Miniature Medical Implantable Wireless Sensing (MMIWS)

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Abstract

The five words in the title convey many requirements. To satisfy these requirements, a sensor for implantable medical applications needs to be reliable and have a long life -which also means no battery - and it must be body compatible. The device must be miniature for minimal surgical implant intrusion. This device should be wireless to simplify operation and avoid the complications of tethered wires protruding from the body. To be passive (no batteries) wireless, it requires low activation energy for reasonable transmission distance using the approved radio frequency bands to furnish the wake up energy and respond by sending cogent signals at a reasonable distance.

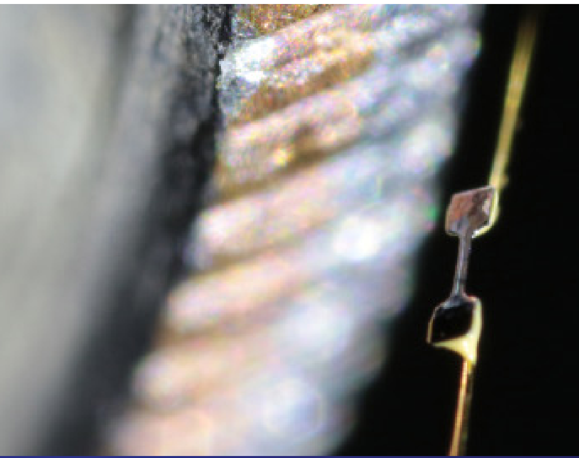
There may be many basic sensing mechanisms that would meet the above requirements. This paper will deal with one already in production and proven to meet all requirements when properly housed and conditioned. It is the miniature homogeneous single crystal doped Silicon semiconductor. It already exists in two main versions, the strain gage and the temperature sensor. This gage cannot guarantee that the lifetime of the sensor or that performance and reliability of the final product is achieved, since there are other materials and processes in the final product; but the use of these strain gages provides a higher probability of success.

Introduction

Semiconductor strain gages were discovered during the transistor era and became commercially available early in the 1950's. These gages may be homogeneous or diffused. Diffused gages have a variety of problems that limits useful life and affects performance. There are two main elements from which semiconductor gages are made. These elements are Geranium and Silicon and they can be P or N doped. For this paper, the P doped (Boron) Silicon gage will be selected for the basic strain sensor and the N doped Silicon will be used for the temperature sensor. Silicon gages have been proven to be more stable and more corrosion resistant than the Geranium gages.

The Piezo-Metrics Miniature P-doped Silicon Semiconductor Strain Gage

This strain gage will be manufactured from a Boron Doped Silicon ingot grown as a single crystal. The strain gage crystalline axis used will be where the longitudinal over the transverse ratio is maximized. The reverse is true for the Silicon temperature sensor. This means that the finished gages will be unidirectional and transverse strains will have no significant effect on performance.



Semiconductor Gages

Our strain gages are extremely small and range in length from 0.018 in. to 0.090 in 0.46 mm to 2.3 mm. This small size makes them suitable for many applications such as implanted medical devices which have extremely limited space to mount strain gages.

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Gage shape is application sensitive. Semiconductor strain gages are normally bar shaped; the length and resistivity varies but the width is nominally 0.005 inches[1] and the thickness 0.0005 inches. A gold lead is bonded to ends of the gage for electrical connection. For miniature sensors, it can be important that the gold electrical leads come out the same end, requiring U shaped gages. The U shaped gage also has twice the resistance over the same length, making it desirable for small areas of high strain or for wireless applications where higher resistances are important. There are also M shaped gages, which provide four times the resistance of the same length bar gage when an ever higher resistance is required.

A Conceptual Design for the MMIWS Sensor using Semiconductor Gages.

