An Implantable Telemetry Platform System for *In Vivo* Monitoring of Physiological Parameters

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***Abstract*—This paper describes a microcontroller-based multichannel telemetry system, suitable for *in vivo* monitoring of physiological parameters. The device can digitalize and transmit up to three analog signals coming from different sensors. The telemetry transmission is obtained by using a carrier frequency of 433.92 MHz and an amplitude-shift keying modulation. The signal data rate is 13 kb/s per channel. The digital microcontroller provides good flexibility and interesting performance, such as the threshold monitoring, the transmission error detection, and a low power consumption, thanks to the implementation of a *sleep* mode. The small overall size (less than 1 cm^3), the power density compatible with current regulations for the design of implantable devices, and the dedicated packaging make the system suitable for *in vivo* monitoring in humans. The design, fabrication, operation, packaging, and performance of the system are described in this paper. An *in vivo* pressure monitoring case study is described as well.**

***Index Terms*—Biotelmetry, data acquisition, implantable devices, in vivo monitoring, wireless sensors.**

I. Introduction

CURRENT therapeutic and diagnostic procedures address the *quality* of patients' care and are aimed at reducing pain and discomfort. This trend leads to the development of novel monitoring systems which are minimally invasive and can be used during normal life activities. The *disappearing* of wires and cables from implanted sensors to data acquisition and storing units is a problem addressed from many research groups all over the world and supported from many international research programs.[1]

First examples of wireless monitoring systems date back to 1957: Endoradiosondes, also called the radio-pills, were developed by Jacobsen, Mackay, Zworykin, and others, and they were used in many medical and biological studies [1]. In these systems, the frequency of a *L-C* oscillator was directly changed by the parameter (pressure, pH, or temperature) to be sensed [2]. A few years later (1962), Nagumo *et al.* developed a passive echo capsule for temperature and pH monitoring [3]. In this system, the battery was replaced by a capacitor, charged with a radio-frequency (RF) energy burst which was transmitted from external circuitry.

In recent years, the interest in endoscopic radiosondes increased significantly, with efforts from various research centers and commercial institutions. An autonomous image vision system with wireless data transmission, integrated in a small pill, received recently the approval for clinical evaluation in the U.S. [4], [5]. The system is equipped with a complementary metal–oxide–semiconductor imager, a transmitter, light-emitting diodes for illumination, and watch-like batteries. The main limitations of this device are related to the image quality in terms of dynamic range, resolution, and color reliability, the lack of active control of the pill motion, and a localization procedure derived by software algorithms and triangulation process. These problems have been partially overcome by a similar device, produced by RF Norika (Nagano, Japan), which uses a wireless power transmission and possesses localization capabilities.[2] On the other hand, no detailed information about the pill performance was provided at the time of this paper and working prototypes are not generally available. Another example of miniaturized telemetry module with bidirectional transmission capabilities is described in [6]: This can simultaneously transmit a video signal and receive a control signal, in order to modify the behavior of the capsule. Thus, the power consumption can be reduced by turning off the on-board camera power during dead times.

Other devices with important clinical applications, where radio telemetry plays an important role, are implantable drug delivery systems [7], intracorporeal neuromuscular stimulators [8], chronically implanted glucose sensors for diabetics [9], [10], and pH monitoring systems for the gastro-esophageal tract [11].

Despite this great interest in biotelemetry, most of the existing telemetry systems do not take advantage of microcontroller-based architectures and digital codification of the transmitted signal [12].

This paper describes the design and implementation of a microcontroller-based multichannel telemetry system. The objective of this work is to obtain a versatile and implantable telemetry module which can read different types of sensors. Moreover, the module must be easily reprogrammable in order to fulfill different application requirements.

The fabricated device can acquire signals from three different sensors, which can be sent to an external receiver by exploiting a digital modulation and a robust error control. The firmware programmability of the microcontroller enables different programming solutions, all devoted to power consumption minimization. The receiving unit can be easily connected to a serial port of a personal computer. Acquired data are then displayed and stored using an intuitive graphical user interface (GUI).

In Section II-C, a possible firmware implementation, "threshold monitoring," is presented. In Section II-D, we de-

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[1][Online]. Available: http://www.disappearing-computer.net.

[2][Online]. Available: http://www.rfnorika.com.

