

I. Purpose

CardioMEMS Corporation intends to use this experimental license to further the development of a new medical technology. Specifically, this license is sought to permit experimentation in scientific and radio technical research in connection with development of technology that will provide a non-invasive technique for measuring specific physiologic parameters related to body function.

CardioMEMS technology is a significant advance in the medical and the RF field. There are currently limited technologies for measuring pressure within the body and these technologies are usually not useful for preventive patient care management. CardioMEMS, we believe, is the first successful demonstration of using RF to measure pressure within the human body in a fashion not requiring an internal power source. This technology allows the measurement of blood pressure and potentially other biological parameters that currently cannot be made with the same amount of ease and convenience to the patient and physician using current commercially available technology.

The system consists of two functionally independent systems; (a) an inductive system whose purpose is to power, via coupling of RF energy, a separate transmitting device (sensor) that has been implanted in an individual and (b) a communications system that provides a link from the sensor transmitter to a receiver located outside the human body.

An overview of the functionality of the system follows:

II. System Operation

Inductive system

The inductive system used to power the sensor operates over a frequency band from 32 to 37 MHz in discrete steps. Frequency variation is necessary in order to match the resonant frequency of the sensor. This operation is somewhat similar to the use of inductive energy to couple power to a device for battery charging with the primary difference being the power is stored in a resonant circuit. The system employed uses a coil to magnetically couple a low-duty-cycle, gated pulse of RF energy at a single frequency with a constant amplitude to the sensor. Coil diameter is approximately 20 cm and must be placed on the implanted patient as close as possible to the location of the implanted sensor. Radiated power is of the order of 100 milliwatts or less. The magnetic coupling between this external powering coil and the implanted sensor follows the Biot-Savart relationship of magnetically coupled loops and is quite similar to a very loosely coupled transformer.

Communications system: Transmitter

The sensor transmitter is a slightly folded disk approximately 1cm in diameter that can be implanted within the body to measure physiological parameters such as arterial pressure and potentially other biological parameters. It consists of an interconnected inductor coil and a movable-plate capacitor forming a resonant circuit. The capacitor plates are arranged such that they face each other across a cavity, which may contain either gas or vacuum. External applied pressure will deflect the membranes closer to or further from each other, thereby altering the capacitance of the capacitor. Power to the sensor is supplied by the inductive system described above via magnetic coupling.

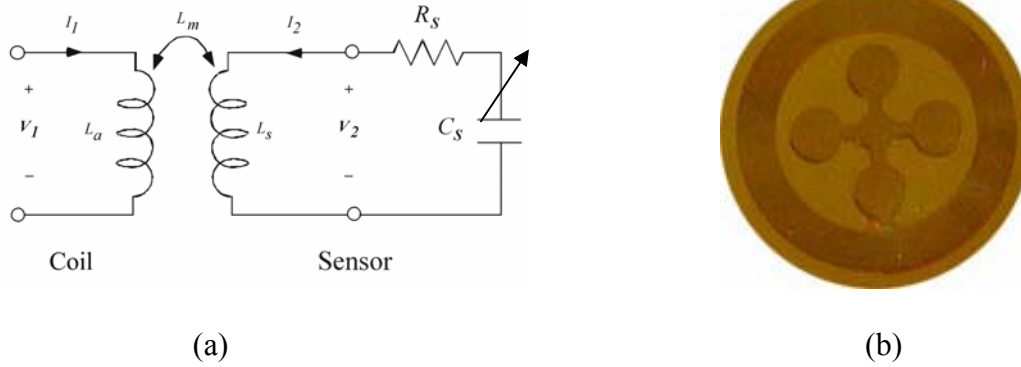


Figure 1. (a) Schematic view of the sensor illustrating inductor, capacitor, and pressure-sensitive elements; (b) photomicrograph of typical sensor.

Together, the inductor and capacitor, along with any associated parasitic resistances, form a resonant circuit with a resonant frequency and quality factor. The resonant frequency can be modeled simply as:

$$f = \frac{1}{2\pi\sqrt{LC}}$$

Since, as described above, the capacitance is a function of applied pressure, this equation shows that the frequency of the resonance is also a function of the pressure. Therefore, knowledge of the resonant frequency combined with appropriate mechanical models allows determination of the applied pressure. The sensor transmits an RF pulse at the end of the inductive powering cycle. The radiated power of this signal is on the order of a few nanowatts.

Communications System: Receiver:

The front end of the electronics is a custom single conversion receiver. The IF is 4.725 MHz, which is phase coherent to a low phase noise master oscillator. Since the sensor transmitter radiates magnetic field at its resonant frequency, the receiver uses a coil. Proximity of this receiving coil is as close as possible to the implanted sensor. Receiver tuning is achieved using two simultaneous phase-locked loops. One phase-locked loop varies the phase of the excitation signal at a predetermined interval to compensate for the phase delay of the receiver as well as compensate for phase rotation caused by

environmental effects. The other phase-locked loop generates a receiver output which is used to vary the frequency of the induction system used to power the sensor and lock the induction frequency to the resonate frequency of the sensor. A microprocessor relays the frequency of the excitation signal to a data acquisition routine that converts the frequency to a relative pressure change.

III. Conclusion

The ability to measure pressure within the human body will become a powerful tool for physicians who diagnose, manage and treat disease. One example of the utility of this concept is non-invasive pressure monitoring in patients who undergo endovascular aneurysm repair. Following their surgery, these patients are subjected to an extensive and expensive series of noninvasive and invasive studies including enhanced CT and Duplex ultrasound for monitoring the durability of the repair. These tests are surrogate measurements for intra-sac pressure, which is believed to be the critical variable that determines the risk of aneurysm rupture. An implantable pressure sensor strategically located within the excluded aneurysm sac could provide long term, non-invasive, real-time measurements of intra-sac pressure. The capability to perform this measurement wirelessly has been termed “the holy grail in vascular surgery” in a prominent peer-reviewed medical journal.