Final Report
Accessible Incontinence Control Device

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Abstract

The Accessible Incontinence Control device is designed to assist patients who suffer from any type of urinary incontinence. This design will be able to treat incontinence whether it is a result of a dysfunctional bladder, weak abdomen muscles, or a weak urinary sphincter. The purpose of the device is to assist any patients with a dysfunctional bladder by controlling the flow and release time of urine from the body. This device will be designed so that the patient or caregiver will be able to control urine flow on demand. The incontinence device will be discrete, durable, and easily used by patients with disabilities. The device will provide an accurate status of the bladder by receiving stretch readings from the bladder and converting the readings to a proportional bladder volume percentage. This percentage will then be displayed to the patient on an LCD screen located in the user remote control. The device will be completely implantable with the exception of the user remote, and will not cause any adverse tissue effects, toxicity to cells, or necrosis of surrounding cells. The device will not absorb any proteins, and will be completely biocompatible with body fluid, pH, and temperature. The urinary incontinence device will be light weight, cost efficient, environmentally friendly, and most of all user friendly. The incontinence device will consist of many sub components to ensure efficiency and accuracy of the device.

The first component is the artificial sphincter that will be automatically operated through the use of a micro pump. This automated system will ensure that the device will be easy to use by a patient or caregiver. Urinary sphincter contraction and relaxation will be stimulated simply by the push of a button on the user remote control. The remote will then send a signal through wireless transmission to the implanted device, signaling the micro pump to either contract or relax the artificial sphincter. This will control the flow of urine out of the body and provide the patient with the control over their bladder that they are seeking.

The second component is the user remote control that will be able to control the entire device. The remote will consist of the liquid crystal display (LCD), wireless transceiver, audio speaker, power supply, and a microprocessor which will provide the digital logic for the device. The remote will output all the necessary information to the patient through the use of the LCD or optional audio alerts.

The unique feature of this urinary incontinence device using a stretch sensor and an artificial sphincter is that it consists of two main mechanisms. The first mechanism of the device is urinary control phase that will prevent unwanted leakage of urine from the body. The second phase will be a status indication of the bladder that will alert the patient or caregiver the status indication of the bladder on the liquid crystal display screen on the remote, indicating that it is time to release urine from the body. In addition, this device will be able to be used by both male and female. It will be implantable device will be able to remain in the human body for long term without any adverse side effect.
1. Introduction
   1.1. Background

Urinary incontinence is a major problem millions of men and women. Between 10 and 30% of adults are afflicted with urinary incontinence, or about 13 million Americans. Urinary incontinence occurs more commonly with an increase in age. Patients who suffer from urinary incontinence sometimes develop it as a result of other diseases such as pathology, spinal cord injuries, brain trauma and also as a side effect to medications. Urinary incontinence occurs when patients have a dysfunctional bladder, sacral nerve, or urinary sphincter. A dysfunctional bladder may cause overflow of urine or partial release of urine from the bladder. An overflow of urine from the bladder occurs when an inactive bladder muscle doesn’t fully contract occurring in a less active bladder resulting in swelling or stretching of the internal sphincter. When the urinary sphincter is dysfunction it causes unwanted leakages leading to embarrassment and discomfort of the patients. A dysfunctional sacral nerve results in urinary retention which in turn will eventually lead to urine overflow. The overflow of urine causes skin irritation and external infection. The partial release or no release of urine from the bladder often results in urinary tract infection and internal infections causing the patients to be in a lot of pain. In addition to clinical problems associated with urinary incontinence, patients suffering from this condition face public embarrassment, greatly altered lifestyle, and general decreased quality of life.

For this project a fictional list of potential clients was provided. There were three clients who could benefit from the use of an accessible incontinence control device. Keisha is 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, requiring a simple to use device with visual output. 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.

1.2. Purpose

The purpose of the device is to assist any patients with a dysfunctional bladder by controlling the flow and release time of urine from the body. This device will be designed so that the patient or caregiver will be able to control their urine flow. This incontinence device will be discrete, durable, and easily used by patients with disabilities. The device will provide accurate readings of the status of the bladder by receiving signals from the bladder to the screen on the monitor and will alert to the patient or caregiver if the bladder should be emptied. The device will also be able to provide a measurement and indication of the status of the bladder at any time the patient or caregiver desires. The device will be designed so that it can be used for both male and female patients. The device is implantable and it will not cause any adverse effect, toxicity to cells, and absorption of proteins. It will be biocompatible with body fluid, pH and temperature. The urinary incontinence device will be light weight, cost efficient, environmentally friendly and easy to use.
1.3. Previous Work Done by Others

1.3.1. Products

1.3.1.1. Commercially Available Products

Since urinary incontinence is such a common problem there are several commercially available incontinence control devices. The available products encompass a wide range of device types, a few of which are summarized in this section. There are also various behavioral modifications, such as pelvic muscle exercises and diet modification, and medications available to treat urinary incontinence. A urethral insert, which is like a small tampon, can be used by women with incontinence problems and inserted into the urethra for limited amount of time. In Figure 1 below a urethral insert is shown next to a Q-tip and a tampon for size comparison. The particular insert shown is a Reliance® urethral insert.

