Alternative Design 1
Accessible Incontinence Control Device

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1. Alternative Design Project 1
   1.1. Introduction

The Accessible Incontinence Control device is designed to assist patients with urinary incontinence. Urinary incontinence is the result of a dysfunctional bladder. Normally patients who suffer from urinary incontinence sometimes develop it as a result of other diseases such as pathology, spinal cord injuries, brain trauma and other diseases. There are three main types of urinary incontinence; Stress, Urge, and Overflow. Stress incontinence is when urine is released from the bladder due to increasing pressure in the abdomen. Uncontrolled urine release usually occurs during coughing, straining, or sneezing. Urge incontinence is when the patient experiences uncontrollable urges followed by uncontrollable urine loss. 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 was designed to meet the individual requirements of each specific patient individual 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 wants 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 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 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 conduit. The transducer will send a signal to the wireless transmitter located on the leg strap where this information will then be relayed to the handheld user remote. 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.

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.
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. 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. 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.
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.

![Figure 7 – Tubing Measurements](image)

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. Remote Control

The remote controller will contain a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. The remote will be used to initially program the device according to the individual patient. Each device will have to be individually calibrated for each specific patient. This will be necessary since the volume of urine in the bladder will be obtained by a calculated conversion from the pressure reading of the transducer. This will be similar for each patient, but to create a more personalized and accurate device this will be incorporated into the procedure on installing the device.

All of the processing for 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. The RF receiver in the remote will receive the signal from the transmitter and then send the signal to the microcontroller where it can be processed. The microcontroller will be programmed to take the pressure transducer reading and then convert the pressure into 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 then vibrate sending an alert to the patient that it is necessary to release the urine in a timely manor.

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 microcontroller 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 right away of a leakage on their own.

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 be a minimum as the volume of the bladder can be displayed using images and 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 since the control of urine flow will be operated manually by the valve of the catheter.
1.2.4. Pressure Transducer

A pressure transducer is an electrical component that converts a pressure reading into an analog electrical signal. Although there are various types of pressure transducers, one of the most common is the strain-gage transducer. The conversion of pressure into an analog electrical signal is achieved by measuring the physical deformation of the strain gages which are bonded into the diaphragm of the pressure transducer and wired into a Wheatstone Bridge Configuration. Pressure applied to the pressure transducer produces a deflection of the diaphragm which introduces strain to the gages. The strain will produce an electrical resistance change proportional to the pressure. The pressure transducer used in this design is a millivolt output pressure transducer.

Transducers with millivolt output are normally the most economical pressure transducers. The output of the millivolt transducer is nominally around 30 mV. 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 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 9. The transducer will send a signal through a wire to the wireless transmitter that is outside the patient's body.

![Figure 9 – 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.
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. A sample V-P graph for a patient is shown below in Figure 10.

Figure 10 – Sample Volume vs. Pressure

1.2.5. Valve Leakage Alarm System

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 then output a signal inputted by the patient or caregiver, whether they want it to light up and sound or vibrate. The alarm system transducer a signal to the remote control which will then display on the LCD 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. The alarm system will also have a voice recorder so that the patient or caregiver can record their voice and the desires alert sound they would like to have. This alarm system will be biocompatible, discrete, user friendly, environmentally safe and durable. It will have an operating temperature range of 0 °C to 55°C, weight of approximately 2 ounces, and 2 inches by 2 inches in size. Two commercially available sensors that could be used are shown below in Figure 11.

Figure 11 – Malem Alarm System
Sensors shown: Standard Flat Sensor for Malem Alarms and the Malem Alarm

Figure 12 – Valve Leakage Alarm
1.2.6. Wireless Transmission

The 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 transducer and 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.

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 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 below in Figure 13.
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 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 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 \textit{in vitro} tests in a simulated environment. Then \textit{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 a nurse insert 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.
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 sensitive, this design is universal and will be compatible with both men and women. The device will be user friendly, provide accurate bladder volume readings, and will be cost efficient.

The device will have little 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 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.

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. This device will provide an improved quality of life for the patient and help to create independence and allow the patient to be able to continue on with normal day activities and not be hindered by their incontinence.

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. Our 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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