TABLE I
TELEMETRY SYSTEM SPECIFICATIONS

Analog input channels	3
A/D converter input range	0..3V
A/D converter rate	25 kSa/sec max
A/D converter resolution	10 bits
Power supply	3V battery
Carrier frequency	433.92 MHz
Data rate	40 Kbps max.
Transmission range when implanted	Up to 5 meters
Transmission power	5.623 mW
Emitted plane wave power density	<30 mW/m^2
Output format	RS232C
Error checking	Parity bit evaluation
On board memory	128 bytes EEPROM
Operative lifetime	Up to two weeks
Interface between receiver and PC	Serial or USB
Size (unpackaged)	18 mm × 9 mm × 5 mm
Size (packaged with signal conditioning circuitry)	27 mm × 19 mm × 19 mm

scribe a multilayer packaging solution, suitable for the recovery of the electronic components once the monitoring is over. Finally, an *in vivo* gastric pressure monitoring test, using a miniaturized pressure sensor, is reported in Section III.

II. METHODS

When designing telemetric implantable devices, the first constraint is the selection of a carrier frequency that can go through human tissues with the lowest power transmission. Once a frequency range has been selected, commercial devices working with an appropriate carrier frequency have been considered. Finally, the transmission power level has been fixed, in order to meet the International Commission on Non-Ionizing Radiation Protection (ICNIRP) Guidelines [13].

Table I shows the telemetry system specifications.

A. Carrier Frequency Selection

The human body absorbs energy from electromagnetic waves generated by any transmission circuits; thus, electrical properties of human tissues have to be considered when addressing the design of any telemetric module. This phenomenon is caused by electric and magnetic forces exerted onto the ions present in human tissues. From an electrical point of view, the human tissue can be considered as a nonideal dielectric material [14] and can be modeled as the parallel of a capacitor and a resistor. The value of the capacitor is given by the tissue capability to align the charged molecules to an external electromagnetic field; on the other hand, the value of the resistor is given by ions mobility. Since human tissue is a multicomponent and multiphase material, with many nonhomogeneities at cellular level, the reaction of each tissue component would depend on its histological characteristics.

To better quantify this behavior, we can apply the electrical equivalent circuit $R//C$ to an infinitesimal tissue sample

$$R = \frac{d}{S\sigma}; \quad C = \varepsilon\varepsilon_0 \frac{S}{d} \tag{1}$$

where d and S are length and section of the sample, σ its conductivity, and ε its relative permittivity. From experimental plots of these two parameters[3] shown in Figs. 1 and 2, it is possible to observe the dispersive behavior due to human tissues dishomogeneities. Another important piece of information which can be derived from the plots is that σ rises asymptotically with frequency, while ε remains quite constant in tissues with high water content, like muscles, liver, and stomach. Applying this phenomenological result to the tissue electrical model, we obtain

$$\lim_{f\to\infty} |R//C|^2 = \lim_{f\to\infty} \left| \frac{1}{\sigma\frac{S}{d} + j2\pi f\varepsilon\varepsilon_0\frac{S}{d}} \right|^2 \to 0. \tag{2}$$

The interaction between implanted transmitter, tissues, and external receiver can be simplified by the electrical schematic illustrated in Fig. 3, which is derived from [15]. In this model, V_{tx} is the transmitted signal, R_{rx} models the power absorption of the receiver, R_{l1} and R_{l2} take into account the antenna efficiency and signal energy loss along the transmission path. As signal frequency grows, the electromagnetic energy absorption from human tissues increases. Thus, the received power signal becomes lower. From these remarks, it is possible to conclude that the transmission frequency has to be lower than a few gigahertz in order to avoid signal attenuation along the path. This result is confirmed from experimental studies on radiowave propagation from an implanted source [16]: By defining radiation efficiency η_b as the ratio between total radiated power for an implanted source and the same source in free space, we have $\eta_b = 1.2\%$ for a 418-MHz source and $\eta_b = 0.37\%$ for a 916.5-MHz source. The 418-MHz band is currently allocated for general telemetry use within the U.K., whereas the 916.5-MHz band is a U.S. Industrial, Scientific, and Medical frequency band.

Considering electromagnetic signals with frequency below 1 MHz, the main interaction with human tissues is the generation of inducted currents [14]. This phenomenon is strictly related to σ and ε: Therefore, it is very hard to predict the energy loss along the transmission path in different human structures.

From the stated above observations, it is, therefore, possible to conclude that a suitable frequency for the transmitted signal, in order to avoid energy attenuation in human tissues, ranges approximately between 1 MHz and 1 GHz. The hardware components will be selected in order to safely operate in this bandwidth. Section II-B will describe the performed choices.

