Accessible catheter valve system for managing urinary incontinence

Arin Ellingson, Jon Sass, Ben Schoepke, David Schurter, Mitch Tyler*
Department of Biomedical Engineering
University of Wisconsin-Madison,
1550 Engineering Drive Madison, WI 53706
*E-mail: metyler1@facstaff.wisc.edu

May 8, 2008

Abstract

Urinary incontinence in affects 10 million people the United States, leading to $36 billion in annual healthcare costs. Currently, few products on the market sufficiently meet the needs of many of those suffering from incontinence: the elderly and disabled. In this paper, a new accessible incontinence control device is presented. The design utilizes a modified 3-way Foley catheter that allows the user to control urine flow with an electric valve and monitor bladder status using a pressure sensor. The user receives visual, aural and tactile feedback of bladder status. User control and feedback is provided through a belt-mounted controller.

1 Introduction

Urinary incontinencethe inability to control urine flowis a major quality of life issue. Those who suffer from it often experience embarrassment and a decreased will to participate in social activities. It can lead to several psychiatric disorders, such as anxiety, depression, alcoholism, and psychosis. In addition to these factors, there are several neurologic, metabolic, infectious, and cardiovascular diseases and disorders that are associated with urinary incontinence. Some examples include stroke, multiple sclerosis, Parkinsons disease, spinal cord injury, diabetes mellitus, and HIV.

All of this leads to $36 billion in related healthcare costs annually. Individuals who suffer from incontinence may also have some sort of sensory-motor, physical, or cognitive impairment. The prevalence of urinary incontinence increases with age. The rate among community elderly is $10 - 15\%$, among hospitalized seniors is 30%, and among long-term care institutions is 50%. Urinary incontinence affects approximately twice as many women as men, up until the age of 80, where prevalence is approximately equal between men and women. There are several different types of urinary incontinence. Many age-related changes increase the probability that a person may develop urinary incontinence, including the following: [1]

- Detrusor (bladder smooth muscle) overactivity
- Benign prostatic hyperplasia
- Increased urine output later in the day
- Atrophic vaginitis and urethritis
- Increased postvoid residual urine volume
- Decreased ability to postpone voiding

- Decreased bladder capacity
- Decreased strength of detrusor muscle

A few common examples along with their symptoms and characteristics are shown in Table 1 on page 3.

1.1 Problem Statement

The task was to design a device to allow an incontinent patient (or their caregiver) to manage urine flow. The device should:

1. Be easily used by male and female patients with disabilities.
2. Allow emptying of the bladder when desired.
3. Prevent urine flow when not desired.
4. Provide an indication of the status of the bladder.
5. Remain indwelling for up to 30 days without adverse tissue reaction or material degradation.

1.2 Existing Technologies

There are several existing devices [2] for treating urinary incontinence and they fall into one of three groups: absorbent products, surgical options, and catheterization. Absorbent products include a variety of designs ranging from perineal pads or panty liners, for light leakage, to adult-diapers for heavier leakage. These options are bulky, embarrassing, and difficult to for disabled individuals to change independently. Surgical options are becoming more popular, however they are invasive and many of them require an intact nervous system for an implantable strain gauge to sense the stretching of the bladder wall or an implantable external urethral sphincter to be controlled by bodies own nervous system. The major drawback is that many patients associated with incontinence also suffer from other complications, such as nerve damage, neurological disorders, and even paralysis. The final major solution is the catheter. Catheter solutions range from external catheters (male's only), to intermittent catheters (one time use for every urination), to indwelling catheters (remain in for up to 30 days). Indwelling catheters are normally connected to a collection bag, which is strapped to the body allowing patient mobility (Figure). The use of an indwelling catheter connected to a valve at the end is another solution used to provide the patient with more mobility and a higher quality of life. Using the patient's own bladder as the reservoir, the valve prevents urine flow out of the body only until desired, and can be used with virtually all patients with incontinence. Wilson et al. showed in a study of 94 patients that 92% were satisfied with a catheter valve system while only 35% were happy with a standard drainage bag system. In addition, catheter valve systems showed no difference in the incidence of urinary tract infections [3].

