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Rehabilitation Engineering
Research Center on Accessible
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[Accessible Incontinence Device]

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Abstract

Incontinence in the United States affects 10 million people leading to $36 billion in healthcare costs annually. Currently, few devices on the market sufficiently meet the needs of those suffering from incontinence. In this project, an accessible incontinence device was designed and a prototype was created. The design utilizes a modified 3-way Foley catheter that allows the user to monitor bladder status using a pressure sensor, controls urine flow with a pinch valve and is governed by a microcontroller. The user receives visual, aural and tactile feedback indicating bladder status. A power grip control is implemented for hand stability to accommodate people with decreased physical strength and/or tremors. The user display is belt-mounted and the complete system is powered by a Li-Ion battery. The invention was publically disclosed on December 7, 2007 during the UW-Madison biomedical engineering poster session. A formal Invention Disclosure Report will be submitted to the Wisconsin Alumni Research Foundation (WARF) in December 2007.

1.0 Problem Statement

Patients with urinary incontinence are unable to control urine flow due to specific disease pathology, trauma, or other causes. Incontinence affects men and women, occurs more frequently with age, and can cause infection, skin irritation, and embarrassment. It negatively affects quality of life and many incontinent patients avoid activities in public, for instance due to the potential for a spastic bladder to spontaneously cause release of urine without warning.

2.0 Background and Motivation

Continence requires several factors. The person must be physically mobile enough to make it to a restroom. Once at the restroom, manual dexterity is required to do things such as lifting a toilet seat, removing clothing, and position properly to use the toilet. It requires enough cognitive ability to recognize and react to bladder filling and mental motivation to stay dry. It also requires physiological capabilities, such as the coordination of bladder smooth muscle and urethral sphincter control mechanisms. These are controlled by both the sympathetic and parasympathetic nervous systems.

Urinary incontinence—the inability to control urine flow—is 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 are shown in Table 1. All of this leads to $36 billion in related healthcare costs annually.

Table 1: Diseases and disorders that can predispose a person to urinary incontinence

Neurologic	Metabolic	Infectious	Cardiovascular
Stroke	Diabetes mellitus	Herpes zoster	Arteriovascular disease
Delerium	Hypercalcemia	HIV	Congestive heart failure
Dementia	Vitamin B12 deficiency	Neurosyphillis	
Multiple sclerosis		Tuberculosis	
Multisystem atrophy			
Normal-pressure hydrocephalus			
Parkinson's disease			
Spinal cord injury			
Spinal stenosis			

Individuals who suffer from incontinence also may have some sort of cognitive, sensory-motor, or physical impairment. Because of these disabilities, any design needs to follow the principles of Universal Design, as outlined in Appendix B (Story, 1998).

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 it 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. Several age-related changes increase the probability that a person may develop urinary incontinence:

- Detrusor (bladder smooth muscle) overactivity
- Benign prostatic hyperplasia
- Increase 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
  (American Geriatric Society, 2007)

There are several different types of urinary incontinence. A few common examples along with their symptoms and characteristics are shown in Table 2.

Table 2: 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

2.1 Existing Solutions for Bladder Status Monitoring

Currently, there are a few solutions on the market to monitor the bladder status during filling. Medtronic's Interstim solution is an implantable strain gage that mounts on the side of the bladder. The gage senses the stretching of the bladder wall to provide feedback on how full the bladder is. The product then sends the electric impulses to the sacral nerve, which controls the urinary sphincter. This device could be interfaced with an external controller designed to manage dispelling of the bladder. However, this connection would be rigorous and this specific solution would require an invasive surgery, which we wanted to avoid. American Medical Systems also produces a surgical answer. They have developed an implantable artificial urinary sphincter. The implant would take the place of a defective external urethral sphincter. One major drawback is this surgical replacement is only valid if the patient has an undamaged nervous system, thus it would not be applicable to patients who are paralyzed or have other neurological damage in this area.

There is one option currently being used that does not entail surgery. Ultrasound can be used to create an image of the bladder. The dimensions of the bladder can then be found, giving insight into the size of the bladder. Since the patient must remain still throughout the procedure to gain an accurate image,

ultrasound is not a viable option for providing a constant status of the bladder. Also, continuous monitoring of the bladder with ultrasound would prove to be too expensive of a solution.

According to a recent publication by Chiumello et. al., they showed there is a direct relationship between the amount of fluid in the bladder and the intra-bladder pressure (Chiumello, 2007). To test the relationship Chiumello's group inserted a Foley catheter into the bladder and split one exit port two ways. In one port they quantitatively injected saline solution (0-200 mL), while the other port was equipped with an external disposable pressure transducer. Figure 1 displays the findings. This relationship has been verified by a minimum of three additional studies (Malbrain & Deeren, 2006) (Rikken, Johan, & Mastrigt, 1999) (Damaser, 1999).

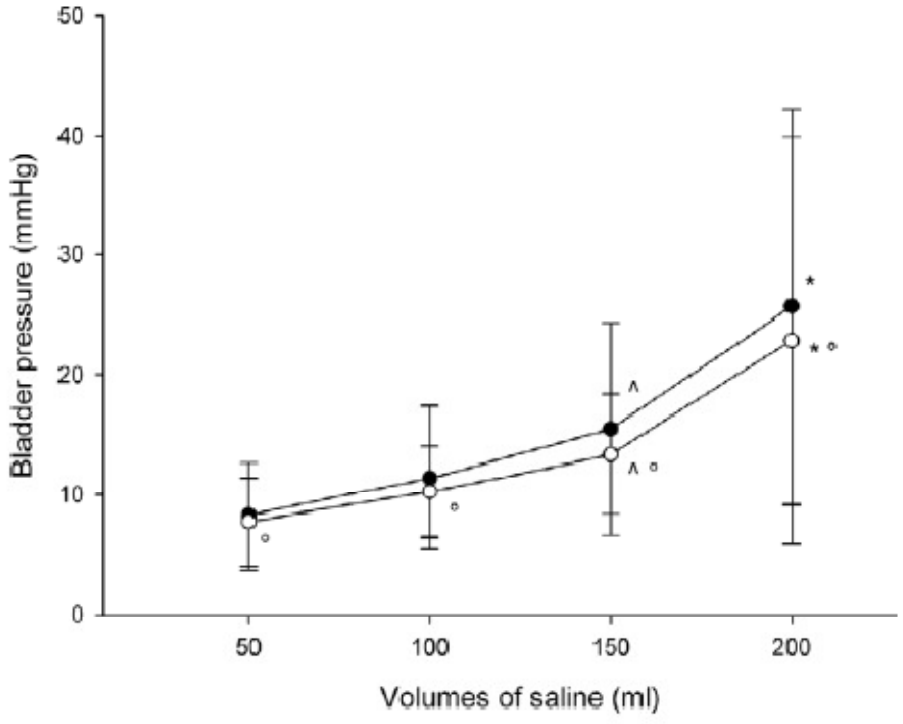

Figure 1: Relationship between intra-bladder pressure (mmHg) and volumes of injected saline (mL). Black circles represent the response at room temperature and white circles represent the represent response at body temperature (Chiumello, et al., 2007).

Our team chose to use external pressure measuring for indicating the status of the bladder. Since the transducer is located outside the bladder, only the Foley catheter is internal. There is no need for an invasive surgery and since Foley catheters have been approved by all regulating entities, such as the FDA there is little concern for material degradation.

