power consumption, cost, and complexity for fixed or portable devices operating in a Low Rate (250 kbps) Wireless Personal Area Network (LR-WPAN).

As clearly stated by Hofmann et al. [17], ZigBee is perfectly suitable in terms of data rate for the wireless transmission of physiological vital signs. Even the continuous monitoring of an electrocardiogram (ECG) waveform, which is known as one of the most demanding biomedical signals in terms of sampling rate, was reliably accomplished using ZigBee. The power consumption due to data transmission is nearly equivalent to the Bluetooth standard, but ZigBee benefits from its ultra low power sleep mode and very short wake up times, thus achieving typical operative lifecycles of several years with no need for batteries replacement. Furthermore, the ZigBee standard enables the creation of very complex networks, thanks to address specifications that allow to connect up to 65,536 devices. This represents a very promising opportunity for the development of multi-subject monitoring applications or implantable networks with both diagnostic and related drug delivery capabilities.

Lubrin et al. have recently reported a wireless remote healthcare monitoring that takes advantage of he ZigBee wireless link [18]. This system is based on the Berkeley Motes platform [19] and each node could be used to monitor body temperature, heart rate, as well as many other parameters. However this work is focused on a set of wearable sensors and does not directly address implantable solutions.

In order to implement a standard approach to the telemetric link, a digital is almost mandatory as the core component of the remote unit. Thanks to the presence of a certain amount of digital and programmable "intelligence", it is possible to design a smart Analog Front End (AFE), capable, for example, of multiplexing the different sensor inputs, remove an eventual offset level and changing the channel amplification in order to fit the output dynamic range [15,20–22]. Furthermore, the signal conditioning parameters can be selected in real time by the user, through the telemetric link, and the sensing part of the remote board can be temporarily switched off to save power during periods of inactivity.

In the present study the authors developed an implantable, μC-based platform for biotelemetry with a "smart" AFE. A system overview of both the implanted unit and the external data collector is given in Section 2. The ZigBee standard has been chosen as the ideal candidate for the telemetric link with the implantable unit. One of the main goals of this study was to evaluate the performance of ZigBee compatible device for data transmission during an *in vivo* experiment. The power level required for a reliable transmission has been experimentally evaluated and the results are discussed in Section 3, with a particular focus on safety issues. To achieve this objective, a point to point wireless connection has been implemented, even if the ZigBee standard allows very complex network configurations. Lower layers and low level features of ZigBee stack were implemented in the chosen hardware and in the firmware, according to this goal. The *in vivo* assessment of the functionality and reliability of the telemetric link would then enable the future development of star and mesh wireless topologies of implanted and external monitoring units.

2. System overview

The whole platform is composed of the implantable unit, described in Section 2.1, the receiving unit, connected to a Personal Computer (PC) by the serial cable, and a simple Graphical User Interface (GUI), both described in Section 2.2.

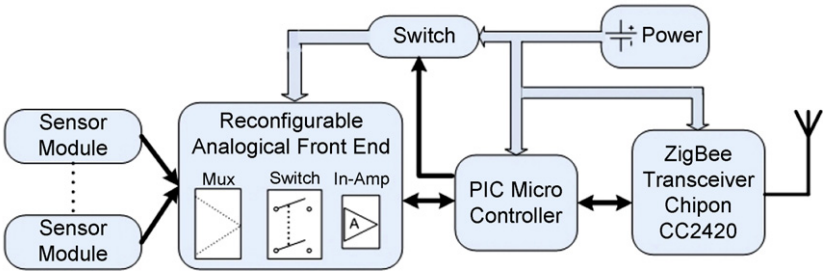

Fig. 1. Block diagram of the implantable unit.

2.1. Implantable unit

The block diagram of the implantable unit is shown in Fig. 1.

A μC controls the configuration of the AFE through an electrical switching system, therefore different kinds of sensors can be connected to the system and operated just by changing some parts in the firmware code.

2.1.1. Hardware overview

The CC2420 (Chipcon AS, Norway) has been selected as transceiver for both the implanted and the host units. This device implements several features of the ZigBee standard in its hardware structure. In particular, the entire Physical Layer (PHY) is embedded in the hardware together with some features of the Medium Access Control Layer (MAC), as the Frame Check Sequence (FCS) control for error detection. Bidirectional communication and programmability of the system over the telemetric link are two available features that play a fundamental role in achieving a high level of flexibility.

