A Mini-invasive Long-term Bladder Urine Pressure Measurement ASIC and System

Chua-Chin Wang, *Senior Member, IEEE*, Chi-Chun Huang, Jian-Sing Liou, Yan-Jhin Ciou, I-Yu Huang§,
Chih-Peng Li†, Yun-Chin Lee‡, and Wen-Jen Wu‡

***Abstract*— A mini-invasive system for long-term bladder urine pressure measurement system is presented. Not only is the design cost reduced, but also the reliability is enhanced by using a 1-atm canceling sensing IA (instrumentation amplifier). Because the urine pressure inside the bladder does not vary drastically, both the sleeping and working modes are required in order to save the battery power for long-term observation. The IA amplifies the signal sensed by the pressure sensor, which is then fed into the following ADC (analog-to-digital converter). Owing to the intrinsic 1-atm pressure (one atmospheric pressure) existing inside the bladder, the IA must be able to cancel such a pressure from the signal picked up by the pressure sensor to keep the required linearity and the resolution for pressure measurement of the bladder urine. The pressure range of the proposed system is found out to be 14.7∼19.7 Psi, which covers the range of all of the known unusual bladder syndromes or complications.**

***Index Terms*— urine pressure, mini-invasive, bladder, IA, linearity, low power consumption**

I. INTRODUCTION

Many hemiplegic or disabled patients are suffering from urocystitis and other bladder diseases, which might cause death by complication and infection therewith. However, almost all of these bladder diseases can be prevented or predicted by observing the abnormal bladder urine pressure variations. For instance, patients whose leak point pressure is greater than 40 cm-H_2O might have upper urinary tract deterioration because of voiding control by prevention of the normal neural pathway, [1], [2], [3]. Therefore, periodic evaluation of these patients to discover their urodynamic situations and help these uro-ataxic to urinate normally has been recognized as one of the most important research topics in clinical medical investigations, [4]. Sensing pressure in bladders is an important topic among many uro-researches. According to several prior reports, the pressure of the urine inside of the bladder is not exactly proportional to the volume. However, the urine pressure reveals the syndromes of a lot of urinary anomalisms, such as unusual LLP (leak point pressure), [5]. The involuntarily reflex contraction of a bladder with a small fluid volume may cause inconvenience of daily life. By contrast, the loss of continence given a high bladder pressure during bladder-urethral sphincter dyssynergia can result in long-term renal damages, frequent urinary tract infections, and infections of the kidneys, [6], [7].

Many methods for the measurement of the urine pressure in a bladder have been reported in the literature, e.g, [8]. Prior researchers utilized a bladder or its model in a controllable *in vitro* experimental site, and observed the response of every charging influence, [9]. However, the result of such an experiment on a dead organ or a model is hard to prove being the same as the that *in vivo*. By contrast, we can insert a pressure sensor, *in vivo*, by catheterization through urethra or other incision [11] and get the readings of the pressure inside the bladder under different conditions. Besides possible infection, it will make experimental target uncomfortable, which then cause the significant difference between in experiment and in reality. Cystometrogram (CMG) has been known to be a better way to plot the pressure-volume curve of bladder pressure. However, CMG is not a proper long-term recoding platform because it is very time-consuming and costly [12].

We propose a mini-invasive long-term bladder urine pressure measurement system shown in Fig. 1 composed of a pressure sensor, a RF module and a control ASIC chip containing a high-linearity IA . Because of its tiny size and low power, we can implant the device in the bladder to measure the pressure after properly packaging the proposed system. Therefore, not only can we read the bladder pressure directly in real time *in vivo*, but also reduce the effects caused by the discomfort of experimental target. The accuracy of the pressure measurement will be ensured. Fig. 2 shows one of applications of the whole system. The proposed mini-invasive system measures the urine pressure in the bladder and transmits the reading to the external reader. The Data Analyzer will analyze the reading received from external reader to diagnose the situation of the bladder. Notably, the sleeping mode make the device very power efficient, which can monitor the urine pressure over an interval of about two weeks.

