Alternative Design 2
Accessible Incontinence Control Device

Team 8:
Maroun Bousleiman
Erica Kramer
Yamalia Roberts
Zachary Smith

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Client Contact:
RERC-AMI National Student Design Competition
Dr. John D. Enderle
Biomedical Engineering, University of Connecticut
Email: jenderle@bme.uconn.edu
Phone: (860) 486 – 5521
1. Alternative Design Project 2

1.1. Introduction

This design will include an ultrasound bladder scanner that will be able to detect the status of the bladder by ultrasonic transducers. The ultrasound transducer compares to that of the first design which was the pressure transducer, in that it will give a more precise and accurate reading of the bladder as it will be doing a continuous scan of the bladder in three dimensions. The pressure transducer was not able to give a continuous scan of the bladder, it was only able to detect the pressure of the bladder as it became full then transmit the signal by RF wireless to the remote where the output was displayed. The continuous scan of the bladder will not only be beneficial in preventing urinary incontinence, but it will be able to detect any bladder abnormalities and proper diagnosis and treatment can be done immediately. The ultrasound bladder scanner will be placed around the lower abdominal of the patients where it will run a continuous scan of the bladder, the output will be transmitted by the RF wireless signal to the remote where the patient will be constantly notified the status of their bladder. The ultrasound will be an effective method because it is fast and a painless procedure. There is no radiation involved so this limits the amount of side effects on the patients. The use of the ultrasound bladder scanner will also reduce the rate of infections and will improve the overall quality of life for the patients giving them a little more independence and being able to perform outdoor activities without the embarrassment of unwanted urine flow.

The device will be:
- Light weight
- Durable
- Discrete
- Good battery life
- Biocompatible- help to reduce infections
- Remote will be wireless
- Environmentally friendly
- User friendly
- Able to be used both my male and female
- Reliable
- Continuous scan of bladder

The device needs to help the user control the release of urine from their bladder. It also needs to provide the user with an indication of the status of the bladder and how full it is at any given point in time. Therefore the design is divided into two main phases. The first phase of the device design is the urinary control phase. This will prevent unwanted voided of urine and it will also allow the user to urinate when appropriate. The second phase of the design is the status indication phase. This part of the design will measure the status of the bladder and then relay the information to the user in a clear manner. An overview of the device function is shown below in Figure 1.
Each phase of the design is broken down into subunits. The incontinence control phase will be accomplished using catheter like tubing inserted into the urethra. The tubing will extend outside the body, about 4 inches for men and about 9 inches for females. There will be a twist/pull drain valve at the bottom of the tubing that can be opened by the user to release urine. The urine conduit will be made of Soft MFXAG antimicrobial tubing to reduce the infection and increase the time the device can remain in the patient. The function of the conduit is to transport urine from the bladder to the outside of the body to the valve. The urine conduit will be held in place on the patient’s inner thigh by straps. The urine conduit will be made of biocompatible materials that are non biodegradable and non toxic to the body. This urine conduit tubing will be environmentally friendly.

The valve will be located at the distal end of the urine conduit tubing. It will allow the user to release urine when necessary. The valve will remain in closed position to prevent unwanted leakage of the urine from the tube. The valve will be controlled by a twist control valve and stopcocks to prevent leakage of urine from the valve. The twist-pull mechanism will help to prevent accidental valve opening during normal everyday activity. The twist control valve will be made of polyvinyl chloride (PVC) and the turn top will be polyethylene. Both materials are biocompatible and will not cause any tissue irritation.

The status indicator subunit will be comprised of the ultrasound transducer described above. The ultrasound bladder scanner will be used to view the bladder and the transducer within the ultrasound bladder scanner emits sound and detects the returning echoes when it has scanned the bladder and sends the output to the remote by wireless RF signal. The returning echoing signals produced by the bladder, when sent to the remote will be converted...
by the microprocessor within the remote then output on the Liquid crystal display screen. The echoing sounds are formed by the ultrasound waves that can are passed through the skin, body fluid and the surrounding tissues of the bladder. The ultrasound bladder scanner will be precise in its bladder volume detection, safe, user-friendly, reliable and most of all discrete.

