

# Novel Long-Term Implantable Blood Pressure Monitoring System with Reduced Baseline Drift

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**Abstract**— A novel long-term less-invasive blood pressure monitoring system with fluid-filled cuff is proposed for advanced biological research. The system employs an instrumented elastic cuff attached with a rigid isolation ring on the outside wall of the cuff. The cuff is wrapped around a blood vessel for real-time blood pressure monitoring. The elastic cuff is made of bio-compatible soft silicone material and is filled with bio-compatible insulating silicone oil with an immersed MEMS pressure sensor. This technique avoids vessel penetration and substantially minimizes vessel restriction due to the soft cuff elasticity, thus attractive for long-term monitoring. A rigid isolation ring is used to isolate the cuff from environmental variations to suppress baseline drift in the measured waveform inside the monitoring cuff. The prototype monitoring cuff is wrapped around the right carotid artery of a laboratory rat to measure real-time blood pressure waveform. The measured *in vivo* blood waveform is compared with a reference waveform recorded simultaneously by using a commercial catheter-tip transducer inserted into the left carotid artery, showing matched waveforms with a scaling factor about 0.03 and a baseline drift of 0.6 mm Hg. The measured baseline drift is three times smaller compared to using a cuff without a rigid isolation ring.

## I. INTRODUCTION

DNA sequencing of small laboratory animals together with *in vivo* real-time biological information, such as blood pressure, temperature, activity and bio-potential signals, is ultimately crucial for various biomedical and genetic research to identify genetic variation susceptibility to diseases, for example hypertension, obesity, epilepsy and cancers [1], and to potentially develop new treatments for diseases. A small-size, light-weight, long-term, reliable bio-sensing implantable system with two-way wireless telemetry capability is highly desirable to capture the real-time biological information from a “free” roaming animal housed in its home cage as shown in Figure 1. The implantable microsystem employs a micro-fabricated sensor array for multi-channel vital signal monitoring and integrated electronics for sensor interfacing, RF powering and two-way data telemetry. This paper focuses on the development of blood pressure monitoring system, which is important for biological research [2].

The most common techniques for monitoring blood pressure in small animals rely on using an invasive catheter-tip transducer inserted into an artery [3] or a tail cuff device [4]. The implantable catheter-tip transducers require a complex surgical procedure and potentially suffer from blood clotting and reduced sensitivity with drift over time.

Tail cuffs require animal restraint, thus resulting in a stress-induced signal distortion. Furthermore, tail cuffs can only obtain systolic and diastolic blood pressure levels instead of a continuous blood pressure waveform with detailed signatures, which are critical for advanced biomedical research. Therefore, both technologies are inadequate for long-term real-time monitoring. Miniature implantable pressure sensor cuffs for tonometric blood pressure measurement have been demonstrated [5]. The principle is that if a blood vessel is pressed against a flat surface of a pressure sensor diaphragm until vessel flattening occurs, according to Laplace’s law the pressure measured by the sensor will be approximately equal to the pressure inside the vessel. This technique can solve the issues associated with the conventional methods listed above, but significantly deforms the blood vessel shape, which could cause long-term physiological effects to the vessel property and thus may not be suitable for long-term monitoring. It is, therefore, desirable to develop a long-term implantable blood pressure monitoring system without the aforementioned concerns.

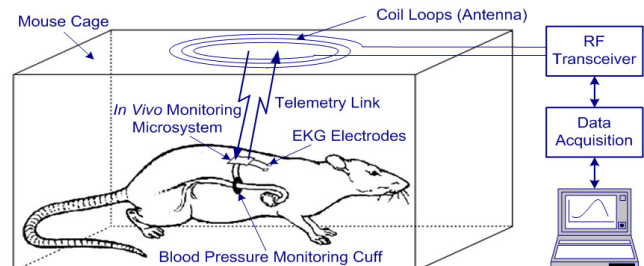


Figure 1. Miniature implantable wireless monitoring system

A novel less-invasive blood pressure monitoring system with fluid-filled cuff has been designed and evaluated in laboratory animals previously [6]. The system employs an instrumented elastic cuff, wrapped around a blood vessel to sense real-time blood pressure waveforms as shown in Figure 2. The elastic cuff is made of bio-compatible elastomer and is filled with low viscosity bio-compatible insulating fluid with an immersed sensitive MEMS pressure sensor. The MEMS sensor measures the pressure waveform coupled from the expansion and contraction of the vessel. The measured waveform represents a scaled version of the vessel blood pressure waveform as shown in the equation below:

$$P_b(t) = \frac{1}{\eta} [P_m(t) - P_{Bias}]$$

where  $P_m(t)$  and  $P_b(t)$  are pressures inside the monitoring cuff and blood vessel, respectively.  $P_{Bias}$  is the cuff bias pressure, and  $\eta$  is a scaling factor.  $P_{Bias}$  and  $\eta$ , which can be used to re-construct the blood pressure waveform from the recorded waveform in the monitoring cuff, are constant after implant and can be accurately obtained by a calibration process during and after the implant [6, 7].

The proposed method avoids vessel occlusion, bleeding, and blood clotting. Furthermore, since the cuff is made of soft elastic material and its stiffness can be much smaller than that of a blood vessel, the restrictive effect on the vessel is thus substantially minimized.

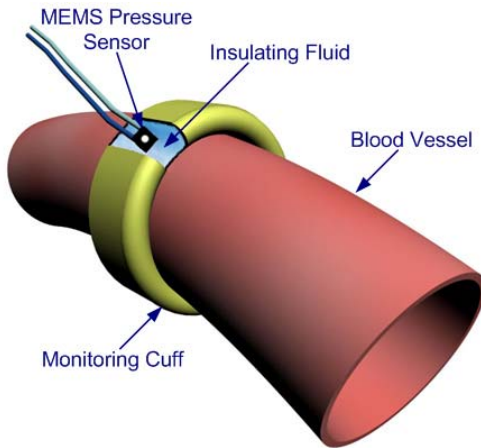


Figure 2. Implantable blood pressure monitoring system

Previous implant study shows that the *in vivo* waveform recorded from the right carotid of a rat by the implantable blood pressure monitoring cuff is closely matched to a reference blood pressure waveform simultaneously recorded by using a catheter-tip transducer inserted into the left carotid artery in shape [6]. However, a low frequency baseline drift with a typical value of 2 mm Hg was found in the measured waveforms inside the cuff with a scaling factor of 0.065. Though the pulse pressure and all the waveform signatures can still be accurately obtained, it is difficult to accurately estimate the absolute diastolic and systolic pressure levels by using the previous cuff design. To solve this problem a new cuff design is proposed in this paper and implant experiment results are presented.

## II. BASELINE DRIFT ANALYSIS AND NEW CUFF DESIGN

The baseline drift is likely caused by the soft outside wall of the cuff. Because of the soft nature of the cuff outside wall, the pressure inside the cuff is quite susceptible to environmental variations, such as animal muscle and tissue movement. The cuff outside wall can be made more rigid to decrease the effects, however, at the same time the restraint to the vessel will increase, thus leading to a trade off between measurement baseline drift and the vessel constraint. However, it is difficult to address the trade off due to the limited research currently available on the long-term

influence on animals with different amount of vessel constraint. Therefore, a rigid isolation ring is employed to isolate the cuff from the outside environment in the new design.

Figure 3 shows the top view and cross-sectional view of the proposed cuff design with a rigid isolation ring. The rigid isolation ring is attached to the outside wall of the original cuff to isolate the cuff from the environmental variation. At the same time, the isolation ring is designed so that an air cavity between the isolation ring and the cuff outside wall will be formed upon completion of the fabrication process, as shown in the figure. As a result, the cuff outside wall can move freely and would not influence the stiffness of the cuff in the center.