II. ARCHITECTURE OF THE URINE PRESSURE MEASUREMENT SYSTEM

Due to the demand of size miniaturization of mini-invasive devices and low power consumption for a long-term measurement, the proposed system has to adopt a wireless transmission such that the urine pressure information can be collected outside of the body using an external data reader. Referring to Fig. 3, the infrastructure of the entire mini-invasive long-term bladder urine pressure measurement system

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Prof. C.-C. Wang are with the Department of Electrical Engineering, National Sun Yat-Sen University, Kaohsiung, Taiwan 80424 (e-mail: ccwang@ee.nsysu.edu.tw).

C.-C. Wang is the contact author.

§ Prof. I.-Y. Huang is an assistant professor with Dept. of Electrical Engineering, National Sun Yat-Sen University, Taiwan.

† Prof. C.-P. Li is an assistant professor with Institute of Communication Engineering, National Sun Yat-Sen University, Taiwan.

‡ Dr. W.-J. Wu and Dr. Y.-C. Lee are with Dept. of Urology, Kaohsiung Medical University Chung-Ho Memorial Hospital, Taiwan.

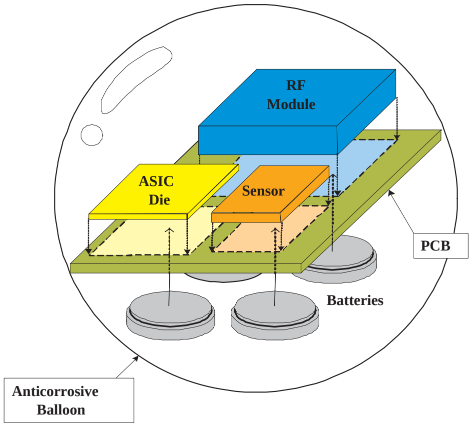


Fig. 1. Sketch of the mini-invasive system.

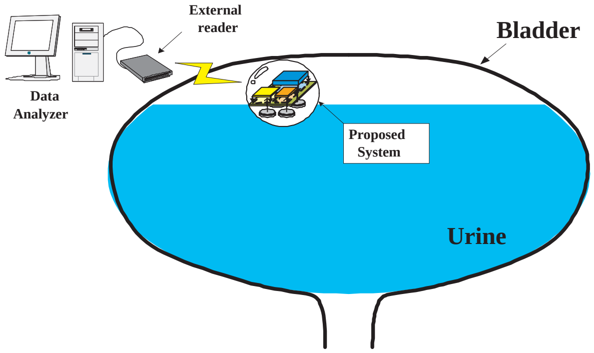


Fig. 2. Application example of whole system.

is composed of three major components : a pressure sensor, a control ASIC, and an RF module. Notably, “Timer & Control” in Fig. 3 is in charge of the mode selection where the sleeping mode is activated by shutting down the power of each block powered by “Power Buffer”. The clock to these blocks is also disabled at the same time when the sleeping mode is chosen. The pressure sensor is an absolute pressure sensor, which means its differential output voltage is proportional to the absolute pressure. The differential output voltage will be amplified by IA (instrumentation amplifier) in the ASIC and then quantized by the ADC after canceling intrinsic 1 atm pressure in the bladder. “PtoS” (parallel to serial circuit) is responsible for serializing the ADC output samples and framing with sync bits [13]. Then, the data frames are delivered to the RF (radio-frequency) module for wireless communication with an external data reader (not shown).

A. Control Sequence

The pressure in the bladder isn’t varied frequently or drastically. Hence, the proposed system is turned on 10 seconds into the working mode for every 5 minutes to save the battery power for long-term observation. By contrast, we shut down the unnecessary function blocks by cutting off their supply power in other time span, i.e., the sleeping mode.