Starting with the miniature sensor requirement, Piezo-Metrics' **SS-018-011-3000PU** is a U shape semiconductor gage 0.018 long (less than 1/2 mm) - the smallest gage presently in stock. The proposed design is for a flush mounted pressure sensor. The most efficient use of the pressure-induced strain on a fixed edge diaphragm with this gage is the pressure- induced radial strain. We would like the gage in radial tensile strain (center of the diaphragm) to be the same in radial compressive strain (at the inner circumference of the diaphragm). This means the shorter compressive region has to be 0.020 long, which is one third of the radius, making the inner diaphragm diameter dimension 0.120. Assuming the sensor will be working at low pressures in the region of 10 psi or less, the diaphragm thickness (to avoid behaving like a membrane) needs to be about 0.003 thick and the outside diameter, allowing for a wall thickness of 0.010, would be 0.140. This is for optimum signal performance. The minimum outside diameter size could be 0.090 without the temperature sensor and with lower signal performance.

The SS-018 is made from 1.0 ohm-cm resistivity P doped Silicon. The contact pads and back cure of the gage are metalized and shorted. Only the 0.011 long center section is active and is approximately 3,000 ohms at ambient temperature. The SS-018 has gold pads on the ends of the gage, gold lead wires off the pads, and a single crystal miniature gage that resists corrosion and has a mean time to failure of 99 years. The impedance is high enough for wireless transmission and the gage factor is approximately 200, permitting an output signal 67 times higher than a foil gage with a gage factor of 3.

This gage is already in use in a miniature pressure sensor measuring the heart pressure profile through the left Ventricle wall. It was decided that the sensor should be a flush diaphragm for best pressure transduction at 0.100 diameter (2.5mm), and be made of Titanium 6AL4V which is corrosion resistant and body compatible. Some reasonable wall thickness was required, which lead to the decision to use a wall thickness of 0.010 (1/4 mm), leaving the diaphragm 0.080 in diameter and plenty of room to install the four 0.018 gages onto the inside diaphragm. These gages are wired into a fully active bridge. There is no room for a temperature sensor and the diameter is not optimum. Smaller overall diameter was traded for less output without any other performance compromises. Data communication for this sensor is a handheld computer held near the coil (within a few inches) to read the sensor data.

[1] All dimensions herein shall be in inches, unless specified otherwise.

New Implantable Optimum Pressure Sensing Design.

Figure 1 shows the sensor with strain gage and temperature sensor location for optimum performance. Strain gages are wired into a fully active four-legged bridge as shown in the wiring diagram. ST-037-022-5000N is the temperature sensor, located across the radial inflection point (neutral axis) to optimize performance.

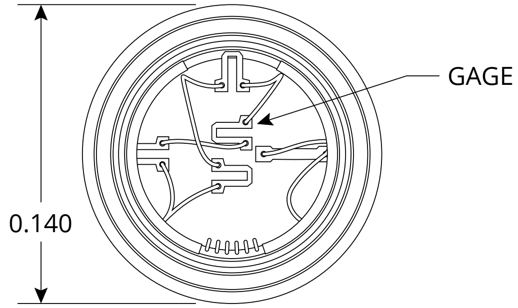

Figure 1

Wireless Considerations.

The major benefit of wireless communication for implantable medical sensors is fairly obvious: it's non-intrusive and avoids the many problems with tethered wired sensors. It's also important to avoid implanted power sources that have limited life. The good news is there are passive wireless technologies, covered by international (ISO) standards, which meet most implantable medical device requirements. The transceivers are commercially available and relatively inexpensive.

The passive wireless technology most commonly used for implantable medical devices is "passive high-frequency", or HF, operating at 13.56MHz.

Multiple semiconductor companies offer HF transceivers and interrogators that comply with the ISO 15693 standard and can be used with or without a battery. There is also a Near Field Communication (NFC) standard published by the NFC Forum that supports HF tags compliant with the ISO 14443 A and B standards.

The HF transceiver chips, pictured in **Figure 1A**, can be as small as 0.08 by 0.08 (2mm by 2mm) and about 0.03 (0.75 mm) thick.