A PIC (Microchip Technology Inc., USA) family μC has been selected. In particular, the Pixie system (FlexiPanel Ltd., UK), that offers CC2420 linked to a PIC18F4620 in a smart board of 28.74 mm × 41 mm, has been used. This has suitable features for the purposes of this work, such as small dimensions, versatile power management modes and the Serial Peripheral Interface (SPI), useful to interface the CC2420 to the AFE digital potentiometers. A clock frequency of 1 MHz has been selected during normal operations, while 32 kHz has been used in the low power state in order to save energy. A Successive Approximation Register (SAR) Analog to Digital Converter (ADC) is also included inside the μC.

By comparing the radiation characteristics of small dipole/loop antennas in biological tissues [23], it is possible to conclude that loop antennas would be better candidates for biotelemetry links than dipole antennas, because of radiation performances and safety issues. For this reason, the F type microstrip antenna, already available on board the Pixie module, has been used.

The AFE is based on the instrumentation amplifier (IN-AMP in the following) INA321 from Texas Instruments Incorporated, USA. This component has been chosen for its very low current consumption (40 μA typical), the small package (5 mm × 3 mm) and because it allows a proportional gain control by trimming a resistor.

A four-channel multiplexer, MAX4692 (Maxim Integrated Products, USA), enables multi-sensor applications. A switch system has been designed in order to properly connect different kinds of sensors to the IN-AMP. The MAX4751 (four single-pole/single-throw type) and MAX4758 (four double-pole/double-throw type), both from Maxim Integrated Products, USA, have been chosen as switches for their low R_{on} resistance and their small packages, 0.9 Ω and 3 mm × 3 mm and 2 Ω and 6 mm × 6 mm, respectively. Digital potentiometers, MAX5488 and MAX5489 (Maxim Integrated Products, USA) chosen for the 3 mm × 3 mm package, have been used in order to control some system parameters, such as the gain, the offset rejection, the output for zero differential input, and the balancing when the system works in bridge configuration.

Referring to the AFE main stage electronic design, represented in Fig. 2, the INA321 gain can be selected with two resistors according to

$$G = 5\left(1 + \frac{R_1}{R_2}\right) \tag{1}$$

R_1 can be programmed through a 100 kΩ end-to-end digital potentiometer, resulting in

$$R_1\,(\mathrm{k}\Omega) = N\frac{100}{256} \tag{2}$$

where N is the 8 bit number stored in the potentiometer register. For R_2 a fixed resistor of 470 Ω has been chosen. Thus the law for the gain G results:

$$G = 5(1 + 0.83N) \tag{3}$$

The offset rejection is obtained by connecting the low input of the IN-AMP to another digital potentiometer, R_{off}, controlled by the μC, that divides the power supply level. A step resolution of 11.8 mV has been obtained with the nominal 3 V power supply. When operating in bridge configuration, the balancing can also be programmed with a 50 kΩ end-to-end resistance. In that case the resolution becomes 196 Ω.

Finally, the output level for null differential input (zero line) can also be programmed.

Taken together, these features, which can be controlled by the host through the telemetric link, allow a real time optimization of the signal output dynamic.

The unit is also able to provide a controlled voltage, ranging from 0.7 to 3 V or directly connected to the power supply. This feature can be exploited either when the sensor needs a voltage supply or for drug delivery applications.

Different AFE configurations can be obtained thanks to the switching architecture. It is possible to acquire from a sensor

