Alternative Design 3
Accessible Incontinence Control Device

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1. Alternative Design Project 3

1.1. Introduction

The Accessible Incontinence Control device is designed to assist patients who suffer from any type of urinary incontinence. Urinary incontinence can be the result of a dysfunctional bladder, weak abdomen muscles, or a weak urinary sphincter. Normally patients who suffer from urinary incontinence develop it as a result of other diseases or some type of physical trauma such as pathology, spinal cord injuries, brain trauma, or simply as a result of old age. There are three main types of urinary incontinence; Stress Incontinence, Urge Incontinence, and Overflow Incontinence. Stress incontinence is a result of urine being released from the bladder due to an increasing pressure in the abdomen. Uncontrolled urine release usually occurs during coughing, straining, or sneezing. Urge incontinence is a result of the patient experiencing uncontrollable urination urges followed by the uncontrollable loss of urine. Overflow Incontinence is when the bladder leaks small amounts of urine due to weak bladder muscles. The final project will be able to suppress each of the three main types of urinary incontinence.

The device is designed to meet the individual requirements of each individual patient’s specific needs. The clients for this project are; Keisha an 84 year old female stroke victim with hemiplegia on the right side of her body. This means a device would have to be created that she could control using only one hand. In addition to incontinence she suffers from memory and hearing losses. Jerry is an 82 year old male Parkinson’s patient. Besides incontinence his symptoms include tremor, rigidity, decreased range of motion, and some dementia. Jamie is a female 44 year old who suffered a T11 spinal cord injury. She is confined to a manual wheelchair and she would like to have better urinary control when she is playing basketball.

The device will be:

- Reliable
- Durable
- Discrete
- Biocompatible
- Environmentally friendly
- User friendly
- Consume little power
- Light weight
- Controlled by a wireless remote
- Compatible for male and female
The device will help the user control the release of urine from their bladder. It also needs to provide the user with a status indication of the bladder. This will be accomplished by providing the user with a percentage of urine in the bladder at any given point in time. Therefore the design is divided into two main mechanisms. The first mechanism of the device design is the urinary control phase. This will prevent unwanted voiding of urine and it will also allow the user to urinate when the time is convenient to the patient. The second mechanism of the design is the bladder status indication. This part of the design will measure the pressure build up of urine in the urethra and then convert that pressure into a proper percentage of urine in 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 an artificial urinary sphincter. This sphincter will be automated and all the user will have to do to release urine is to push a button on their personal remote. The button will then send a signal to a small stepper motor to turn on, and the fluid that fills the cuff of the sphincter will flow back into the reservoir, allowing urine to pass through the urethra. The cuff portion of the device will surround the urethra and the other components of the device will be implanted into the abdomen of the patient.

![Device Function Diagram](image-url)
The status indication subunit of the design will be accomplished using a pressure transducer. The pressure transducer will measure the pressure buildup at the beginning of the urethra. The transducer will send a signal via the wireless transmitter located in the housing of the sphincter reservoir and the small motor. This transmitter will send a signal to the microprocessor of the remote control unit. The pressure reading will be converted into a volume percentage and displayed to the user on the remote controller.

The remote controller will consist of a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. The programming of the remote will be based on the individual patients, as the total volume of urine in the bladder varies from patient to patient. 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 the pressure reading of the transducer. The entire output of the device will take place in the remote controller, as the RF transmitter receives signals from the pressure 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 alerts the patient if the valve is leaking.
1.2. Subunits

1.2.1. Artificial Urinary Sphincter

To control the flow of urine an artificial sphincter will be implemented. This artificial sphincter device will consist of an inflatable cuff, a fluid reservoir, a stepper motor connected to a rotational wheel, a track, and two mechanical wheels. All of the device components, with the exception of the inflatable cuff, will be housed in a bioinert housing that will be implanted under the skin of the abdomen. The process of sphincter contraction and relaxation will be simulated by moving a saline solution between the inflatable cuff and the saline reservoir. When the inflatable cuff is filled with the saline solution, this will mimic the urinary sphincter contraction and prevent urine flow out of the body. When the saline reservoir is filled with the saline solution the sphincter will relax and allow for the flow of urine out of the body.