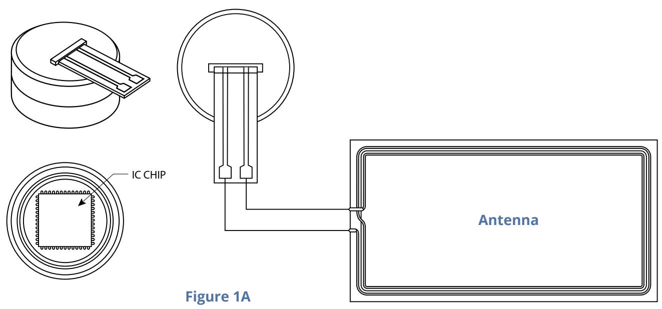

Figure 1A

For simple operation, a smart phone app can be used either with built-in NFC or a plug-in interrogator. The interrogator provides power through its transmission to prompt the chip to broadcast back a unique ID and the measured data. The data can be displayed by the app and stored as part of medical records. The range for HF passive operation is typically less than 6 inches, depending on the size of the antenna coil and the transmitted energy from the interrogator. A major benefit of Piezo-Metrics' semiconductor strain gages is the high-impedance options, potentially up to 30,000 ohms, which dramatically reduces the power required by the sensor to deliver the data to the wireless transceiver.

The four strain gages are connected into a fully active bridge at the solder tabs at the sidewall of the sensor. Two wires from the Temperature Sensor are also connected to the solder tabs on the sidewall. A miniature flex connector will be bonded to the sidewall and all sensing connections will terminate on the flex that connects to the microprocessor ("MP"). The MP will correct pressure offset, Balance Tc, Sensitivity Tc and any non-linearity. Connected to the MP is the transceiver, which is connected to the communication coil (antenna) via a body compatible cable, thereby allowing the antenna to be located under the skin anywhere convenient on the body.

All components will need to be sealed and body compatible, which is best optimized by having one container housing the Sensor, MP and communicator, with a cable connecting to a remote sensing coil. It should be possible, by design, for the container to be 0.120 in diameter and 0.375 long. Anchors can be put onto the sides of the sensor depending and what functions and where the sensor is being used. The sensor microprocessor and communicator will be one component inside the sensor. The size of a commercially available 13.56MHz antenna is shown in **Figure 2.**

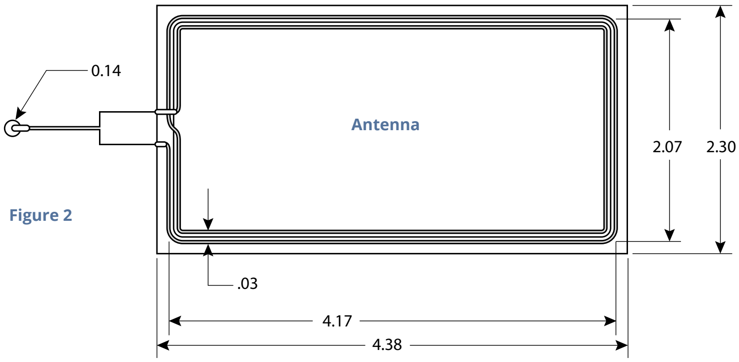

Figure 2

Although the strain gages are available, it would be a simple change to increase the 3,000-ohm impedance of the present gages to 30,000 ohms, making the circuit much more sensitive and enabling communication at a much longer distance.

Medical Sensor Solutions using Semiconductor Strain Gages.

While the above section describes a pressure temperature sensor, the miniature size, high impedance and sensitivity opens up many IMPLANTABLE MEDICAL possibilities.

It would be possible to design a miniature version of the water tunnel or wind tunnel force sensors measuring longitudinal force (bending in two dimensions 90 degrees from each other) and torsional forces, simultaneously, on one miniature rod. This rod could be attached to operating tools allowing a specialist doctor in Berlin to operate robotically on a patient in Madrid with full tactical and video feedback as if he were in the operating room himself. The miniature, high resistance and high sensitivity gages make all of this possible. The operating tool could advise when a tissue is first touched, show the force on the tissue, what angle the tool is at, and could be made to tell if the tissue is diseased.

Contact Us.

Piezo-Metrics has already worked with innovative companies on optimal selection, placement, and processing of semiconductor strain gages for implantable wireless sensors for the heart, the brain, the spine, and specialized post-surgical monitoring. If you'd like to discuss your application or design with us, please contact us for a free, confidential consultation either by email using our **Contact Us Form** or phone **(805-522-4676).**