UP-Link: An Ultra-Low Power Implantable Wireless System for Long-Term Ambulatory Urodynamics

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***Abstract*—Monitoring of bladder pressure, known as cystometry, is a key diagnostic tool in urodynamic studies of patients that exhibit lower urinary tract symptoms. Over the past few years, there has been an increased interest in ambulatory urodynamics due to the increased convenience and more realistic monitoring environment. This paper presents an ultra-low power implantable wireless platform, UP-Link, for long-term ambulatory bladder pressure monitoring. The proposed platform, which is built using off-the-shelf components and uses the MICS (Medical Implant Communication Service) radio frequency band for communication, enables more cost-effective and rapid development compared to existing ASIC-based solutions. The UP-Link platform is powered by two coin cell batteries with a total capacity of 560mAh and has an estimated battery life of several months to years. Results obtained through in vitro experiments demonstrate that the pressure data measured using UP-Link shows excellent agreement (0.995 using the intraclass correlation coefficient method) with measurements obtained using a commercial pressure gauge. An accelerated battery-life test was also performed, the results of which validate our lifetime estimates. The longevity of the UP-Link platform enables ambulatory urodynamic studies at much longer time scales than current practice.**

I. Introduction

Millions of patients worldwide suffer from brain and spinal cord injuries that result in neurogenic lower urinary tract dysfunction (NLUTD), such as urinary incontinence, urinary retention, urinary tract infections, and bladder stones [1]. NLUTD can cause many secondary health complications; the most serious being renal damage. In fact, renal failure has been shown to be a leading cause of death in patients with spinal cord injury [2]. It has been established that sustained elevated storage pressure in the bladder is one of the most important risk factors for renal damage [3].

The standard diagnostic procedure for patients presenting with persistent lower urinary tract symptoms is a *urodynamic study* that consists of several tests including cystometry, where bladder pressure is monitored to assess bladder function. Conventional bedside urodynamics involves the insertion of a catheter-based pressure transducer through the urethra and into the bladder in order to measure bladder pressure while it is being filled and drained [4]. In addition to being highly cumbersome to patients, such short-duration tests do not provide any long-term data about changes and trends in bladder pressure as patients go about their daily lives. Therefore, there is a growing interest in the use of ambulatory urodynamics as an acceptable (possibly, even better) alternative to conventional bedside urodynamics and several implantable wireless bladder pressure monitoring systems have been proposed to enable ambulatory monitoring [5]–[10]. However, most of these systems are either based on custom ASIC (Application Specific Integrated Circuit) implementations that are not widely available, or have a battery life of at most a few days. Therefore, they cannot be used for truly long-term urodynamics.

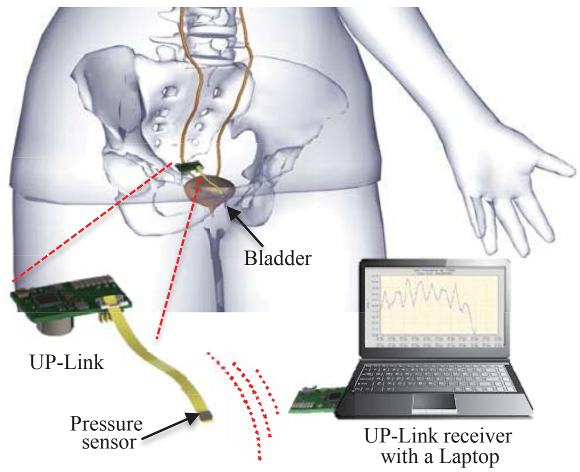


Fig. 1: Overview of the proposed long-term ambulatory urodynamics system based on the UP-Link device.