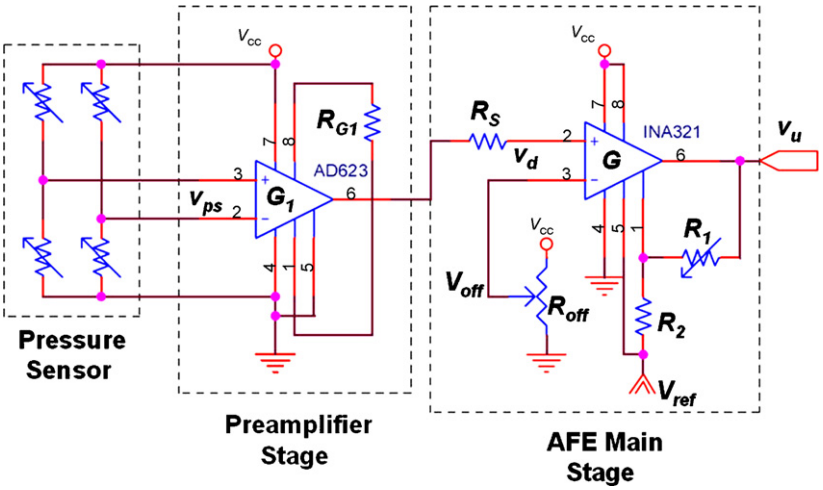

Fig. 2. AFE configuration for pressure measurements.

with a voltage output by direct connection to the IN-AMP input. The signal can also be attenuated through a resistive partition down to a factor 5. The same configuration allows acquisitions from a current output sensor. The offset rejection is also available in all of these configurations. Finally, an internal bridge can be connected in order to acquire data from a resistive sensor.

Thanks to a dedicated switch, the AFE subsystem can be shut down by the μC in order to save battery life.

To properly investigate the system performances, two sensors working close to the AFE dynamic range limit were chosen.

The first one consists of a thermistor (EC95, Thermometrics, GE Industrial Systems, USA), with a sensitivity of SV = 38.8 mV/K. The maximum offset, due to the error in the bridge balancing, is 103.3 mV.

The second sensor is a pressure transducer (LL-3-072-15, Kulite Semiconductor, USA), with an internal bridge of four piezoresistors. The small dimensions (6 mm × 1 mm × 1.3 mm) render it very interesting for implantable applications. However, LL-3-072-15 is an absolute sensor, while in medical practice the typical range is 100–120 and 100 kPa is assumed as the zero level.[1] Thus, this sensor generates an offset due to the atmospheric pressure output of 30 mV. However, for the right ventricular pressure, the maximum differential output that can be achieved is 4.86 mV (0–16 kPa), while for the aortic differential pressure it becomes 1.8 mV, with a sensitivity of 0.293 mV/kPa. Therefore the sensor needs a fixed pre-amplifying block in order to adjust the signal for the input range of the IN-AMP, so that the system is able to reject the offset and configures the gain in order to have a good output signal. The pre-amplifying stage is obtained with an AD623 (Analog Devices, USA), where the gain is fixed at 15 by R_{G1}.

The AFE configuration for pressure measurements via the aforementioned sensor is represented in Fig. 2.

The sensors have been sealed in 70 cm long catheters, and only the sensitive parts were exposed. As regards packaging of the electronic system, the same technique described in [7] was adopted.

The final prototype, before packaging, was 48 mm × 33 mm × 15 mm and is shown in Fig. 3, together with the sensing catheter.

2.1.2. Firmware overview

Since the main goal of this work is a first evaluation of ZigBee lower layers in an implanted biomedical monitoring application, a reduced version of the ZigBee stack was implemented in the μC code. The firmware, from the protocol viewpoint, was developed in order to complete the features implemented by the chosen hardware. The code was written in assembler to maintain a better time control of the hardware functions and the unemployed ZigBee features were not included, as suggested in [24]. The communication was based on "nonbeacon-enabled" [16] bidirectional data transfers and the whole Physical Protocol Data Unit (PPDU) was implemented both in hardware and firmware. All the issues concerning network creation and management were left to future improvements. Nevertheless, the

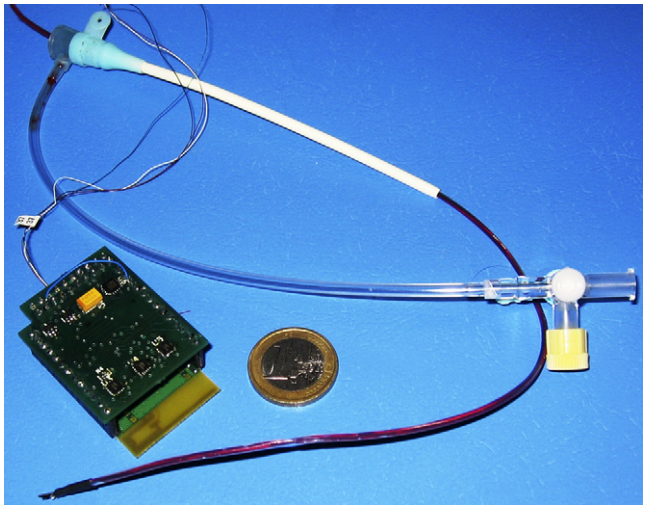

Fig. 3. Implantable unit before packaging.

