Accessible Incontinence Control Device

COLLEGE OF ENGINEERING UNIVERSITY OF WISCONSIN-MADISON

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1 Background

- ***Urinary incontinence*** is the loss of bladder control
- Affects ***>10 million*** people in the US, especially the elderly and disabled[1]
- Affects ***15-30%*** of active elderly and ***50-84%*** of elderly in hospitals and long-term care settings[1]
- $ ***36 billion*** industry annually[2]
- Associated with *diabetes*, *multiple sclerosis*, *Parkinson's disease*, *stroke*, *spinal injury* and others[2]

1. eMedicine.com. (2008). Retrieved 2008, from eMedicine.com: http://www.emedicine.com
2. American Geriatric Society. "Geriatrics Review Syllabus, 5th Edition." (2007). Retrieved 2007, from American Geriatric Society: http://www.americangeriatrics.org

2 Problem Statement

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

3 Existing Technologies

- Are ***bulky***, ***embarrassing, inaccessible*** or require ***surgery***

Foley catheter with collection bag
(emedicine.com, 2008)

Straight catheter
(astratech.us, 2008)

External catheter
(hollister.com, 2008)

Adult diapers
(kimberly-clark.com, 2008)

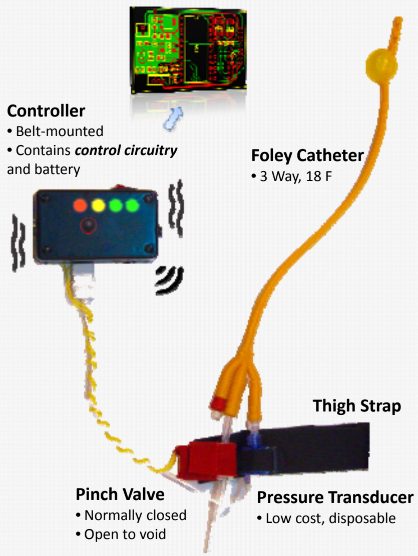
Medtronic Interstim
(medtronic.com, 2008)

AMS Artificial Sphincter
(americanmedicalsystems.com, 2008)

4 Our Solution

Gain control over lost bodily function
Monitor your bladder and void when you want to

- Allows ***voluntary*** emptying of the bladder
- ***Prevents*** undesired urine flow
- Provides an indication of ***bladder status***... know when you have to go
- Can remain indwelling for up to 30 days

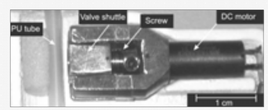


Accessibility Features

- Target audience: individuals with ***sensory-motor***, ***physical***, and/or ***cognitive*** disabilities
- Provides ***personalized*** visual, audible, & tactile feedback of bladder status
  - ➡ LEDs, piezoelectric speaker, vibration motor
- Requires ***minimal*** fine motor movements to operate: only a button push to check bladder status or void
- ***Safety switch*** to prevent accidental voiding
- Enclosure is designed to ***stabilize*** hand

Valve

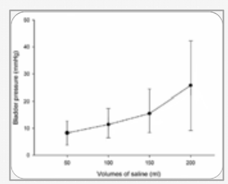
- Prototype uses a solenoid pinch valve
- Production model would use smaller, lower power ***Shan-Lai valve*** mechanism[3]
  - 618 mL/min flow rate
  - 30 mAh energy consumption over 30 days



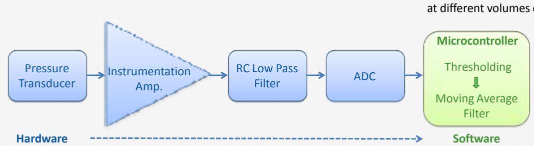
Shan-Lai valve proposed for production model

Determining Bladder Status

- Bladder volume and pressure are ***directly related***
- Pressure measured externally with ***disposable*** transducer
- Calibrated per patient using ***cystometry***
- High frequency changes in bladder pressure due to increases in intra-abdominal pressure (e.g., movement, coughing, etc.) are filtered out:



The intra-bladder pressure measured at different volumes of injected saline[4]



3. Lee, S., et al. Design and development of a novel automatic valve system for long-term catheterized urinary incontinence patients. *Proc. IMechE.*, 2007, **221**, 665-676
4. Chiumello, D., et al. The effect of different volumes and temperatures of saline on the bladder pressure measurement of critically ill patients. *Crit. Care.*, 2007, **11**(4): R82

5 Testing and Validation

Usability

Usability testing was conducted on ***27*** students in the ISyE 349 lab course. Physical, visual, and hearing disabilities were simulated. Each student was asked to operate the device in accordance with our protocol and several observations were made that led to design ***improvements*** :

• Made smaller box for better handling	• Safety switched moved closer to void switch	• Changed void button operation to press once instead of press and release
• LEDs remain on longer • LED locations changed	• Added status indicator to safety switch • Belt clip replaced with one that was easier to use	• Made void and status buttons visually distinguishable • Feedback of valve being open

Each student was able to successfully operate the device despite disability simulations.

Functional

- Flow rate: ***170 mL/min***
- Battery life: ***26 hours***
  - *Assumes fully charged 11.1V, 850 mAh lithium polymer battery pack
- Valve force requirement: ***5.46 N*** to pinch off tube

Lithium polymer battery pack

6 Cost Analysis

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**

- These costs account for the assembly of ***one prototype***
- Only recurring costs for patient are monthly catheter and pressure transducer replacements
- Significant ***cost savings*** can be realized by utilizing a custom-built valve (-$100) and a PIC microcontroller (-$40)

7 Conclusion

Our solution offers significant improvements over current devices. It is usable by patients with sensory-motor, physical, and/or cognitive disabilities and provides them the mobility needed for daily activities. Results will be submitted to the RESNA 2008 Conference.

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