MICROMACHINED INTRALUMINAL DEVICES FOR ACTIVE AND PASSIVE ELECTROMAGNETIC MEASUREMENTS OF FLOW

Kenichi Takahata* and Yogesh B. Gianchandani
Department of Electrical Engineering and Computer Science, University of Michigan, Ann Arbor

ABSTRACT

This paper outlines architectures for implantable (active and passive) sub-systems intended for monitoring of intraluminal blood flow by electromagnetic transduction, and presents the fabrication and test results of select components within these sub-systems. Central to both schemes is a ring-shaped intraluminal stainless steel cuff with two electrodes. In the presence of a magnetic field, it produces a voltage proportional to the flow velocity. It is fabricated by micro-electro-discharge machining and deployed by an angioplasty balloon. Cuffs deployed within 3-mm i.d. silicone tubes demonstrate linear and symmetric responses of 3.1-4.3 μV per cm/sec over 180 cm/sec with magnetic fields of about 0.25 T. In the passive monitoring scheme, voltage from the cuff modulates a varactor that is also connected to an antenna stent (stentenna). This approach is explored using a hybrid diode for the varactor and a stentenna deployed within a mock artery. Preliminary tests in saline indicate that an external transmitting coil will experience shifts in phase spectrum of 2.0-3.3 KHz/mV of output from the cuff.

I. INTRODUCTION

Chronic measurement of blood flow is important for long-term monitoring of vascular diseases, including coronary artery disease, which is commonly treated by balloon angioplasty with stent implantation. However, re-closures often occur due to recoil of the blood vessels or further plaque deposition. Wireless monitoring of blood flow can provide advance notice of such failures. Implantable flow sensors based on thermal resistor [1], blood conductivity [1] and differential pressure measurement using capacitive diaphragms [2] have been proposed in the past. Electromagnetic (EM) detection [3] is another promising candidate since it has several potential advantages over each of these options, which include direct and linear relationship between the output and flow, less dependence on cross-sectional flow profile, and elimination of the sensing diaphragms, which can potentially improve reliability and lifetime. EM flow sensors typically have two electrodes located on inner walls of the fluid channel. In the presence of a magnetic field, a voltage proportional to the flow velocity is developed between electrodes. The principle has been demonstrated in micro domain as well [4, 5].

II. SYSTEM ARCHITECTURE

The construction of intraluminal EM devices for wireless blood flow monitoring can be approached by active or passive scheme. In each scheme, the architecture consists of three components, i.e., EM probe, signal readout and telemetry circuitry, and antenna. The EM probe is designed to be an intraluminal ring-shape cuff that supports two insulated electrodes located diametrically across. The active scheme architecture uses a microchip that resides outside the blood vessel (Fig. 1a). An antenna for this implementation can be either a planar microcoil which may be integrated with the chip or an antenna stent (stentenna) [6, 7] that is implanted inside a blood vessel together with the EM cuff probe. Since this architecture requires access to both the inside and outside of the blood vessel, it is appropriate for bypass surgery. The lead transfer through the walls of the vessel can be located at the suture sites (Fig. 1c). The passive scheme architecture consists of entirely passive components including the stentenna that are all implanted inside a blood vessel (Fig. 1b). This potentially offers the compatibility with standard angioplasty/stenting procedures, i.e., less invasiveness than the active scheme. In this effort, this passive architecture is explored experimentally. Section III describes the design and fabrication of the cuff and measurement results with the cuff. Section IV reports the use of a varactor diode to wirelessly detect the voltage shift that would be generated by the cuff.

