Implantable Intelligent Bladder Pressure Sensor

Anusha Bandari, TAlekhya Chaudary, Ibrahim Patel

Abstract: In recent days, there has been major improvement on implantable biomedical systems that support most of the functionalities of implantable medical devices uses wires or wireless radiofrequency telemetry to communicate with circuitry outside the body. However, the wires are a common source of surgical complications, including breakage, infection and electrical noise. In addition, radiofrequency telemetry requires large amounts of power and results in low-efficiency transmission through biological tissue. Communication with implanted devices is usually accomplished with a wired connection or with wireless radiofrequency (RF) transmission. However, wires can break, become infected or introduce noise in the recording through movement artifacts or by antenna effects. Complications with wires are frequently reported with deep brain stimulation devices and with pacemakers and implantable cardioverter-defibrillators. Wireless RF telemetry has been used in several implantable medical devices to avoid the complications of wired implant. However, wireless RF telemetry requires significant power and suffers from poor transmission through biological tissue. RF telemetry also needs a relatively large antenna, which limits how small the implantable devices can be and prevents implantation in organs such as the brain, heart and spinal cord without causing significant damage.

Keywords: Wireless Power, Transmission, Duplex ASK-LSK, Low Power, Implantable Device.

I. Introduction

Physiologists and scientists have been seeking to develop wireless and implantable sensing devices for direct and reliable measurement of biological signals which are difficult to access using surface recording techniques. Nowadays, these systems share many features and basic components, and are being used in different applications such as neural signal recording, functional muscular stimulation, and neural prostheses. Due to implant size limitations in a wide range of applications, and the necessity for avoiding wires to reduce the risk of infection, wireless operation of implantable biomedical Microsystems (IBMs) is expected.

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Hence, an IBM is usually interfaced with an external host through a wireless link. In order to minimize the complexity and size of an implant, most of the signal processing units are kept outside the body and embedded in the external host. Moreover, the power needed for the implant modules including a central processing and control unit, stimulators and sensors is transmitted by the external host via wireless interfacing. The wireless link is also used for bidirectional data transfer between the implanted device and the outside world. Thus, as shown in Fig. 1, the wireless interface on the implant needs to contain a power regulator, a demodulator for receiving control/programming data (forward data telemetry), and a modulator for sending the recorded signals and implant status to the external host (reverse data telemetry).

Day by day increase in the complexity of IBMs leads to demand for sending higher power and data rates towards the implants. This is more noticeable in high-density stimulating microsystems such as an artificial body part. Therefore, forward telemetry, which is the main focus of this propose paper, has an important role in today's high performance IBMs. Design of RF links for power and data telemetry is usually performed based on both system level aspects (i.e., functional architecture and physical structure), and power transfer efficiency and data rate requirements. This includes physical design of the link, carrier frequency and power of the RF signal, data rate, and also modulation scheme considered for forward and reverse data telemetry. It should be added that there are other important concerns that need to be studied in this area, such as safety levels for the exposure of the human body to electromagnetic waves.

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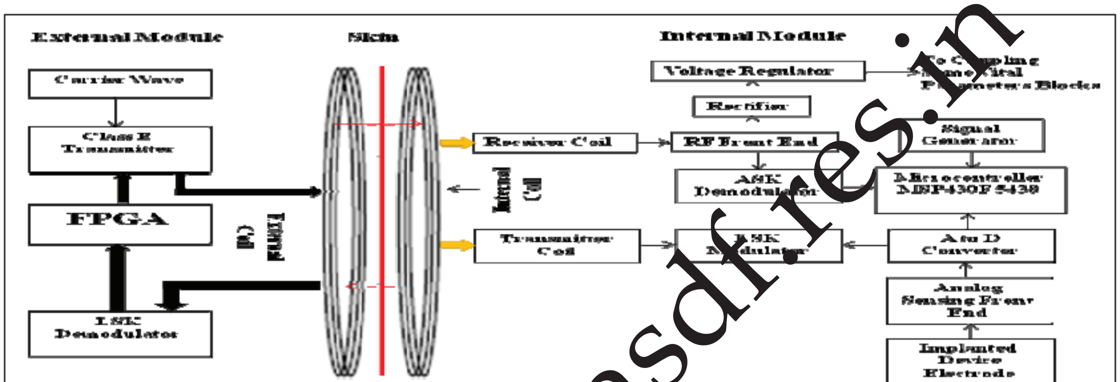

Fig. 1: General block diagram of the wireless interface of the system.