There will also be a safeguard built in to the device so that accidental leaking from the valve will be detected. The alarm system will alert the patient or caregiver of any urine leakage from the valve or if the valve has a malfunction. The alarm system will consist of a water proof sensor that will detect an overflow of urine. The sensor will provide a signal to the wireless transmitter and the signal will then be sent to the remote providing an immediate alarm to the patient. This alarm will cause the remote to vibrate and the LCD to display an alert message to the user. There will be an optional audio alert that will be useful to a caregiver or to a patient who is sleeping.

The remote controller will consist of a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. The remote will display the status of the bladder and the volume of urine in the bladder will be obtained by a calculated conversion from transducer produced by the bladder ultrasound scanner. The entire output of the device will take place in the remote controller, as the RF transmitter receives signals from the ultrasound transducer and valve leakage sensors it will transmit the signals to the remote. It will continuously give the patient or caregiver the status of the bladder, the volume of urine in the bladder and it will also alert the patient if the urine control valve is leaking.
1.2. Subunits

1.2.1. Urine Control Valve

At the distal end of the urine conduit tubing will be a valve that will allow the user to release urine when necessary. The valve will normally remain in closed position preventing urine from leaving the tube. Valves that would be appropriate for this application come in a variety of forms: push/pull valves, twist control valves, turnvalves, push cross drain valves, and stopcocks.

In order to prevent accidental opening of the valve during physical activity, the valve for this design will be opened and closed a combined twisting and pulling mechanism. The specific part that will be used is the Urinary Kit Twist/Pull Drain Valve (part number 11647, Qosina Corp, New York). In order to open the valve it will have to be pulled away from the body and twisted counterclockwise simultaneously. The mechanism used to open the valve is similar to that used in operating the water faucet in many private showers. Then to close the valve the patient will again have to pull the valve top and then turn the valve top clockwise. A schematic of the valve operating mechanism is shown below in Figure 4.
The body of the twist/pull drain valve will be made of PVC and the turn top will be composed of polyethylene. These materials were chosen so there would be no tissue irritation for the patient caused by the device. The turn top will also be a different color than the white valve body to make it easy for patients with limited vision to determine what portion of the valve needs to be manipulated. The valve will require minimum strength to open and close. The valve could optionally be fitted with a flat handle which would increase the area of the component that needs to be manipulated and therefore decrease the level of fine motor control necessary to operate the valve. This optional handle will be a helpful addition to a patient with certain disabilities that may limit their motor skills. This will also be useful in operating the device with simply one hand. The optional handle that could be affixed to the valve will also be made of a study PVC polymer material. It will be attached in such a way that when the valve is closed the handle will lie flat against the patient’s inner thigh as opposed to facing in at an angle and causing potential discomfort. This optional configuration is shown below in Figure 5.
The interface between the valve and the conduit must be completely leak resistant. In order to make sure that the valve and the urine conduit junction is leak proof it will be necessary to use a stepped connector. This will provide an optimum fit that will eliminate leaks from the device. The diameter of the valve being used in this design is 0.313 inch, compared to the smaller tubing with an outer diameter of 0.250 inch. The stepped connector will provide for a smooth transition from the conduit to the valve. The stepped connector, shown below in Figure 6 will also be made of PVC to prevent tissue irritation, and will also be purchased from Qosina Corp.
1.2.2. Urine Conduit

The device will have a component that will act as conduit moving urine from the bladder to the outside of the body. The conduit will be made of Soft MFXAG Antimicrobial Tubing which is made of polyethylene, a biocompatible polymer. This tubing will provide the optimum amount time the tubing will be able to remain inside the patient without causing tissue irritation. The operating temperature range of this tubing is -70°F to 135°F. This means it will be safe to use inside the body at about 98.6° and it can also easily be stored at room temperature, about 72°F. The tubing will have an inner diameter of 0.125 inches with an outer diameter of 0.250 inches. The length of the tube will be 12 inches. A second material option for the tubing material is Tygon® Medical/Surgical Tubing, with an outer diameter of about 0.220 inches. A diagram showing the measurements of the conduit component is shown below in Figure 7.