In the working mode, the data processing sequence is shown in Fig. 4. When $\overline{\mathrm{AD}\_rst}$ is pulled high, ADC begins to sample and quantize. It takes a total of 6 AD_clk periods before the EOC (end of conversion) signal is asserted. The PtoS, then, frames the code with the sync bits (1010) to deliver them serially to the RF module.

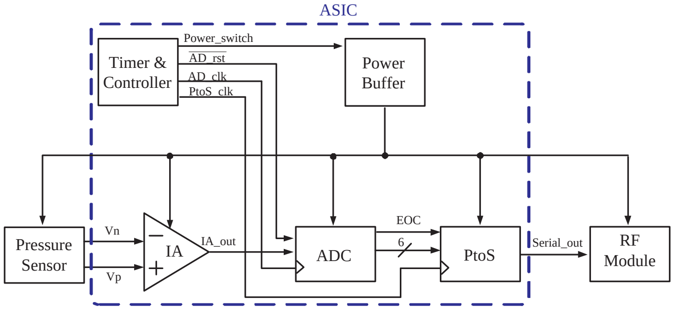


Fig. 3. Architecture of the mini-invasive system.

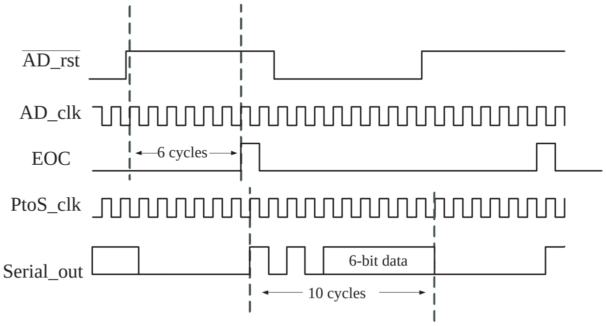


Fig. 4. Control sequence in the working mode.

B. Pressure Sensor

The pressure sensor of the proposed system is ATP015, which is a product of Asia Pacific Microsystem, Inc. It’s equivalant circuit is shown in Fig. 5. It is basically composed of bridging resistors. A stable power supply is applied between S_VDD and S_GND. The differential output voltage on SO+ and SO- will be changed by the pressure applied on the surface of the sensor. According to the specifications, the output voltage is 87 mV when the applied pressure is 15 Psi given a 3.0 V supply voltage. The ratio of the pressure against voltage drop is 0.1724 Psi/mV. Notably, 1 Psi = 68 cm-H_2O, and then 1 mV = 11.723 cm-H_2O. Thus, we can estimate the pressure based upon the measured voltage.

C. IA with 1-atm canceling

The schematic of the proposed IA is shown in Fig. 6. Without R5s and the OPA (operational amplifier) in the middle of R5s, A_{cen}, the schematic is a normal amplifier in text books. The R5s and the A_{cen} can remove the unwanted voltage overhead. Besides providing the required amplification of the sensed signal, the most important function thereof is to remove the intrinsic 1-atm ($\approx$ 85 mV) pressure of the pressure sensor output voltage. The absolute pressure sensor provides a differential output voltage 85 $\sim$ 114 mV in the range of 1 atm $\sim$ 19.7 Psi. (In other words, 5 Psi above 1 atm) However, the required resolution of proposed ADC is 6 bits. If we set the

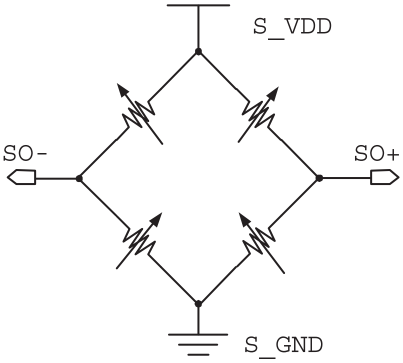


Fig. 5. Equivalent circuit of the pressure sensor

largest sensor output voltage, 114 mV, to be the upper bound and 0 mV be the lower bound, 1 LSB will be presented as 114 mV / 64 = 1.781 mV = 20.88 cm-H_2O. There is no way to identify the normal pressure of a bladder (about 10 cm-H_2O, [10]) in such a scenario. By contrast, if we set the input range proportional to the possible output voltage range of the pressure sensor (85 $\sim$ 114 mV), 1 LSB will be presented as (114-85) mV / 64 = 0.453 mV = 5.31 cm-H_2O. The resolution of entire system as well as the linearity is then ensured.