![Figure 1 – Reliance Urethral Insert](www.allegromedical.com)

A pessary is also available for women with incontinence. It is a stiff plastic ring inserted into the vagina, and it is removed regularly for cleaning. It is effective for use by women who have incontinence due to a prolapsed uterus. One commonly available is the 2.25 inch Rusch Pessary shown below in Figure 2.

![Figure 2 – Rusch Pessary Model #RUS563001](www.allegromedical.com)
An artificial urinary sphincter can be used by men or women, but it is more commonly used by men. It is a fluid filled ring that is implanted around the neck of the bladder. It is controlled by a pump implanted under the skin. The AMS 800, which is American Medical Systems version of an artificial urinary sphincter, has three components. It contains a cuff, a control pump, and a pressure regulating balloon. The device is shown below in Figure 3.

![Figure 3 – AMS 800](image)

The InterStim® system is an example of a sacral nerve stimulator. The device is implanted under the skin of your abdomen, and it resembles a pacemaker. It emits electrical pulses through a wire that is connected to the sacral nerve. By stimulating the nerve the bladder can be better controlled. The device can be seen in Figure 4.

![Figure 4 – InterStim II](image)

Catheters are also commonly used by patients who suffer from some form of urinary incontinence. Catheters are soft tubes that are inserted into the urethra to drain the bladder. Male patients have the option of using external catheters which are attached around the penis similar to a condom.

Some patients opt to monitor bladder status in an attempt to control incontinence problems. A device that allows patients to do this is a BladderScan® from the company Verathon Medical. The BladderScan® device is a small portable ultrasound device that calculated and displays bladder volume based on a three dimensional image that is generated. The BVI 6300, shown below in Figure 5, is one of the devices in the BladderScan® product line (http://www.verathon.com).
1.3.1.2. **Previous Student Design Projects**

A device extremely relevant to this project was developed by student Angelene Ozolins in the 2007 Australian International Design Awards. This student developed a device called “AssureFlow”. The device is a two element incontinence control device. The first element is an internal valve comprised of three concentric tubes. The inner two tubes, which are the functional tubes of the valve, are made of a shape memory alloy. The second element of the device design is an external actuator that is used to heat the shape memory valve, thus modifying its shape. As the valve cools the original shape is resumed. When the valve is cool it is effectively closed, blocking urine from flowing out of the bladder. As the valve changes shape upon heating the urine present in the bladder is able to flow through the valve and leave the body. The actuator, which resembles a remote control, also stored information about the patient’s daily urinating patterns for potential use by a physician.

A second relevant device was created for the 1990 NSF competition by a team at the Texas A&M University. This team developed a micturition alarm for use by caretakers at a medical facility. The device is able to provide visual and audible signals that a patient’s absorbable pad needs to be changed. The sensor is placed within, or outside, a patient’s absorbent pad. Fluid provides continuity across the terminals of the sensor producing current flowing through the op amps. The op amps then power the relay, which provides indication that the absorbent pad is wet and needs to be changed. The sensor is reproducible and easily cleaned. It is also cost effective, and it was made of speaker wire.
1.3.1.3. Patent Search Results

A Google patent search revealed that there are well over a hundred US patents relating to this device. A brief and by no means exhaustive listing of the patents most relevant to this project is provided below.

US Patent #2455859: This patent was filed May 13, 1946 and issued December 7, 1948. It is an early design for an artificial urinary sphincter. In females the device is surgically implanted and in males it can be used as either a surgical implant or an external control device. The sphincter is a fluid filled ring clamping ring that is controlled externally by pressing a button. The control, although external, is not a separate and disconnected unit such as a wireless remote control.

US Patent #6432038: This patent was filed February 15, 2001 and issued on August 13, 2002. It described a single component artificial sphincter. It consists of two concentric cuffs controlled by a spring loaded button. The clams being made include simple single incisions surgical implantation is possible and that the single component design will lower the chance of failure and simplify repairs if necessary.

US Patent #4800900: This patent was filed September 25, 1987 and issued January 31, 1989. It is an external cloth strap that is useable by male incontinence patients. The strap encircles the penis. It also contains compressible pads with an inflatable sac between them. The sac can be inflated via a syringe and a tube. When inflated the device puts pressure on the penis, and therefore the urethra, blocking the passage of urine from the body.

US Patent #5823972: This patent was filed June 6, 1996 and it was issued October 20, 1998. It is a two part device that can measure bladder pressure and urine flow. The first part of the device is an inflatable cuff that is mounted to the penis. The second part is a catheter that has a pressure transducer on the end of it. The transducer end of the catheter is inserted into the urethra to a point beyond the penile cuff. The cuff can be inflated to prevent urine flow and deflated to allow urine flow. The pressure transducer can sense the presence of urine in the urethra. The signal form the transducer is send to a signal processor and the results are then printed.