B. Implantable Unit: Hardware Overview

A block diagram of the implantable unit is illustrated in Fig. 4: Up to three sensors can be plugged to an analog-to-digital converter (ADC) chip by a 3 : 1 multiplexer; the digital signal is sent to a microcontroller, which encodes the information and transfers them to the transmitter unit. Moreover, the microcontroller has to select the input channel for the multiplexer, implement the error checking algorithm, and switch the whole system between two working modalities: *normal* and *low power*.

The transmitter unit is a custom design double-sided surface mount printed circuit board (PCB), with size 1.8 × 0.9 cm. The core component is an 8-bit microcontroller (rfPIC12F675F,

[3][Online]. Available: http://safeemf.iroe.fi.cnr.it/tissprop.

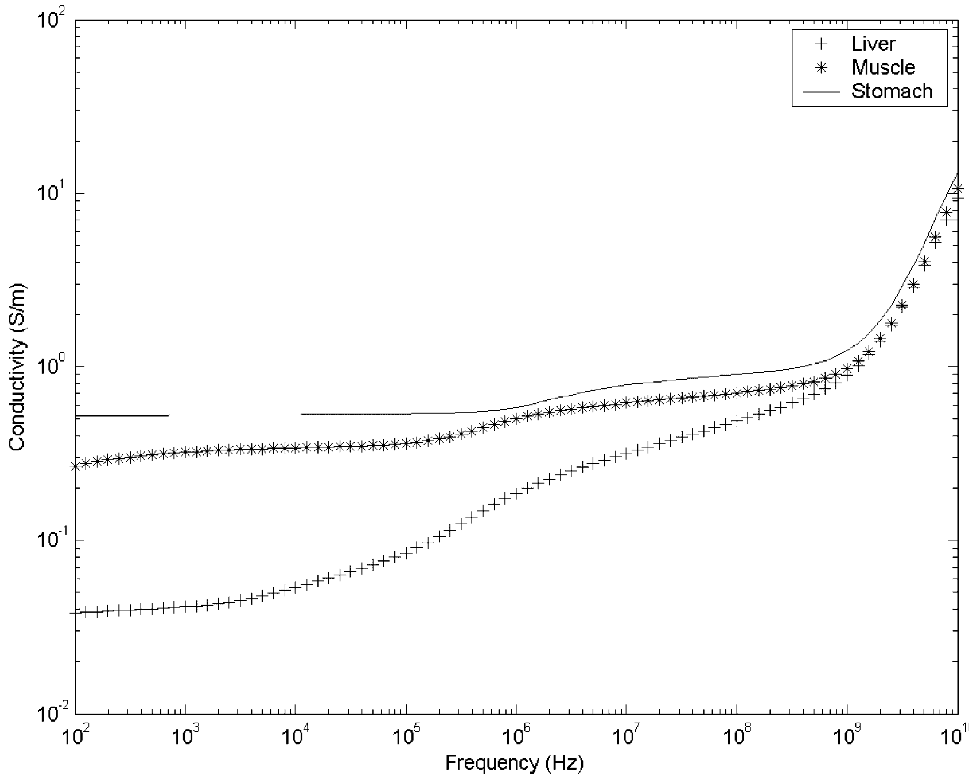

Fig. 1. Dispersion of conductivity for muscle, liver, and stomach, in the frequency range between 100 Hz and 10 GHz.