3.0 Design Requirements

The device must enable control and management of urine flow by patients with disabilities, be able to be switched on and off, and provide an indication of the status of the bladder. It must also be able to remain indwelling for up to 30 days without adverse patient reaction or material degradation. The

design will be based on a traditional Foley catheter design, with several modifications for improved accessibility and performance. Because the device will be inserted into the urethra and remain indwelling for some time, it must be made of materials that will not cause a reaction or infection in the patient. Foley catheters are typically made of Latex or silicone. Also, to prevent overpressure and rupture of the bladder, the mechanism used to control flow must have an overpressure safety function where it will release before bladder pressure reaches dangerous levels. The device must be accessible for patients with disabilities, specifically those with Parkinson's and those with limited strength and motor control (RERC Competition Suggested Users, Appendix F). The flow control mechanism must be easy to use and the bladder status indication must be simple and clear. The device should not be obtrusive or interfere with the patient's daily activities. The control mechanism should be small and the user interface should be simple and easy to operate.

4.0 Design Overview

The device incorporates a Foley catheter, and only builds on the external features of the catheter. The device consists of two main components: A leg mounted strap that holds a pinch valve and pressure transducer and a belt-worn device that contains the electrical components to the system, including the microcontroller and battery. Figure 2 presents the logic to our overall system design. The design's "brain" is a Parallax BASIC Stamp 2 microcontroller®. The purpose of this device is to analyze the data from the bladder status transducer and alert the user to the bladder status.

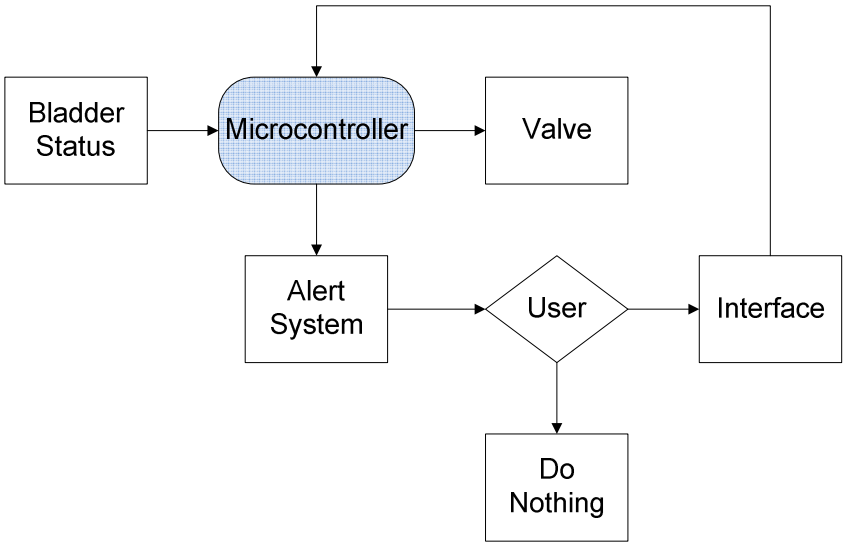

Figure 2: This figure was the basic design logic used in developing a prototype.

The system then relays information on bladder fullness to the user using multiple stimuli (visual, auditory, and tactile) to gain the users attention. The user can then interact with the interface to either empty the bladder or ignore the status. Urine flow is controlled with the pinch valve, which pinches the external Foley catheter to restrict flow. This is the concept the rest of the research and development was based around.

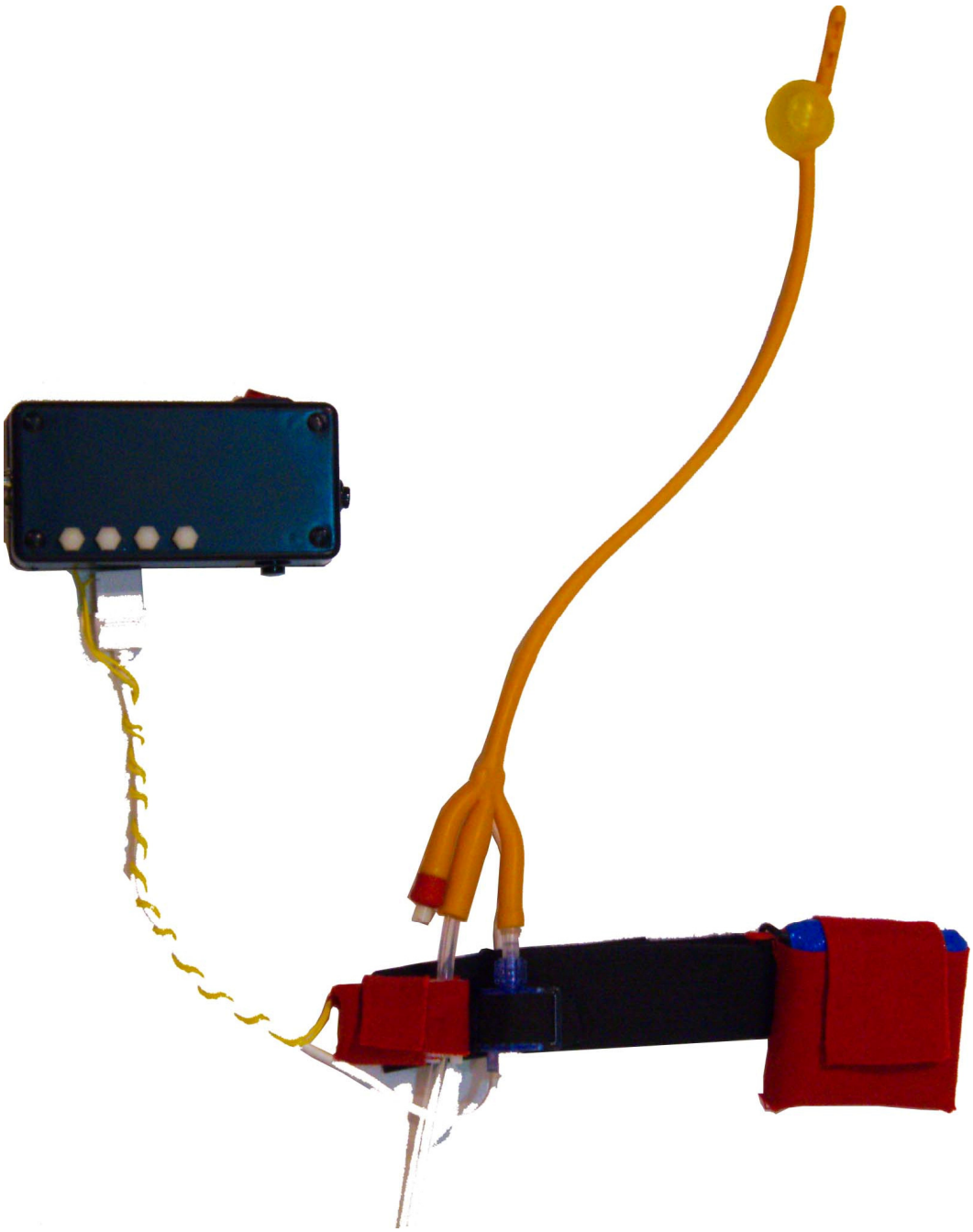

Figure 3: Complete Design. The pinch valve, battery, and pressure transducer are thigh-mounted. One cable runs to the belt-mounted control box.