![Diagram of tubing measurements]

The above dimensions are within the acceptable range according to the ASTM Standard F623-99. The external diameter of a catheter must be between 0.158 inches and 0.315 inches. The standard also required that flow rate needs to be an average at least 100 milliliter per minute. In order to test whether the tubing meets this requirement the tubing will have to be injected with a known amount of liquid and the rate of the liquid’s flow will be measured. An acceptable liquid to use for this test would be either water or saline solution because urine is about 95% water.
1.2.3. Ultrasound Transducer

The status of the bladder will be indicated by a small ultrasound system. The ultrasound transducer will be incorporated into a lightweight and flexible belt that can be worn around the waist. The body strap will be a comfortable elastic belt that will provide for easy movement and will not hinder the patient in any physical activity. The weight of the belt will be less than 5 pounds so that the patient will barely notice that he or she is wearing the belt. The enclosure will be shock absorbent and durable to provide protection to the components contained in the enclosure. The waist belt will also include a rechargeable battery pack and a wireless transmitter which will be able to transmit the signal from the ultrasound transducer to the wireless remote. The wireless remote will be able to obtain the signal and then produce a bladder volume that will be output to the user. This will be able to inform the user as to when they need to empty the bladder.

The waste belt will have to be located directly over the bladder; this position may vary slightly from patient to patient. The optimum location for the belt can be determined through a physical exam by a physician where an ultrasound is performed to find the exact location. During this examination the maximum capacity of the bladder will need to be determined so that the device can be programmed accordingly. The device will not determine the size of the bladder, it will just determine the amount of liquid in the bladder and then the microprocessor will be able to make the appropriate calculations to determine the overall percentage of urine in the bladder. The belt will vary in size according to the weight of the patient so that the device relatively maintains its positioning throughout activity.

The ultrasound transducer must be able to produce a 2-phased array that can travel between 4-24 centimeters into the body. The range of frequencies that is required to accomplish this goal is between 2 and 4 MHz. A 10 mm 4 MHz transducer will be purchased from Ultrasonic Doppler Velocimeters. The price of the transducer will be around $1000.00. This transducer is very small which will help keep the size of the waste belt at a minimum which keeps the system discrete and comfortable. The frequency that has been used to determine bladder volume in other devices is around 3 MHz. This is the optimum frequency to determine most accurately the level of urine in the bladder. The transducer will need a small power supply and require a simple circuit with a small microprocessor that provides a clock for the transducer. The reasoning for this is to
conserve power by only taking a reading every fifteen minutes. The bladder will take time to fill so it is not necessary to be sending a continuous signal. To power the system a lithium ion battery will be used. The reasoning for this is it will again maintain a small size and provide a comparable power supply to the transducer. The pack will be rechargeable. This can be at a convenient time for the patient. This transducer will be connected to a wireless transmitter which will output the signal to the microprocessor in the remote for signal processing and then display the bladder volume to the patient.

![Figure 9 – Ultrasound Flow](image)

In Figure 9 above, a simple flow chart of the system is provided. All of the necessary calculations and processing will be completed by the microprocessor in the remote of the system. This allows for a smaller abdomen pack and allows for a more discrete system.

### 1.2.4. Remote Control

The remote controller will contain a Liquid Crystal Display (LCD), RF receiver, power supply, and the microprocessors. All of the processing for the device will take place in the remote controller. As the RF transmitters receive signals from the ultrasound transducer and valve leakage sensors it will transmit the signals to the remote. The RF receivers in the remote will receive the signals from the transmitters and then send the signals to the microprocessor where the data can be processed. The microprocessor will
be programmed to take the ultrasound transducer reading and then convert it to an accurate urine volume. The volume of the bladder will then be displayed onto the LCD. Once the volume reaches a specific percentage the remote will also vibrate sending an alert to the patient that it is necessary to release the urine in a timely manner.

An LCD screen will be used because it consumes very little power, allowing for long battery life. Although a character display could be used in this device to display a numerical representation of bladder volume, a graphic display will be used. This will present the user with a simple numerical volume percent that the bladder is full as well as a visual representation of the urine level in the bladder. This will provide a user with a more clear idea of whether it is appropriate to urinate at a specific time or not. A super-twisted nematic (STN) display will be used because it provides better contrast and wider viewing angle than the twisted nematic option. It is also cheaper and available in smaller sizes than the highest contrast film compensated twisted nematic (FSTN). The display will also be backlit so it is usable in all light conditions. The LCD screen that will be used has an operating temperature range of 32° to 122°F, and its dimensions are 1.5" by about 5" (PDK-460U, Industrial Electrical Engineers Inc., CA).