In this paper, we present UP-Link, an ultra-low power implantable wireless system for long-term ambulatory urodynamics. UP-Link is built using only off-the-shelf components, enabling rapid and cost-effective development. Our analysis and experiments show that UP-Link can operate for several months to years before running out of energy. Figure 1 depicts an overview of the proposed system, which employs the UP-Link platform as an implantable wireless manometer as well as a PC-side RF receiver for data logging. Rather than implanting the entire device into the bladder, UP-Link uses a sensor cable to avoid interfering with the functioning of the bladder. The sensor is placed at the tip of the cable and sutured over the bladder wall to measure bladder pressure. It is connected to the rest of the circuitry, which is implanted behind the pelvic bone where sufficient space is available.

II. UP-Link Architecture and Design

This section presents an overview of the hardware and software architecture of UP-Link and an analysis of its power consumption and battery life.

A. UP-LINK *Hardware Architecture*

Figure 2 shows an architectural block diagram of the UP-LINK device. The hardware platform consists mainly of a Radio-Frequency System-on-Chip (RF-SoC)[1] that contains a sub-1GHz RF transceiver with an 8051 MCU, and a digital temperature/pressure sensor[2]. The sensor outputs 24-bit digital values for pressure and temperature with a resolution of 0.016 mbar and 0.002 °C, respectively. The temperature data is used to calibrate and correct the pressure data, which is originally just a digital representation of the uncompensated analog output voltage from the piezo-resistive pressure sensor. Mechanically, the sensor is connected to the RF-SoC using a 5cm long sensor cable to provide surgical flexibility, as seen in the photograph of the platform, shown in Figure 3. The sensor is placed at one end of the cable and interfaced with the RF-SoC through an I^2C communication bus. The RF-SoC reads and transmits sensor data to a base station over the MICS (Medical Implant Communication Service, 402-405 MHz) RF band. The board is powered by two coin-cell batteries[3] connected in series to provide 2.8V. The total capacity of the two coin-cell batteries is 560mAh, which is sufficient to power the device for several years for our application, which consists of a sensor measurement followed by a transmission every hour (lifetime estimation will be discussed in Section II-D).

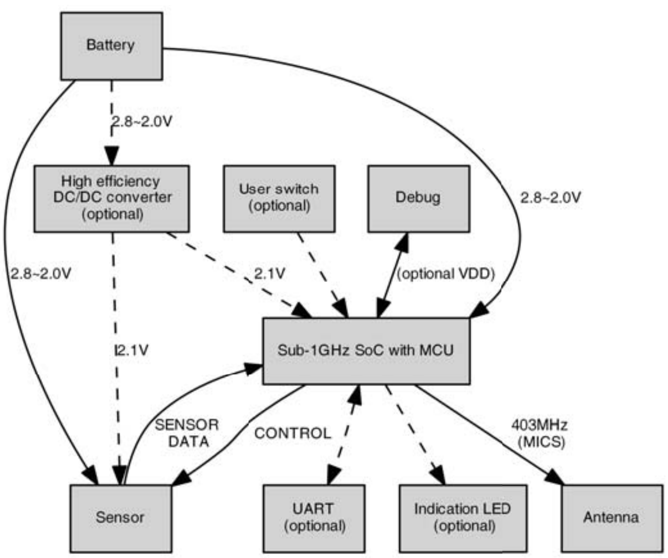


Fig. 2: The hardware architecture of UP-LINK**.**

The battery output can either directly power the platform or be regulated to 2.1V to reduce the active-mode power consumption of the RF-SoC. Based on the application, a DC/DC down-converter[4] can be selectively used by configuring a hardware jumper. For instance, the down-converter can be omitted in an application where the system will be in sleep mode for most of the time because the quiescent current of the converter will adversely impact battery life. UP-LINK also contains several optional components, such as a user switch, LED, and UART, for enhanced debuggability of the platform.

Although UP-LINK is equipped with an RF tranceiver, it is used only as a transmitter once implanted to avoid wasting any power listening for incoming packets. However, if connected to a PC through a USB port, it receives power from the USB port and is used as a receiver. In this configuration, UP-LINK forwards any received RF packets to the PC.

