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Ultra low-power smart medical sensor node based on a central venous catheter for in-body biomonitoring

M. Alonso-Arce [a,*], P. Bustamante [a], C. Schmidt [a], J. Legarda [b], B. Sedano [a]

[a] *CEIT and Tecnun (University of Navarra), Pº Manuel Lardizábal 15, 20018, Donostia, Spain*
[b] *Deusto Institute of Technology – DeustoTech (University of Deusto), Av. Universidades 24, 48007, Bilbao, Spain*

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Abstract

New advances in biosensor and electronic technologies will merge in new health assistance paradigms strongly based on the remote biomonitoring. Biomedical circuit and systems have much to say on this, as for example the Central Venous Catheters (CVC). Central venous catheters are commonly used in clinical practice to improve a patient's quality of life. Nevertheless, there remains a large risk of infection associated with microbial biofilm (about 80% of all human bacterial infections). The standardization bodies, the radiofrequency devices and the biosensor technology are taking their positions, and the integration of all that effort is the work proposed in this paper.

An ultra-low power active medical implant is presented for in-body monitoring of Electrical BioImpedance (EBI) based sensors with a new 3-D antenna. Transmission test and detailed evaluation have been done based on two typical monitoring parameters: the frequency of the internal sensor measuring and the frequency of external communication requests. The results show up to 20 months lifetime powered with a 50 mA coin-cell battery.

1. Introduction

Microbial biofilms are responsible of a wide range of infectious diseases associated with indwelling medical devices. Intravenous catheters, prosthetic heart valves, prosthetic joints, pacemakers, etc. are widely used in the healthcare attention saving millions of lives, but assuming an intrinsic risk of infection [1]. Medical implants are the propitious environment for the development of bacterial biofilms, which will lead to an infection. The importance of biofilm-associated infection was estimated to represent over 80% of human microbial infections [2]. On the other hand the routine monitoring of patients is usually inefficient for detecting biofilm-related infectious pathologies [3], so the detection and diagnosis before the treatment of the infectious processes caused by microbial biofilms are not really solved. Besides the period between the infection and the detection, the process to analyze which bacteria is growing, often results too time-consuming.

In this context the infectious process not detected on time may end up in several medical complications for which, in many cases, the only way to ensure a good outcome is removing the infected device [4,5]. These events have a high cost on top of the high importance of the patient health risk under such medical complications. For this reason it is necessary to develop new devices and methods to improve biofilm early detection.

Nowadays there is a wide variety of novel techniques that allow in-depth in vitro study of the most important aspects of the formation of bacterial biofilms, from gene expression to microscopic characterization. However, there still remains a great demand in the field of in vivo detection specially for indwelling devices. To achieve this purpose it would necessary to develop new intravascular catheters that provides a continuous monitoring of the content of the reservoir of the CVC and to send an alarm signal in case of bacterial colonization. For this purpose

* Corresponding author.
E-mail address: maarce@ceit.es (M. Alonso-Arce).

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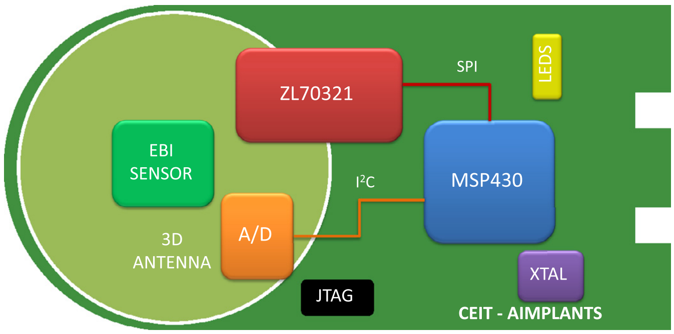

Fig. 1. Scheme of the developed platform.