4.1 Foley Catheter

The Foley Catheter is a standard medical device that is used to address incontinence. The basic function of the device is to collect urine directly from the bladder and redirect it to a bag worn by or positioned nearby the patient. The device does not control the flow of urine at all; it only redirects it.

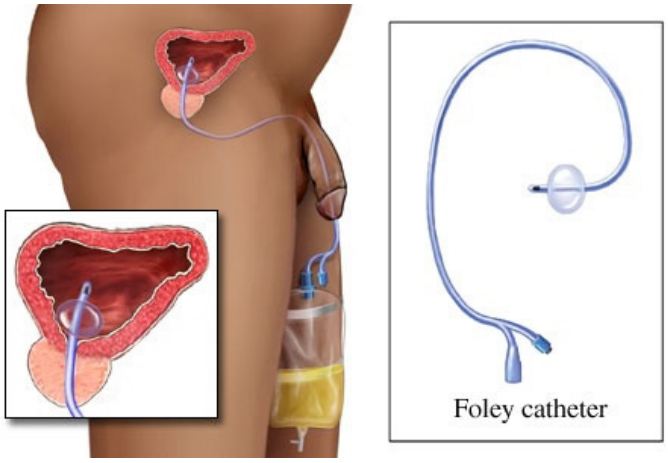

Figure 4: Standard Foley catheter use. The figure shows both the device and the devices placement anatomically (eMedicine.com, 2007).

The device consists of tubing typically made of latex or silicone that is inserted in the urethra and anchored into the bladder. It is anchored through the use of a balloon (made from the same material as the tubing) that is inflated with fluid once positioned in the bladder. Typically, urinary catheters must be replaced every 30 days. This can either be done by a trained professional or by the patient if the patient is capable and willing.

4.2 Pressure Transducer

To monitor the intrabladder pressure, a Deltran disposable pressure transducer from Utah Medical was used. A disposable transducer was chosen because a new transducer should be used every time the indwelling Foley catheter is replaced (approximately every 30 days). The valves are relatively low cost, making this a feasible option.

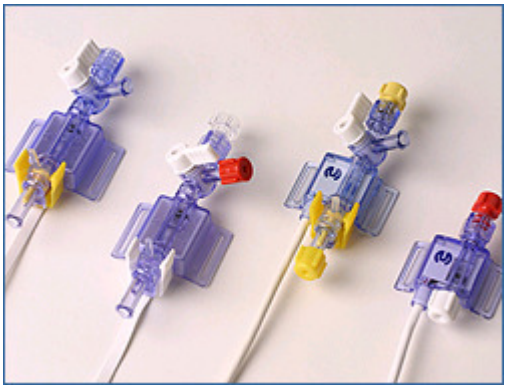

Figure 5: Deltran disposable pressure transducers from Utah Medical (Utah Medical, 2007).

4.3 Control Circuit

The flow logic for the major components in the circuit is shown in the following figure. A description of important components follows.

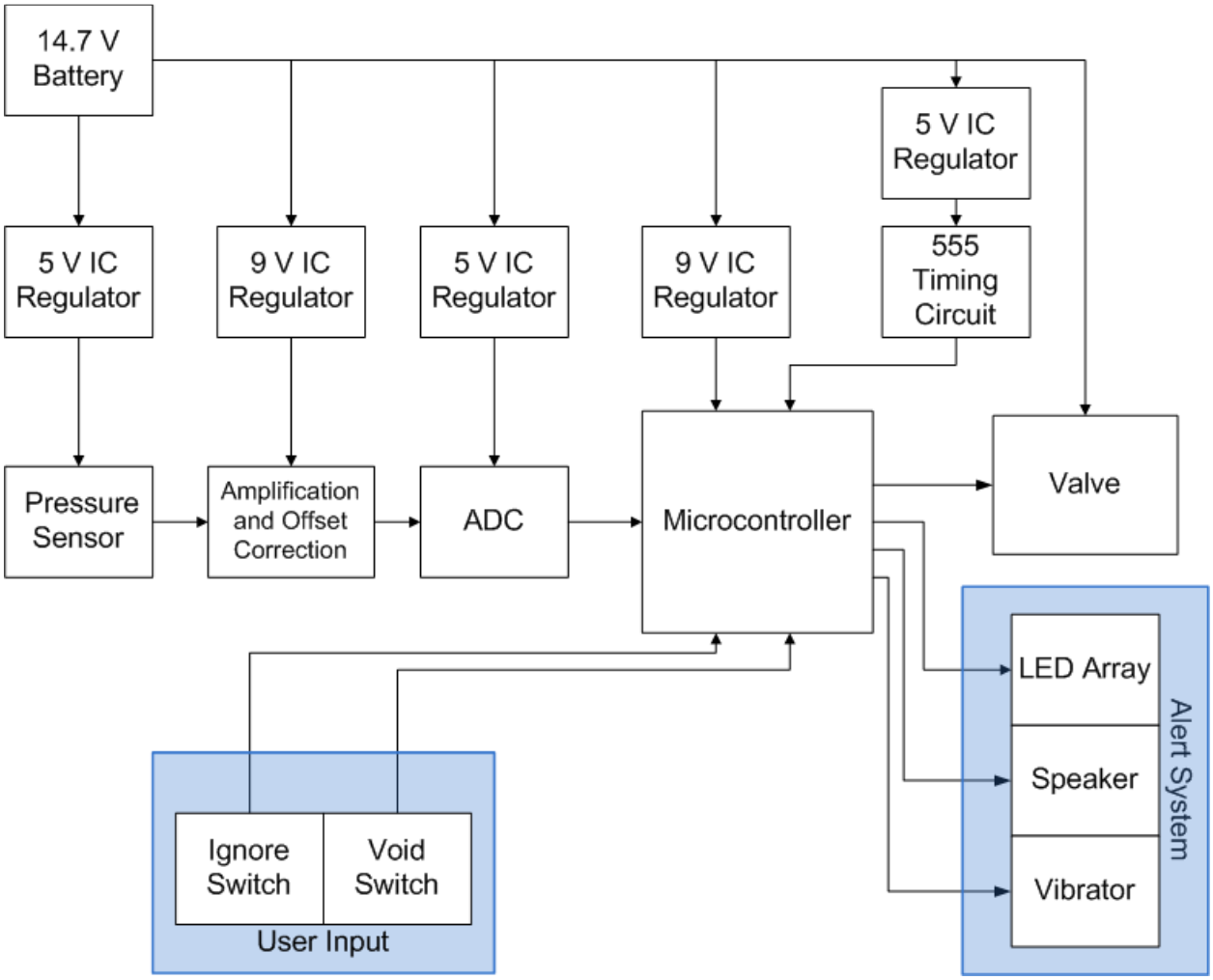

Figure 6: Circuit component diagram. This schematic illustrates the interrelation of each component.

4.3.1 ADC

The ADC is an ADC0831CN 8 Bit converter. The ADC receives an anlog input from the pressure transducer sends a digital signal to be processed by the microcontroller.

4.3.2 555 Timing Circuit

Assembled in a stable mode using 555L IC. The timer sends a pulse in given intervals. For this circuit, the pulse is sent every 5s, with a duty cycle of about 5%. The circuit is coupled from DC offset with a 2.2 µF capacitor.

4.3.3 5V IC Regulator

Simple regulation circuit incorporating LM7805 5 V regulating IC. The regulator acts as a constant 5 V source to the pressure transducer, ADC, and 555 timing circuit. The regulator is coupled using 2.2 µF capacitors.