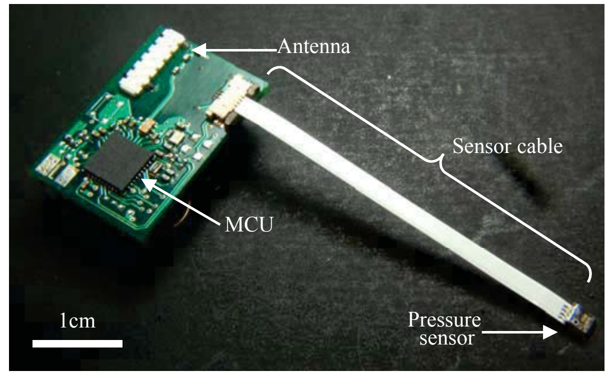


Fig. 3: A photograph of the UP-LINK **device.**

B. UP-LINK *Software Architecture*

The UP-LINK software architecture is fully interrupt-driven and optimized to enable ultra-low power operation. Since the hardware platform can be used either as the implantable sensor or as the PC-side RF receiver, it executes different software depending on its role. The flowcharts depicted in Figure 4 show the execution flow for each mode of operation.

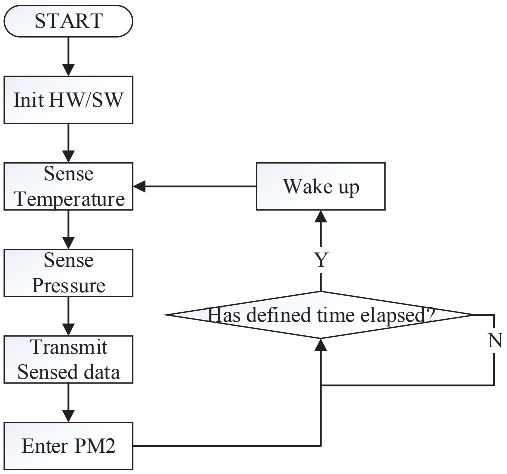
In both modes, UP-LINK starts by initializing software and hardware peripherals, such as clocks, timers, and I/O. If the device is configured as an implantable sensor, it remains in sleep mode by default and wakes up periodically based on a timer interrupt. The time interval between wakeup interrupts, *i.e.,* sleep duration, can be pre-configured by the user to either be constant or change dynamically. For instance, it may be desirable to have a lower sleep duration during (and immediately after) surgery to obtain enough confidence about the device's correct operation. Once active, UP-LINK reads pressure and temperature data over the I^2C bus. After correcting the uncompensated pressure measurement using the measured temperature, it transmits the values to a base station. Upon completion of the transmission, it returns to the sleep mode until the next wake up interrupt. Specifically, UP-LINK utilizes power-down mode 2 (PM2) of the RF-SoC that turns off all the on-chip peripherals except the 32.768KHz crystal oscillator, which is used to run the sleep timer. Since the contents of RAM are retained even in the power down mode, it is possible to conduct uninterrupted processing of the sensor data (*e.g.,* moving average) across the sleep cycles.

If configured as a receiver, UP-LINK is connected to a PC using a UART-to-USB interface and works as a communication gateway for implanted UP-LINK devices. In this mode, UP-LINK is powered by the USB port and never goes into sleep mode. It continuously listens for incoming RF packets and forwards them to the PC for logging.

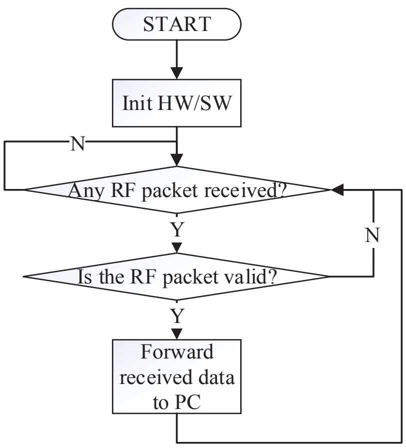
C. UP-LINK *Communication Stack*

UP-LINK features a simple, yet efficient, RF communication stack. Rather than using a full-blown network protocol stack, UP-LINK only supports one-hop communication, in order to

[1] CC1110F32, a sub-1GHz RF-SoC from Texas Instruments.
[2] MS5637-02BA03 from Measurement Specialties. [3] AC13, size 13 batteries from Energizer. [4] TPS62730DRYT from TI.