2 Design

The device, shown in Fig. 1 on page 4, monitors bladder volume by measuring intra-bladder pressure using a pressure transducer connected to one outlet of a three-way Foley catheter. The user is able to control bladder flow using a thigh-mounted valve. The device provides customizable feedback through multiple sensory channels, including auditory, visual, and tactile responses, making the device accessible for patients with various disabilities. The device uses a discreet belt-mounted interface to relay bladder status to the patient and allow the patient to control the device. The system is powered by a lithium polymer battery.

2.1 Accessibility Features

The goal of this product was to create a user interface with a high degree of accessibility for users with a diverse background. The user interface can be broken down into two main ideas: bladder status feedback and the physical design of the enclosure. The current status features implemented target visual, aural and tactile receptors. Four LED indicator lights alert the patient to 25%, 50%, 75% and 100% bladder fullness.

Table 1: Types of incontinence and their associated characteristics.

Type	**Symptoms**	**Timing of leakage**	**Volume**
Stress	Leak with cough, laugh, exercise, lifting	Day	Small
Urge	Leak on way to toilet	Day and night	Variable
Mixed	Both urge and stress	Day and night	Variable
Overflow	Constant dribbling	Day and night	Small
Functional	Physically can't get to toilet	Day and night	Variable

The colors of the lights are green, green, yellow and red respectively. These colors were chosen because studies have shown the concepts most frequently associated with each color. For the American population green was recognized as safe by 61.4%, yellow as caution by 81.1%, and red as danger by 89.8% [4]. A small vibrating motor is attached to the inside of the enclosure to provide the tactile feedback. A small speaker is also embedded within the box for auditory feedback. This speaker resonates within the optimum frequency for auditory alerts of 500-3000 Hz as well as 15-25 db above ambient noise [4]. Another feature to increase personalization of the device is the implementation of a DIP switch that the user can use to deactivate any of the forms of feedback. The design of the enclosure utilizes a rectangular box construction. There is an illuminated rocker switch on top. This switch acts as a safety and must be engaged in order for the user to activate the push button valve release. This switch is illuminated when it is in the engaged position to give the user feedback that the valve can be released. There is also a push button status indicator on the front of the device. When depressed, this button alerts the user to their bladder status. In the event that the users bladder becomes full, the device will automatically set off an alarm, after which the user can depress the status button to silence it. The placement of the buttons is designed for people with minimal hand strength (e.g., a person with arthritis) and to counteract tremors from people suffering from Parkinsons by utilizing a power grip for hand stability. This size of the box is designed around the grip breadth for the 5th percentile female hand size of 4 cm [4].

2.2 Control Circuitry

The control circuit consists of three major parts: An 11.1 V Lithium Polymer Battery and its respective power regulation circuit, an analog signal processing system, and a digital control circuit powered by a Parallax Basic Stamp 2 microcontroller. A flow chart describing the control circuit is shown in Fig. 2.

DC Power Regulation: An 11.1 V lithium polymer battery supplies an overall potential of 11.1 V. This powers the amplification and the valve in the system. A 5 volt linear IC regulator is used to adjust the voltage and supply the remaining active circuit elements.

Analog Signal Processing: A signal ranging from 0-3 mV is obtained from the pressure sensor. This signal is then amplified, using a high common mode rejection ratio instrumentation amplifier, to a 0-5 V linear range. A first order low pass RC filter is then used to smooth the signal and eliminate high frequency disturbances. One obvious area for improvement is the implementation of a higher order filter in order to better stop high frequency transients.

Digital Control Circuit: The digital part of the circuit is programmed using a Parallax Basic Stamp 2 microcontroller and serves multiple purposes. First, the analog signal is converted to an 8-Bit signal, providing a resolution of 0.020 V on the usable range. The signal is then sampled using the microcontroller in conjunction with the 555 astable timing circuit. Digital signal processing techniques are used to filter the signal further.