4.3.4 9V IC Regulator

Incorporates a LM317 variable voltage regulator. The regulator is set to 9.5 V due to resistor restrictions. The LM317 supplies the voltage to the microcontroller and possibly a future offset correction circuit. The regulator is coupled using 2.2 µF capacitors.

4.3.5 Alert System

The alert system is an array of several stimuli located in the box. The speaker is a Parallax Piezoelectric Speaker®. The LED array consists of four Super Bright LED's®: Two green, one yellow, and one red. The vibrator is a Jameco Electronics 1.3V vibrating motor.

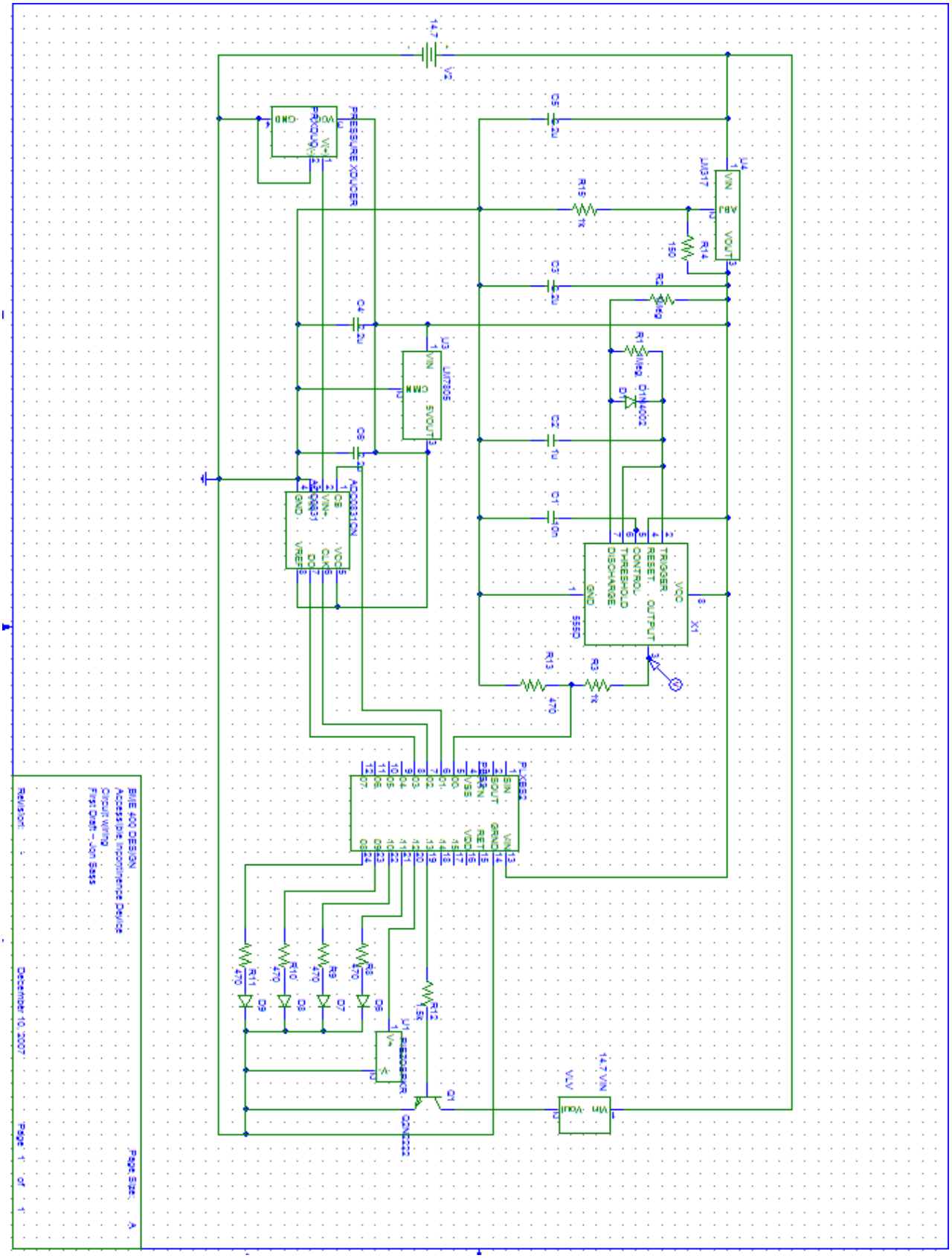

Figure 7: Detailed circuit schematic. Drawn in PSPICE.

4.4 Microcontroller

A microcontroller was used to process input data and control user feedback. The Parallax BASIC Stamp 2 microcontroller was selected for several reasons. It is relatively easy to program since it comes with a user-friendly IDE and uses a simplified version of the BASIC programming language. It also has 16 input/output pins that each can be configured as either inputs or outputs. While a single BASIC Stamp 2 module is significantly more expensive than alternatives, the ease of programming justified the additional cost for the prototype. An image of the microcontroller is shown below in Figure 8. A diagram of the microcontroller with its pins labeled is shown below in Figure 7.

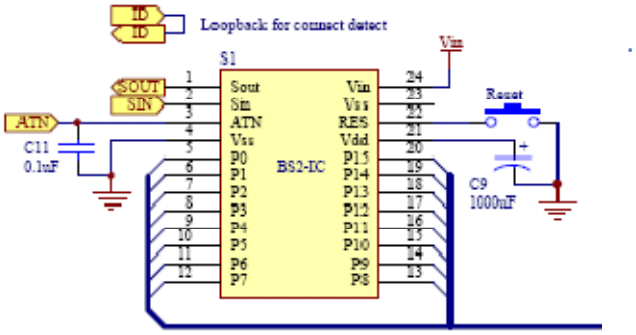

Figure 9: Pin-out diagram for microcontroller (Parallax, 2007).

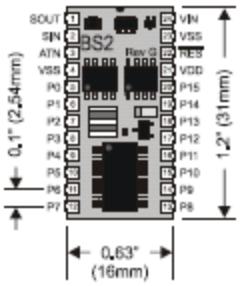

Figure 8: Parallax BASIC Stamp 2 Microcontroller with dimensions (Parallax, 2007).

The microcontroller was purchased along with Parallax's USB Discovery Kit. The kit included a prototyping board with a USB port that allowed for coding on a Windows computer and loading it onto the microcontroller. The kit also came with documentation and several electrical components that served as a good introduction to programming the BASIC Stamp 2.

A future prototype could make use of a less expensive alternative such as the Microchip PIC 16F57. These microcontrollers are physically smaller, consume less power, and cost less than $1 each. The downside to these microcontrollers is that they require programming in machine language or C (if you purchase Microchip's C compiler), which is generally more difficult than programming for the BASIC Stamp 2. The current code could be directly ported over to the PIC microcontroller since it has similar processing power and memory capabilities as the BASIC Stamp 2.