US Patent #7128707: This patent, filed on July 25, 2005 and issued on October 31, 2006, is an artificial sphincter cuff which can be implanted around the beginning of the urethra. The cuff is made of electroactive polymer which can be expanded or contracted by an external electrical actuation device.

US Patent #6319208: This patent was filed on December 3, 1999 and it was issued on November 20, 2001. The device is a small floating recorder floats in the bladder and telemetrically relays information to an external receiver regarding urinary tract pressure. It can be used for diagnosing urinary tract diseases or as a monitoring system for a patient with urinary incontinence.
1.4. Map for the rest of the Report

The rest of the report will discuss various design alternatives that were developed to accomplish the project objectives for an accessible urinary incontinence control device. First a brief synopsis of three alternative designs will be offered. Then a detailed description and analysis of the optimal design selected for the device will be laid out. The design will be broken down into subunits, each of which will be described in great detail. The design description will be accompanied by diagrams and flow charts to clarify the function of each subunit. The report will detail the final design that was successfully built and how it differs from the optimal paper design. The report will also contain brief summaries of realistic constraints and safety concerns related to an accessible incontinence control device. The report will conclude with a detailed budget for the components required to implement the design and a timeline of tasks that needed to be carried out to complete the project as well as an allotted timeframe for each task.

2. Project Design
2.1. Design Alternatives

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.

![Figure 6 – Overview of device function](image-url)
2.1.1. Design I

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 held in place on the patient’s inner thigh by a leg strap.

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. 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 waterproof 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.
Urinary Control

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.

In order to prevent accidental opening of the valve during physical activity, the valve for this design will be opened and closed by 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.
Remote Control

The remote controller will contain a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. 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 manner.

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.

Pressure Transducer

A pressure transducer is an electrical component that converts a pressure reading into an analog electrical signal. 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.
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.

**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. When the alarm system is triggered it will send the signal to the remote, where the microprocessor will process the information and alert the patient that the valve has a malfunction or it is leaking.

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.
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.

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 9.

![Figure 9 – Leg Strap](image-url)
2.1.2. Design II

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 held in place on the patient’s inner thigh by a leg strap. This phase of the device is identical to the incontinence control phase of Design 1.

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. This subunit is also a component in Design 1.

The status indicator subunit for this design is radically different from the pressure transducer used in Design 1. The status indicator subunit will be comprised of an ultrasound transducer. The signals generated by the transducer will be sent to the microcontroller in the remote control.

The remote control will consist of a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. The remote will display the status of the obtained from the ultrasound signal. The signal will be modified by the microprocessor and displayed on the LCD screen.
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.

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.
**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 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.

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.
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°F 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 12 – Function of User Remote Unit (a) Bladder Status Indication (b) Leakage Alarm
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. When the alarm system is triggered it will send the signal to the remote, where the microprocessor will process the information and alert the patient that the valve has a malfunction or it is leaking.

The alarm system will consist of a waterproof 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.

Wireless Transmitter

A wireless transmitter will be contained in the leg strap of the device. 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.

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.

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.


**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.

![Figure 13 - Leg Strap](image)

2.1.3. Design III

The design is divided into two main phases. The first phase 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 phase 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.

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. This design uses a very different incontinence control component than the previous two designs. This component is implantable and fully automated. This improves on the level of discreetness of the device as well as the ease with which the patient can use the device. Additionally, this design differs in that the urine flow will be stopped prior to leaving the bladder. In previous designs the urine could freely leave the bladder, but it was stopped before it could leave the urine conduit tubing.
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 pressure transducer was also used as the status indication subunit of Design 1. Pressure transducer was selected over ultrasound because it is both more discreet and much more cost effective.

The remote controller will consist of a Liquid Crystal Display (LCD), RF receiver, power supply, and the microcontroller. 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.

![Figure 14 – Design 3 Layout](image)

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 15 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 15 – 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.
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.

**Pressure Transducer**

A pressure transducer is an electrical component that converts a pressure reading into an analog electrical signal. The specific transducer that will be user 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 27. The transducer will send a signal through a wire to the wireless transmitter that is outside the patient's body.

**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 houses 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.

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

**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).

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 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 Figure 17.

Figure 17 – Function of User Remote Unit (a) Bladder Status Indication (b) Urinary Control
2.2. Optimal Design

2.2.1. Objective

The objective of this project is to design a urinary incontinence control device that that will help patients with disabilities control urinary incontinence. Urinary incontinence, the loss of ability to control the release of urine from the bladder, is a problem that affects about 12 million adults in the United States. Risk factors for urinary incontinence include age, obesity, sex, vascular disease, and other diseases such as diabetes and Parkinson’s disease. Urinary incontinence decreases a patient’s quality of life due to complications such as skin problems, urinary tract infections, embarrassment, and changes in personal life and activities.

There are currently several treatment methods available for patients with urinary incontinence. These treatments vary from behavioral changes to medical devices or surgical procedures depending on the cause of the incontinence. For patients whose incontinence cannot be controlled there are catheters and absorbent pads which are used to lessen the side effects of the incontinence. One problem with current incontinence control devices is that they tend to be very specific to a particular type of user; for example, specifically for a female with predictable incontinence due to high impact activities. It would be beneficial if a device could be developed that would help a wide array of patients or caregivers to control and manage urine flow, including patients with disabilities. Additionally, a patient would be able to assume greater control over urinary function if their incontinence control device had the ability to provide an indication of the status of the bladder.