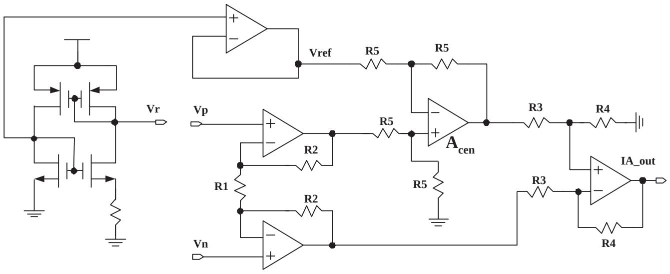


Fig. 6. Schematic of the IA.

D. 6-bit ADC

A charge-redistribution successive approximation ADC (SA ADC) is employed in this work, as shown in Fig. 7. A binary search through all possible quantization levels is performed to attain the final digital value. When the $\overline{\text{AD}\_rst}$ is pulled high, the voltage of V_in is sampled. the Control block will generate D_out bit by bit at each AD_clk cycle to the input of the DAC. The DAC, thus, generates an analog voltage according to the digits of the D_out which is to be compared with V_in. EOC will be asserted after 6 AD_clk cycles to indicate that the D_out is the final code.

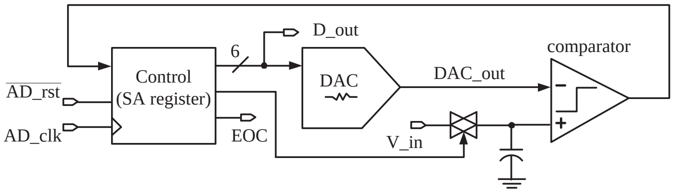


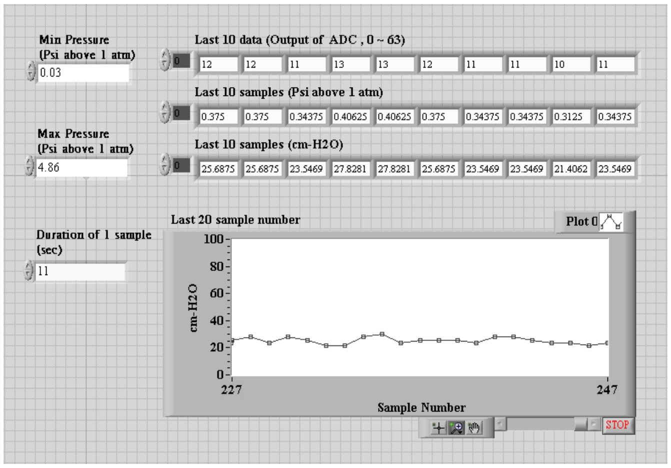
Fig. 7. SA ADC.

E. RF module considerations

Because the proposed system will be implanted in a balloon floating over the urine and surrounded by live tissues, the frequency of the carrier generated by the RF module should be quite low to transmit through the body. In addition, the data amount to be transmitted is not really heavy, which implies that the low ISM bands, either 2.0 MHz or 13.5 MHz, are better selections. Many off-shelf miniature RF products which meet the mentioned RF bands are available to be integrated into proposed system. We employ one of these commercial RF transmission modules (SHY-J6122TR 434 MHz) using another ISM band, 434 MHz. The reason is that it is lower enough to transmit through live tissues, but high enough to layout a tiny antenna on a PCB. The size of the RF module is 5 × 7 × 3 mm^3. Its transmitting distance is over 1 meter. Furthermore, the performance of the module when soaked in a tank with electrolyte (which mimics a bladder with urine) is as good as in the air.