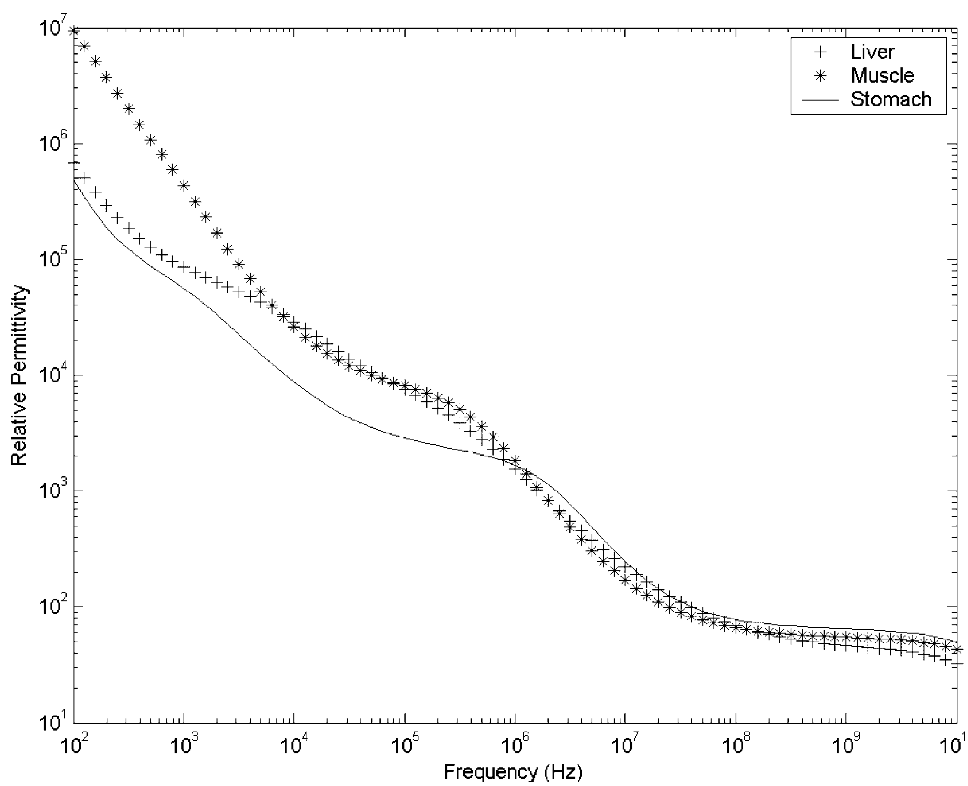

Fig. 2. Dispersion of relative permittivity for muscle, liver, and stomach in the frequency range between 100 Hz and 10 GHz.

Microchip Technologies, Chandler, Arizona, USA), which includes a Successive Approximation Register, an ADC, and a transmission module.

Each analog channel has an input range of 3 V and it is multiplexed to a 10-bit ADC, which produces two bytes for each sample. The input channel number and the sample rate are programmable. The maximum achievable sample rate is 25 KSa/s. A 128-byte electrically erasable programmable read only memory, integrated into the microcontroller, could be used for storing acquired data or software parameters.

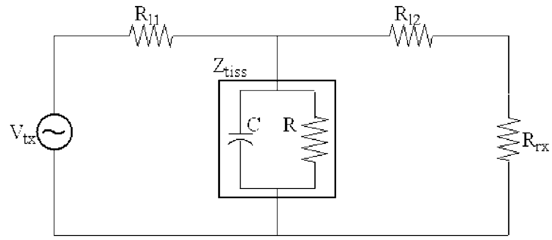

Fig. 3. Equivalent electrical circuit of the whole system.

The transmitter is a fully integrated ultrahigh frequency amplitude-shift keying (ASK) transmitter consisting of crystal oscillator, phase-locked loop, power amplifier with open collector output, and mode control logic. A transmission frequency of 433.92 MHz has been selected, from commercially available products, in order to meet the above listed requirements. The carrier frequency is fixed and determined by an oscillating crystal mounted on the PCB and connected to the transmitter. Therefore, if several transmitters are used with different crystals, the transmitted signals possess a different carrier frequency and they do not interfere with each other. This feature enables the realization of a real sensor network exploiting the same architecture.

The sampled data are encoded by using an ASK modulation, which is obtained by varying the output power. The digital modulation is more reliable and it is free from interference problems if compared to analog modulation. The whole circuit works with a clock frequency of 4 MHz; the power is supplied by a 3-V lithium coin cell (CR1025, Panasonic), with a capacity of 30 mAh at room temperature. Implanted circuit operative lifetime is related to the algorithm implemented by the microcontroller.

The battery is connected to the system via a magnetic switch (TLE4913, Infineon Technologies): Once the unit is implanted, an external user can activate the acquisition by applying a magnetic field in its proximity. A helical copper antenna with length of 17 mm, diameter 5 mm, and fabricated by a wire 1 mm in diameter is integrated in the circuit. A photograph of the double-sided transmission circuit is shown in Fig. 5.

The maximum transmission power achievable from the transmitter is 5.623 mW, using a voltage supply of 3 V. In order to check if this value meets the ICNIRP Guidelines, we measured the plane wave power density with a portable field strength meter (8053, PMM, Milan, Italy). The maximum value obtained from these tests has been 30 $\mathrm{mW/m^2}$, which is much lower than the ICNIRP reference level for general public exposure to time varying electric and magnetic fields, fixed at 2.17 $\mathrm{W/m^2}$ for a signal frequency of 433.92 MHz.