[1] The atmospheric pressure, 100 kPa, is also here assumed as zero from this point.

developed code is C-compatible, making the device "ready" for an easy integration with the full ZigBee stack.

Particular care has been devoted to power management. The most demanding states, from this point of view, are reception and transmission, e.g. when the CC2420 is completely switched on. In these states the current absorption is about 30 and 18 mA, respectively. Thus the firmware is organized in order to establish the communication with the receiver as seldom as possible and always using a very short time window. Then the system shuts down and, in case of failure, it retries after a fixed amount of time.

A flow diagram of the firmware code is shown in Fig. 4.

The communication is always established by the implanted unit that chooses whenever to activate or to shut down the transceiver. In particular, after the initialization phase, a command request is sent and, as soon as an acknowledgement is received, the system switches to the receiving state. Since this is a high power state, the host must pass the command in the shortest time as possible.

The available commands are:

- modify the AFE parameters for each sensor,
- perform a calibration,
- define the transmission power,
- modify the time length of the sleep state.

The real time choice of the transmission power is key to reduce power consumption. Normally the CC2420 output power is 1 mW, but it can be reduced down to 3.16 μW. In order to avoid signal loss from the implanted unit, an acknowledgement is requested as the answer to the transmission carrying the new power level value. If this does not return within 4 ms, then the transmission power is restored to its maximum value. This strategy was used during the *in vivo* test described in Section 3 to estimate the lowest power threshold required for a reliable communication from the implanted ZigBee system.

The sensor calibration procedures implement a SAR algorithm to calculate the offset rejection level for the pressure sensor and the bridge balancing for the thermistor. In particular, for the pressure sensor, the maximum and the minimum signal levels are calculated, then the offset rejection is increased according to the SAR algorithm, trying to fit the middle value to the programmed zero line. After calibration, the system performs a data acquisition and sends it, giving a feedback to the user on the result of this process.

The main state consists of a loop in which the system switches to the sleep mode and periodically wakes up, acquires a sample and stores it in the memory. As soon as the buffer memory is saturated, the system sends all the data at once and starts waiting for a host command.

Because the data acquisition can take a long time, depending on the measurement protocol, the transceiver can be switched off even for several days, thus saving power. However, it prevents any communication between the implant and the user. If the signal to be monitored is life critical, a thresholds strategy can be defined. Therefore, if the acquired sample is outside a user-