F. Data recording and analyzing system

The data recording is particularly important when the proposed system is used for long-term observing. The data recording and analyzing system including RF RX front-end, data recording and analyzing computer, and GUI (graphic user interface) can process the signal sent by the mini-invasive system. Fig. 8 shows the GUI of our external data recording and analyzing program designed for the proposed system. We can adjust the offset resulted from the deviations of the sensor or the analog block in the ASIC by varying the values on the left-hand side of the GUI. The right-hand side of the GUI shows the last 10 readings in a digital format and pressure values in two different units. We can see the variation of the pressure over last 20 readings on the GUI form the chart.



Min Pressure (Psi above 1 atm)
0.03

Max Pressure (Psi above 1 atm)
4.86

Duration of 1 sample (sec)
11

Last 10 data (Output of ADC , 0 ~ 63)

0	12	12	11	13	13	12	11	11	10	11

Last 10 samples (Psi above 1 atm)

0	0.375	0.375	0.34375	0.40625	0.40625	0.375	0.34375	0.34375	0.3125	0.34375

Last 10 samples (cm-H2O)

0	25.6875	25.6875	23.5469	27.8281	27.8281	25.6875	23.5469	23.5469	21.4062	23.5469

Fig. 8. GUI of the data recording and analyzing program.

The main function of this program is to analyze all of the binary digits delivered by the receiver module. After synchronization and safety check, it can record the effective readings in the working mode and discard useless bits in the sleeping mode depending on the predefined function. It also averages the readings in a certain period to avoid noise and records them into a file for the convenience of statistics and analysis.

III. IMPLEMENT AND MEASUREMENT

TSMC (Taiwan Semiconductor Manufacturing Company) 0.35μm 2P4M CMOS process is adopted to carry out the proposed mini-invasive ASIC chip design. Referring to the die photo shown in Fig. 9, the chip area is 1650 μm × 1480 μm (850 μm × 740 μm without pads).

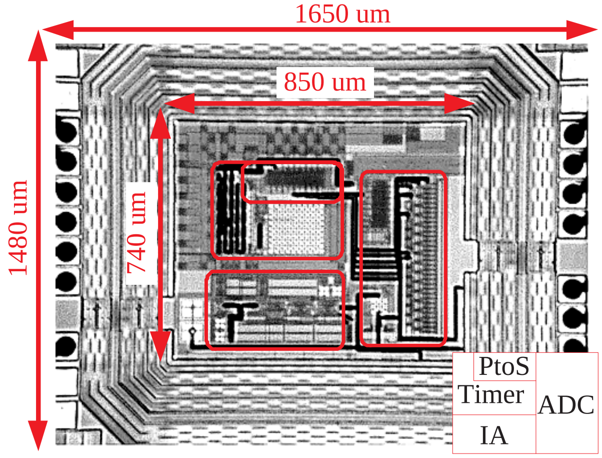
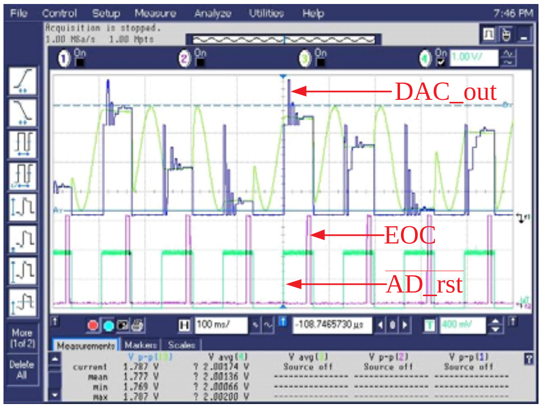


Fig. 9. The die photo of the control ASIC in the proposed system.

Fig. 10 shows that the ADC works correctly according to the DAC_out signal and the EOC pulse. The SFDR (spurious free dynamic range) measurement result of the ADC, as shown in Fig. 11, is 37 dB in the working range. INL and DNL of the ADC are both found to be less than 0.7 LSB. The Serial_out is in the right package format, starting with the sync bit (1010), as shown in Fig. 12. The measurement result of the control sequence in the working mode is totally correct. The measurement results of the ASIC is as good as the simulation specification.