Another important feature of the system is its capability to exit from a *low power* mode as soon as one sensor signal crosses a preselected threshold. This function can be realized by using the comparator unit integrated in the microcontroller, in combination with a hardware interrupt sensitive firmware. This "threshold monitoring" is very useful to save battery power during extensive acquisition of physiological parameters.

The telemetry system has been tested *in vivo* with a pressure silicon microsensor (LL-3-072-15, Kulite Semiconductor). The sensor measures the absolute pressure with a full range of 100 kPa, and a sensitivity of 14 mV/kPa with a voltage supply of 3 V. Sensor output is a full Wheatstone bridge requiring an amplification stage: A low-power instrumentation amplifier (AD620, Analog Devices) has been mounted on a second custom design double-sided surface mount PCB, with size 1.8 $\times$ 0.8 cm. The amplifier output was connected both to an input channel of telemetry module and to the threshold comparator. The amplifier gain is $G = 42$ in order to adapt the sensor output range to the microcontroller ADC input dynamic.

C. Implantable Unit: Firmware Overview

Thanks to the microcontroller-based architecture of the implantable unit, an application-specific designed firmware can be developed and implemented by *in circuit* programming: The microcontroller is programmed by using a five-pole connector on the transmitter circuit. Moreover, this feature allows program debug during operation.

A firmware for gastric pressure monitoring was developed starting from requirements defined by physicians. The system specifications consisted of acquiring one pressure sample every 30 s, until it exceeds a fixed range centered in the value acquired at the beginning of the experiment, which is considered as the steady state value. When the pressure exits from that range, 25 pressure samples have to be acquired each second for 30 s; the final value of this acquisition becomes the new threshold value. This sample rate is higher than the rate used in previous research dealing with the same problem [17], thus, higher frequency details of the signal can be monitored. This operation modality allows power saving during periods that do not possess relevant pressure information, and a continuous monitoring when interesting events occur. This kind of "threshold monitoring" can be applied almost to all physiological parameters monitoring by adapting the two sample rates to the frequency band of the interesting signal.

Thanks to the magnetic switch, the acquisition starts as soon as a magnet with a magnetic flux density larger than 2 mT is brought in the outer proximity of the implanted unit. This avoids power consumption during implanting operations.

The data stream before transmission is encoded in the serial standard EIA232C, with 2400 bits per second, 1 start bit, 1 parity bit, and 2 stop bits. This allows the receiver to be directly plugged, via a serial level adapter, to a standard personal computer communication (PC COM) port.

In order to enhance transmission reliability, each data burst starts with 2 bytes containing the number "48," the ASCII encoding for "0" character. Moreover, for each transmitted bit, the microcontroller evaluates the parity bit and includes it in the serial codification.

Software data filtering is implemented as well: When the sensor signal exceeds the steady state range, the implanted circuit starts to acquire 50 samples per second. This oversampling allows the microcontroller to send an average value of the pressure, in order to minimize acquisition noise.

Operative battery lifetime depends on the number of times that pressure exceeds the steady state range, therefore, it cannot be exactly predicted. The maximum battery lifetime is achieved if pressure never exits from the initial range, so that one acquisition is done every 30 s; in this case, the selected battery (having

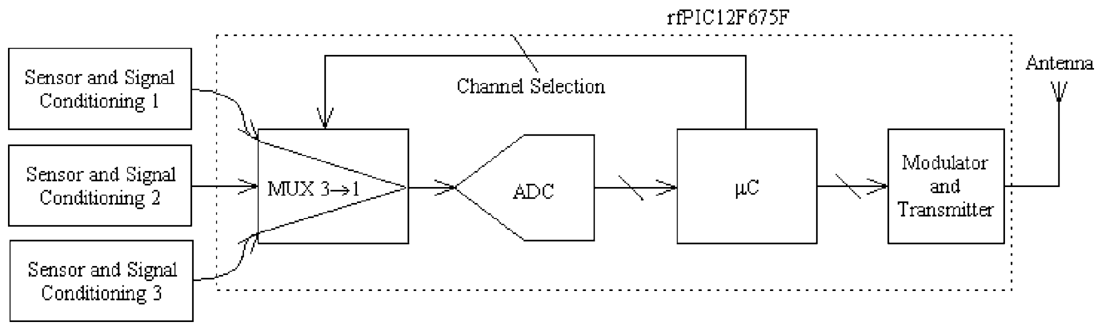

Fig. 4. Implanted circuit block diagram.