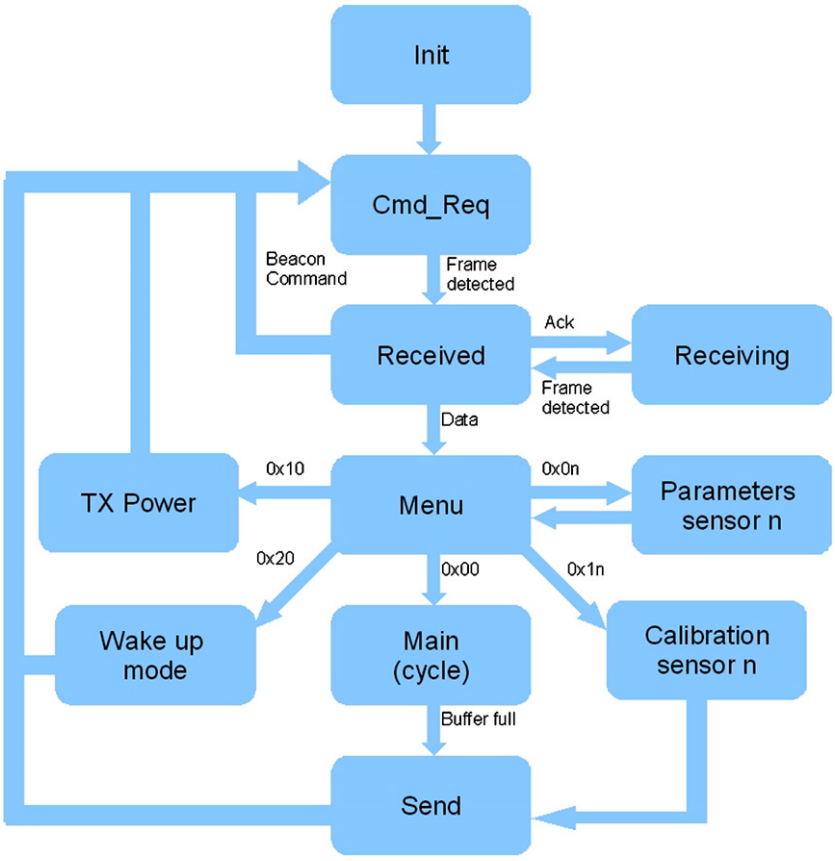

Fig. 4. Flow diagram of the implantable unit firmware.

defined range, then the system immediately transmits all the buffer and establishes a communication with the host, allowing for the user intervention.

The described firmware requires just 12.5 kB, including both of the transceiver routines and the AFE controls.

2.2. Receiver system and GUI

Although the best solution for the receiver is probably a portable version powered by rechargeable batteries and provided with large memory and PC interface, in the present study a fixed host was implemented. The host must drive the implantable unit by sending it the proper commands and by retrieving data when the implantable unit has them ready. Moreover, the host must perform all the communications as fast as possible in order to save battery life of the implantable unit.

For better time efficiency, the CC2420 used for the host is driven by a μC with a dedicated firmware and not directly by a PC. A Pixie board has been used also at the host side, and it has been linked to the PC trough the serial port. The μC located in the host board is programmed to bridge the PC user interface and the implanted unit.

A GUI has been implemented using Labview Express 7 (National Instruments, USA). This allows the user to input the commands to be sent to the implantable unit and to know when they have been received. Furthermore, it can display and store the data acquired by the implant for off-line processing.

3. Experimental results

The platform has been extensively tested *in vitro*, devoting particular attention to the AFE performances during host controlled calibration. The firmware codes of both transmitter and receiver have been debugged with the CC2420DK (Chipcon AS, Norway) developing tool. In order to minimize power consumption, the time window during which the implant waits for a response from the host has been reduced to 4 ms.

Once the correct platform performances were verified, two *in vivo* tests were executed using both of pressure and temperature sensors. The aims of these experiments were to evaluate the system in a biological context simulating a biomedical application and to estimate the lowest power level that still allows a reliable communication from an implanted device using the ZigBee standard. To the best of the authors knowledge these latter data were not available in literature before the present study.

The biotelemetric unit has been implanted in two 25 kg pigs, under general anesthesia. 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 first test was devoted to the *in vivo* evaluation of the AFE performances. Thus the pressure sensor was inserted in aorta, while the system was kept external to the animal. The results of the calibration process are represented in Fig. 5, where the outputs from the ADC (a byte value ranging from 0 to 255, determined by $v_u = V_{cc}(N_u/256)$) are plotted against time for different values of the AFE parameters.

Since all the parameters of the AFE configuration have been recorded, it is possible to obtain the differential pressure value from the schematic shown in Fig. 2. In particular, from the gain values of the pre-amplifier stage (G_1) and of the INA321 (G), the values programmed in the digital potentiometers for the offset rejection (N_{off} determining $V_{off} = V_{cc}(N_{off}/256)$) and the zero line ($N_{ref}$ determining $V_{ref} = V_{cc}(N_{ref}/256)$), it results:

$$v_u = Gv_d - V_{ref} \tag{4}$$

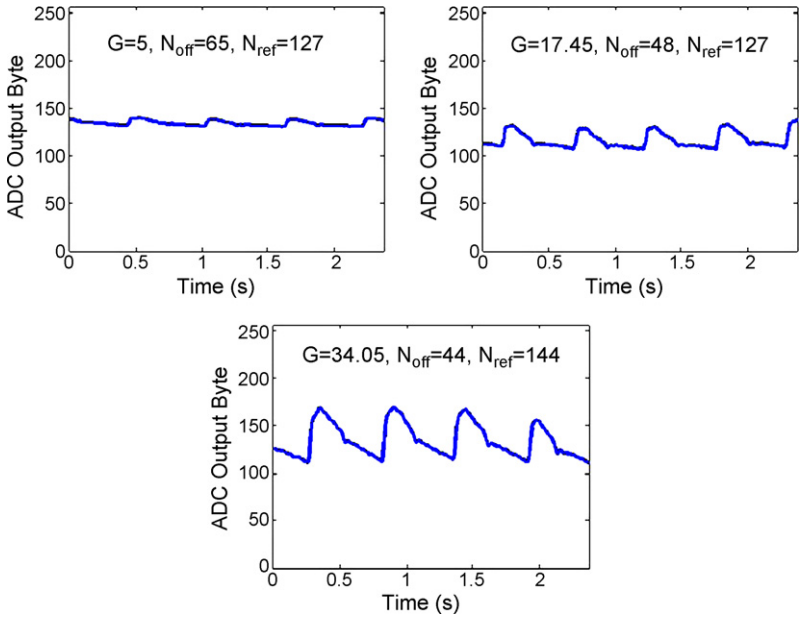

Fig. 5. Calibration procedure: sequence of acquisitions increasing the gain in order to match the signal dynamics. The INA321 gain (G), the offset rejection (N_{off}) and the zero line (N_{ref}) are indicated for each subplot.

with v_d as the differential input of INA321:

$$v_d = G_1 v_{ps} = G_1 S_p p_d \tag{5}$$

where v_{ps} is the bridge output of the pressure sensor, $S_p = 97.6 \times 10^{-6} \cdot V_{cc}$ is the pressure sensor sensitivity and p_d is the differential pressure. Thus the ADC output byte can be derived as

$$N_u = G G_1 S_p p_d \frac{256}{V_{cc}} - N_{ref} \tag{6}$$

and

$$p_d = \frac{N_u - N_{ref}}{G G_1 S_p (256/V_{cc})} \tag{7}$$

In Fig. 6 a plot of the differential pressure against time is reported.

For the temperature sensor, the AFE configuration using the internal bridge and the related calibration functions were used. A steady value of 38 °C was recorded, consistent with the animal physiological temperature. This demonstrates that AFE was capable of multiple sensors calibration and acquisition during an *in vivo* procedure.

For the second test, a healthy male farm pig was instrumented under general anesthesia. After premedication with atropine (0.01 mg/kg, IM, Zoletil, Boeringer Ingelheim, Denmark) and tiletamin-zolazepam (5 mg/kg, IM, Zoletil, Boeringer Ingelheim, Denmark), general anesthesia was induced with propofol (4 mg/kg IV, Diprivan 1%, AstraZeneca, USA). The trachea was intubated with a cuffed tube and the animal was ventilated with room air by a Servo 900 ventilator (Siemens, Germany). The implantable unit, powered with a LS14250 (Saft, France) battery, was implanted under the skin (3–4 cm depth) at chest level and the incision was sutured.

The host unit was placed approximately 2 m away from the animal, in the animal laboratory. In order to assess the platform performances in a sort of "worst case" scenario, no particular care was devoted to preventing RF interference coming from other instrumentations utilized for measurements physiological parameters such as electrocardiogram, pressure and flow.

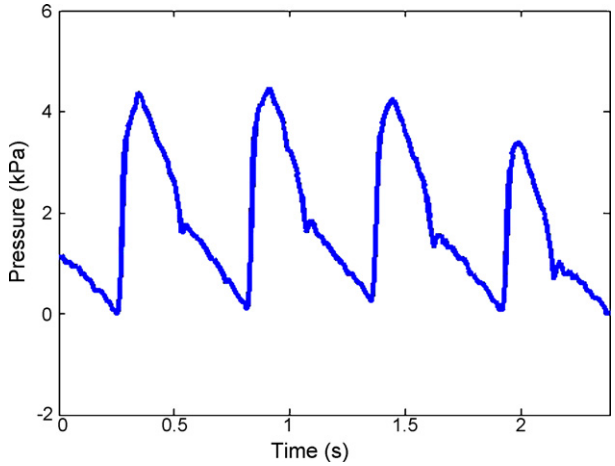

Fig. 6. Differential aortic pressure vs. time.