In the event that there is a valve leakage the remote will also be able to alert the user of this leak. The RF transmitter will receive a signal from the valve leakage sensors and transmit this signal to the remote. This signal will be processed by the microprocessor and the remote will vibrate and alert the user of the leakage. This feature will be very beneficial to the clients with spinal cord injury who would not necessarily notice a leakage on their own right away.

The remote will also include a small speaker that will be able to provide audio alerts to the user. The speaker’s volume will be able to be adjusted and will be able to be eliminated so the device can be discrete when in public settings. The speaker will be useful mostly to caretakers that are monitoring a patient in a hospital setting, or to a patient that is sleeping and needs to be woken up in response to the status of the bladder or a possible valve leakage.

The size of the remote is going to be relatively small. The design will be the keep it as discrete and as small as the components will allow for. Budget will also have to be considered in the situation as the price of certain components can rise with decreasing size. The remote shape will be an ergonomically sound design to provide a comfortable feel for the user. The interface will be simple and user friendly. The text will as simple as possible and the volume of the bladder can be displayed using images as well as text. The remote will have the ability to vibrate to alert the user when necessary. There will not need to be much interaction with the patient and the remote in a public bathroom setting since the control of urine flow will be operated manually by the valve.
Figure 10 – Function of User Remote Unit (a) Bladder Status Indication (b) Leakage Alarm
1.2.5. Valve Leakage Alarm System

The alarm system will alert the patient or caregiver of any urine leakage from the valve or if the valve has a malfunction. The alarm system will consist of a water proof sensor that will detect an overflow of urine and the alarm will give an output. The signal will also be sent to the remote control which will display the information about the urine flow from the valve. The remote system will have 3 different output signal depending on which output signal the patient or caregiver programs. The outputs will be:

1) The liquid crystal display screen light up
2) Liquid crystal display screen light up and sounds
3) No light or sound, it vibrates

The device will contain an alarm system that will alert the patient or caregiver if the urine is leaking from the valve or if the valve has a malfunction. The alarm system is necessary because our patients will be doing outdoor activities such as playing basketball or just socially conversing with friends and families. When the alarm system is triggered it will let the patients or caregivers know that they should leave the public area and empty the valve. The alarm system will send the signal to the remote, where the microprocessor will process the information and alerts the patient that the valve has a malfunction or it is
leaking. The alarm system will be versatile, so it can be used when the patient is active or sleeping. The alarm system will also decrease the chance of patients having skin irritation from the urine in contact with the skin, because it will alarm the patient or caregiver of the flow of urine at the instant it is occurring.

The alarm system will consist of a water proof sensor that will send signal to the alarm system the moment it detects moisture. The alarm system will send the output signal to the remote control. The output signal will be specified by the signal inputted by the patient or caregiver, whether they want the liquid crystal display screen to light up only, liquid crystal display screen light up and sound or vibrate. The alarm system transducer a signal to the remote control which will then display on the liquid crystal display screen that the valve is leaking or there is a malfunction. The different signaling outputs are necessary depending on the atmosphere in which the patient is in. This alarm system will be biocompatible, discrete, user friendly, environmentally safe and durable. It will have an operating temperature range of 0 to 55°C, weight of approximately 2 oz, and 2 inches by 2 inches in size.

1.2.5.1. Sensor

The alarm sensor is a main component of the alarm system will be discrete and efficient in detecting overflow of urine from the bladder. The sensor will be very accurate and sensitive as it will be able to detect as small as a drop of urine from the body. The sensor will provide a rapid response as soon as it detects moisture. The sensor will be flat, light weight, and waterproof to prevent any discomfort and embarrassment to the patient. The sensor will also be portable and discrete so that the patients will be able to take it along with them. The sensor will be connected by a wire to the wireless control system, where the output will be displayed. The advantages of the sensor of our device are that it eliminates the continuous need of manual or human detection, fast, reliable, cost effective, and waterproof.