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Acquisition is stopped.
1.00 MSa/s   1.00 Mpts

          V p-p(1)    V avg(4)       V avg(3)       V p-p(2)       V p-p(1)
current   1.787 V     ? 2.00174 V    Source off     Source off     Source off
   mean   1.777 V     ? 2.00136 V    -------------  -------------  -------------
    min   1.769 V     ? 2.00066 V    -------------  -------------  -------------
    max   1.787 V     ? 2.00200 V    -------------  -------------  -------------
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Fig. 10. Measurement results of ADC in the working mode.

The mini-invasive system shown in Fig. 13 is sealed in the floating balloon with a diameter of 25 mm. The thickness of the proposed system is about 10 mm, such that the diagonal length is about 22.2 mm. The volume of the balloon is 8.2 c.c.,

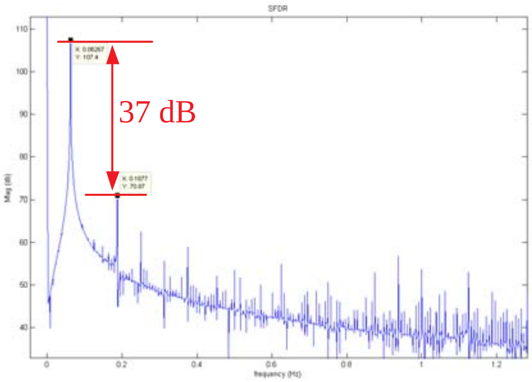
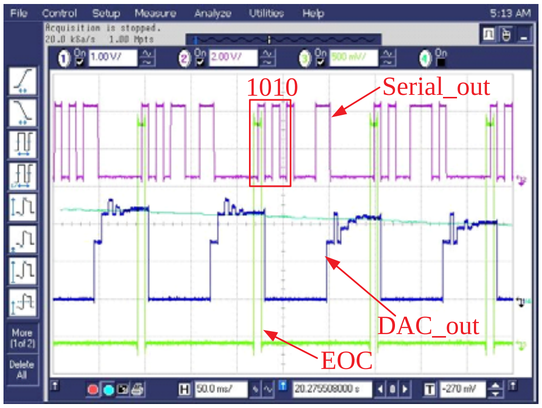


Fig. 11. SFDR of ADC in the working range.



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Acquisition is stopped.
20.0 kSa/s   1.00 Mpts
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Fig. 12. Measurement results of the control sequence.

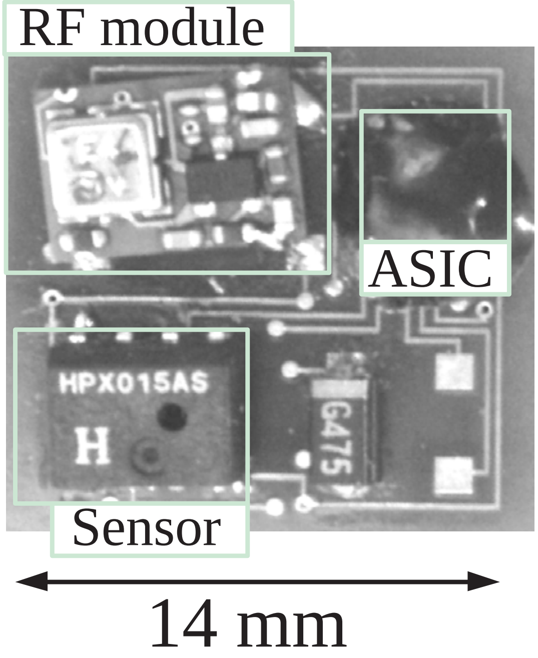

Fig. 13. The photo of the mini-invasive system.