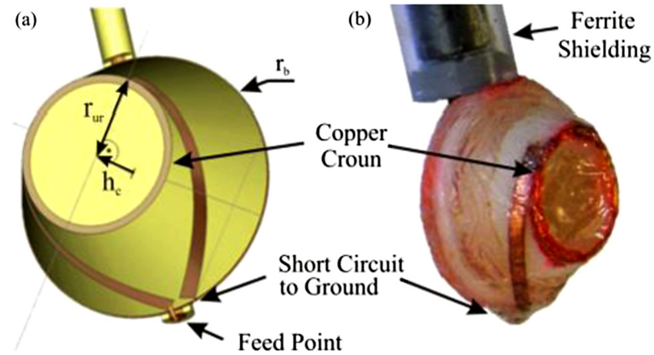

Fig. 2. SCVC-antenna showing (a) simulation model and (b) prototype.

a biosensor that could measure bacterial biofilm development is used [6]. This biosensor is an Electrical BioImpedance (EBI) which needs to measure its complex impedance.

There is a large amount of work oriented towards on-body medical devices using the ISM 2.4 GHz technologies [7–11] but they are not suitable for in-body medical implants, according to the European legislation [12], despite the availability of specific electronic devices specifically for standards like the EN301 839 [13]. This work tries to take a step forward from circuits to systems in implanted biosensor monitoring applications, integrating radiofrequency communications, embedded decision capabilities and EBIs, measuring them in an autonomous In-Body Sensor Node (IBSN).

This paper is organized as follows: Section 2 introduces the Hardware/Software implementation, Section 3 describes the duty cycle of the use case selected for the present work, Sections 4 and 5 show transmission test and an estimation of the lifetime of the implanted device and finally Section 6 gives the main conclusions.

2. In-body sensor node

This section describes the HW/SW design of a wireless IBSN for the measuring of different types of EBIs based on the AD5933 impedance converter.

2.1. Use case

The use case that has been considered in this work connects an IBSN located in a central venous access device with an external dedicated gateway device based on the Medical Implant Communication Service, which is the standard specification for these devices in the frequency range 402 MHz to 405 MHz. Afterwards, the dedicated gateway is connected to a Local Area Network where a Home Server manages and forwards the Personal Health Records to a remote Medical Server through the Internet. This work is only focused on the IBSN and its interaction with the external dedicated gateway.

2.2. Hardware implementation

The IBSN platform is composed by 4 main components: the microcontroller, the transceiver and antenna, and the sensor measuring circuit and the EBI sensor. The layout on the board of these components is shown in Fig. 1.

The core of the IBSN is the ultra low power MSP430F248 microcontroller of Texas Instruments (2 KB RAM, 48 KB Flash, 256 KB EEPROM). It is a 16-bit RISC microcontroller with 4 different low power modes, between 0.1 µA in Off mode (RAM Retention) and 0.3 µA in Standby mode. The operation voltage is between 1.8 V and 3.6 V.

The transceiver is the ZL70321 of Zarlink Semiconductors, a complete MICS radiofrequency (RF) telemetry transceiver that meets the regulatory requirements. The main power features can be summarized as follows: 2.05 V to 3.50 V supply voltage, 5 mA in continuous average transmission and reception, 1 mA idle power mode, and 2.4 GHz ISM wake-up (290 nA at 1 s strobe period).

Along with an efficient electronics, an adequate antenna design is mandatory. A stable long range communication together with low power consumption requires the antenna to be insensitive to changing human tissue properties, which vary with age, sex and anatomy. Although the MICS frequency band is 402–405 MHz, the broader operating bandwidth is necessary.

While the top part of the liquid reservoir is close to the skin, this area is disregarded as antenna locus. That area is to be unobstructed for liquid exchange capability purposes between the implant inner reservoir and external catheters or syringes.

Therefore the antenna is determined to be three-dimensional, conformal to the side walls of the reservoir. Ideally it is low-profile as no extra volume should be added on the SCVC. The antenna is to be insulated from the body, preventing harmful physiological interaction with the surrounding tissue.

The shape of the supporting reservoir is given to be a truncated cone with a base radius $r_b = 16$ mm, upper radius $r_{ur} = 10$ mm and height $h_c = 16$ mm (Fig. 2a).

Taking these constraints into account a monopole-like structure as the radiating element is selected. The base of the cone is covered by a copper film. A short circuit between the end of the monopole and this ground plane is implemented as miniaturization technique. By using a narrow, closed loop on the top of the implant the input impedance is adjusted to 50 Ω (Fig. 2). The antenna structure is coated with a thin biocompatible synthetic film and sealed with silicone adhesive. The antenna is designed within a single skin tissue phantom as a surrounding environment and simulated (Fig. 3).