(a) Configuration 1: Implantable wireless sensor device



(b) Configuration 2: PC-side receiver

Fig. 4: A software flowchart showing the operation of the UP-Link **device in two different configurations.**

reduce the memory footprint and minimize power consumption. Encryption can be selectively applied using the 128-bit hardware AES encryption engine that resides in the RF-SoC. Figure 5 shows the packet format used by UP-Link with each block representing 1 byte. The *Preamble*, *Sync*, and *CRC* fields are defined by hardware registers. Besides these hardware-defined fields, 18 bytes are allocated for semantic information. The *Len* field occupies 1 byte and denotes the length of the packet. The packet also contains *Network ID* (2 bytes) and *Node ID* (1 byte) fields to uniquely identify and distinguish UP-Link devices. In addition to 3 bytes each of temperature data in Celsius and pressure data in mBar, the packet also includes additional fields for elapsed system time and an incrementing sequence number, which are both set to zero upon initial power-up. Once the packet is fully assembled, the hardware generates the CRC and appends it to the packet.

D. Power Consumption of UP-Link

Since UP-Link is an implantable device and frequent battery replacement is not feasible, battery lifetime is one of the most critical design concerns for the UP-Link device. In order to provide long operational lifetime and considering the

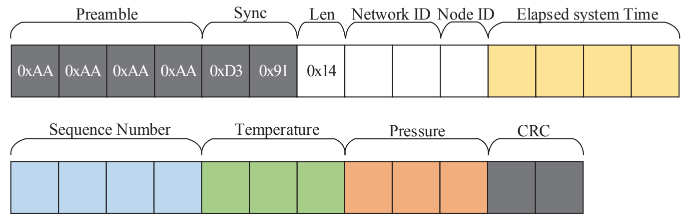


Fig. 5: The RF packet format used in UP-Link**.**

fact that bladder pressure changes relatively slowly, UP-Link becomes active only intermittently and remains in sleep mode for most of the time. As a result, the power consumed in the sleep mode plays a dominant role in determining battery life. UP-Link consumes only 1.5μA in sleep mode and requires only 0.19μAh for sensing and transmitting one sample of data. Figure 6 shows the measured current consumption of the UP-Link device during various stages of operation.

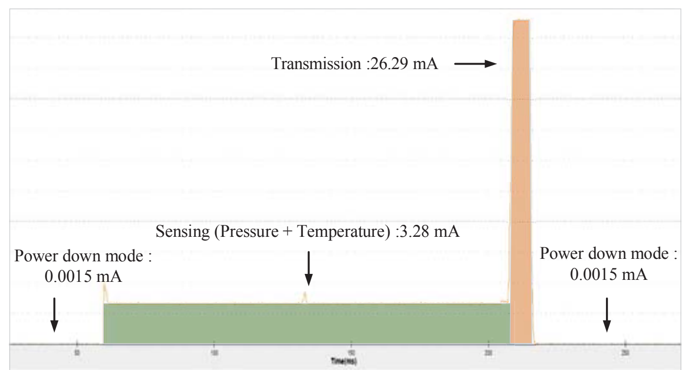


Fig. 6: Measured power consumption of the UP-Link **device.**

Given the measured power consumption of the hardware platform and the initial battery capacity of 560mAh, it is possible to estimate the battery life of an implanted UP-Link device. We adopt a very conservative approach and assume a safety margin of 65% in battery capacity due to variations in the initial capacity as well as other non-idealities that degrade battery performance. In other words, we assume that the batteries can only provide 196mAh to the device (*i.e.,* 35% of the initial capacity). Considering a scenario where UP-Link performs one sensor measurement and data transmission every hour, it requires 40.56μAh of battery capacity for a day and can operate for 4832 days (*i.e.,* 13 years) before it runs out of energy. Table I shows the estimated lifetime of UP-Link for different types of batteries under the assumption that only 35% of the initial capacity specified in their datasheets is actually available to the device.