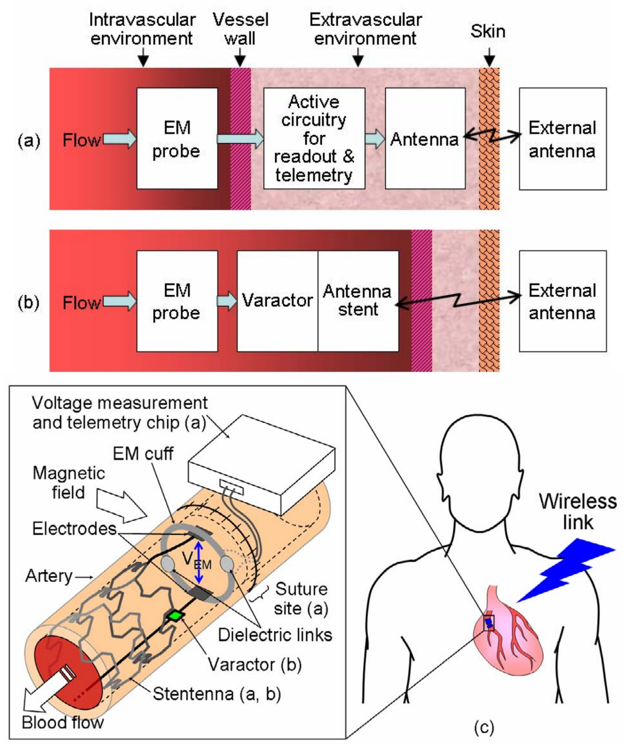

Fig. 1: System architectures for (a) active monitoring, and (b) passive implementation. (c) Illustration of sample placements of devices in scheme (a) and (b).

III. EM CUFF PROBE

Design and Fabrication

When all three orientations of blood flow, magnetic field, and electrical sense axis are perpendicular each other, the induced voltage, V_{EM}, is maximized and given by:

$$V_{EM} = D \cdot B \cdot v$$

where D is the diameter of the flow channel, B is the magnetic flux density and v is the cross-sectional average velocity of the

*Corresponding author: 1301 Beal Avenue, Ann Arbor, MI 48109-2122, USA; Tel: +1-734-647-1782; Fax: 763-9324; Email: ktakahat@eecs.umich.edu

flow. This linear equation assumes that (a) the magnetic field is spatially uniform, (b) the flow velocity profile is axially symmetric, and (c) the fluid is electrically conductive. The condition (b) is valid in typical arterial vessels and also downstream of a narrowed site if the location is reasonably away from the blockage. It is worth noting that despite condition (c), the output voltage is independent of conductivity over a wide range [8].

The cuff presents challenges in both form and material. As part of our past efforts, we developed a fabrication technique for cardiac stents that are machined from planar steel foil by batch-compatible micro-electro-discharge machining (μEDM) [9] and plastically reshaped into a tubular shape by a standard balloon angioplasty procedure [10]. The completed structure does not use any bonded or hinged joints, and demonstrated appropriate mechanical strength. The balloon expansion technique is suitable for tailoring the final diameter of the cuff to actual inner diameter of an artery at the location of the implant. The fabrication process of the stent is also useful for the cuff because it provides a planar approach to the micromachining of stainless steel, which is a suitable structural material. However, it does not accommodate insulating segments that will permit electrical isolation of different parts of the structure which is essential for the cuff probe, and must be modified to meet the needs of the cuff.

The planar design of the ring cuff has a pair of meander bands comprised of 50 μm-wide beams, electrode plates, and two dielectric links which mechanically tie the bands but electrically insulate them from each other (Fig. 2). This pattern is μEDMed in 50 μm-thick #304 stainless steel foil so that two bands are connected to the original foil, maintaining 100-μm gaps at the links. Insulating cement is used to bridge the gaps, and then the device is released from the foil (Fig. 3). This is

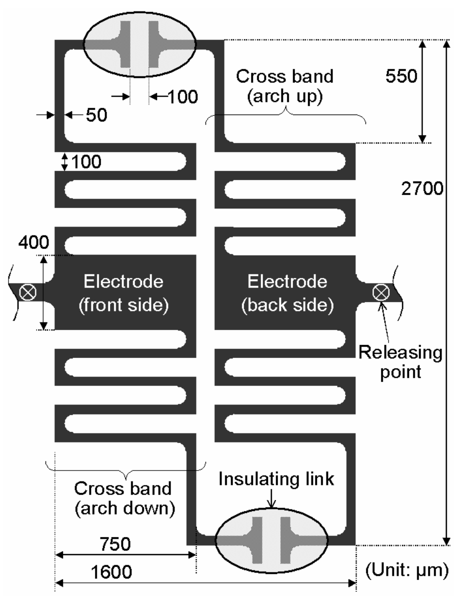

Fig. 2: A layout of the planar cuff structure.