The two main features of this design that make it unique, as well as an improvement over currently available devices, is that is can control incontinence as well as provide the user with the status of the bladder and the device will be universally accessible to male and female patients as well as patients with disabilities. The ability to discern the status of the bladder at any given point in time will increase the control the user has over bladder function.

The design will achieve its objectives by using a surgically implanted component as well as a user control unit. By using this method the device will be both discreet and fully automated. This improves the patient's ease of use as well as their ability to interact normally in public.

This design is radically different from the other designs proposed previously because it is the only design that is an actual implant. Previous designs used semi-invasive methods such as catheters. Additionally, previous designs require manual control of the voiding of urine and in this device that function can be accomplished simply with the push of a button.
2.2.2. Remote Control

The remote controller will contain a Liquid Crystal Display (LCD), ZL70101 wireless transceiver configured as a base, power supply, and microprocessor. The speaker and vibrating alarm will also be contained within the remote control unit. All of the processing for the device will take place in the remote control. 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. This design will use Comfile GHB-3224C LCD screen (Comfile Technology, CA, USA). This LCD screen, which is blue and white, is capable of displaying graphics and characters. One drawback to this particular LCD is that it requires 9 volts of power.

![Figure 18 – CUNET LCD display (cubloc.com)](image-url)
The LCD screen is backlit (controlled by software) which will make it easy to read in many various lighting conditions. The GHLCD is designed in such a way that it is easier to program than typical LCD’s. In order to program the LCD RS232C communication much be used. The display has three independent layers that can be separately programmed. Layer 1 can display text and all three layers can display graphics.
Below is some sample code used to program the LCD. The first example is for turning the backlight on and off.

<table>
<thead>
<tr>
<th>ESC</th>
<th>BL</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1byte</td>
<td>2byte</td>
<td>1byte</td>
</tr>
</tbody>
</table>

Parameters: \( n = \) (0=OFF, 1=ON)
Operation: Set LCD Backlight ON/OFF
Send Example: (Hex) 1B 42 4C 00 01

The programmer can also clear either all three layers or one specific layer.

<table>
<thead>
<tr>
<th>ESC</th>
<th>CL</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1byte</td>
<td>2byte</td>
<td>1byte</td>
</tr>
</tbody>
</table>

Parameters: \( n = \) (0=Clear All layers, 1=Clear Layer 1, 2=Clear Layer 2, 3=Clear Layer3)
Operation: You can clear all layers, or specify the layer you want to clear.
Send Example: (Hex) 1B 43 4C 00

Code can also be used to determine whether the cursor is on or off when the display is programmed to function as a touch screen.

<table>
<thead>
<tr>
<th>ESC</th>
<th>CS</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>1byte</td>
<td>2byte</td>
<td>1byte</td>
</tr>
</tbody>
</table>

Parameters: \( n = \) (0=off, 1=on)
Operation: Turn Text Layer Cursor ON/OFF.
Default is OFF.
Send Example: (Hex) 1B 43 53 01

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 remote control speaker does not need to be large or particularly expensive. All it needs to be able to do is to sound a simple beeping alarm if the user’s bladder has filled to a certain threshold volume and needs to be emptied. The speaker that will be used to accomplish this task is SCB-13A (Star Micronics, NJ, US). The SCB-13A is designed for use in call phones, appliances, electronic games, and other electronics. A picture of the specific speaker model is shown below in Figure 21.

![Figure 21 – SCB-13A speaker.](image1)

The speaker, which has 8 ohms of impedance, has an operating temperature range of -22° to 158°F and a storage temperature range of -40° to 185°F. The speaker is small, with a 7.6 mm diameter and 2.5 mm thickness.

![Figure 22 – Mechanical dimensions of the speaker.](image2)

The user remote is also going to have a vibrate option so that in settings where discreetness is necessary the alarm can alert the user that the bladder must be emptied by a subtle vibrating alarm instead of an audio alarm. The technology that will allow the remote control to vibrate is the same as that which vibrates cell phones and other small
electronics. A small flywheel motor is located inside the housing of the device. The motor has a weight attached. By attaching the weight off-center it creates a wobble when the motor is turned on and beings to spin. This wobble causes vibration of the entire device. The motor generally rotates at least 100 rpm. The figure below shows an example of a vibrating set up. This particular image is from a vibrating toy, but the technology is identical to what will be used in the user remote.