4.5 Software Algorithm

Below is a pseudo-code description of our embedded software that runs continuously on the microcontroller when it is powered on. Specific details like how often the pressure is sampled are omitted since those values still need to be fine-tuned.

```
Initialization phase at power on {
      activate RED LED
      sample pressure several times over ten seconds
      compute average of sampled pressures and save this value
```

```
      blink green LED three times, pulse three vibrations, and play tone to
      indicate initialization is complete
}

Main program loop {
      //check status of void button
      if (void button is activated) {
            wait until button is deactivated
            open valve until button is activated again
      }

      //measure pressure
      if (received pulse from timing circuit) {
            sample several pressure values from ADC input
            compute average of sampled pressures
            if (absolute value(average pressure – existing pressure value) <
            threshold) //simple pressure spike filter {
                  save average pressure value
                  compute current bladder “level” based on saved pressure
                  value
            }
      }

      //check bladder level against alarm threshold
      if (bladder level is at the highest level) {
            activate the visual, audible, and tactile alarms
            if (void button is activated) {
                  deactivate alarms
                  go to voiding subroutine
                  sample new pressure value
            }
            if (status button is activated) {
                  “snooze” alarm for arbitrary amount of time
            }
      }

      //check status of status button
      if (status button is activated) {
            light up the corresponding bladder level # of LEDs, vibrate
            bladder level # of pulses, and chirp speaker bladder level # of
            times
      }
}
```

In the future, the code needs to be fully black- and white-box tested, as there are some known bugs and not all scenarios have been tested due to time constraints. Also, a more robust signal processing algorithm should be developed. The current method of simply comparing the difference between the new sampled value and the old saved value has not been validated in a real world testing environment and may not be reasonable. For example, if the patient experiences a quick yet sustained increase in

bladder pressure (e.g., from increased intra-abdominal pressure due to a change in posture), the code will ignore this indefinitely, even if the bladder continues filling during that time.

4.6 Battery

To maximize patient mobility, battery power is used. A Lithium-Ion 14.8 volt DC, 2200 mAh, rechargeable battery was selected. Lithium-Ion was chose over other battery types because it allows the greatest capacity while keeping a compact size. It also has a longer storage life than NiMH batteries. The battery is also mounted on the thigh strap, opposite the pinch valve. Alternatively, the battery could be mounted on the belt.

Figure 10: 14.8 Volt Li-Ion Battery used to power device (Jameco, 2007).

4.7 Pinch Valve

The pinch valve used is a Valcor Scientific SV23C, 12 volt DC, normally closed valve. The valve draws 4.2 Watts when active. It is 1.25 inches in diameter and 2.25 inches tall (pictured in Figure 10). It can accommodate a tube with an outside diameter of 0.25 inches. This valve was selected for several reasons.

Figure 11: Valcor Scientific pinch valve used to control urine flow by pinching the catheter (Valcor Scientific, 2007).

1. *Size*. The valve's compact size allow it to be placed on a thigh strap without excessive discomfort or added weight.
2. *Normally-closed.* A normally closed valve was used to maximize battery life. The valve only draws current during voiding, when it is open.
3. *Low power draw*. The valve is part of Valcor Scientific's low power draw valve series. This will prolong battery life.
4. *Orifice Size*. The valve will accommodate up catheters 18 French (approximately 6 mm). While Foley catheters range in size from 12 French to 24 French, many hospitals use only one standard size, usually around 16 French or 18 French (Frese, 2007). Larger valves exist that would work for larger catheters if needed, but to maximize battery life this size was chosen.

5.0 Accessibility

The device is designed towards those who will be able to complete the entire monitoring and emptying process by themselves as well as towards empowering people who cannot do those things on their own because it gives them control over when to call for assistance, thus increasing their quality of life by giving them control they did not previously have over a bodily function. The user display can be broken down into two main ideas: status features currently implemented 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. The color of the lights is 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% (Helander, 2006). A small vibrating motor was attached to the inside of the enclosure to provide the user 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 [Karsh]. An 1/8" AV female jack was also implemented into the design of the box. This feature will allow users to connect their own switch in order to activate the pinch valve. Examples of switches that have corresponding male jacks include the Tash Microlight switch and the Origin Instruments Sip/Puff switches. Another feature to increase personalization of the device is the implementation of a dip switch that when activated will short out any feedback the users wishes too.

Figure 12: Accessible control box.

The design of the enclosure utilizes a rectangular box construction (see Figure 11). 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 initiates the microcontroller to initialize the status feedback components alerting the user to the bladder status. In the event the microcontroller signals alerts the user the bladder status, the user may depress the status button to silence the alarms. The placement of the buttons is designed to counteract tremors from people suffering from Parkinson's 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 (Helander, 2006).

6.0 Future Development

This project will be continued through the spring semester of 2008. There are several future additions and modifications planned that will optimize functionality.

First there are several accessibility issues that will be addressed in the next semester. The software for the auxiliary plug will be integrated with the microcontroller to allow for the addition of different trigger

interfaces. The visual alert will also be addressed with the goal of increasing the resolution. A 10 LED bar graph will be implemented in order to utilize the principle of pictorial realism. Since bladder volume is normally sensed by an increase in bladder pressure, further research on pressure cuffs and other tactile feedback mechanisms will be conducted. The reason most of these have not been implemented is because of the hardware constraints we have faced mainly with the number of pins and the amount of memory available on the microcontroller. Also, implementing a pressure cuff would require an external motor. This could significantly change the power consumption we are currently dealing with. Our battery is already too large and we need to minimize the current draw wherever possible in order to be able to use a smaller battery.

Also, the pressure transducer must be implemented and calibrated. Right now, the transducer is not wired to the circuit and pressures are simulated by applying voltages with a power supply. Also, the circuit must be printed to a circuit board to allow it to fit inside the belt-mounted enclosure. A microcontroller with more input and output pins will be researched to possibly allow for better resolution in the user interface.

Finally, besides the needed design improvements, there are several items that relate to project deliverables and validation. First, we will disclose our design to the Wisconsin Alumni Research Foundation. We will also apply for a clinical validation study with the UW Hospital IRB. This study will not only confirm that the device functions well, but also get patient feedback on the interface and operations. In April of 2008, we will compete in the RERC on AMI National Student Design Competition with our completed and validated design.

7.0 Ethical Considerations

The main ethical concern of our device is patient safety. Before we do any human subjects testing, we will carefully develop a testing protocol that ensures the safety of all patients. It is our responsibility to make sure that the device will not expose the patient to disease or inflict physical harm. Our prototype uses a sterile Foley catheter from a medical supply company. We will ensure that the catheter is inserted in a sterile manner to prevent infection. From our conversations with Wade Bushman, M.D., Ph.D., we determined it is not uncommon for patients to have indwelling Foley catheters for a period of thirty days. We can say with confidence that the indwelling component of our device does not pose a safety threat since it follows these standard practices. Once a suitable testing protocol is drafted, it will be submitted to the University of Wisconsin's Health Sciences Institutional Review Board (IRB) for approval. We will provide users with specific instructions on how to safely operate the device (Bushman, 2007).

Another safety concern for the device is its use of a lithium ion battery. Lithium ion batteries can be dangerous or explosive if short-circuited. Our battery, however, contains protective circuitry that shuts itself off in the event of a short circuit or excessive discharge. We have successfully tested this safety feature on several occasions. The battery will be housed inside of the belt-mounted controller. However, power needs to be sent to the valve located on the patient's leg. The valve draws a current of approximately 300-400 mA, which is in a lethal range. However, due to the high resistance of the skin

and the insulation of all wires, we do not feel that this poses a threat to patient safety. We will ensure that any devices destined for patient use have stable, secure, and well insulated electrical circuitry.