The second purpose of the microcontroller is to be the buffer between the user interface and the circuit. Two push button switches send inputs to the controller, one to indicate status and one to control the

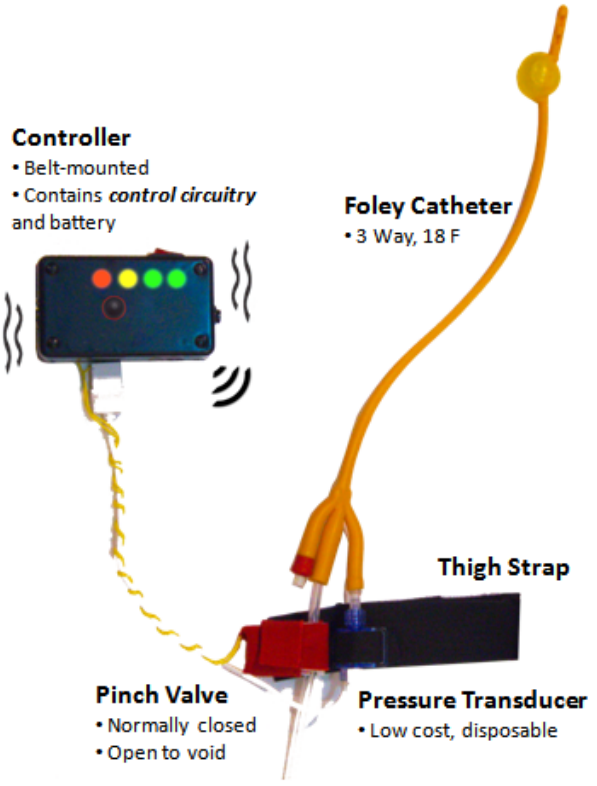

Figure 1: The device consists of a 3-way Foley Catheter with a valve mounted at the end for controlling urine flow and a pressure sensor for measuring bladder fullness. The controller provides the user interface and houses the control circuitry and battery.

valve.

Third, and lastly, the controller controls display elements, consisting of 4 super-bright LEDs, a DC speaker, and a DC vibrator. The entire circuit was implemented on a 2.4 x 1.4 inch printed circuit board, shown in Fig. 3.

2.3 Valve

Our device eliminates the need for a collection bag by placing a pinch valve at the end of the catheter as seen in Figure blah. The current valve solution is a Valcor Scientific SV23C, 12 volt DC, normally closed solenoid pinch valve (Figure). However, the valve to be implemented in the future was developed

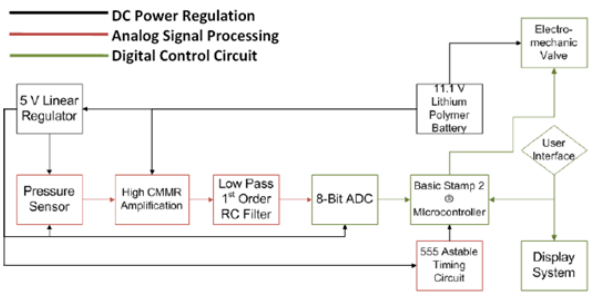

Figure 2: The control circuitry consists of power regulation, a microcontroller, pressure amplification, and I/O from switches and to LEDs, a piezo-electric speaker, and a vibration motor.

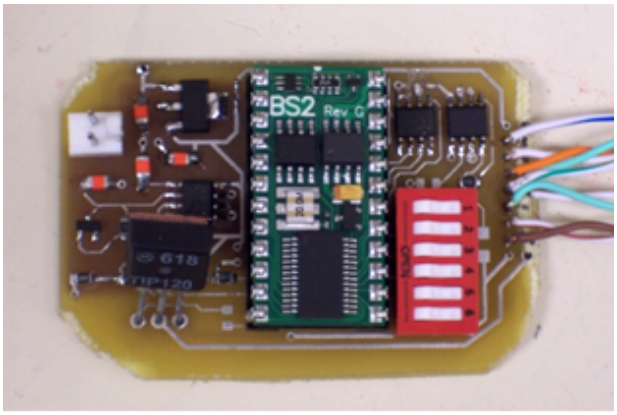

Figure 3: The control circuitry implemented on a small printed circuit board. This board is housed in a small, belt-mountable controller.