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The conductive properties of the body can be used to enable wireless communication with implanted devices. Several methods of intrabody communication are described and compared. In addition to reducing the complications that occur with current implantable medical devices, intrabody communication can enable novel types of miniature devices for research and clinical applications shown in fig.2.

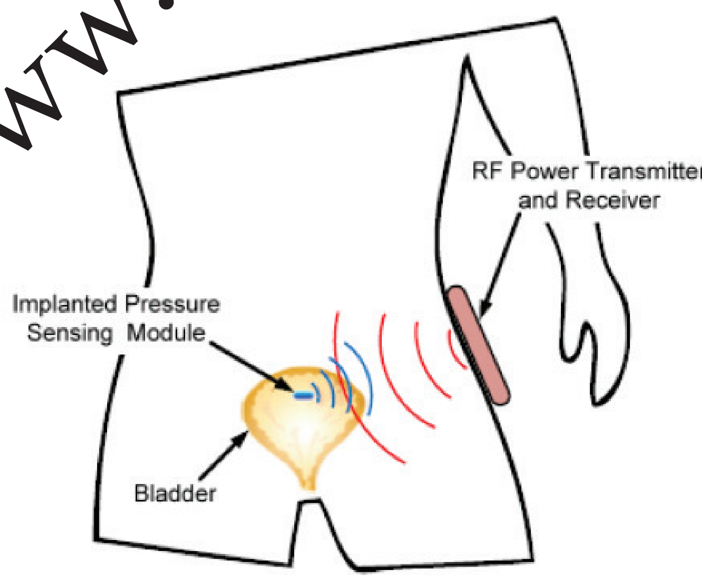

Fig. 2: The implanted module is validated in transcutaneous in the human body

Implementing wireless transmission for implanted medical devices involves two key design issues, namely the transcutaneous coupling of the power and commands to the implanted module and the subsequent outward transmission of the sensed data. Regarding the inward transmission, the efficiency of the power coupling and the demodulation of the inward data are two major concerns. In a transcutaneous coupling, the commands are embedded in a radio frequency (RF) carrier signal, which also transmits the necessary power to drive the battery free implant (Huang and Oberle 1998, Murakawa *et al* 1999). An inductive link between the external and internal modules is generally preferred since this particular arrangement yields a high-power coupling efficiency and is typically less complex. The inductive link is particularly suitable for powered implants within an acceptable close distance (Heetderks 1988, Troyk and Schwan 1992, Akin *et al* 1998). Two coupling strategies are commonly employed to facilitate the backward telemetry of data from the implant to the external module. One approach is simply to use the same inductive field as the inward transmission medium and to utilize the impedance reflection principle to convey the data (Tang *et al* 1995). The second approach is to use an additional RF carrier field as the transmission medium and to employ an appropriate modulation technique

II. Biological Effects of Electromagnetic Radiation

Electromagnetic fields generated by telemetry systems can potentially lead to power dissipation in living tissues and consequently cause damages to the tissue that are sometimes irreversible. Hence, when designing a device capable of wireless data exchange with the external world, it is an inseparable part of the designer's responsibility to make sure that the RF energy generated by the device fulfills the safety levels enforced by the standards for the exposure of human body to RF energy. This is a major concern in the design of wireless portable devices such as laptops and cell phones, and IBMs are not exceptions. Designer of a wireless link needs to make sure that potentially hazardous fields are not exceeded, as indicated in some electromagnetic safety standards. One of the well-known resources in this area is the IEEE standard for safety levels with respect to human exposure to radio frequency electromagnetic fields, 3 KHz to 300 GHz (IEEE Std C95.1- 2005).This standard emphasizes that radio frequency (RF) exposure causes adverse health effects only when the exposure results in detrimental increase in the temperature of the core body or localized area of the body. For frequencies between 100 KHz and 3 GHz (which are used in most telemetry applications), basic restrictions (BRs) are expressed in terms of specific absorption rate (SAR) in the standard. This is, indeed, the power absorbed by (dissipated in) unit mass of tissue.

III. Rechargeable Implantable System

Fig. 2 shows the proposed battery and other implanted system. The skin of human is assumed to be located between the External Module and the Internal Module. The wireless communication technique adopts an ASK (amplitude-shift keying) (inward) and a LSK (outward) methods. The power and command packets can be transmitted to the internal module by an inductive link of the pair of the coils. On the other hand, the implanted pacemaker status can also be transmitted to the external module by the inductive link simultaneously. The detailed descriptions of each block are described as in the following sections.