The wall of the isolation ring is designed to be 1.5 mm in thickness to ensure a proper rigidity for an adequate isolation. The radius of the cuff inside wall is designed to be about 0.5 mm with an outside cuff wall radius of 0.9 mm, which is adequate to wrap around an artery of a small laboratory animal. The shape change of the cuff during measurement changes the pressure in the air cavity by changing its volume, which will introduce an additional equivalent rigidity to the cuff. Therefore, the air cavity needs to be large compare to the shape change of the cuff. In the prototype design, the gap size of the air cavity is chosen to be comparable to the radius of the cuff outside wall to minimize this effect, thus resulting in a radius of the isolation ring of approximately 3.2 mm. A channel opening is designed in the cuff outside wall for connecting the sensor-housing cavity, as shown in Figure 3a, so that a miniature MEMS pressure sensor and interface circuit can be housed there to measure pressure waveform in the cuff.

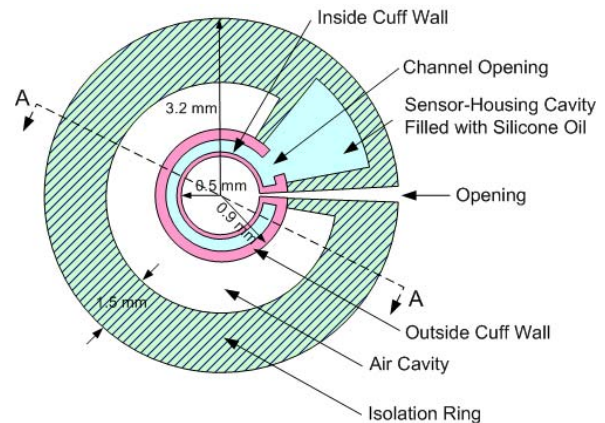


Figure 3a. Top view

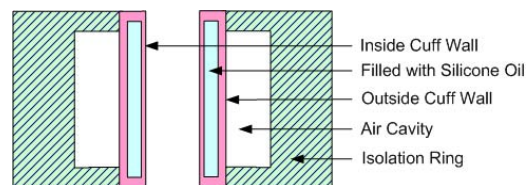


Figure 3a. A-A cross-sectional view

Figure 3. Top and cross-sectional views of monitoring cuff with rigid isolation ring

### III. IMPLANTABLE BLOOD PRESSURE MONITORING CUFF FABRICATION

The cuff is fabricated by attaching a silicone base with a pre-defined geometry to a pre-stretched thin silicone membrane. Biomedical-grade silicone (MDX4-4210) from Dow Corning Company is selected to implement the cuff because of its bio-compatibility and soft elastic properties. Due to the built-in membrane stress, the attached layers would produce a desired circle profile upon completion. The fabrication details can be found in [6].

The isolation ring is fabricated by bonding two parts (Part A and Part B) together with the fabrication process shown in Figure 4. The process begins by making plastic molds through a standard machining technique. Biomedical-grade Class VI stiff elastomer material (C6-570) from Dow Corning Company is then poured onto the mold surface, followed by a de-gassing step. Next, a thin glass substrate is positioned over the elastomer material with an applied weight on top to ensure a proper thickness as shown in Figure 4(b), followed by curing at 110 °C. After curing, Part A and Part B are peeled off from the molds and bonded together by applying a thin layer of bio-compatible adhesive film and external force, followed by a curing step to form the isolation ring as shown in Figure 4c.