Battery	Nominal voltage (V)	Required Number of cells	Total volume (cm^3)	Total capacity (mAh)	Estimated lifetime (years)
Size 13	1.4	2	0.6	560	13.2
CR2354	3.0	1	2.2	560	13.2
CR2032	3.0	1	1	240	5.6
CR2012	3.0	1	0.3	58	1.37

TABLE I: Estimated lifetime of the UP-Link **device**

III. Experimental Results

In this section, we experimentally demonstrate the accuracy in pressure measurement as well as the longevity of the UP-Link platform. The sensing accuracy of UP-Link was evaluated

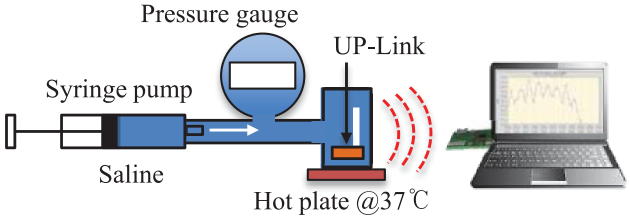


Fig. 7: *In vitro* test setup for evaluating sensing accuracy.

using an *in vitro* experiment. Additionally, an accelerated lifetime test was conducted to validate the lifetime estimation technique discussed in Section II-D.

A. In Vitro Pressure Measurement

Figure 7 shows the experimenal setup used to evaluate the accuracy of pressure data measured by UP-Link. The goal of the experiment was to simultaneously measure a pressure level using UP-Link as well as a commercial pressure gauge[5] and observe the correlation between the measurements. The UP-Link device was packaged in a customized acrylic block and coated with 1.5 µm of *Parylene C* for conformal passivation. The packaged UP-Link device was submerged in a pressure chamber filled with saline solution (7.4pH, 10% $NaOH_3$) that mimics body fluid. The saline solution is maintained at 37 °C to represent the body temperature. Based on the International Continence Society (ICS) minimal standards [11], the pressure of the chamber is varied between 0 and 60 cmH_2O using a syringe pump to mimic the human bladder. The pressure is increased until it reaches the peak and then decreased to simulate the contraction and relaxation of the bladder. Figure 8 plots the pressure measured by the UP-Link device and the commercial pressure gauge (considered to be the ground truth for this experiment). As seen in the figure, both curves are almost identical. The validation has been confirmed using the intraclass correlation coefficient (ICC) method type (2, 1), which gives an agreement of 0.995 between the two (note that an ICC of 1 indicates that two samples are identical).

B. Battery Life Analysis

We conducted an accelerated battery test to analyze the operational lifetime of UP-Link. For this experiment, the UP-Link device was powered by a pair of new, size 13 zinc-air batteries. In order to accelerate the test, the measurement interval was set to one sample every 3 seconds. This setting results in 28,800 samples being measured and transmitted per day, which is estimated to consume 5.508mAh of battery capacity daily (using the measured power consumption listed in Section II-D). Based on this, the lifetime of UP-Link is expected to be 35.5 days if the usable battery capacity is 35% of the rated capacity. In our actual experiment, the UP-Link device remained operational for 34 days before it ran out of energy. This validates the lifetime estimation technique used in Section II-D.