[h]

by Durham University (Shan-Lai) [5], which utilizes a motor that connects to and drives a small screw to pinch the tubing off, thus preventing drainage. The valve uses power only to move the screw back and forth; this will decrease the amount of power draw of the system greatly. It is shown in Fig. 4.

The Shan-Lai valve uses only 30 mAh over 30 days and obtains a flow rate of 618 mL/min, which is over $3x$ faster than the previously described Valcor valve. The low energy consumption and the high flow rate allow for longer battery life.

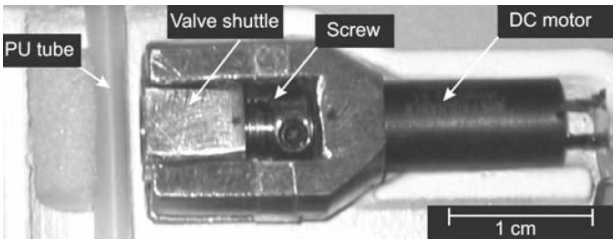

Figure 4: The Shan-Lai valve [5] is ideal for our design because of its small size, high flow rate, and low power requirement. It prevents flow through a tube without coming into contact with the fluid by pinching it closed.

2.4 Determining Bladder Status

Bladder status monitoring was accomplished by measuring urine pressure with a pressure transducer connected to one of the catheter outlets. There is a direct relationship between bladder pressure and volume, as reported in several studies [6]. The pressure data is fed to the microcontroller and the corresponding fill level is determined by comparing the pressure value to pre-programmed values. These values are computed by dividing a patient-specific maximum pressure value by the number of possible levels (4 in the current prototype). This maximum pressure value would be determined through a one-time cystometry test when the patient is being fit for the device.

Filtering is necessary to remove high frequency changes in pressure caused by temporary increases in intra-abdominal pressure. This can be due to movement, coughing, or other sources. Filtering is accomplished through a combination of hardware and software filters. The input signal from the pressure transducer is fed through the differential inputs of an instrumentation amplifier with a high common mode rejection ratio, reducing thermal noise. After amplification, the signal is converted from analog to digital with an 8-bit analog-to-digital converter and fed into the microcontroller for further processing.

Physiologically, the bladder does not fill quickly, so a relatively low sampling rate of 5 Hz was used. This is also advantageous since a lower sampling produces fewer samples and requires less processing time. A moving average filter, given in Eqn. 1, was used to smooth the input signal. This was chosen since it is not computationally intensive and thus desirable for a low power embedded system. M in Eqn. 1 determines the amount of smoothing and computation needed; an M value of 10 was chosen as a good balance.

$$y[i] = \frac{1}{M} \sum_{j=0}^{M-1} x[i-j] \tag{1}$$

In addition to the moving average filter, thresholding is applied to remove samples with an absolute value difference of greater than 10% of the full scale range. This effectively eliminates transient spikes in intra-abdominal pressure.

3 Evaluation

3.1 Testing and Validation

The flow rate of the device was measured to be 170 mL/min. The Rehabilitation Engineering Research Center on Accessible Medical Instrumentation, which funded this project, specified a minimum 100 mL/min flow rate, so this performance requirement was exceeded by the current prototype. Battery life was calculated to be approximately 26 hours, assuming a fully charged 850 mAh lithium polymer battery. This result was achieved by assuming worst-case scenario in which the user would void once per hour for 2 minutes and check bladder status twice an hour with all alarms activated.

Pressure filtering performance was evaluated using a simulated bladder pressure signal, modeled after data found in Pel, et al. [6]. As seen in Fig. 5 on page 6, the filtering solution was successfully able to remove spikes in bladder pressure and smooth out noise. This prevents false bladder status reports to the user and avoids setting off the full bladder alarm when the bladder is not full.