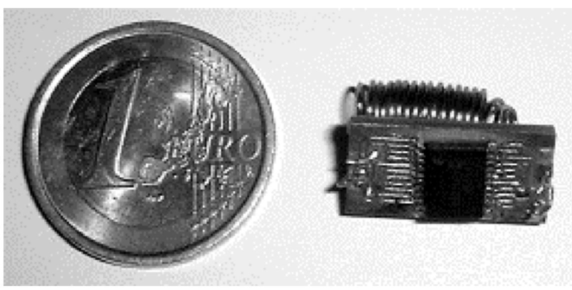

Fig. 5. Photograph of transmitter unit.

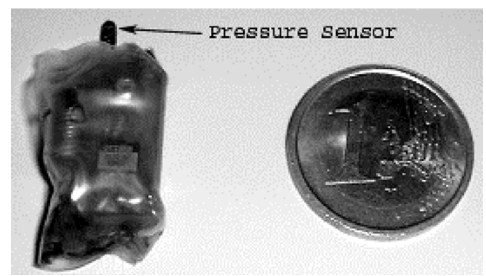

Fig. 6. Transmitter circuit covered with polyurethane film, before silicone embedding.

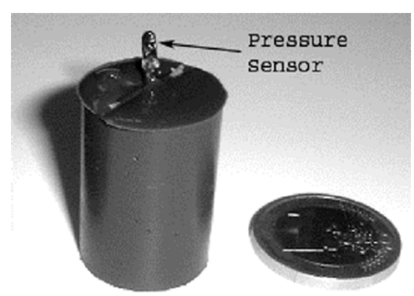

Fig. 7. Photograph of the packaged telemetry system.

a nominal capacity of 30 mAh) lasts approximately more than two weeks. On the other hand, the "worst case" could be represented by a pressure signal without steady state, which means a continuous transmission of 25 pressure samples per second; if this event occurs, the operative lifetime decreases down to 56 h. This lifetime estimation does not consider power consumption of the sensor and its signal conditioning circuitry, because this part of the system can change depending on the particular application.

D. Implantable Unit: Packaging

Several packaging options have been investigated in order to find a reliable and long-term viable solution. The package has to protect the integrity of the acquisition electronic and telemetry link, while allowing the sensors' proximity to the parameters to be measured.

Since the presented telemetry module can be used with many different sensors in different applications, a packaging suitable for rapid prototyping of a monitoring system is desirable. Moreover, if the packaging allows the recovery of the electronic circuit when the diagnostic test is over or when the battery is fully discharged, more than one implantation can be achieved by using the same circuitry during the design phase. This point is crucial, especially during the investigation and development of a new monitoring system.

Complete biocompatibility of the external packaging material is also not a trivial point.

First, packaging tests have been performed with a high tear strength silicone (GI1110, Silicones Inc.) poured directly onto the electronic circuit. By exploiting this packaging solution, the system worked properly, but many problems were encountered in the recovery of components after usage.

A two layers packaging was then implemented, as an improvement of the above preliminary technique: The external layer is soft silicone, and the inner layer is made by paraffin (K28272958, Merck). Similar solutions are reported in [9] and [10]. Although in this case the device can be simply unpackaged by mechanically removing the silicone layer and melting the wax, some paraffin debris still remains on the electronic board.

Better results were obtained wrapping the device with a 5-μm-thick polyurethane layer (MP1820, JPS Elastomerics) and leaving the pressure sensor protruding from the central body, as illustrated in Fig. 6. Thus, the device has been encapsulated in a two-part silicone elastomer (Sylgard 170, Dow Corning) using a cylindrical Delrin mold. The mixed silicone is degassed under vacuum before pouring, in order to avoid air bubbles entrapment. Afterwards, it is cast in the mold, where the polyurethane-coated device was previously placed. Two nylon wires were used to keep the transmitter suspended in the center of the mold. The curing process of the silicone lasted 1 h at room temperature. The final packaged device, shown in Fig. 7, is a cylinder 19 mm in diameter and 27 mm in height.

The after-use unpackaging gave very good results, since no silicone penetrated the polyurethane covering film: Thus, all the electronic components were successfully recovered and reused.