The CC2420 can operate with a transmission power ranging from 1 mW to a minimum of 3.16 μW in 32 steps. In order to quantify the lowest power level that still allows correct communication from the implanted device, the transmission power was gradually reduced and the number of failures among 10 transmission attempts was recorded. The lowest level not affected by transmission errors was 13.33 μW, while a complete lack of communication was observed for the 5.4 μW level.

Considering a transmission power of 31.6 μW, e.g. having a safety gap of 18.27 μW in addition to the 13.33 μW threshold reported above, the compliance with the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines [25] was then investigated. The planewave power density emitted by the implantable unit was measured with a portable field strength meter (8053, PMM, Italy). The maximum value obtained from these tests was 38 mW/m^2, much lower than the ICNIRP reference level for general public exposure to time varying electric and magnetic fields, fixed at 10 W/m^2 for a signal frequency of 2.4 GHz.

A battery life estimation can be predicted starting from this experimental evidence and assuming a transmission power of 31.6 μW. The device must operate turning on and off the single blocks when needed. Therefore, in order to predict the battery life, the mean current I_{med} must be evaluated. This can be done by assuming:

$$I_{med} = \frac{\sum_i I_i t_i}{\sum_i t_i} \tag{8}$$

where t_i is the time window when the current I_i is drained by the active devices. By using the experimental data for I_i and t_i, measured under the different operating conditions of the system, the lifetime can be predicted for two opposite scenarios. The "worst case" is the continuous monitoring. In that case the battery life would be 12 days and 12 h, assuming a 1 Ah lithium cell as the aforementioned LS14250. On the other hand, depending on the medical application, a protocol can be designed for acquiring samples every 30 min and transmitting data when 100 samples have been stored in the implant memory. In this way a battery life can be extended for decades, thus allowing chronic monitoring of physiological parameters.

The pressure sensors readings acquired by the implantable device were compared with a medical golden standard (Winpvan, Johns Hopkins University, USA). A right internal jugular vein catheter was placed for right ventricular pressure monitoring (Fig. 7). Right ventricular pressure was recorded with reference to atmospheric pressure at the mid-thoracic level. Then the pressure probe from the biotelemetry system was advanced through the left internal jugular vein and properly positioned under fluoroscopic guidance for right ventricular pressure recordings (Fig. 8).

The golden standard measurements reported a mean systolic pressure of 2.86 kPa, a mean diastolic pressure of 0.6 kPa, a mean pressure of 1.8 kPa and a heart rate of 73 beats/min. The output of the implanted pressure sensor matched the data obtained from the golden standard, as shown in Fig. 9.

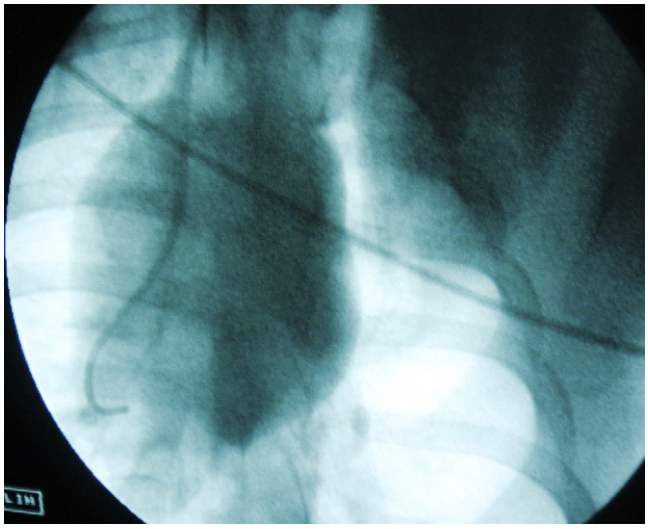

Fig. 7. Fluoroscopic image of the golden standard introduced in the right ventricular chamber.