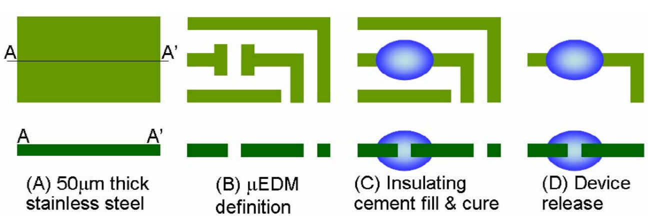

Fig. 3: Fabrication process flow [11].

similar to the process flow for a Kelvin probe described in [11]. Lead wires for testing are bonded to the electrodes with conductive adhesive. All surfaces of the device except front-side planes of the electrodes are coated with an insulating layer. (Without this, spatial averaging will reduce the voltage.) The electrode may optionally be coated with an anti-fouling layer. This feasibility experiment used two-part epoxy and enamel for the cement and the insulation layer respectively.

The planar structure (Fig. 4) is mounted on a deflated balloon of a standard angioplasty catheter so that one of the bands is located above the balloon whereas the other band is below it (Fig. 5). The device is then deployed near a chronically or potentially diseased location in a blood vessel. Figure 6 shows a device that is expanded inside a silicone tube with 3-mm i.d.. The balloon is inflated up to 7 atm. causing the lumen to expand to 3.5 mm in diameter. When the balloon is deflated and removed the expanded cuff remains within the tube (Fig. 7). Tests with flow velocities up to 2 m/s show that both the structure and its placement are robust and immovable. (Maximum arterial flow is typically ≈1.6 m/s.)

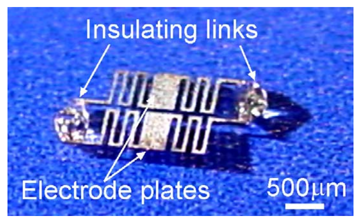

Fig. 4: A stainless steel cuff in the planar form.

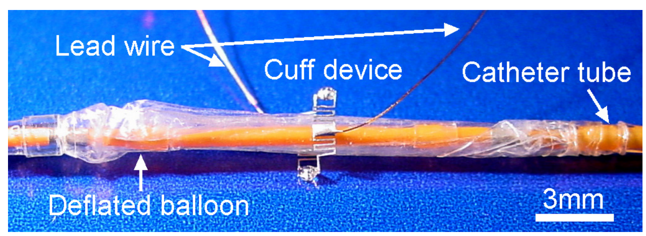

Fig. 5: A planar cuff structure mounted on a standard catheter balloon in the deflated state.

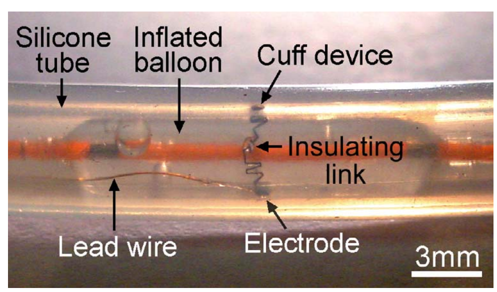

Fig. 6: The planar cuff plastically expanded to a ring shape inside a silicone tube by inflation of the balloon.

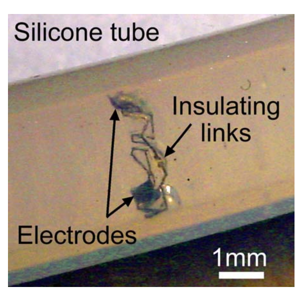

Fig. 7: The cuff remains attached to the on inner walls of the tube by pressure after the balloon is deflated and removed. (The lead wires have been removed.)

Measurement Results

The EM cuff probe was experimentally evaluated in a fluidic set-up shown in Fig. 8: a pump/flow-controller regulates the flow of 2 % wt. saline and a voltmeter measures voltage between the electrode leads. A permanent magnet with dimensions of 25x25x9 mm^3 was used to provide magnetic field in this setup. The field orientation was perpendicular to both flow direction and the voltage sense axis defined by the locations of the two electrodes. The magnetic field was characterized by an InAs Hall sensor (F. W. Bell, FL, model BH-205) and measured to be ≈0.25 T at the location of the cuff. The presence of the cuff had no detectable impact on the externally measured magnetic field. To determine the EM effect, voltage change due to varying flow rate was measured with opposing orientations of the magnetic field as shown in Fig. 9. The voltage change relative to a baseline value, which is associated with polarization and electrochemical effects, is plotted in Fig. 10. The voltage linearly and symmetrically increases or decreases depending on the orientation. The voltage response and sensitivity in this test were 3.1-4.3 μV per cm/sec and 50-70 ppm per cm/sec, respectively.