![Image](image.png)

**Figure 23** – A small motor and attached off-center weight that result in device vibration.

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 wireless transceiver in the remote will transmit as signal to the transceiver in the implantable device which will close the switch and result in power being supplied to the stepper motor, which will in result turn the stepper motor on and begin the process of 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 in Figure 24 on the following page. Figure 25 shows an illustration of the user remote unit.
Figure 24 – Function of User Remote Unit (a) Bladder Status Indication (b) Urinary Control
2.2.3. Microprocessor

A CUBLOC microprocessor (the CB405) will be used to run programs to monitor data from the device’s sensors, communicate with LCD display and implement a simple menu interface for the user to interact with. Programs will be written using BASIC and Ladder Logic. While the BASIC program will run sequentially, the Ladder Logic program will run using parallel processing. This programming method will allow the microprocessor to gather data from sensors and control components in real time. The main advantage of CUBLOC over other PLCs is that it fills Ladder Logic’s weaknesses with BASIC language. Ladder Logic is good enough to replace sequence diagrams, but to collect data, print graphics, and process complex tasks is asking a little bit too much. Another advantage over other BASIC processors is that CUBLOC is able to separate the amount of work and programming between Ladder Logic and BASIC as necessary. The user is able to debug easier by having two processes work together, instead of trudging through lines of BASIC codes.
The major tasks of the microprocessor will be:
- Converts pressure from pressure transducer input to volume with the output displayed on the LCD
- Controls the artificial sphincter via the pump
- Controls the speaker and vibrating alarm
- Allows user input

The required power supply for the microprocessor is 4.5 to 5.5 volts. It has an operating temperature range of -40° to 257°F. A more complete list of microprocessor specifications can be found in Appendix 2.

The dimensions of the microprocessor are 59.4 mm x 47.8 mm. The microprocessor is 9.5 mm thick (about 14 mm when adding in the length of the pins). Figure 26 below shows a mechanical schematic of the CUBLOC microprocessor.

![Figure 26 – CUBLOC microprocessor dimensions.](image)

The microprocessor can easily be powered using a battery. In addition, when a super capacitor is connected to the VBB of a CB405, the memory can be maintained for a couple days to a couple weeks once powered off. The CB405 consumes about 15-20mA of current when idling. For a longer backup period, which would be necessary for this particular device, a battery pack can be used. A protection diode as shown below in Figure 27 is necessary when using a battery, as the device normally attempts to charge a
capacitor through that pin. Due to the relatively high standby current for battery backup, it is recommended to keep the device powered if possible and only maintain battery backup for short periods of emergency use.

![Figure 27 – Electrical schematic for battery powered CB405](image)

One of the tasks required of the microprocessor in this design is outputting data to an LCD screen. Various LCD displays are provided for use with CUBLOC using CUNET (I2C) protocol. With one line commands (PRINT, CLS, etc…), printing to the LCD would be easy and without complex commands. CUNET is especially engineered for CUBLOC displays and therefore the best option for the LCD display in this design. The particular display that will be used in this device, GHLCD, can download black and white BMP images to the onboard memory and retrieve on command.

To use Cubloc Studio, it can be installed on a Windows XP, 2000, or 98 operating system equipped computer. If a Linux/Unix/Macintosh environment is used, virtual machine of some type (such as VMware, etc…) that allows the Windows operating system to run on it will have to be installed. An RS232 port is also required, or a USB-to-RS232C converter.

Download and Monitoring is possible when connected to the PC. When the CUBLOC is disconnected from the PC; it goes into a stand-alone state. The main program is stored in CUBLOC’s flash memory, and will be retained even with no power. The user may download new programs and erase them 10,000 or more times per device. Following are examples showing mainly how the microprocessor will be programmed in this device.

For this device the microprocessor needs to control a small speaker. In this application note, simple ways to create key touch sound, musical notes, and alert sound will be pointed out. An I/O port or a PWM Channel of CUBLOC can be used for sound. With a PWM Channel, we have the advantage of creating different tones of sounds.
The above example in Figure 28 shows PWM Channel 0 of CB405 being used with Freqout command to produce a sound. Sample code is below.

```
Const Device = cb405
Dim PLAYSTR As String
Low 5
Freqout 0, 5236 "Create a sound with frequency of 440Hz"
Delay 500 "Delay"
Pwmoff 0 "Stop Sound by turning off PWM"
```

With commands like Freqout and Delay, simple sounds can be created.

```
Const Device = CB405
Low 5
Freqout 0,4403
Delay 200
Freqout 0,3703
Delay 200
Freqout 0,3114
Delay 200
Freqout 0,2202
Delay 200
Pwmoff 0
```

By changing frequencies, a simple program that can play musical notes can be made.

The microprocessor in this design will also have to control the artificial sphincter. This code will have to be similar to code that would be used to control a stepper motor. To enable a step motor, a simple program that outputs pulses to the motor driver is created. Like the picture shown below in Figure 29, a motor driver will be placed in between CUBLOC and the motor. When the motor driver receives pulses from CUBLOC, it will turn the MOTOR by 1.8 degrees for every pulse.
Sample code is below.

```plaintext
Const Device = CB405
Low 4
Do
  STEPOUT 4,2,1000
Loop
End

Sub STEPOUT(PN As Byte, FR As Integer, LN As Long)
  Dim SJ As Long
  For SJ = 0 To LN
    Reverse PN
    Udelay FR
    Reverse PN
    Udelay FR
  Next
End Sub
```

The section below details how to use the STEPOUT sub function. STEPOUT has 3 parameters PN, FR, and LN. The PN is for the port number used. The second parameter FR is the length of the pulse. The last parameter LN is for the number of pulses to send.