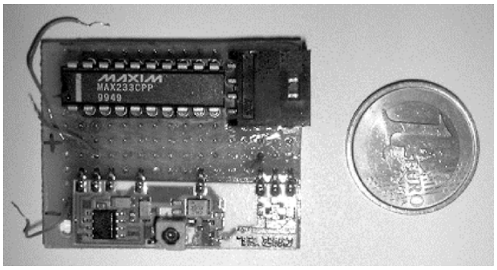

Fig. 8. Photograph of the RF receiver.

E. Receiver System

The receiver module is shown in Fig. 8. For the ASK signal reception, a commercial receiver is used (AC-RX, Aurel). It is a trimmable coil receiver, with low current and low antenna radiation. Moreover, it is highly insensitive to power switching noises. The working frequency of the receiver is 433.92 MHz, the -3-dB RF bandwidth is ± 2 MHz, and the required supply voltage is 5 V.

This module, whose overall dimensions are 38 $\times$ 12 $\times$ 5.5 mm, has been mounted on a surface mount devices board and its output has been connected to a serial level adapter (MAX233, Maxim). This integrated circuit converts output logical levels from the receiver in RS232C standard and allows a direct connection to a standard PC COM port, through a serial cable.

The same system has also been tested with a laptop PC, equipped with universal serial bus (USB) 1.0 port: Using a commercial serial-to-USB converter (205 146 USB to RS232 Converter, Manhattan), the data reception has still worked properly.

A quarter wave-length whip antenna of 17.25 cm has been used. Helical or loop antennas could be exploited as well if this antenna was too bulky for particular applications.

The receiver architecture enhances the system portability thanks both to the small size of the receiver—which could also be battery operated—and to the possibility of data transfer through a standard serial or USB port.

F. GUI

A GUI for the telemetry system has been developed using Labview 7 Express software, from National Instruments.

The GUI is flexible, in order to easily adapt it to different physiological measurements. From the on-screen control panel, the user can select the serial port where the receiver is plugged, the serial transmission data rate, the number of read bytes, and the file where writing the acquired data samples.

Another important control value to set is the "conversion coefficient," which is related to the specific application and to the employed sensor: It must be calculated during the system calibration phase. This coefficient converts the received sample, related to the voltage V_{ADC} acquired by the ADC, to the physiological parameter sensed by the transducer. In the case study of pressure monitoring, by using the previously described hardware system, the "conversion coefficient" becomes

$$C = \frac{1}{AS} \tag{3}$$

where A is the instrumentation amplifier gain and S is the pressure sensor sensitivity. Once C is evaluated, it is possible to obtain the pressure value by considering

$$P = CV_{\text{ADC}}. \tag{4}$$

As soon as these configuration values are selected, the acquisition can begin by activating the start button.

The GUI selects the valid received data bursts thanks to the presence of two bytes equal to "48" transmitted from the implanted unit at the beginning of each burst. The software also checks the parity bit of each valid byte.

The processed data are then plotted on screen and stored in a spreadsheet text file for further elaboration.

The software also displays the number of acquired samples, the acquisition time length, and the string read from the serial port. This last information is useful to check if the telemetric link is working properly. A port initialization error strobe is also present to indicate if a failure occurs during the start-up of the serial port.

Finally, the stop button allows us to finish the acquisition at any time.

III. Results

The transmitter and receiver circuitries were tested on bench in order to verify the individual building blocks and the overall functionality.

The telemetric link and its capabilities to send information through biological tissues were extensively tested *in vitro*. A transmission range of more than 5 m was measured with the transmitter covered by biological tissues (bovine spleen, liver, lung, heart, esophagus, stomach, vessels) placed in a phantom to simulate the human body (Body Form, Limb & Things, Bristol, UK). This transmission range is totally appropriate for ambulatory diagnostic examinations. If the receiver's power is supplied by a battery pack, a wearable diagnostic system can also be implemented.

The transmitter unit, equipped with the pressure sensor described above, has been implanted in two 25-kg female 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 *in vivo* test was useful to evaluate system overall performance, such as transmission range, packaging reliability, battery lifetime, and to optimize the experimental protocol. The transmitter was fixed in the gastric cavity and all the incisions were sutured.

In the second *in vivo* test, the unit was implanted in a closed pocket obtained from the stomach wall. A silicone tube linked the gastric cavity to an external 70-ml syringe, in order to allow the variation of the internal pressure by insufflating water. A flushing valve was also present in the tube, for empting the cavity from the injected water.