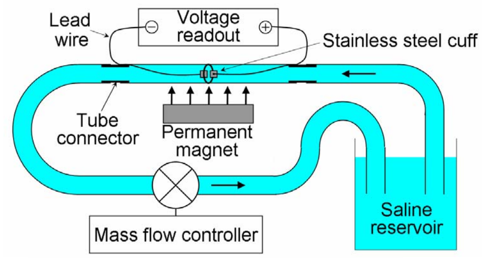

Fig. 8: A set-up for flow measurement.

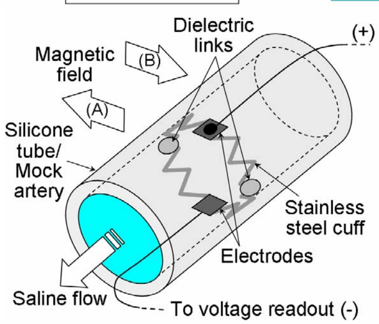

Fig. 9: A close-up of the device in the set-up with different orientations of magnetic field.

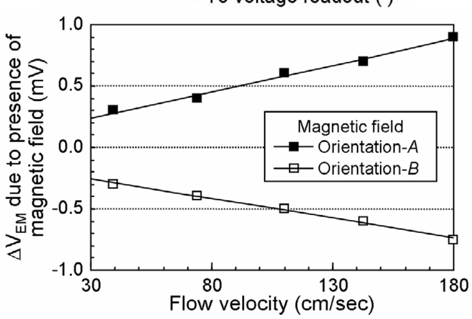

Fig. 10: Measurement result showing linear dependence on flow velocity and symmetric responses with opposing magnetic fields.

IV. PASSIVE CIRCUIT USING VARACTOR AND STENTENNA

Principle

The concept of the passive device is illustrated in Fig. 11. It uses the inductance of the stentenna and the junction capacitance of a varactor to form an L-C tank. The stentenna and the diode are series connected, and ends of the series pair are terminated by two electrodes of the EM cuff so that the diode is biased by the V_{EM} generated between the electrodes to modulate the resonant frequency of the tank. This configuration eliminates the need of multiple pressure sensors for flow sensing demonstrated in [7]. Since the threshold voltage of the diode is much higher than a typical range of V_{EM}, the series-connected tank achieves high input impedance, which is crucial to properly bias the diode. The tank is wirelessly coupled to an external coil, whose resonant frequency in the input impedance, Z_{in}, is monitored by a spectrum analyzer.

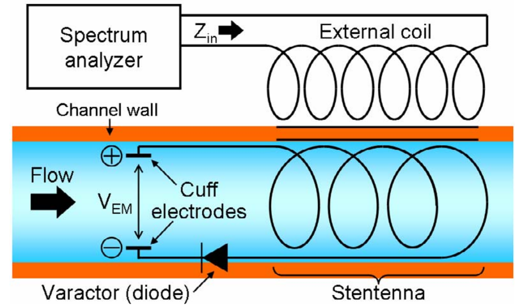

Fig. 11: The concept of the intraluminal passive device and its telemetry setup.

Fabrication and Experimental Results

In this manifestation a diode serves as the varactor. Planar structures of the EM cuff and the stentenna were connected to a diode with a conductive adhesive (Fig. 12a). The stentenna was fabricated by patterning a 50-μm thick stainless steel sheet with μEDM and then electroplated with Cu to reduce the parasitic resistance of the structure i.e. increase quality factor of the tank. The resistance of the stentenna, which was originally 14 Ω, was reduced down to about 1/10 of the value with 3-μm thick Cu coating. The planar structures were then coated with 1-μm thick parylene-C, which is a biocompatible polymer with a proven history for biomedical applications including cardiac stents [12]. The electrode plates of the EM cuff were left uncoated. The diode was packaged with epoxy for both electrical and mechanical protection in this case. The device was deployed inside a 3-mm i.d. silicone mock artery with 0.25-mm wall thickness (Dynatek-Dalta, Inc., MO) by using the balloon catheter. Figure 12b shows the completed device after the balloon is removed. The input impedance Z_{in} and the phase in an external coil were monitored with an HP4195 spectrum analyzer. A wireless test was performed by applying emulated V_{EM} to a device expanded in the saline-filled tube and observing frequency shifts in Z_{in}. Figure 13 shows measured phase dips with the varying voltage. The dip frequency was reduced as the voltage was increased. The diode used in the device for this measurement was 1N3595 (Fairchild