PN: PORT Number
FR: Pulse Length (0~65535)
LN: Number of Pulses (0~2147483647)

STEPOUT 2, 50, 9 'Generate 9 pulses with length of 50.
STEPOUT 2, 20, 30 'Generate 30 pulses with length of 20.
2.2.4. Wireless Transmission

This device will use radio frequency (RF) wireless transmission to communicate between the user remote and the implantable device. 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. Since we have two important signals to send between the implantable device and the user remote, it will be necessary to use a device that can send two independent signals. A transceiver will be used in the implantable device and the user remote to eliminate the need of a separate receiver and transmitter in each component.

The wireless transceiver in the user remote will send the user input signal to the transceiver in the implantable device which will trigger the switch of the power supply to close and thus allowing for power to travel to the stepper motor resulting in 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.

Figure 30 below diagrams the transfer of information to and from the implanted wireless transceiver.

![Diagram of wireless transceiver information flow](image-url)
The wireless transceiver that will be used in this device is the ZL70101 Medical Implantable RF Transceiver (Zarlink Semiconductor Inc., USA). This transceiver functions on the frequency bands of 402-405 MHz (MICS channels) and 433-434 (ISM channels). These frequencies are within a high enough range that they will be able to penetrate body tissue. They are also in the frequency range allowed by the FDA because the wavelength can penetrate tissue without causing damage or tissue death. The transceiver is also requires low power which is important in an implant because of the difficulty in replacing exhausted power sources when they are inside the body.

The specific model transceiver that will be used was designed for medical implant applications. It can be used by pacemakers, neurostimulators, insulin pumps, and bladder control devices. A block diagram of the transceiver is shown in Figure 31 on the next page.

![Figure 31](image)

Medical implant devices need to be extremely reliable. Their function often has a large effect on a patient’s health and well-being so it would be a safety concern if the device was unreliable. Additionally, it is difficult and often impractical to retrieve and troubleshoot an implantable device. The ZL70101 uses Reed-Solomon coding and CRC error detection to ensure reliability.

Reed-Solomon coding is often used for the storage and transmission of digital information. This method is able to retrieve original data signals from signals that got damaged and modified in transmission. A general Reed-Solomon system is shown below in Figure 32.
Figure 32 Reed-Solomon Encoding is used to increase reliability of the data transmission from the implantable device.

This urinary incontinence device requires a transceiver in both the implant and in the user remote unit. The ZL70101 can function as a transceiver in both the implantable medical device and the “base” (in this case the remote control). This means that two ZL70101 transceivers can be purchased and used instead of purchasing the ZL70101 for the implant and a second transceiver model for the remote unit. The transceiver can function in both settings because it can be configured in a low power consumption mode (for the implant) as well as a base mode. There are multiple options for waking up the implanted transceiver when it needs to transmit data. The base can send a specially coded message on a unique frequency that will wake up the transceiver. This method will be implemented when the patient or their caregiver wants to check the status of the bladder. The transceiver can also be coded to wake up without a message from the base in order to transmit an emergency message. The implanted transceiver in this device will wake up and send an emergency message to the user remote when the pressure transducer outputs a signal indicating a threshold volume of urine is in the bladder and the user should void immediately. Figure 33 below shows sample configurations of the ZL70101 as an implant and as a base.
Figure 33 (a) ZL70101 configured as an implantable transceiver. (b) ZL70101 configured as a base. This is the configuration that will be used in the user remote.

The transceiver has dimensions of 7.1mm x 7.1mm x 0.9 mm. These dimensions, which result in a total volume of 45.4 cubic mm, are well within the allowable range for implantable RF transceivers, which is about 250 cubic mm. A picture of the transceiver chip is shown below in Figure 34.

Figure 34 – Wireless transceiver ZL70101
The ZL70101 requires a power supply of 0 to 3.6V. This can easily be supplied by a lithium ion battery. The power consumption of this transceiver is extremely low, the transceiver can operate in a low power sleep mode and be woken up just to transmit data when necessary. Because the transceiver, which require 5mA of current when operating and only 1mA when in sleep mode, requires so little power it can be powered by a battery that cannot be recharged internally. The battery lifetime will last long enough that it would not be unreasonable to require surgery to replace the battery each time it dies. Battery lifetime can be measured by dividing the ampere-hours of the battery with the current being drained by the device. Assuming that the transceiver will be actively transmitting data for about 2 hours a day (likely an overestimate), the average current consumption will be an average of 1.3mA. The company Quallion LLC (CA, USA) produces tiny biomedical implant batteries. These batteries have long lifetimes and operate at normal body temperature. The QL00031 is a lithium ion battery developed particularly for medical implant applications. The battery is biocompatible and has an extended lifetime compared to traditional lithium batteries. The battery is also very small (2.9 x 11.8 mm, .2g) which allows for a smaller and more user friendly implant. Normal body temperature is well within the operating temperature range for this battery, 32° to 107.6°F.