If the device were to go into commercial production in the United States of America, it is our responsibility to submit a Premarket Notification and gain Premarket Approval from the Food and Drug Administration (FDA) before bringing it to market. An overview of FDA medical device regulations is available on their website. The FDA also has specific guidance for Foley catheters that will be adhered to. For example, this guidance requires that we include documentation that instructs the patient on how to prepare the catheter, insert and remove it, and procedures for what to do if the balloon fails to deflate (FDA, 2007).

We have reviewed current literature and conducted internet searches to determine to the best of our ability that our device is an original idea and does not infringe on existing intellectual property. However, our searches may not have been comprehensive due to time constraints.

8.0 Intellectual Property Considerations

The invention was publically disclosed on December 7, 2007 during the UW-Madison biomedical engineering poster session. A formal Invention Disclosure Report will be submitted to the Wisconsin Alumni Research Foundation (WARF) in December 2007 as well. Because federal funding was used during the development of the device, any intellectual property will belong to the university.

9.0 Conclusion

Our group has designed an accessible device that allows incontinent patients increased control over their urinary function. This control grants them greater mobility and improved quality of life. Our design is focused on a three-way Foley catheter, a thigh mounted pinch valve and a pressure transducer. A belt mounted circuit monitors the bladder status and provides the user auditory, tactile and visual feedback. The user is also provided the means to check the bladder status at any time as well as activate the pinch valve to release the bladder. This project is sponsored by RERC on AMI and will continue next semester.

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Appendix A – Product Design Specifications

Title: Accessible Incontinence Control Device

Client:	Dr. John Enderle
Team Members:	Arin Ellingson, Co-Team Leader David Schurter, Co-Team Leader Marty Grasse, Communications Ben Schoepke, Website Coordinator Jon Sass, Biomedical Student Advisor Committee Representative
Advisor:	Mitch Tyler UW-Madison Biomedical Engineering

Problem Statement (Adapted from RERC on AMI project description):

Patients with incontinence are unable to control urine flow due to specific disease pathology, trauma, or other causes. Incontinence affects men and women, occurs more frequently with age, and can cause infection, skin irritation, and embarrassment. It negatively affects quality of life and many incontinent patients avoid activities in public, for instance due to the potential for a spastic bladder to spontaneously cause release of urine without warning.

The aim of the project is to design a device to allow the patient (or caregiver) to control and manage urine flow. It should:

1) Be easily used by a patient 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 with no adverse tissue reaction or material degradation

Design Requirements

1. **Physical and Operational Characteristics**

   a. *Performance requirements*: The device must enable control and management of urine flow by patients with disabilities, be able to be switch flow on and off, and provide an indication of the status of the bladder. It must also be able to remain indwelling for up to 30 days without adverse patient reaction or material degradation. The design is

based on a traditional Foley catheter design, with several modifications for improved accessibility and performance.

b. *Safety*: Because the device will be inserted into the urethra and remain indwelling for some time, it must be made of materials that will not cause a reaction or infection in the patient. Foley catheters are typically made of Latex or silicone. According to a urologist, if the device malfunctions and the bladder reaches over-pressures, urine will leak around the catheter before causing damage.

c. *Accuracy and Reliability*: The device will be used to monitor the status of the bladder. This information will be used to assist the patient and caregivers in flow control.

d. *Life in Service*: The device must be able to remain indwelling for up to 30 days before replacement, at which point the Foley catheter and pressure transducer will be discarded. The control circuit, battery pack, and pinch valve should remain viable indefinitely.

e. *Shelf Life*: The device will be sterilized prior to use and should have a shelf life of 5 years, as this is standard for urinary catheters.

f. *Operating Environment*: During use, the device will be inserted through the urethra and into the bladder. It will be in prolonged contact with urine, with typical pH values varying between 4.5 and 8.0.

g. *Ergonomics*: The device must be accessible for patients with disabilities. The flow control mechanism must be easy to use and the bladder status indication must be simple and clear.

h. *Size and Weight:* Traditional Foley catheters range in size from 8 French to 24 French. The device should not be obtrusive or interfere with the patient's daily activities. The control circuit is 5 inches by 2.5 inches by 1.25 inches and is belt-mounted.

i. *Materials:* Materials used must not cause any reaction or infection in the patient. Also, the device must be able to remain indwelling for 30 days with no material degradation. Foley catheters are traditionally made of Latex or silicone

j. *Aesthetics, Appearance, and Finish:* The device should have a smooth and lubricious finish for easy insertion. The control mechanism should be small and the user interface should be simple and easy to operate.

2. Production Characteristics

a. *Quantity:* At this stage, a single prototype device will be designed and produced.

b. *Target Product Cost:* The total cost to design the device must not exceed $2,000.

3. Miscellaneous

a. *Standards and Specifications:* The device must comply with established industry standards for Foley catheters and other urological medical devices.

b. *Customer:* The device should be simple to use and cater to patients with disabilities such as hearing or vision loss, spinal injuries, or limited movement.

c. *Competition:* Based on our initial research, there are currently no devices on the market that include bladder status monitoring coupled with a patient-controlled valve.

Appendix B – Principles of Universal Design

Universal Design: Principles & Performance Measures (Story, 1998)	
Principles	**Performance Measures for Products**
Principle One - Equitable Use: The design is useful and marketable to people with diverse abilities	
Provide the same means of use for all users; identical whenever possible; equivalent when not.	All potential users could use this product in essentially the same way, regardless of differences in personal capabilities.
Avoid segregating or stigmatizing any users.	Potential uses could use this product without feeling segregated or stigmatized because of differences in personal capabilities.
Make provisions for privacy, security, and safety equally available to all users.	Potential users of this product have access to all features of privacy, security, and safety, regardless of personal capabilities.
Make the design appealing to all users.	This product appeals to all potential users.
Principle Two - Flexibility in Use: The design accommodates a wide range of individual preferences and abilities	
Provide choice in methods of use.	Every potential user can find at least one way to use this product effectively.
Accommodate right- or left-handed access and use.	This product can be used with either the right or left had alone.
Facilitate the user's accuracy and precision.	This product facilitates (or does not require) user accuracy and precision.
Provide adaptability to the user's pace.	This product can be used at whatever pace (quickly or slowly) the user prefers.
Principle Three - Simple and Intuitive Use: The design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level	
Eliminate unnecessary complexity.	This product is as simple and straightforward as it can be.
Be consistent with user expectations and intuition.	An untrained person could use this product without instructions.
Accommodate a wide range of literacy and language skills.	Any potential user can understand the language used in this product.
Arrange information consistent with its importance.	The most important features of this product are the most obvious.
Provide effective prompting and feedback during and after task completion.	This product provides feedback to the user.
Principle Four - Perceptible Information: The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities.	
Use different modes (pictorial, verbal, tactile) for	This product can be used without hearing.