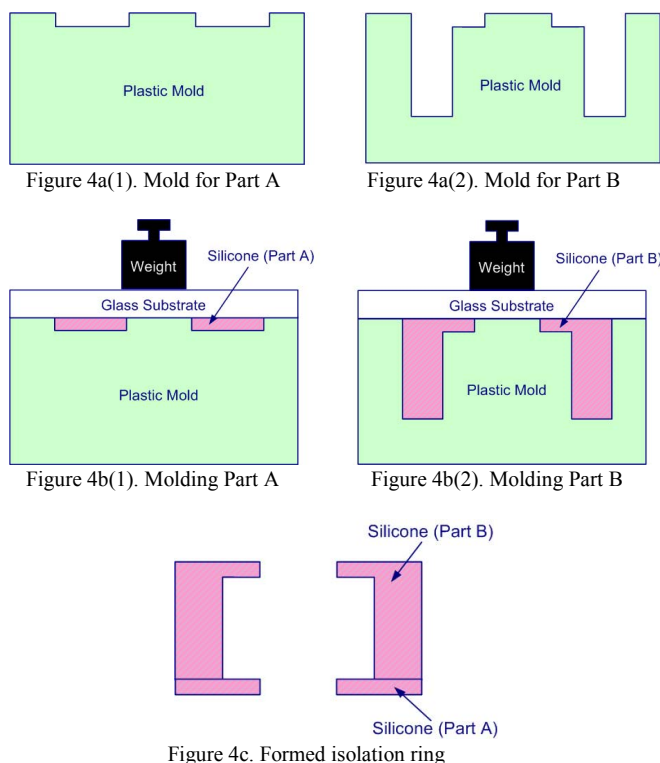


Figure 4. Process flow for making isolation ring

The isolation ring is then carefully glued to the cuff outside wall by using bio-comparable silicone adhesive. For the initial testing, a piezoresistive pressure sensor with an area of 1.3 mm x 3.8 mm was used, which is not small

enough to fit into the sensor-housing cavity. Therefore, a relatively large rigid tube is required to house the device. The cuff and the sensor-housing cavity are then filled with silicone oil and sealed with the large tubing on the sidewall of the sensor-housing cavity. The large rigid tubing can be eliminated in the future by employing a miniaturized pressure sensor and integrated electronics. A suture thread is then attached to the outside wall of the isolation ring by using silicone bio-comparable adhesive, which is used for securing the cuff during implant as shown in Figure 5.

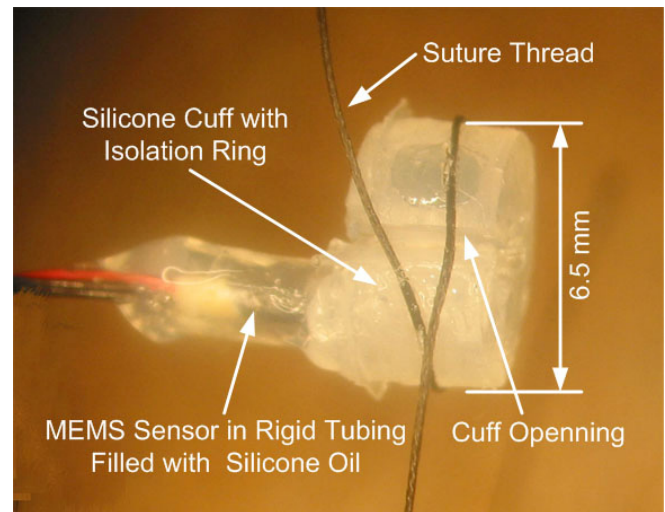


Figure 5. Prototype implantable blood pressure monitoring cuff with rigid isolation ring

### IV. *IN VIVO* RESULTS

A laboratory rat from Charles River Co. with a weight of 630 g is used for implant evaluation due to their relatively large artery size around 1 mm. The blood pressure monitoring cuff is wrapped around the right carotid artery and secured by suture threads; a commercial catheter-tip transducer from Micro-Med Inc. is inserted into the left carotid artery as a reference for comparison. Figure 6 shows the relative position of the monitoring cuff and catheter-tip transducer during the implant measurement. Blood pressure waveform is measured by the monitoring cuff and the catheter-tip transducer and recorded simultaneously by a two-channel data acquisition system sampled at 1 KHz.

Figure 7 presents a 120-second time-frame blood pressure waveforms. The top waveform in the figure is measured by using the monitoring cuff with a rigid isolation ring; the bottom waveform in the figure is from the commercial catheter-tip transducer. The baseline drift is measured about 0.6 mm Hg. Figure 8 presents a 120-second time-frame blood pressure waveforms in previous study by using the monitoring cuff without a rigid isolation ring. The baseline drift is about 2 mm Hg. The measurement results show that the baseline drift was suppressed by factor of 3 by adding a rigid isolation ring to the cuff. Moreover, it was found that there was a low frequency drift associated with the



piezoresistive sensor with a value of about 0.5 mm Hg, which is comparable to the baseline drift in the measured waveform. Therefore it will be desirable to design a miniature, highly sensitive, and stable pressure sensor and interface circuits to study the baseline drift issue measured in the monitoring cuff, which is planned as the next step.