Quallion batteries use matrix technology. There is a series of small cells inside each battery instead of one large cell. This increases battery reliability because the battery can continue to function even if it contains some bad cells. Because the battery is a series of small cells instead of one large cell it will dissipate heat faster. This reduces concerns about heat generation by implants damaging surrounding tissue.

Wireless technology is being used to prevent the patient from having to wear a device close to their body at all times so that data could be transmitted by wires. It is impractical to use an implant with wires. Running wires from inside the body to outside opens up the possibility of electrical injury to the patient, electrical failure of the device, and infection. Wireless technology is the more efficient and most practical way to convey information about the bladder to an external source. It also makes the device more attractive and marketable than a device that requires wires to transmit data. RF technology was chosen over Bluetooth for the purposes of this device because data transmission in this device is short range and simple.
2.2.5. Pressure Transducer

The bladder status indication portion of the device will be accomplished through the use of a pressure transducer. A pressure transducer is an electrical component that converts a measured pressure reading into an analog or digital electrical signal that can be used for certain analysis. 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 with a pressure-variable resistor in each leg. The Wheatstone bridge will consist of a minimum resistance of 350 ohms and maximum of 440 ohm. A basic schematic of the Wheatstone Bridge Configuration is shown below in Figure 36.

![Figure 36 – Wheatstone Bridge Configuration](image)

Once pressure has been applied to the pressure transducer, a deflection of the device 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, transmitted to a microprocessor, and thus further analyzed. For this design the pressure of interest is the urine pressure buildup in the urethra located slightly above the implantable inflatable cuff or the artificial sphincter. This pressure will be measured by a pressure transducer sensor and then that pressure reading will be transmitted to an operation amplifier then wirelessly transmitted to the microprocessor of the user remote control where it can then be converted into a proportional bladder volume percentage and be displayed to the patient. The pressure transducer that will be used in this design will be the M-060 Strain Gauge Pressure Transducer from the Precision Measurement Company. This transducer was chosen on the basis of its small size and low power consumption.
The M-060 transducer has an output signal of 0.7 millivolts per volt. Since the microprocessor used in the device will need an input in the 5 volt range, the signal from the pressure transducer must be amplified so that the pressure signal output produced by the pressure transducer can be converted to a proportional volume percentage by the microprocessor. For the purpose of the accessible incontinence control device, the pressure reading will first go through an operational amplifier, then will be transmitted via wireless transmission to the microprocessor in the user remote control for signal analysis. The microprocessor will then convert the pressure reading into a corresponding bladder volume percentage output by comparing the pressure to a pressure to volume curve that will be in the processors memory bank. The resulting bladder volume percentage will then be displayed on the remotes LCD screen for the patient to view. The microprocessor will also be able to alert the user via speaker or vibration when the volume percentage reaches an unstable amount and needs an immediate emptying.

Due to the low output signal, 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. This will not be an issue as the pressure transducer will be implanted in the urethra and will not be near any other electrical components. The distance from the transducer will be a relatively short distance to the implantable device housing that will be located in the abdomen. The pressure transducer in this device will be directly connected to an amplifier in the implantable device housing. The wired connections will provide power and a path for the transmission of the pressure reading. The connections will run along the silicon tubing that will be connected to the inflatable cuff. The wire needs to be carefully and tightly insulated to prevent damage to the device or electrical danger to the patient. The connections will have to be shielded in a biocompatible material, such as silicon, to make sure there are no adverse tissue reactions. The data will be put through the amplifier and then passed on to the wireless transceiver, which will send the data to the microprocessor in the user remote control. A simple schematic of the pressure transducer connections is shown below in Figure 37.

![Figure 37 – Pressure Transducer Circuit](image)
The M-060 miniature pressure transducer has an output voltage of 0.7 mV per volt and a pressure range of 0-350 kPa. The pressure signal from the transducer will be amplified to approximately 5V so that it can be processed by the microprocessor. This specific pressure transducer sensor is designed for critical biological or medical applications. This transducer utilizes a 350 ohm foil strain gage carefully attached to the substrate for maximum stability. It is furnished with 1 meter, 3 conductors stranded copper lead wires with Teflon coating.

![Figure 38– M-060 Strain Gauge Pressure Transducer (Dimensions in millimeters)](image)

The transducer will include an inductor and a capacitor connected in parallel to form a resonant capacitance and inductance circuit. One of the components is variable, is which will vary the value of capacitance or inductance and also the resonant frequency of the inductance and capacitance circuit in response to pressure changes of the fluid in which the bellows is immersed. A bellow is a device for delivering pressurized air in a controlled quantity to a controlled location. The transducer will be electromagnetically coupled to the remote of variable-frequency energy such as a grid-dip oscillator, enabling external detection of the transducer resonant frequency which will be a measure of the urine pressure in the bladder being sensed. An antenna coil will be inductively coupled to the transducer inductor, so that when implanted, it will provide efficient coupling of the external oscillator and the internal resonant circuit of the transducer.