IV. Conclusions and Future Work

In this paper, we presented UP-Link, an implantable ultra-low power wireless system for long-term (months to years) ambulatory urodynamics. The platform is built using off-the-shelf

[5] DPG4000 from Omega

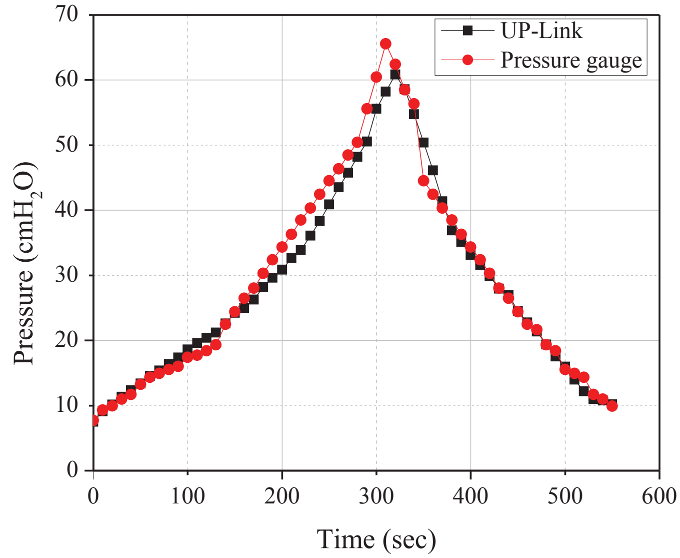


Fig. 8: Pressure measurements obtained using UP-Link and a commercial pressure gauge.

components and enables cost-effective and rapid development. The accuracy of the pressure measurements and the longevity of the platform have been demonstrated using *in vitro* tests. Current and future work includes improving the design for enhanced bio-compatibility and further power optimizations before moving to long-term *in vivo* experiments.

References

[1] E. J. McGuire, "Urodynamics of the neurogenic bladder," *Urologic Clinics of North America*, vol. 37, no. 4, pp. 507–516, 2010.

[2] R. Hackler, "A 25-year prospective mortality study in the spinal cord injured patient: comparison with the long-term living paraplegic.," *The Journal of urology*, vol. 117, no. 4, pp. 486–488, 1977.

[3] R. Gerridzen, A. Thijssen, and E. Dehoux, "Risk factors for upper tract deterioration in chronic spinal cord injury patients.," *The Journal of urology*, vol. 147, no. 2, pp. 416–418, 1992.

[4] P. Abrams, R. Feneley, and M. Torrens, *Urodynamics*. Springer, 2006.

[5] J. Coosemans and R. Puers, "An autonomous bladder pressure monitoring system," *Sensors and actuators A: Physical*, vol. 123, pp. 155–161, 2005.

[6] P. Cong, M. A. Suster, N. Chaimanonart, and D. J. Young, "Wireless power recharging for implantable bladder pressure sensor," in *Sensors, 2009 IEEE*, pp. 1670–1673, IEEE, 2009.

[7] P. C. Fletter, S. Majerus, P. Cong, M. S. Damaser, W. H. Ko, D. J. Young, and S. L. Garverick, "Wireless micromanometer system for chronic bladder pressure monitoring," in *Networked Sensing Systems (INSS), 2009 Sixth International Conference on*, pp. 1–4, IEEE, 2009.

[8] R. Tan, T. McClure, C. Lin, D. Jea, F. Dabiri, T. Massey, M. Sarrafzadeh, M. Srivastava, C. Montemagno, P. Schulam, *et al.*, "Development of a fully implantable wireless pressure monitoring system," *Biomedical microdevices*, vol. 11, no. 1, pp. 259–264, 2009.

[9] E. Siwapornsathain, A. Lal, and J. Binard, "A telemetry and sensor platform for ambulatory urodynamics," in *Microtechnologies in Medicine & Biology 2nd Annual International IEEE-EMB Special Topic Conference on*, pp. 283–287, IEEE, 2002.

[10] S. Wille, D. Tenholte, and U. Engelmann, "A system for long-term urodynamic studies without catheters," *European Urology*, vol. 63, no. 5, pp. 966 – 968, 2013.

[11] P. Abrams, L. Cardozo, M. Fall, D. Griffiths, P. Rosier, U. Ulmsten, P. van Kerrebroeck, A. Victor, and A. Wein, "The standardisation of terminology of lower urinary tract function: report from the standardisation sub-committee of the international continence society," *Journal of Neurourology and Urodynamics*, vol. 21, no. 2, pp. 167–178, 2002.