redundant presentation of essential information.	
Maximize "legibility" of essential information.	This product can be used without sight.
Differentiate elements in ways that can be described (i.e., make it easy to give instructions or directions).	The features of this product can be clearly described in words (e.g., in instruction manuals or on telephone help lines).
Provide compatibility with a variety of techniques or devices used by people with sensory limitations.	This product can be used by persons who use assistive devices (e.g., eyeglasses, hearing aids, sign language, or service animals).
Principle Five - Tolerance for Error: The design minimizes hazards and the adverse consequences of accidental or unintended actions.	
Arrange elements to minimize hazards and errors: most used elements, most accessible; hazardous elements eliminated, isolated, or shielded.	Product features are arranged according to their importance.
Provide warnings of hazards and errors.	This product draws the user's attention to errors or hazards.
Provide fail safe features.	If the use makes a mistake with this product, it won't cause damage or injure the user.
Discourage unconscious action in tasks that require vigilance.	This product prompts the user to pay attention during critical tasks.
Principle Six - Low Physical Effort: The design can be used efficiently and comfortably and with a minimum of fatigue.	
Allow user to maintain a neutral body position.	This product can be used comfortably (e.g., without awkward movements or postures).
Use reasonable operating forces.	This product can be used by someone who is weak or tired.
Minimize repetitive actions.	This product can be used without repeating any motion enough to cause fatigue or pain.
Minimize sustained physical effort.	This product can be used without having to rest afterward.
Principle Seven - Size and Space for Approach & Use: Appropriate size and space is provided for approach, reach, manipulation, and use regardless of user's body size, posture, or mobility.	
Provide a clear line of sight to important elements for any seated or standing user.	It is easy for a person of any size to see all the important elements of this product from any position (e.g., standing or seated).
Make reach to all components comfortable for any seated or standing user.	It is easy for a person of any size to reach all the important elements of this product from any position (e.g., standing or seated).
Accommodate variations in hand and grip size.	This product can be used by a person with hands of any size.
Provide adequate space for the use of assistive devices or personal assistance.	There is enough space to use this product with devices or assistance (e.g., wheelchair, oxygen tank, or service animal).

Appendix C – Utah Medical Deltran Pressure Transducer Specifications

Deltran® IV disposable pressure transducers reflect more than 20 years of experience in critical care monitoring and it is our goal to continually seek ways to improve accuracy and safety, and to make Deltran® products the easiest to use.

- Consistent and accurate readings during monitoring.
- Components that simplify setup.
- The transducer can easily be mounted on either the patient, bed or IV pole.
- Fully integrated flow-thru component design simplifies filling and debubbling.
- Versatile, dual function Snap-Tab™ allows dynamic response testing.
- Superior fluid path visualization.
- 3cc or 30cc per hour flow rates.
- With a variety of interface cables available (see Deltran® Accessories), Deltran® can be connected to most types of monitors.

Since 1978, Utah Medical Products® has been a leader in disposables for blood pressure monitoring. By continually striving to anticipate the critical needs of clinicians, Utah Medical is constantly refining technology to develop transducer products of the highest value to clinicians and patients.

With the introduction of Deltran® disposable pressure transducers, Utah Medical established new standards for patient safety and ease of use, standards by which competitors are measured.

Deltran® I, II, IV	
Continuous Flow Rate	3 cc/hr (± 1 cc/hr) or 30 cc/hr (± 10 cc/hr) at 300 mmHg
Operating Pressure Range	-50 to +300 mmHg
Sensitivity	5 µV/V/mmHg, ±2% (typically $\leq$ ±1%)
Zero Drift With Time	$\leq$ ±1.0 mmHg/8 hours after 10 min. warm-up to operating temperature
Leakage Current	<2 µA @ 115 Vac rms at 60 Hz
Unbalance	±75 mmHg
Overpressure Protection	-400 to +4000 mmHg
Operating Temperature	15° C to 40° C
Excitation Voltage and Frequency	2 to 10 Vdc; or Vac rms to 5 kHz
Operating Life	>500 hours
Storage Temperature	-25° C to +65° C
Defibrillation Withstand	5 discharges/5 minutes of 400 joules @ 50 ohm load
Natural Frequency	>200 Hz in saline
Phase Shift	<5° at 5 kHz
Output Impedance	270 Ohms to 400 Ohms
Input Impedance	270 Ohms to 400 Ohms

Appendix D – Valcor Scientific Pinch Valve Specifications

VALCOR®

Valcor Scientific

Pinch Valves

1 & 2 Tube Units

Our 2-way normally closed, 2-way normally open and closed-open solenoid pinch valves are an excellent choice for applications where the fluid needs to be isolated from the valve parts. They are available with single or multiple tubes. These valves are capable of handling a wide variety of corrosive or high purity media by isolating all metallic components from the media. In addition, they feature:

- Compact size
- Low power consumption
- Handles particulate matter
- Adaptability
- Hygienic

Performance specifications:

Model	Electrical	Configuration	# of Tubes	P/N	ID	OD	Max. Pressure	Wattage
SV23A	12 & 24 vdc	NC or NO	1	-01	1/32"	1/16"	30 PSIG	1.0 watts
		NC or NO	1	-11	1/32"	3/32"	30 PSIG	1.0 watts
		C/O	2	-01	1/32	1/16"	30 PSIG	1.0 watts
SV23B	12 & 24 vdc	NC or NO	1 or 2	-11	1/32"	3/32"	30 PSIG	1.5 watts
		NC or NO	1 or 2	-21	1/16"	1/8"	30 PSIG	1.5 watts
		C/O	2	-11	1/32"	3/32"	30 PSIG	1.5 watts
		C/O	2	21	1/16"	1/8"	30 PSIG	1.5 watts
SV23C	12 & 24 vdc	NC or NO	1 or 2	-22	1/16"	3/16"	30 PSIG	4.2 watts
		NC or NO	1 or 2	-42	1/8"	1/4"	20 PSIG	4.2 watts
		C/O	2	22	1/16"	3/16"	30 PSIG	4.2 watts
		C/O	2	-42	1/8"	1/4"	20 PSIG	4.2 watts
SV23D	12 or 24 vdc	NC or NO	2	-42	1/8"	1/4"	20 PSIG	7.2 watts
		NC or NO	1	62	3/16"	5/16"	20 PSIG	7.2 watts
		NC or NO	1	-82	1/4"	3/8"	20 PSIG	7.2 watts
		C/O	2	-62	3/16"	5/16"	20 PSIG	7.2 watts

(1) Alternate voltages of 6VDC and 115V/ 50-60 Hz available upon request.
(2) NC - Normally Closed, NO - Normally Open, C/O - 3 way, one tube closed & one tube open.
(3) Standard tube material - Silicone.

Part Number Example:	Model	Voltage	Conf	# Tubes	Tube Size
	SV23B	24	NO	1	-21

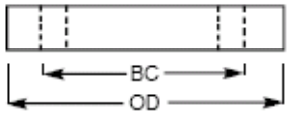
SV23B24NO1-21

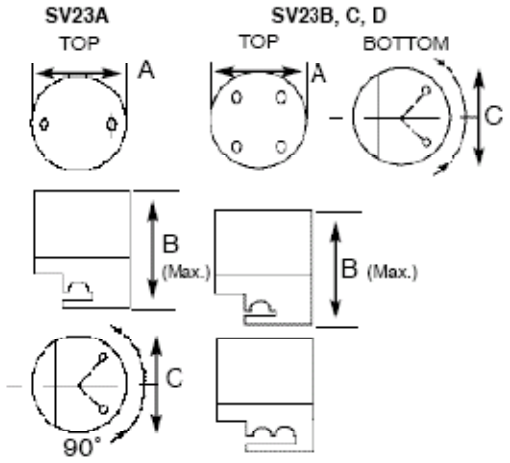
For more information, call Valcor Scientific @ 1•973•467•8400 or Visit www.valvor.com/teflon