The flow of the saline solution will be controlled by a tiny 8 millimeter stepper motor attached to a rotational sprocket wheel which will move along a track in the device housing. Then two mechanical wheels will collapse the saline reservoir when moved forward and then allow the reservoir to refill when moved back. The stepper motor that will be implemented in this design will be the AM 0820 motor, a product of NetMotion Inc. The motor requires 3 volts for operation. This power supply can be provided by a simple 6 volt lithium iodine battery. When activated by the user remote, the motor will rotate the rotation wheel that will move along the track of the device creating motion in two directions providing for sphincter contraction and relaxation. As the device begins to move forward, the two mechanical wheels will move forward causing the saline to be pushed out of the reservoir and thus resulting in the saline solution flowing into the inflatable cuff creating sphincter contraction. Figure 3 depicts the sphincter contraction showing the saline solution in the inflatable cuff and a collapse saline reservoir. This will be the standard position of the device. When the motor is in the position the artificial sphincter is in contraction and this prevents the flow of urine from the body.

![Figure 3 – Contraction of the Artificial Sphincter](image)
Once the urine pressure in the urethra has reached a certain level the device remote will notify the user. When the patient is ready to release urine from the body, they will be able to simply use the remote to trigger the stepper motor. Once the stepper motor has been turned on the mechanical wheels will be pulled back resulting in the flow of saline solution into the reservoir. Once the fluid is in the reservoir the artificial sphincter is then in the relaxation state. Once in the relaxation state, urine is then able to flow out of the body. The saline solution will flow into the reservoir as a result of gravity on the device. The implanted housing for the reservoir and other electrical components will need to be implanted lower than the inflatable cuff resulting in the fluid always wanting to flow downward into the reservoir. This will provide for simpler mechanics of the device and will help minimize components and inevitably help to reduce the cost of the device.

![Figure 4 – Artificial Sphincter Relaxation](image)

The movement of the device will be controlled by the small 8 millimeter stepper motor. The motor will rotate the rotation wheel which will be connected to a track that will have interlocking teeth resulting in the forward and backwards movement of the device. As the motor rotates in a clockwise direction the device will move to the right allowing for the fluid reservoir to fill and release urine from the body. To contract the sphincter and prevent urine flow from the body the motor will rotate clockwise moving the device left resulting in the cuff filling with saline and resulting in sphincter contraction. The track can be seen in Figure 5. The movement mechanism can also be seen below in Figure 6.
The movement of the device will be controlled by the user remote. The user will be able to tell the device to contract and relax with the simple press of a button. The remote will provide an indication as to when the bladder needs to be released and then the user will be able to allow for release when the time is convenient to the patient. When the patient is ready they will be able to activate the stepper motor which will force the fluid into the reservoir. Once the bladder has been emptied the user will have to reengage the device by pressing the button again causing the stepper motor to return to its original position resulting in the filling of the cuff and sphincter contraction.

The device housing will also contain the power supply, and a wireless transmitter and receiver. The wireless transmitter will be wired directly to the pressure transducer in the urethra and will transmit the pressure information to the microprocessor in the remote. The wireless receiver will receive the signal to trigger the motor to cause contraction and relaxation.
1.2.2. Pressure Transducer

A pressure transducer is an electrical component that converts a pressure reading into an analog or digital electrical signal. Although there are various types of pressure transducers, one of the most common is the strain-gauge transducer. The conversion of pressure into an analog electrical signal is achieved by measuring the physical deformation of the strain gauges which are bonded to the diaphragm of the pressure transducer and wired into a Wheatstone Bridge Configuration. A basic schematic of the Wheatstone Bridge Configuration is shown below in Figure 7.