A. External Module

The External Module is composed of an FPGA (field programmable gate array), a Class E Transmitter, and an External Coil and a LSK (load-shift keying) Demodulator. The FPGA is used to generate the serial digital signal output according to the packet of the configuration settings for the user. The digital signal is sent to the Class E Transmitter to be modulated which is then transmitted from the External Coil to the Internal Coil by the inductive link. Fig. 3 shows the schematic of the Class E Transmitter and the LSK Demodulator. The description of Fig. 3 is given as follows.

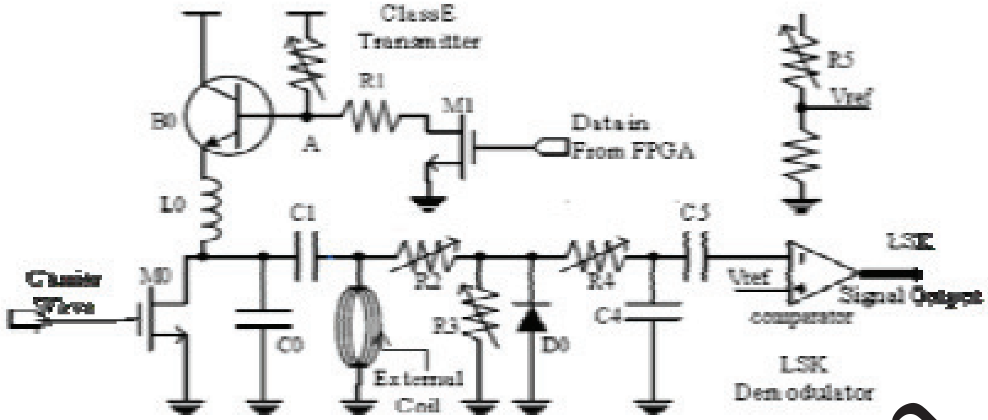

Fig. 3: Schematic of the Class E Transmitter and the LSK Demodulator

LSK Demodulator: The LSK modulation method utilizes an impedance reflection technique, which is usually adopted in RFID (radio-frequency identification) or biomedical systems. When the load impedance variation of the internal LSK Modulator is reflected to the External Coil by the inductive link, the resonant point leading the amplitude of the modulation signal is changed. The aim of the divided resistor series, R2 and R3, is used to reduce the modulation signal to an appropriate voltage, which the diode, D0, is used to be a half wave rectification. A low pass filter is composed of R4 and C4, which is adopted to smooth the half-wave modulation signal, which will be passed through C5 to the negative input of comparator. By comparing with Vref, the output, LSK signal, can be recovered to the same as internal LSK control signal from the Baseband Circuit.

B. Internal Module

The Internal Module is composed of the SOC (system on chip), the Li-ion batteries, analog switch ICs (MAX4525), and other off-chip discreteness. According to the external control signal, Internal Module (or called pulse generator) generates corresponding stimulating waveforms to the nerves. The detailed description of each block is described as follows.

Ask Demodulator: The proposed ASK Demodulator is employed to demodulate the modulation signal received by the Internal Coil into a digital signal, which is shown in Fig.2. Because the amplitude of the modulation signal from the Internal Coil is large, the modulation signal must be reduced into an appropriate potential by Voltage Divider to the ASK Demodulator. The modulation signal is rectified to a half wave by the Rectifier. The Envelope detector is adopted to enhance the headroom of the rectified half-wave. The Load driver is basically a CMOS buffer, which is used to improve the fan out capability. By using the ASK Demodulator, Demo out can be restored the same as the external digitally serial data.

IV. Methodology

Fig. 3 presents a flowchart of the inward transmission of power and commands to the implanted module and the subsequent outward transmission of the sensed data. A up based controller utilizes a developed by using embedded C software to specify the sensing configuration required for data acquisition as well as to visualize the data. The current wireless transmission setup adopts the half-duplex transmission mode in which either the inward commands or outward sensed data were transmitted wirelessly. Initially, the internal module is in an idle condition, waiting to receive commands from the external controller. Having sensed the signal data, the internal module transmits the sensed data to the external module via inductive coupling. During the data outward transmission period, the external transceiver simply transmits a pure power carrier signal to the internal module hich can minimize the interference.