Valcor Scientific

Pinch Valves

Mounting Ring





Model#	OD	Thickness	Holes	BC
SV23A	Ø1.5" (Ø38.1)	0.5" (12.7)	0.196" (4.978)	1.125" (28.575)
SV23B	Ø1.75" (Ø44.45)	0.5" (12.7)	0.196" (4.978)	1.375" (34.925)
SV23C	Ø2.0625" (Ø52.388)	0.5" (12.7)	0.196" (4.978)	1.656" (42.062)
SV23D	Ø2.375" (Ø60.325)	0.563" (14.3)	0.196" (4.978)	1.938" (49.225)

(Metric dimensions in parenthesis)

Model#	A	B	C	Hole Thread
SV23A	Ø0.75" (Ø19.0)	1.15" (29.21)	0.5" (12.7)	2-56
SV23B	Ø1.0" (Ø25.4)	1.8" (45.7)	0.687" (17.45)	4-40
SV23C	Ø1.25" (Ø31.75)	2.25" (57.1)	0.875" (22.225)	4-40
SV23D	Ø1.5" (Ø38.1)	2.6" (66.0)	1.125" (28.58)	4-40

(Metric dimensions in parenthesis)

Standard Units

NC—Normally Closed

SV23A12NC1-01	SV23B12NC1-11	SV23C12NC1-42	SV23D12NC1-82
SV23A24NC1-01	SV23B24NC1-11	SV23C24NC1-42	SV23D24NC1-82
	SV23B12NC1-21		
	SV23B24NC1-21		

NO—Normally Open

SV23A12NO1-01	SV23B12NO1-11	SV23C12NO1-22	SV23D12NO1-82
SV23A24NO1-01	SV23B24NO1-11	SV23C24NO1-22	SV23D24NO1-82
	SV23B12NO1-21	SV23C12NO1-42	
	SV23B24NO1-21	SV23C24NO1-42	

CO—Normally Closed/Normally Open

SV23A12CO2-01	SV23B12CO2-11	SV23C12CO2-42	
SV23A24CO2-01	SV23B24CO2-11	SV23C24CO2-42	
	SV23B12CO2-21		
	SV23B24CO2-21		

For more information, call Valcor Scientific @ 1•973•467•8400 or Visit www.valvor.com/teflon

Appendix E – Parts List

Part	Price/ Unit	Quantity	Price	Cost/ 1000
Piezo Speaker	$1.95	1	$1.95	$1.950
470 Ω resistor	$0.01	4	$0.04	$0.006
1.5 kΩ resistor	$0.01	1	$0.01	$0.006
1 kΩ resistor	$0.01	1	$0.01	$0.006
150 Ω resistor	$0.01	1	$0.01	$0.006
TIP 120 npn BJT	$1.20	1	$1.20	$0.720
LM7805 5V Regulator	$0.43	1	$0.43	$0.130
LM317 Adjustable voltage regulator	$1.05	1	$1.05	$0.780
2.2 uF @ 50 V	$0.12	4	$0.48	$0.059
1 uF @ 100 V	$0.17	1	$0.17	$0.059
5mm Super Bright LED (Red)	$0.59	1	$0.59	$0.290
5mm Super Bright LED (Yellow)	$0.24	1	$0.24	$0.120
5mm Super Bright LED (Green)	$0.54	2	$1.08	$0.300
1.3VDC 11000 RPM Vibrating Motor	$3.05	1	$3.05	$2.510
ADC0831CCN	$2.97	1	$2.97	$1.398
Project enclosure	$3.69	2	$7.38	n/a
Coaxial Power Plug	$2.99	1	$2.99	n/a
2.1 mm Power Jack	$2.99	1	$2.99	n/a
15 W Microcircuit Soldering Iron	$8.99	1	$8.99	n/a
1CB96 PC Board	$4.49	1	$4.49	n/a
Neon Rocker Switch	$3.99	1	$3.99	n/a
Pushbutton Switch	$2.69	2	$5.38	n/a
Slider Switch	$2.69	1	$2.69	n/a
Phono Jack	$3.99	1	$3.99	n/a
Adjustable Voltage Regulator	$2.29	2	$4.58	n/a
25A LED Switch	$3.69	1	$3.69	n/a
2.5 mm Power Jack	$2.99	1	$2.99	n/a
ASCO SCH284B014 Pinch Valve V24	$28.00	1	$28.00	n/a
Nitro Hawk Rubber Balloons	$8.34	1	$8.34	n/a
Valcor SV23C12NC1-42 Solenoid Valve	$135.30	1	$135.30	n/a
Li-Ion 14.8 VDC 2200mAh Battery	$30.95	1	$30.95	n/a
Smart battery charger	$32.47	1	$32.47	n/a
BASIC Stamp Discovery Kit (Microcontroller)	$158.61	1	$158.61	$25.480
Vibrating Motor, 1.3V/85mA, 11000RPM	$3.05	1	$3.05	n/a
Fabric	4.74	1	$4.74	n/a
Elastic	1.67	1	$1.67	n/a
Thread	2.74	1	$2.74	n/a
Velcro	6.99	1	$6.99	n/a
SB24 Tape	0.96	1	$0.96	n/a
Rusch Gold 18F Foley Catheter	4.27	1	$4.27	n/a
		Total	**$485.52**	

Notes:

- Microcontroller can be purchased alone (w/out development kit for 49.99, or for 25.48 for 1000
- Costs per 1000 parts are listed for marketability purposes
  to illustrate decreased costs of mass production

Appendix F – RERC Suggested Target Users

Client list for design challenges above:

Phylis is an active 77-year-old woman with rheumatoid arthritis that has caused diminished hand strength, joint stiffness, and pain. Phylis also has age-related macular degeneration and hearing loss, but she is determined to remain active and independent. Although she is outgoing and bold in general, she is easily intimidated by many of the high-tech gadgets her grandchildren use; she prefers simple interfaces.

Aaron is a 23-year-old man, a returning Iraq war veteran, with an arm amputation above the elbow, chronic neck pain and recurring headaches. Although Aaron sometimes wears a prosthetic device with a pinching mechanism, most often he improvises and uses one hand to complete tasks. He takes a number of medications, mostly for pain management.

Keisha is an 84-year-old woman who recently had a stroke, causing hemiplegia on her right side that has affected the function in her dominant hand. She has also experienced some memory loss after the stroke, so she appreciates the reminders her family provides her. Before the stroke, Keisha had minor hearing loss, and it has continued to worsen in recent years due to aging. Although she wears a hearing aid every once in a while if she's going out, at home and at most other times she does not use it. She also has occasional challenges with incontinence.

Jerry is an 82-year-old man with Parkinson's disease, which causes him to have tremor, rigidity, and decreased range of motion; he also has difficulty with urinary control. Jerry has recently started experiencing symptoms of Dementia, but with the help of his family he is determined to remain in his own home as long as possible.

Jamie is a 42-year-old woman with a T11 spinal cord injury. She mainly uses a manual wheelchair and is a serious wheelchair basketball athlete. She would like to have better control of her urinary function while participating in athletic activities.

Betty is a 65-year-old woman who has limited and asymmetrical lower extremity range of motion due to a bad hip. She also has limited strength in her right leg due to decreased use of her right leg because of the pain caused by her hip.

Violet is a 32-year-old woman of short stature who is on blood pressure medication. She is also a mother of 3, and is very active within her family and community.

Paul is a 43-year-old man with diabetes. The diabetes has caused neuropathy in his hands and feet, which eventually necessitated two below-the-knee amputations, and some loss of vision.

Appendix G – Detailed Enclosure Drawings