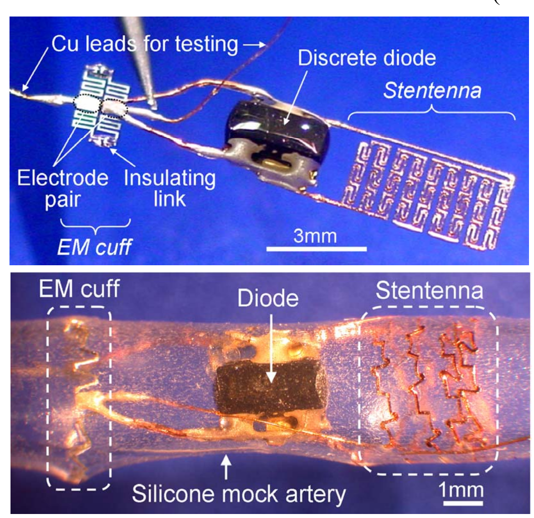

Fig. 12: (a: upper) The planar state of a fabricated hybrid device, and (b: lower) the device deployed inside a mock artery tube.

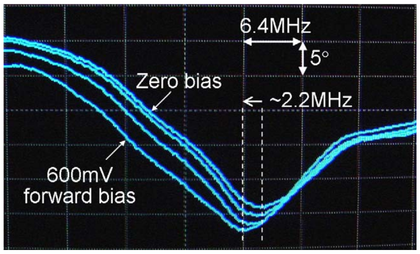

Fig. 13: Measured shift in phase dip of external with emulated V_{EM} varied by 200mV per step.

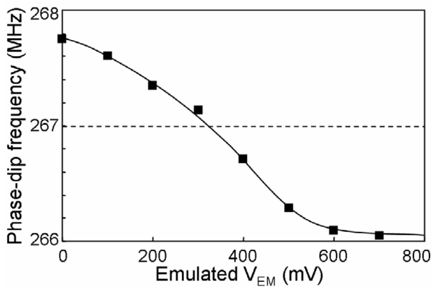

Fig. 14: Measured frequency shift with the emulated V_{EM}.

Semiconductor Co., ME, USA). Figure 14 shows a measured response of 2.0-3.3KHz/mV that saturates as it reaches a turn-on voltage of the diode, which is 680 mV in this case. (In these preliminary tests the V_{EM} was provided by a power supply.)

Simulation

The experiment result was evaluated by performing circuit simulations with SPICE™. Figure 15a shows an equivalent circuit model used to simulate the wireless set-up shown in Fig. 11. In this model, L_{EX}, L_{ST}, D and k respectively denote inductance of the external coil, inductance of the stentenna, diode, and coupling coefficient between the external and stentenna inductors. Other elements are measured or fitted parasitics. It also used a 1N3595 diode model provided by the manufacturer [13]. The simulation results show that the phase-dip in the response of the external coil is shifted in frequency by the loading from the LC tank by ≈1.24MHz for a cuff voltage shift of ΔV_{EM}=10mV (Fig. 15b).

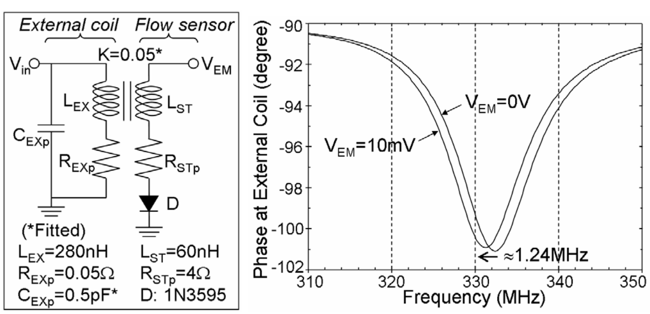

Fig. 15: (a: left) SPICE model of the wireless set-up, and (b: right) simulation result showing a shift of L-C tank resonance due to ΔV_{EM}.

V. DISCUSSION

It can be seen that there are differences in the degree of responses as well as the resonant frequency of the dips between the experimental and simulation results. This can be partially due to parasitic capacitances that exist parallel to both the stentenna and the diode. An additional simulation showed that the capacitances reduce both the response and the frequency, approaching the experimental result. To obtain resolvable frequency shift with a practical range of V_{EM}, the device will need further improvement, which includes having varactors with higher sensitivity and achieving higher quality factor of the tank. The latter can be approached by increasing inductance of the stentenna with higher turns and reducing parasitics.