![Figure 7 – Wheatstone Bridge Configuration](image)

Once pressure has been applied to the pressure transducer, a deflection of the devices diaphragm introduces strain to the device gages. The strain then produces an electrical resistance change proportional to the pressure. This electrical resistance can then be measured and thus analyzed for whatever specific need. The pressure transducer used in this design is a millivolt output pressure transducer. For the purpose of the accessible incontinence control device, this pressure reading will be transmitted via an RF transmitter to the microprocessor in the user remote control. The microprocessor will then convert the pressure reading into a corresponding bladder volume output which will then be displayed on the remotes LCD screen for the user to view.
Transducers with millivolt output are normally the most economical pressure transducers. The output of the millivolt transducer is nominally around 30 millivolts. The actual output is directly proportional to the pressure transducer input power. If the excitation fluctuates, the output will change also. Because of this dependence on the excitation level, regulated power supplies are suggested for use with millivolt transducers. Because the output signal is so low, the transducer should not be located in an electrically noisy environment. The distances between the transducer and the readout instrument should also be kept relatively short. The pressure transducer in this device will have its wires running into the device housing. There they will connect to a wireless transmitter, which will send the data to the user remote.

The specific transducer that will be used for the purposes of this design is the PX26-005DV made by the international company Omega Engineering. This particular component is designed for environments where liquid can be put on either side of the sensor; therefore, it will not be damaged by contact with urine. The component has a silicone sensor and plastic housing. The device is also small, with dimensions of 0.31 x 0.50 x 1.35 inches. It is also affordable, costing just $36.00. A schematic of the pressure transducer is shown below in Figure 8. The transducer will send a signal through a wire to the wireless transmitter that is contained in the housing of the urine flow control portion of the device. The wire needs to be carefully and tightly insulated to prevent damage to the device or electrical danger to the patient.

![Figure 8 – Pressure Transducer](image)
In order to determine the threshold volume that activates urine release, as well as calculate a volume value for each pressure reading provided by the transducer, a simple laboratory experiment could be implemented; water can be injected continuously into a bladder with the volume injected being a known value. After each and every injection, pressure in the bladder is measured. A volume versus pressure graph is then plotted. Then according to the obtained graph and the bladder observation, the threshold volume is determined and consequently the threshold pressure for the pressure transducer, as well as the volume that corresponds to each pressure measurement. All of the data conversion from pressure to volume values will take place in the user remote unit, not at the pressure transducer.

Ideally this test would be conducted on each individual patient and their user remote would be programmed for their results because the volume of urine corresponding to each pressure measurement will vary from person to person. The maximum volume of an individual's bladder could also be estimated using the equation shown below:

$$\text{Volume} = (\text{Age in years} + 2) \times 30 \text{ mL}$$

Unfortunately this formula is only valid for patient's age 1 to 19 years. A more accurate way of determining the maximum bladder volume would be the use of an ultrasound performed by an urologist. Then specific measurements could be acquired and a more accurate calculation could be performed according to the following equation:

$$\text{Volume} = (\text{Height} \times \text{Width} \times \text{Depth}) \times 0.625 \text{ m}$$

![Figure 9 – Sample Volume vs. Pressure](image-url)
1.2.3. Wireless Transmitter

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. Radio frequency transmitters are useful for this application because they are relatively low cost and can be small in size.

There will be a wireless transmitter housed in the implantable device housing that will collect data from the pressure transducer and send it to the remote unit. A frequency modulation (FM) transmitter will be used for this function. The RFD21134 transmitter from RF Digital Corporation (California) functions on a frequency band of 902 to 928 MHz. Its operating temperature is between 0°C and 70°C, which covers all possible human body temperatures.

This specific transmitter is the best option because it is small in size which helps to keep the device size small which improves the ability to implant the device in a patient. It measures only 1.9”x1.12”x.14” and it weighs only 1 ounce. A diagram of the component is shown below in Figure 10.

![Figure 10 – FM RF Transmitter](image)
The wireless transmitter will send the user input signal to the stepper motor resulting on turning the motor on and off. This will result in sphincter contraction and relaxation and thus resulting in the prevention and release of urine from the body. An On-Off Key (OOK) functioning transmitter is the easiest way to accomplish this goal.