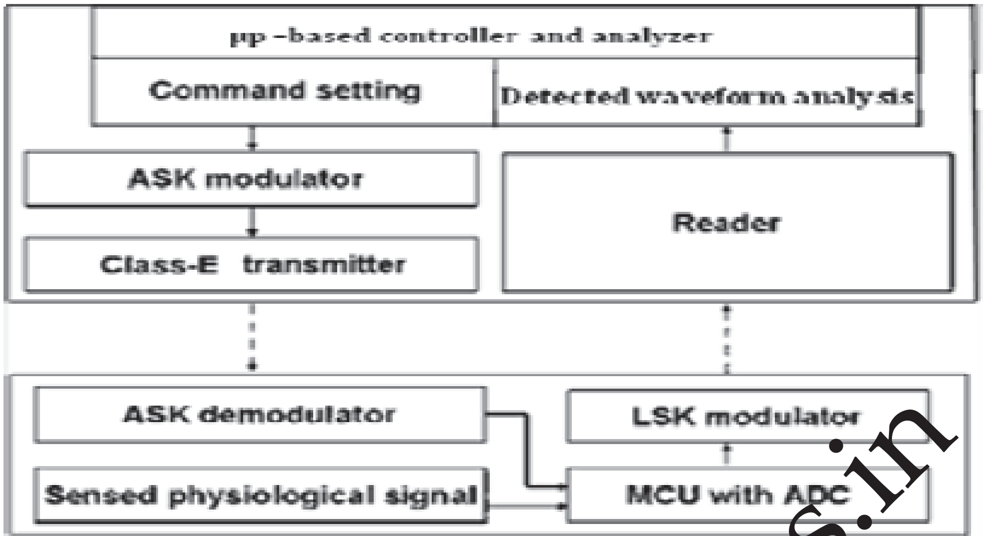

Fig. 3: power and commands in the inward direction along with physiological signals in the outward direction

A. Transmission of Physiological Signals in The Outward Direction

Having received the combined power and command signal, the internal module sets up the sampling rate and channel for sensing the biological signals and then executes backward telemetry with the external module to transmit the sensed data to a PC for further processing. The receiver coil is 2.5 cm in diameter and the transmitter coil is wound around the perimeter of the printed circuit board. The photograph of the implantable sensing device before casting with its receiver and transmitter coils, and of the developed RF transceiver coil, is shown in figure 4 and 5. The key components of the outward transmission path are presented in the following sections.

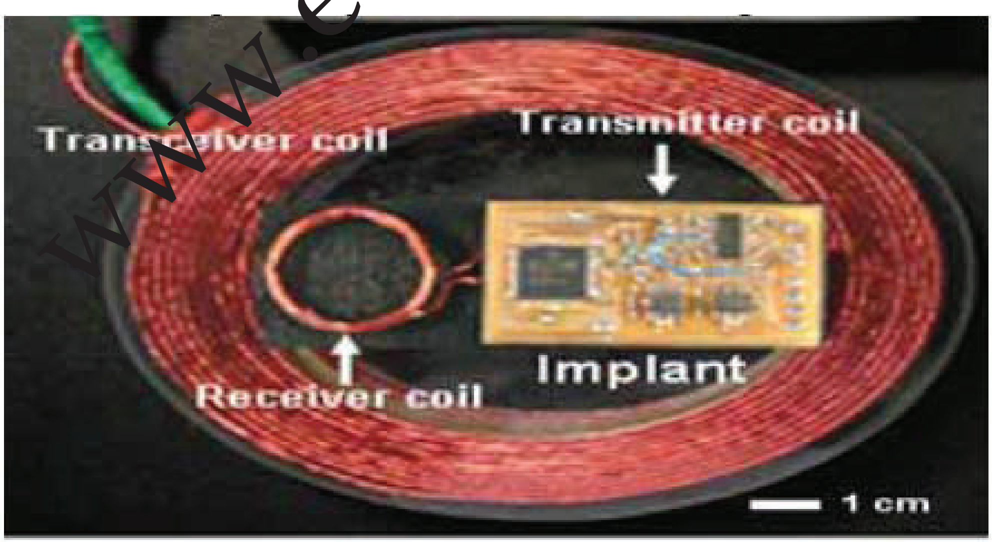

Fig. 4: Photograph of the implantable wireless sensing module before casting with receiver coil (for inward power/command receiving) and transmitter coil (for outward data transmission), and of the transceiver coil of external read.