Several pressure variations were imposed by insufflating 370 ml of water and then opening the releasing valve. All of them were sensed by the sensor and registered by the external acquisition unit. The relative pressure variations observed were

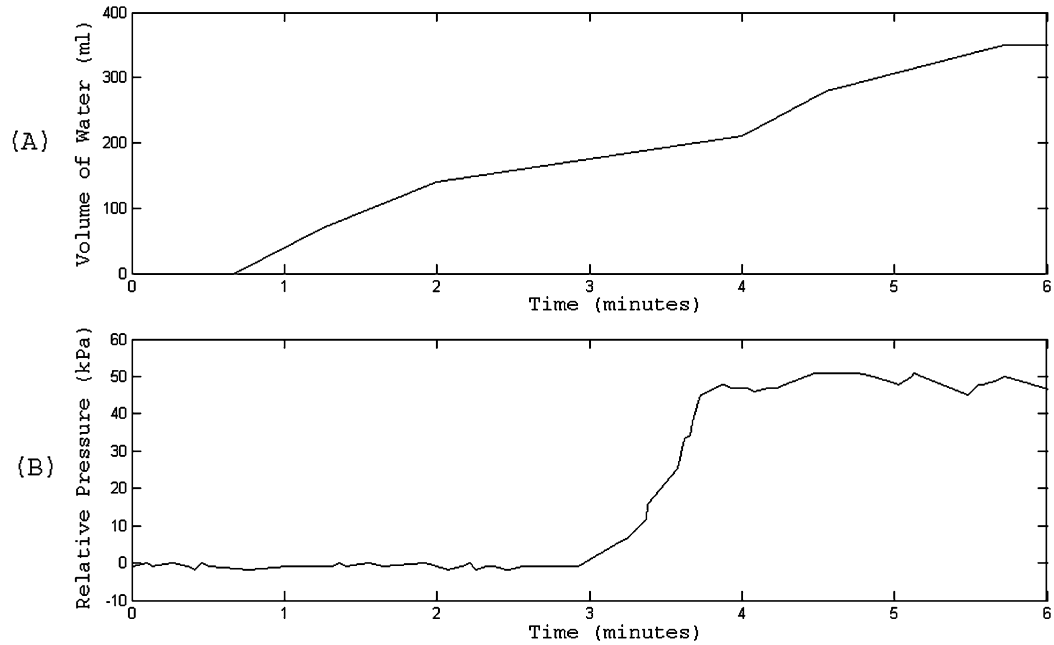

Fig. 9. (A) Volume of insufflated water and (B) acquired pressure variation in the gastric cavity.

in the range of 60 kPa. One typical plot is shown in Fig. 9: The upper trace is the volume of insufflated water and the lower is the acquired data. Comparing these plots, we observe an isobaric volume increasing for the first 3 min. During this period, the pressure signal remains in the steady state range and the transmitter sends one sample every 30 s, thus saving battery lifetime. As soon as the pressure exits from the initial range, the transmitter starts to send 25 sample per second until another steady state is reached. In the final part of the plot, a leakage of the insufflated water occurs, thus, the internal pressure stops to increase.

IV. Conclusion

An implantable radiotelemetry platform system is described in this paper. It can transmit through the human body up to three analog signals acquired from implanted sensors. The selected carrier frequency, in combination with the low transmission power (30 $\mathrm{mW/m^2}$), allows the system to meet international safety standards on electromagnetic field exposure. The small size of the electronic circuit make the system suitable for minimally invasive diagnostic tests, e.g., for gastroesophageus pressure, pH, glucose monitoring, according to the different used sensors.

A low-cost packaging technique is described as well. It allows the complete circuit recovery after use. This feature can constitute an advantage especially in future tests—when the telemetry platform will be applied to different sensors—and in any design and optimization phase. The easy-to-use receiver system allows data visualization and storing on a standard desktop or laptop PC, equipped with a COM or a USB port.

The reported *in vivo* tests demonstrate the system capabilities to acquire a pressure signal from the gastric cavity of a pig and to transmit the signal to the external receiver.

The telemetric module is intrinsically suitable to be connected to an implantable sensor network, thus producing a totally wireless monitoring system. In fact, the whole module can be replicated virtually infinite times just using different transmission carrier frequencies: This can be easily achieved by changing the crystal in the transmission circuit.

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