3.2 Cost Analysis

The total cost for one prototype is $327.41. This would be a one- time purchase followed by monthly

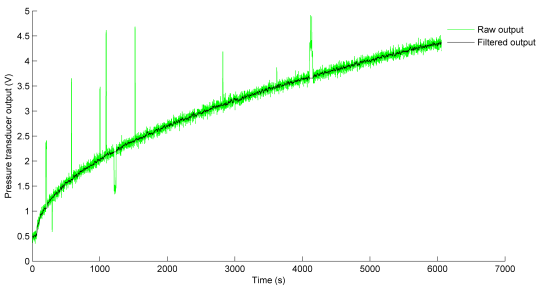

Figure 5: Result of moving average and thresholding filter applied to a simulated pressure transducer output signal over the course of a normal bladder filling. Spikes in intra-abdominal pressure are removed and the output signal is smoothed.

expenditures of $13.02 to replace the pressure sensor and the catheter. Some patients may have also have to pay a monthly cost to have a new catheter inserted, while others may be able to do this themselves. Cost reductions from the prototype to a production model can be achieved by utilizing the Shan-Lai valve (-$100) and a PIC microcontroller (-$45). With these design modifications and mass production, the cost to manufacture one device is estimated to be around $150. Costs for the production of one prototype are summarized in Table 2.

Table 2: Cost of the production of one prototype.

Valve	$135.30
Microcontroller	$49.00
Battery charger	$29.50
Electronics	$26.93
PCB	$19.97
Enclosure	$18.99
Battery	$17.60
Leg Strap	$17.10
Pressure Sensor	$8.75
Catheter	$4.27
Grand total	$327.41

4 Conclusion

Our solution offers a significant advancement for urinary incontinence patients wearing indwelling catheters connected to drainage bags. It provides them with the mobility needed for an active lifestyle and avoids the embarrassment associated with wearing a large drainage bag. Unlike a drainage bag system, this device is easily usable by patients with sensory-motor, physical, and/or cognitive disabilities through the use of a simple interface that requires only button pushes to operate. In addition, it provides multi-sensory indication of bladder status, allowing patients with nerve damage to know when they have to go.

Going forward, the device needs to go through human subjects testing for further validation. The prototype would need to be optimized to make the controller more discreet and aesthetically pleasing. Another option would be to integrate the user interface and pressure monitoring into a cell phone application. This would eliminate the need for a separate controller and would likely be a more attractive option for patients who already own cell phones. In this case, a wireless data between the pressure sensor/valve control circuitry and cell phone would be required, possibly over a serial Bluetooth connection. An additional battery would also be required to power the valve and pressure sensor.

5 Acknowledgements

The authors would like to thank the Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC-AMI) for funding this research. We would also like to thank the following individuals for all of their contributions to the project: Ben-Tzion Karsh, Ph.D., Wade Bushman, M.D., Ph.D., Amit Nimunkar, Willis Tompkins, Ph.D., Naomi Chesler, Ph.D., Abby Frese, R.N., and L. Burke O'Neal.

References

[1] E. L. Cobbs, E. H. Duthie, and J. B. Murphy, *Geriatrics Review Syllabus*. Blackwell Publishing, 5 ed., 2002.

[2] D. K. Newman, "Incontinence products and devices for the elderly.," *Urol Nurs*, vol. 24, no. 4, pp. 316–33; quiz 334, 2004.

[3] C. Wilson, S. S. Sandhu, and A. V. Kaisary, "A prospective randomized study comparing a catheter-valve with a standard drainage system.," *Br J Urol*, vol. 80, no. 6, pp. 915–7, 1997.

[4] M. Helander, *A Guide to Human Factors and Ergonomics*. CRC Press, 2 ed., 2005.

[5] S. M. Lee, T. D. Short, and A. Unsworth, "Design and development of a novel automatic valve system for long-term catheterized urinary incontinence patients.," *Proc Inst Mech Eng [H]*, vol. 221, no. 6, pp. 665–76, 2007.

[6] J. J. Pel and R. van Mastrigt, "Non-invasive measurement of bladder pressure using an external catheter.," *Neurourol Urodyn*, vol. 18, no. 5, pp. 455–69; discussion 469–75, 1999.