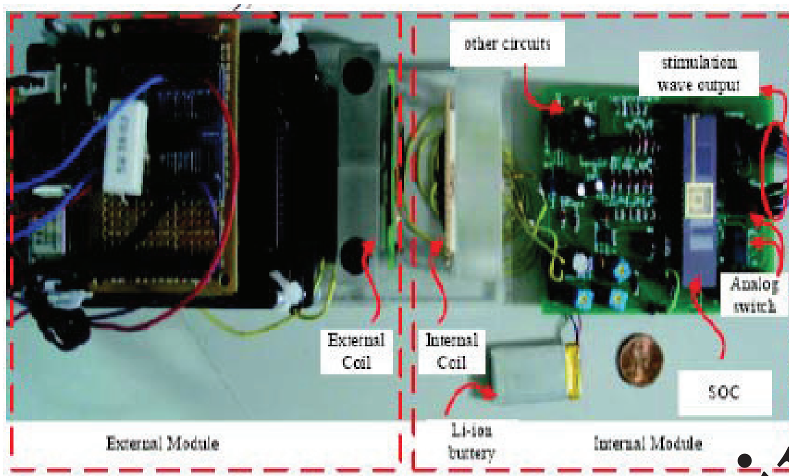

Fig. 5: Internal and External Circuit diagram.

B. Data Acquisition Using Microcontroller Unit and Sensing Front End

Low-noise instrumentation amplifiers with high common mode rejected ratios (CMRR) (>110 dB at gain = 1000) (IA, INA118) are used to perform an initial amplification of the recorded biological signals. A quasi-tri polar cuff electrode is used to sense the ENG signals from the peripheral nerve (Donaldson *et al* 2003). The recorded signals are amplified (gain: 10 000) and band-pass filtered and are then digitized by an analog-to-digital converter (ADC) at 10-bit resolution. The data acquisition process is controlled by an SMD-type microcontroller (MSP438F5438) with embedded ADCs. The entire sensing front-end is shielded to minimize the effects of magnetic interference.

V. Simulation and Implementation

TSMC (Taiwan Semiconductor Manufacturing Company) standard 0.18 μm CMOS technology is adopted to carry out the proposed Baseband Circuit. Fig. 4 shows the die photo of the proposed Baseband Circuit, where the area is 1800 × 1250 μm2. Fig. 6 exhibits the modulation signals of the External Coil and Internal Coil. The modulation signal of the Internal Coil can be demodulated to a serial of digital signals by the ASK Demodulator. The LSK control signal is given to the LSK Modulator to change the load impedance, which is then reflected to the External Coil. Thus, the amplitude of the External Coil's modulation signal is changed as well. Furthermore, the rectified signal of the External Coil and the LSK demodulation signal are shown in Fig. 7. The LSK demodulation signal is the same the LSK control signal. Therefore, the full-duplex transmission is realized. Fig. 8-9 show the stimulation waves, which are, respectively, measured in different conditions.

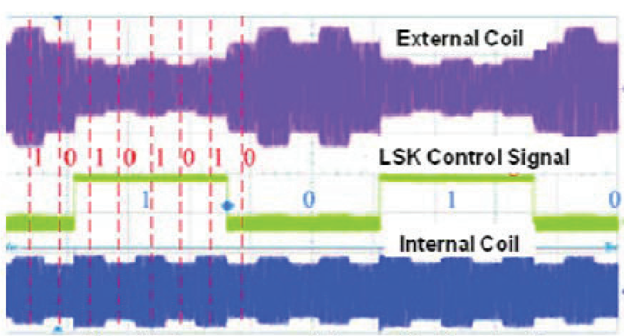

Fig. 6: Measurement of the modulation signal.