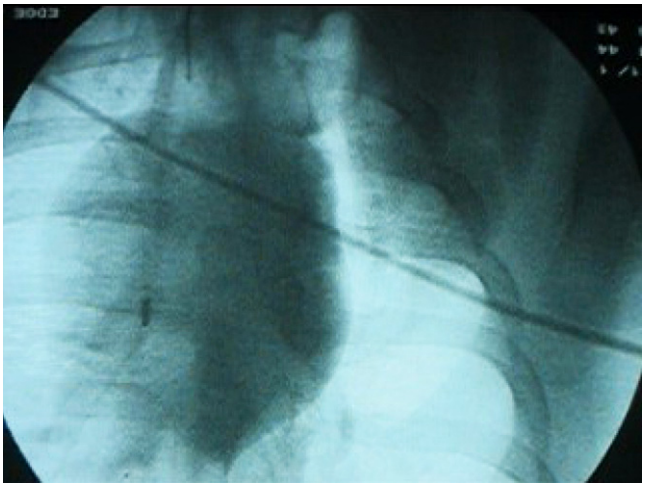

Fig. 8. Fluoroscopic image of the pressure sensor introduced in the right ventricular chamber.

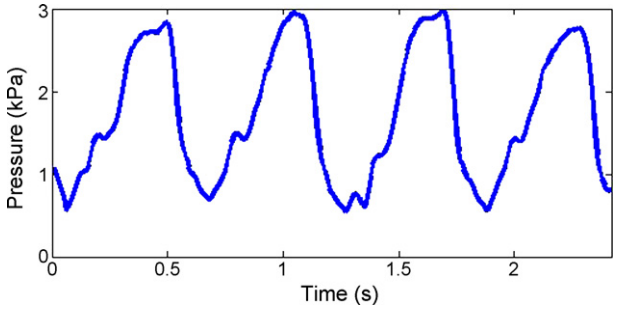

Fig. 9. A recording of the right ventricular pressure acquired by the implanted unit.

4. Conclusions and future work

An implantable, μC based, ZigBee ready platform for real time monitoring of several physiological parameters was designed, developed and extensively tested both *in vitro* and *in vivo*. It possesses a reconfigurable AFE for easy connection of several kinds of sensors, a dynamic gain control, automatic offset rejection capabilities and a customizable protocol for data acquisition and transmission.

The μC firmware sections dealing with the communication protocol were developed in order to validate the low level features of the IEEE 802.15.4 standard in an implanted *in vivo* monitoring task. This resulted in a lighter version of the ZigBee stack. In particular, the complete firmware of the implantable unit required 12.5 kB, whereas 32 kB would be necessary for the whole ZigBee stack. Nevertheless, the two main advantages of the ZigBee protocol, i.e. low power consumption and possibility to setup complex wireless sensor networks, remain available for the presented platform.

High flexibility is achieved thanks to bidirectional communication capabilities, in addition to the possibility of reprogramming the implanted unit firmware through the telemetric link.

A four-channel smart AFE was designed and developed. This system allows real time autonomous optimization of both offset and gain of the signals coming from the sensors. Thanks to a switching architecture, different kinds of transducers, ranging from resistive to current or voltage output sensors, can be directly connected to the front end. The AFE can be temporarily switched off to save power during periods of inactivity.

The dimensions of the implant, before packaging, are 48 mm × 33 mm × 15 mm. These can be further reduced by using the CC2430 (Chipcon AS, Norway), that embeds the CC2420 ZigBee transceiver and a 8051 μC unit in a 7 mm × 7 mm chip.

The lowest power required for an under skin implanted ZigBee transmission was assessed with an *in vivo* experiment. A transmission power of 13.33 μW was enough to achieve a stable and reliable communication.

The compliance of the presented system with the reference level for general public exposure to time varying electric and magnetic fields was assessed considering a transmission power of 31.6 μW, substantially higher than the threshold for a reliable communication that is 13.33 μW.

A battery lifetime of decades can be estimated in case of a very low data rate monitoring protocol, e.g. acquisition of one sample every 30 min and data transmission occurring only when the memory is full. This would enable a chronic monitoring of physiological parameters by using an implantable device.

Further *in vivo* tests demonstrated that the AFE was capable of performing multiple sensors calibration and data acquisition, thus allowing a real time optimization of the signals output dynamics. Moreover, a golden standard comparison for pressure sensing was used for additional validation of the proposed system.

Future works will be devoted to upgrade the presented platform to the "full" compliance with ZigBee. This would enable to perform a chronic multi-sensor implant and to test the platform performance in a complex and long lasting monitoring task. In addition, the overall dimensions of the implant will be reduced by using a CC2430 instead of the Pixie board and the host platform will be implemented onto a portable device, such as a mobile phone or a Personal Digital Assistant.

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