![Figure 12. – Malem Alarm System Sensor](image)
1.2.6. Wireless Transmitter

A wireless transmitter will be contained in the leg strap of the device. The transmitter will consume little power to provide for little maintenance for the patient. The transmitter and power supply will be contained in a small shock resistant protective container that will be inserted into the leg strap. This container will help protect the device from damage that may occur.

The container on the leg strap will do no calculations it will only receive a signal from the leakage sensor and then transmit the signal to the remote where the information can be processed. The wireless transmitter and receive do not need to transfer a signal any further than a maximum of about 5 feet from the body and will not have to transmit through any major surfaces. Because of this the transmitters can be inexpensive and small providing for smaller components which will help to keep the device discrete.

This device will use a radio frequency (RF) wireless transmitter. RF Transmitters use oscillators to convert signals into sine waves; these are then encoded by modulators and transmitted as radio signals to a receiver. The wireless transmissions in this particular design will only transmit information from the leakage alarm. A signal will need to be sent to the wireless receiver in the user remote only if the valve is leaking. On-off key (OOK) modulation, the simplest form of modulation, can be used because all that needs to be accomplished is turning a signal on and off.

The TRF4903 transmitter from Texas Instruments Incorporated (Dallas, Texas) is an OOK operating transmitter. It can be used on 315MHz, 433 MHz, 868 MHz, or 915MHz.
Industrial, Scientific, and Medical (ISM) bands. It has requires 2.2-3.6 volts of power input. This is low power consumption, and power could be provided by a 2.4 V NiCd medical equipment battery (AMED1020, Interstate Battery System of America, Inc.). The battery will be contained in the pocket of the leg strap with the wireless transmitter.

The operating temperature for the transmitter is -40° to 185° F. Both room temperature and body temperature are well within that range. Due to the location of the transmitter against the leg of the patient the temperature at which it will be operating is somewhere between room and body temperature.

A second wireless transmitter will be contained in the body strap that houses the ultrasound transducer. This transmitter cannot be OOK because more than a simple on-off needs to be relayed. The transmitter for this portion of the device will be an amplitude modulation (AM) transmitter. The NRF2402G-REEL (Nordic Semiconductors, CA) operates at voltages ranging from 1.9-3.6V.

Because two different wireless transmitters are being used in the same device, precautions will have to be taken to prevent interference. This could potentially be accomplished by setting the two transmitters to operate on different frequencies. However, it is important to use two separate transmitters because two separate sets of data will be sent, and the transmitter sending the ultrasound data will be continuously transmitting information. Also, the two transmitters are sending their information to two separate locations, the data from the transmitter located in the leg strap will be directed to the leakage alarm alert, and the data from the transmitter in the body strap will be sent to a microprocessor that will display information on an LCD screen.

1.2.7. Leg Strap

The urinary conduit tubing will be held in place by a leg strap. The wireless transmitter will also be attached to the leg strap. The strap will be made of a comfortable and non-irritating material, such as cotton. It will be secured in place by Velcro, which will give the user the ability to attach the strap comfortably. The tubing will simply lie between the strap and the thigh. There will be a small pocket on the strap in which the wireless transmitter and its battery will be contained. The wireless transmitter needs to be able to be detached from the strap so that the user could wash the strap if desired. A diagram of the strap is shown in Figure 14 on the following page.
2. **Realistic Constraints**

This design has some engineering standards it must comply with. First of all, the catheter like portion of the device must meet ASTM Standard F623-99. The conduit must have an outer diameter between 4 and 8 millimeter (about 0.158 - 0.315 inches). The flow rate must have an average minimum of 100 milliliter per minute. This standard will be addressed in this device by selecting appropriately sized tubing and conducting trials to ensure the appropriate flow of water occurs through the tube. The device must also be able to be sterilized prior to use. This is especially important for a device that will be inserted into the body. The tubing will be made of a polymer material that will be able to be sterilized by a variety of means including radiation.
The device must meet certain performance standards. It should provide accurate indications of the status of the bladder. It should also be reliable in preventing leakage of urine from the tube. The device will need to be tested after it is built using a simulated testing environment to ensure that its performance meets expectations.