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 operating temperature for the transmitter is -40° to 185° F. Both room temperature and body temperature are well within that range.

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 pressure transducer data will be continuously transmitting information. The transmitter sending information to control the motor in the artificial sphincter will only be sending a signal when the user decided to empty their bladder. Also, the two transmitters are sending their information to two separate locations.

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. The RF receiver in the remote will receive the signals from the transmitter and then send the signals to the microprocessor where the data can be processed. The microprocessor will be programmed to take the pressure 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.

A character liquid crystal screen (LCD) will be used because it consumes very little power, allowing for long battery life. The LCD will display a numerical representation of bladder volume and other text output to the patient. 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 order for the LCD screen to be character based it must be programmed so that it will deliver the response to the user in a number based output and not only a graphical output. To receive the text display to the LCD screen it must first and foremost be configured from the microprocessor to the LCD controller is given set commands of the type of screen is being used whether graphical or character so that it will format and display the correct output on the desired screen. The text code representation below is an example of how the LCD is configured using various functions depending on what the user want the screen to display.

![Figure 11 – Hardware configuration from micro to LCD](image)

Once the programming is done, to ensure it will output the text to the screen it has to be coded again often times using string parameters for the code memory. A typical example of string parameter is shown below.

```assembly
TEXT0: DB 'ANALOG DEVICES '; welcome message
         DB 099h
         DB 'LCD EXAMPLE CODE '
         DB 099h
```

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The remote control will also include a small speaker that will be able to provide audio alerts to the user if desired. 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. To turn the speaker off, the user will simply be able to enter into some speaker options that will be displayed onto the LCD screen and choose a mute option to eliminate sound from the device. The remote will still have the ability to vibrate to notify the user discreetly as to when the bladder has reached an indicated amount and requires attention from the patient.

The design of the remote will keep it as discrete and as small as the components will allow. 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. The remote will have the ability to vibrate to alert the user when necessary. The remote will have user options to navigate through the device functions that will be similar to an easy to use cellular telephone. This way buttons can be limited to provide for ease of use by the user. The remote will also have to ability to lock the device so there is no accidental release of urine at an inconvenient moment.

The user remote will also have a button that the user can press to allow urine flow and empty their bladder. When the button is pressed the OOK wireless transmitter will transmit as signal to the stepper motor, which will in result turn the stepper motor on and begin the process of the artificial sphincter relaxation process allowing for urine to flow out of the body. In order to prevent accidental release of urine, there will again be a key lock function to prevent accidental release. An overview of the entire process described above is shown below in Fig. 12.
Figure 13 – Function of User Remote Unit (a) Bladder Status Indication (b) Urinary Control
2. Realistic Constraints

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. Because the surgical procedure to implant the device will be costly the price of the actual device should be kept as low as possible. Also, device sustainability is an issue because if any parts fail and need to be replaced an additional surgical procedure might be required.
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 implantable, 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 device, 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 sphincter 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 in vivo. 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 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 retrievable. Additionally, for components requiring polymer material, a polymer other than Latex should be used because many patients develop an allergy to Latex after prolonged use.

A concern for surgical implants is infection. In order to minimize infection precautions need to be taken. The device should be inserted only in a sterile medical setting. The components need to be able to undergo sterilization before being implanted into the body. 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.

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.

There are also numerous FDA requirements for medical implant devices. The device needs to be non-toxic, non-allergenic, non-carcinogenic, non-mutagenic, and not cause an immune response. The device cannot let off significant amounts of heat because it will kill surrounding tissue. The device needs to be composed of biocompatible materials. It also will have to undergo several different tests to ensure it is safe and effective before it could be marketed to the public.
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 remote unit could possibly even be reused by other patients once one patient was done with it. 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.

There will be a major cost associated with the surgical procedure required to implant the device. However, many current incontinence treatment options, including a standard artificial urinary sphincter, already require surgical procedure, so this would not be a previously unnecessary cost.

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.

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.
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