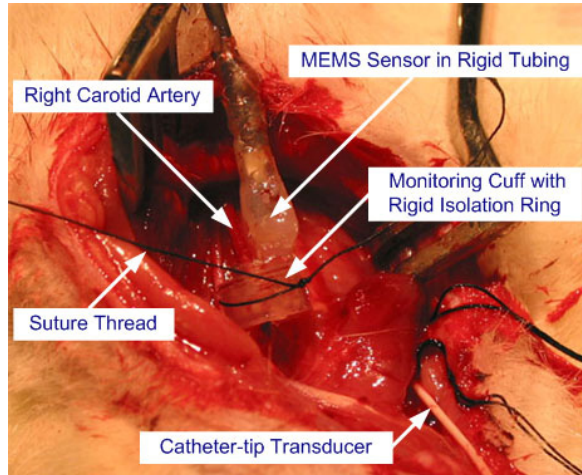


Figure 6. Monitoring cuff and catheter-tip transducer for calibration

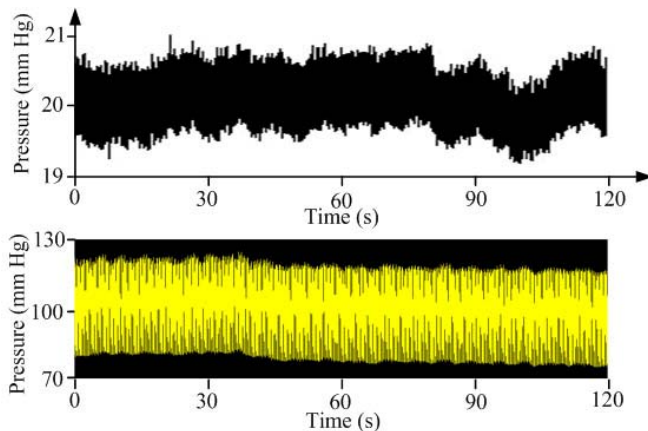


Figure 7. 120 second waveforms measured by the monitoring cuff with rigid isolation ring and a catheter-tip transducer

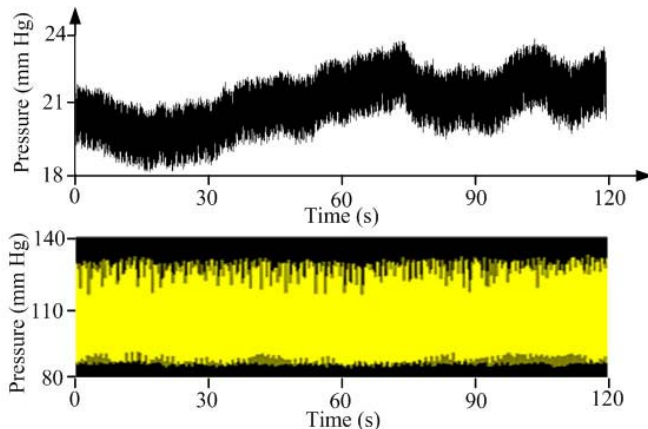


Figure 8. 120 second waveforms by a monitoring cuff without rigid isolation ring and a catheter-tip transducer

## V. CONCLUSION

A novel less-invasive blood pressure monitoring system with fluid-filled cuff is proposed for advanced biological research. The system employs an instrumented elastic cuff attached with a rigid isolation ring on the outside wall of the cuff. The cuff is wrapped around a blood vessel for real-time blood pressure monitoring. The proposed method avoids vessel occlusion, bleeding, and potential blood clotting, thus is suitable for long-term implant applications. *In vivo* blood pressure measurement in a rat shows the new cuff design with a rigid isolation ring can suppress the baseline drift of the measured waveform. Thus, blood pressure waveform with higher fidelity and accuracy can be obtained. The proposed cuff-based sensing architecture can be used to realize a complete implantable wireless small animal monitoring system for advanced biological research and can be potentially useful for human implant monitoring to improve health care quality in the future.

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