Economic constrains are a major concern for this design, as they are for any engineering design. The cost of this device needs to be low enough that it is affordable and attractive for patients who already may face extensive medical bills or else live on a fixed income because many consumers of this product would have health issues or be elderly. Also, portions of this device need to be replaced on a regular basis. The catheter like tubing will be able to be used for 2 to 4 weeks before being replaced. In order to keep the cost of replacing parts as low as possible the pressure transducer, valve, leakage alarm, wireless transmitter, leg strap, and user remote unit should all be able to be re-used each time the tubing is replaced. Also, device sustainability would be an issue if the reusable components are not durable enough or if the procedure required to detach them from one tube and reattach them to a new one puts unnecessary strain on them.

Because the tubing will be replaced on a regular basis, convenience for the user is a major constraint of this device. The device should be inserted by a doctor to ensure it is cleaned, reassembled, and inserted properly each time. Although this will lower the risk of infection due to a non-sterile insertion environment and urethral damage due to incorrect insertion the device should be designed to go as long as possible between changing to cause less of an inconvenience to the patient.

A major set of constraints that will need to be dealt with by the design are health and safety. The device, because it will be inserted into the urethra and will be in close proximity to the user at all times, must be made of biocompatible materials. Any potentially harmful device failures need to have safeguards designed to prevent electrical shock or injury to the user. These topics will be discussed in greater detail in the next section, section 3.

A political constraint faced by this device design would be FDA approval prior to being sold on the market. Before a medical device can be marketed it needs to meet electrical and biocompatibility safety requirements. The device, as well as its manufacturing process, needs to be approved by the FDA's Quality System. Getting marketing clearance for a device is a three step process: make sure the device is a medical deice, classifying the device, and selecting an appropriate application. Additional steps that need to be completed to get FDA approval for a medical device include pre-market registration, in vivo testing, in vitro testing if applicable, and quality system surveillance, among others.

Manufacturability constraints should not be a major problem for this design. The device is relatively simple. It can be constructed in separate components and then put together easily. For example, the tubing and the pressure transducer can be manufactured at different facilities and then put together right before packaging and distribution. The manufacturing cost should also be relatively low because most components can be mass produced by simple and cheap procedures. Many of the components of this design are composed of polymer materials. Polymer processing techniques are flexible and typically simple and economic. For example, extrusion would be an
appropriate processing technique for the polymer tubing, and long tubes could be created and then cut to appropriate length segments after cooling.

The environment in which the device will be tested is a limitation for this design. This device in its final form would be used by human patients who would insert part of the device through their urethra and into their bladder. Before this could happen the design would need to undergo a series of in vitro tests in a simulated environment. Then in vivo tests would need to be conducted as well.

A major source of constraint for this particular device is social. There is considerable embarrassment and social stigmas that can be attached to urinary incontinence. This device needs to be fully dependable to prevent malfunction and loss of the user’s bladder control in public. It will also need to be designed in such a way that it is not only easy to use for a wide range of patients but it should also be discreet enough that it will not draw a lot of attention. One way that this is being addressed is by designing the status indicator alarm in such a way that the sound output is optional and can be turned off in public settings.

An ethical constraint for this device is that the money provided to complete the project should be used responsibly. Just because there might be extra money does not mean it should be used on unnecessary expenditures. It is better to spend under budget than at budget. Many of the components for this device are simple and relatively cheap. It would be unethical as well as financially impractical to buy unnecessarily extravagant parts.

3. Safety Issues

A major safety issue for this device design is biocompatibility and host reaction to biomaterials. Although this design is not for an implantable device, the device is invasive and will be inserted into the urethra and left in for an extended period of time. The materials selected should be non-allergenic and non-irritating. The polymer tubing should be made of a bioinert material. The device should not cause adverse tissue reaction but it also should not be bioactive and degrade within the body or allow tissue in growth because the device needs to be removable. Additionally, a polymer other than Latex should be used because many patients develop an allergy to Latex after prolonged use.