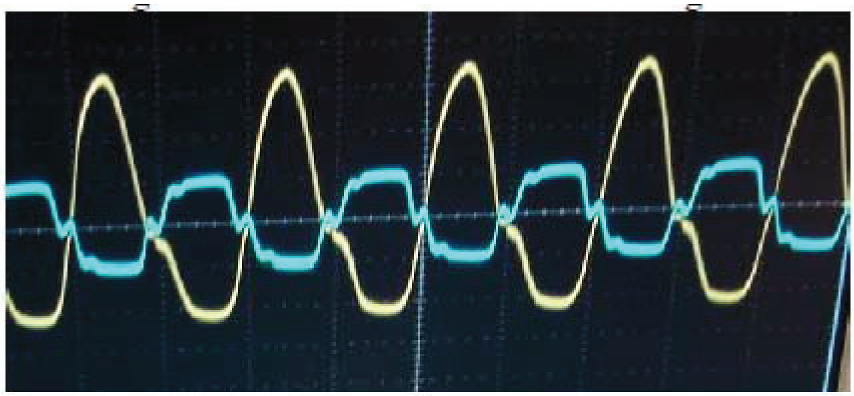

Fig. 7: Measurement of the LSK demodulation

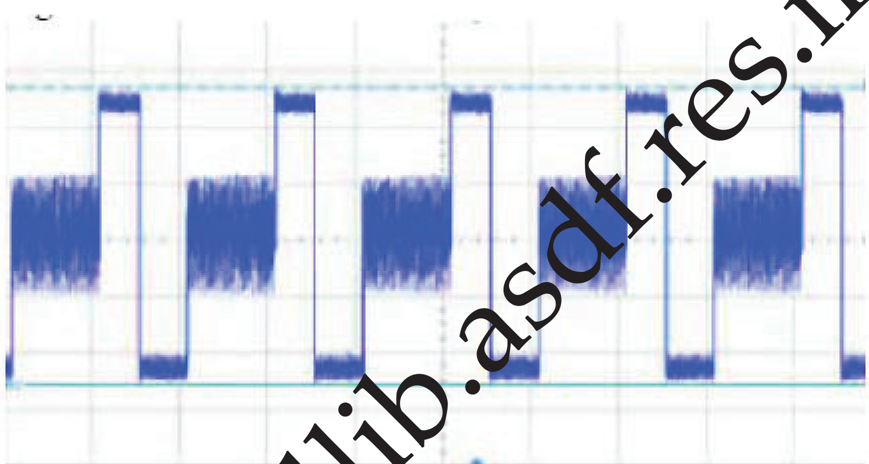

Fig. 8; Measurement of the stimulation wave (5 V at 10K Hz)

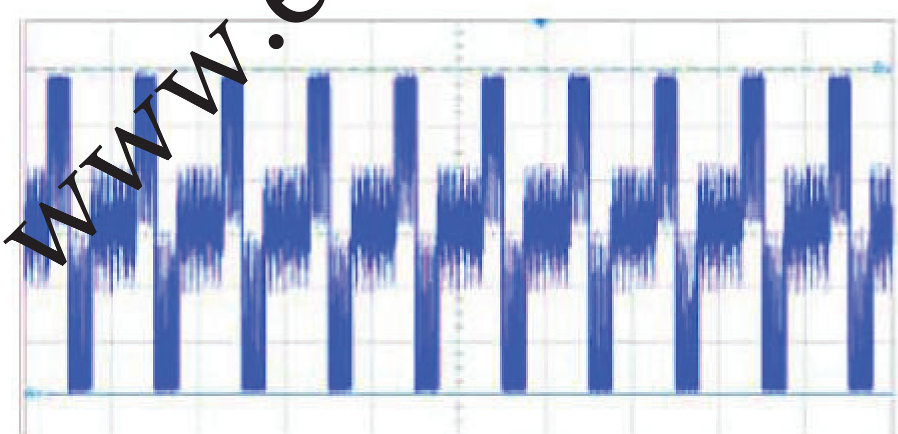

Fig. 9: Measurement of the stimulation wave (5.5 V at 100K Hz)

VI. Conclusion

This paper proposes a prototype of a one-time implantable wireless power and bidirectional transmission artificial implantable device system. By using the duplex ASK-LSK technique, the data can be transmitted by an inductive link. Moreover, the power is also transmitted via the inductive link to supply the Internal

Module circuit. To extend the life time, a Li-ion battery is adopted to store the excess power in the Internal Module. The maximum reliable operating distance between the transceiver coil and receiver coil reaches about 3.5 cm under the overall efficiency of 25%. A low-power, high-performance circuit block has been adopted and modified that is crucial for implantable device utilizing wireless RF telemetry for power and data transmission by ASK modulation. However, the interference of strong electromagnetic wave could saturate the preamplifier and cause interference in the sensed weak biological signal. Therefore, two pairs of coupling coils were implemented in the implantable module in an attempt to alleviate the magnetic interference induced by the inductive coupling. The LSK strategy and its corresponding demodulator (reader) were developed for back telemetry, and that obtained good results from ENG validation tests.

VII. References

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