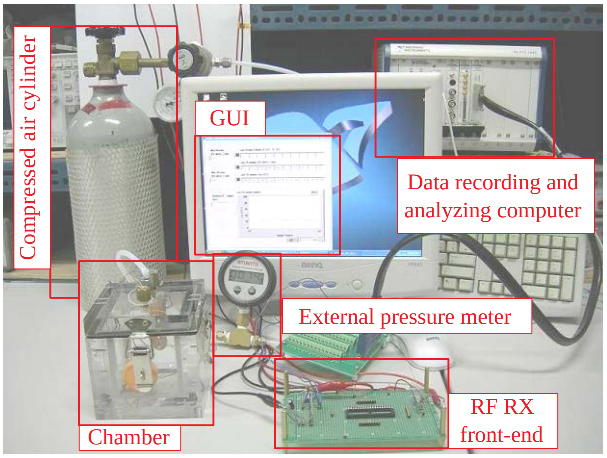

Fig. 14. The measurement site of the propose system.

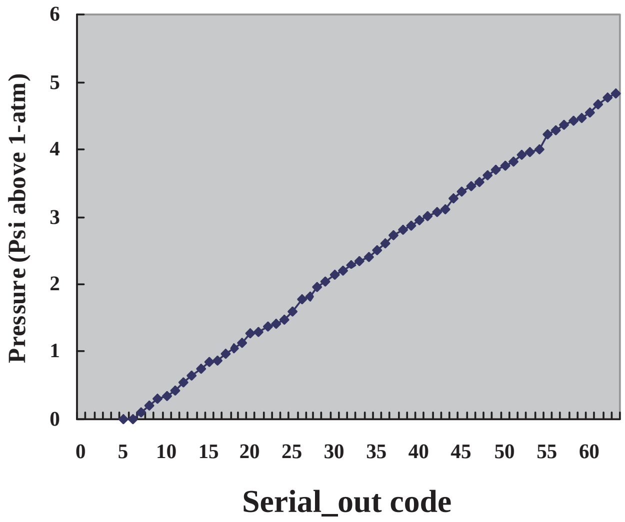

Fig. 15. The linearity of the 6-bit Serial_out code relative to pressure.

which is much less than the volume capacity of the normal bladder. The measurement site of the system is revealed in Fig. 14. The internal pressure of the chamber is controllable by a compressed air cylinder such that the overall pressure range of the bladder can be fully tested. The external pressure meter can measure the pressure in the chamber to calibrate the proposed mini-invasive system. The RF RX front end works like the external reader to demodulate the RF signal and feed the serial digital signal into the data recording and analyzing computer. The computer can process the digital signal by the program of the GUI. The linearity of the whole system (form pressure sensor to the RF RX front-end) is revealed in Fig. 15 indicating that the mean square error (MSE) is merely 0.2454%. All of the characteristics of the proposed system is summarized in Table I.

IV. CONCLUSION

We have proposed a mini-invasive long-term bladder urine pressure measurement system as well as the controller ASIC. Besides utilizing the pressure sensor and the RF module to shorten the design time and cost, the ASIC in charge of commanding all of the components ensures the reliability besides miniaturization. In order to carry out long-term observation, the sleeping and working mode are alternatively activated to extend the battery life. The system is able to precisely sense the pressure in the range of 14.7∼19.7 Psi, which has been deemed as a quite large range for the research of bladder malfunctions.

diameter of system balloon	25 mm
weight	$\approx$ 4.1 g
sensing range	14.7 $\sim$ 19.7 Psi
ADC resolution	6 bits
ADC INL	0.65 LSB
ADC DNL	0.67 LSB
system MSE	0.2454%
sleeping mode interval	5 minutes
working mode duration	10 seconds
supply voltage	3V
max. transfer distance	1m
average power consumption	1.25 mW
working days	14 days @ 4 × 70 mA-h batteries

TABLE I

CHARACTERISTICS OF THE PROPOSED MINI-INVASIVE SYSTEM.

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