A concern for catheter like devices is infection. Infections often occur during prolonged catheterizations. The biggest risk factor for microbial infection from catheterization is prolonged use greater than 7 days. The device designed in this project should Ideally remain in the body much longer than a week. In order to minimize infection precautions need to be taken. The device should be inserted only in a sterile medical setting. Also, using a closed valve instead of a drainage bag such as typical catheters use will lower the risk of infection because many bacteria gain access to the body via the drainage bag. The user should always wash their hands carefully before manipulating the valve in order to reduce risk of infection as well. By using antimicrobial tubing many infections will not be able to access the body through the inside of the tubing. Additionally, the reusable components of the device should be washed carefully and sterilized before being attached to new tubing.
Damage to the urethra can occur from improper catheterization. This will be prevented if the device user has a medical practitioner such as a physician or nurse inserts the tubing every time it needs to be changed.

Sterilization techniques that are used prior to inserting the device into the body should be effective and they should not alter the properties of the materials being used. An acceptable sterilization technique for the polymer components of the device is radiation. A major drawback for radiation sterilization is that it may change the colors of the polymer being sterilized. This is not a concern for this particular device because it is not used for optical purposes nor will it be visible to others when the user is wearing it.

Electrical protection of the user is a concern for this particular design. All wires and electrical components should be securely protected by an insulating material such as plastic. Additionally, the device should be designed in such a way that there is as low a voltage being used as possible. A low millivolt output pressure transducer is much safer than a voltage output pressure transducer. Also, the electrical components being used should not give off a significant amount of heat or else surrounding body tissues will be damaged and potentially killed.

In most cases ultrasounds used for medical purposes are considered perfectly safe. In over two decades of common ultrasound use there has been no evidence of harmful side effects. Concerns have arisen lately that larger and more powerful modern ultrasound machines are more likely to cause harm. This device will be using a small and not very powerful ultrasound transducer and this should eliminate any safety concerns regarding ultrasound technology.

The FDA has developed a set of guidelines for the design and implementation of RF wireless medical devices that might use RF technology for the transfer of data, transfer of power, control of device, remote sensing, or identification. This device will be using RF technology for data transfer. In order to adhere to FDA standards for safe use of RF technology the lowest power output that will accomplish the task will be used. Another major concern with RF devices is that they will cause interference to other nearby medical devices. In general this device will be used outside a clinical setting, minimizing the chances of interference to or from other wireless medical devices. Another major safety concern is the malfunction of an RF device due to operating temperature and humidity limitations. The RF transmitters selected for this design function well within the operating conditions there will be subjected to.

4. Impact of Engineering Solutions

The differences between this device and others on the market will be substantial in the field of incontinence devices. This design is unique because of its double functionality; it will not only control the flow of urine but will also provide an indication of the bladder’s volume. There are numerous devices available currently on the market that controls the flow of urine. There is also at least one device available to indicate the status of the bladder. This design provides a more convenient and economic option because one device can be purchased to do the jobs that two separate devices were previously necessary for. While most devices on the market are gender specific, this design is universal and will be compatible with both men and women patients. The device will be user friendly, provide accurate bladder volume readings, and will be cost efficient.
The device will have little negative impact environmentally. This product will produce very minute harm if any, to the ecosystem or other people. The tubing materials used in the device will need to be properly disposed of after they are no longer used. The other components could be reused by the patient each time the tubing was replaced, and ideally they would last the entire duration that the patient needs the device. The remote and transmitter could possibly be reused by other patients once one patient was done with them, but the catheter and leg strap would not be recycled. The device will not produce any pollution and it will not produce high and disruptive levels of noise. This device will actually decrease the amount of waste produced by incontinence patients, especially in healthcare settings. Many incontinence patients currently use products that are not recycled or re-used, but thrown away. These products include disposable absorbable insert pads, disposable diapers or underwear, disposable mattress pads, and cleansing wipes.

The economic impact of this device can affect consumers of the product, both companies and patients. There is a need for a device that can provide the status of the bladder and control the flow of urine. The addition of the status indication provides the patient with more control and independence from their incontinence. The device will be low cost and it could have a strong impact in the market for urinary incontinence devices. Not only will there be an economic benefit to purchasing one device in the place of two, but a major goal of the device is to be made in such a manner and with such materials that it is a relatively inexpensive and affordable product. The device will also eliminate the recurring cost of absorbent pads or adult diapers which cost from 50 cents to a dollar each.