VI. CONCLUSION

This research has investigated a micromachined intraluminal device for wireless sensing of blood flow with an EM detection mechanism. The device consists of an EM cuff probe and an L-C tank that serves as a readout and telemetry circuitry as well as an antenna. A planar microstructure of the EM cuff with overall dimensions of 2.7x1.6 mm^2 was fabricated from 50-μm thick stainless steel foil to have a pair of electrodes that were mechanically coupled but electrically isolated by dielectric links. The planar structure was plastically expanded to ring shape by inflation of the balloon inside a silicone tube. Fluidic tests that used saline and DC magnetic field of 0.25 T demonstrated linear response of electromagnetically induced voltage to varied flow speed. A combination of a diode varactor and an antenna stent was used to form the L-C tank. A wireless test with emulated V_{EM} successfully demonstrated the device concept. The planar design of these devices offers a path to batch fabrication of them with either monolithic or hybrid integration of diodes.

REFERENCES

[1] A. Bolz, V. Lang, B. Merkely, M. Schaldach, "First Results of an Implantable Sensor for Blood Flow Measurement," *IEEE Conf. EMBS*, 1997, pp. 2341-3

[2] A. DeHennis, K.D. Wise, "A Fully-Integrated Multi-Site Pressure Sensor for Wireless Arterial Flow Characterization," *Solid-State Sensor, Actuator, Microsys. Workshop (Hilton Head 2004)*, 2004, pp. 168-71

[3] B.H Brown, R.H. Smallwood, D.C. Barber, P.V. Lawford, D.R. Hose, "Medical Physics and Biomedical Engineering," *Institute of Physics Publishing, Bristol and Philadelphia*, 1999, pp. 608-11

[4] H.J. Yoon, S.Y. Kim, S.W. Lee, S.S. Yang, "Fabrication of a Micro Electromagnetic Flow Sensor for Micro Flow Rate Measurement," *SPIE Symp. Smart Struc. Mat.*, 2000, pp. 264-71

[5] K. Takahata, Y.B. Gianchandani, "A Micromachined Stainless Steel Cuff for Electromagnetic Measurement of Flow in Blood Vessels," *Solid-State Sensor, Actuator, Microsys. Workshop (Hilton Head 2004)*, 2004, pp. 290-3

[6] K. Takahata, A. DeHennis, K.D. Wise, Y.B. Gianchandani, "Stentenna: A Micromachined Antenna Stent for Wireless Monitoring of Implantable Microsensors," *IEEE Conf. EMBS*, 2003, pp. 3360-3

[7] K. Takahata, A. DeHennis, K.D. Wise, Y.B. Gianchandani, "A Wireless Microsensor for Monitoring Flow and Pressure in a Blood Vessel Utilizing a Dual-Inductor Antenna Stent and Two Pressure Sensors," *IEEE Conf. MEMS*, 2004, pp. 216-9

[8] A. Kolin, "An Alternating Field Induction Flow Meter of High Sensitivity," *Rev. Sci. Instrum.*, 16(5), 1945, pp.109-16

[9] K. Takahata, Y.B. Gianchandani, "Batch Mode Micro-Electro-Discharge Machining," *IEEE J. MEMS*, 11(2), 2002, pp.102-10

[10] K. Takahata, Y.B. Gianchandani, "Coronary Artery Stents Microfabricated from Planar Metal Foil: Design, Fabrication, and Mechanical Testing," *IEEE Conf. MEMS*, 2003, pp. 462-5

[11] L.L. Chu, K. Takahata, P. Selvaganapathy, J.L. Shohet, Y.B. Gianchandani, "A Micromachined Kelvin Probe for Surface Potential Measurements in Microfluidic Channels and Solid-State Applications," *IEEE Conf. Solid-State Sensor, Actuators, Microsys. (Transducers 2003)*, 2003, pp. 384-7

[12] A.B Fontaine, K. Koelling, S.D. Passos, J. Cearlock, R. Hoffman, D.G. Spigos, "Polymeric Surface Modifications of Tantalum Stents," *J. Endovasc. Surg.*, 3(3), 1996, pp. 276-83

[13] http://www.fairchildsemi.com/pf/1N/1N3595.html