Socially, this device can really provide a sense of independence for patients with urinary incontinence and will help to minimize or eliminate embarrassing moments brought on by their incontinence issues. In the United States alone this device has the potential to help the over 13 million people who suffer from some form of urinary incontinence. Urinary incontinence is not confined to people in this country; it is a widespread problem with about 65 million women worldwide being affected by stress incontinence alone. This device will provide an improved quality of life for these millions of patients and help to create independence and allow the patients to be able to continue on with normal day activities and not be hindered by their incontinence. Benefits will include a decrease in social anxiety and embarrassment, as well as a decrease in urinary tract infections and skin irritations in incontinence patients.

The device can also be modified for use by a caretaker, increasing the level of treatment and incontinence control in nursing homes where an average of about 50% of residents are affected by urinary incontinence. This will improve general healthcare, especially for elderly patients, worldwide.

5. Life Long Learning

Through the development of this device, various knowledge and techniques were acquired throughout the design process. Taking on a project of this magnitude has required a lot of research and critical thinking.
In designing this project certain knowledge of the urinary system was required. The anatomy and physiology course provided some understanding of the urinary system, but research was necessary to gather more detailed information. To be able to control urine flow it was necessary to understand the path that urine travels and a relative knowledge of the parts of the urinary system. Also to be able to provide an indication of the status of the bladder would require knowledge of the bladder, its capacity, and normal function.

In researching various methods to create a bladder status indication system, several methods were evaluated. There was need for an understanding of pressure transducers, ultrasound, and flow sensors. These methods were then evaluated on practicality, cost, and efficiency. This was a process that required evaluating ideas and theories of the group. By using three completely different methods to create a status indication system we were able to have three very different designs that could be compared and contrasted and the most optimal design could be decided by the group.

The design called for a wireless remote to provide an accurate indication of the bladder status. This required an understanding of microcontrollers and wireless technology. Microcontrollers would be the driving component of the system, all calculations and conversions would have to be completed by the microcontroller. Wireless technology was needed to transfer information from the internal device to the external hand held remote. RF transmitters and Blue Tooth technology were researched and considered.

Budget constraints also had to be considered. When creating a design certain aspects of the design certain components have to be evaluated and then a decision had to be made if there was a need for the component and if it was practical and cost efficient. This is a technique that becomes very important in designing a device. There are requirements that have to be met and then there are aspects that can be added to make the device better, but these improvements have to be cost efficient and practical.

Also when creating this device various client consideration had to be evaluated. The device will be used by multiple clients with different types of incontinence and thus requiring different needs. This presented a challenge to create a device that would meet all the needs of all the clients. The device needed to be easy for a person with disabilities to use but also needed to meet the needs of a young active patient. The device had to be evaluated to make sure that the design would be compatible for each individual client. It is important to create a design to meet the needs of the client, but also beneficial if the design can meet the needs of many clients. This was all taken into consideration.

Throughout the design process many new techniques were presented. The design provided some obstacles that had to be overcome. These challenges provided many good learning experiences and helped to develop certain techniques that will be helpful throughout the life long process of engineering design.
References

Catheter/Tubing:
http://www.usplastic.com/catalog/product.asp?catalog_name=USPlastic&category_name=29331 &product_id=7689&clickid=land
http://www.tygon.com/media/documents/S000000000000001013/TygS50HL.pdf

Valve Options:
www.qosina.com

FDA approval:
http://www.fda.gov/cdrh/devadvice/3122.html

Alarm picture:
http://www.bedwettingstore.com/Bedwetting_Alarms/view_ultimate.htm

General Incontinence Information
http://www.urologychannel.com/incontinence/index.shtml
http://www.medicalnewstoday.com/articles/31822.php

RF Wireless Technology:
http://www.fda.gov/cdrh/osel/guidance/1618.html#1

Medical Batteries:
http://www.interstatebatteries.com/estore/

Ultrasound Bladder Monitoring:

LCD screen:
http://videoequipment.globalspec.com/LearnMore/Video_Imaging_Equipment/Meters_Readouts _Indicators/Liquid_Crystal_Display_LCD_Modules?SrcHItem=2&frmqry=lcd%20screens

Ultrasonic Doppler Velocimeters: Transducer
http://www.signal-processing.com/transducers/udv_transducers_overview.htm