### 2.2.6. Signal Amplification

Signal amplification increases the power of a signal to a degree that falls within the analog to digital conversion input range. To be able to calculate the bladder volume from a pressure reading, the output signal from the pressure transducer sensor must be amplified to a range that can be processed by the microprocessor. The M-060 transducer being used in this design has an output signal in the 0.7 mV/V range. That signal must be amplified to a 5 V signal so that it can be processed by the microprocessor. To increase the 0.7 mV range output signal of the pressure transducer a simple amplifier can be used to increase the gain to the necessary range that will be required by the microprocessor. The microprocessor in the remote control will be able to do the necessary analog to digital conversions and be able to perform linearization to the pressure transducer output signal and compare the readings to a predetermined volume curve. But the first step is getting the output signal in a form that can be processed by the microprocessor. This can be accomplished by passing the pressure reading through a simple amplifier which will
create the necessary gain to provide a 5 volt signal to the microprocessor. Shown below in Figure 39 is a layout of the pressure transducer amplification subunit.

Operational amplifiers are high-gain electronic voltage amplifiers with various inputs and, usually, a single output. Operational amplifiers are usually controlled by negative feedback where outputs from the systems are inverted, into the system's input and generally results in fluctuations that are attenuated. Also, with the operational amplifier, it will also realize the filter function by adding a resistor capacitor circuit around the amplifier. A schematic example of a low pass high pass and band pass operational amplifiers is illustrated in Figure 40 on the next page.
Finally it is important to ensure that the analog to digital conversion is bandwidth limiting. This ensures the highest allowable frequency component in the analog signal before sampling with an analog to digital conversion is less than or equal to the one half of the sampling frequency to ensure that the component frequency is not above the Nyquist limit. In order to ensure this a low pass filter was be designed to cutoff frequency that is close to the Nyquist limit imposed by the analog to digital sampling frequency.

2.2.7. Volume Calculation

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 can 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 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 a more accurate calculation could be performed according to the following equation:

\[
\text{Volume} = (\text{Height} \times \text{Width} \times \text{Depth}) \times 0.625 \text{ m}
\]
For the purpose of this project a standard pressure to volume calculation will be performed. This will be determined from averaging data from previously conducted experiments. A sample curve relating bladder volume to urinary pressure is shown below in Figure 41. Once the microprocessor has been programmed with this information, it can simply compare the pressure reading to the bladder volume curve and produce an appropriate volume percentage for the patient.

![Sample Volume vs. Pressure](image)

**Figure 41 – Sample Volume vs. Pressure**

### 2.2.8. Artificial Sphincter

To control the flow of urine out of the body, the design will use a surgically implantable artificial sphincter to replace the incorrectly functioning urinary sphincter. An artificial sphincter is a device usually used in men, though it can be altered for use by females, to treat Urinary Stress Incontinence. The artificial sphincter that will be used in this design will be the AMS 800 Urinary Control System. The Artificial Sphincter is made completely out of silicon elastomer, a completely biocompatible material. The artificial sphincter can be seen below in Figure 42. The sphincter consists of three main parts: an inflatable cuff, a fluid reservoir, and a mechanical pump. The pump is implanted into the scrotum of a male patient, and in the labia for women with urinary incontinence. The pump controls the flow of fluid from the reservoir to the inflatable cuff. The fluid is usually an iodine-based solution, this is so the device will show up in x-rays. To operate the device the patient must compress the pump to divert the fluid into the fluid reservoir to simulate sphincter relaxation. The device will automatically re-inflate the artificial sphincter in about 3 to 5 minutes. The disadvantage of this device is that it must be manually controlled by the patient. The pump control is small and ends up being a
difficult solution for a patient with disabilities or poor motor skills. The location of the pump is also undesirable.

Figure 42 – AMS 800 Artificial Sphincter

For our design we will remove the mechanical pump from the artificial sphincter and replace it with an electrically operated two-way micro pump. The micro pump will be implantable in the abdomen and will be controlled by a wireless remote control. This will provide for an easy to use interface for controlling the flow of urine. By eliminating the manually operated pump from the design, the device will provide a better control system for individuals with disabilities and poor motor skills. Patients also will not have to try to operate a mechanical pump in an undesirable location. This design will be more convenient to the patient and also should provide a more discrete operation of the device. The implantable device will consist of the inflatable cuff, a pressure transducer in a small piece of catheter, and the implantable device housing which contains all of the electrical components for the device.

Figure 43– Overall Design Layout
The inflatable cuff will be implanted surrounding the bulbar urethra. The cuff will be placed here as clinical studies have shown that the continence rate is 92% in males when the inflatable cuff is located at the bulbar urethra versus only an 84% continence rate when the cuff is placed at the neck of the bladder. Figure 44 below shows the anatomy of the urinary system and the location of the bulbar urethra.

The implantable device housing will be implanted in the abdomen. This is the optimum location for the implant. The pressure transducer will be connected to a small piece of catheter and will be inserted into the urethra and will be located slightly above the inflatable cuff. This will provide the best recordings of the pressure, which will be transferred to the implantable device housing for amplification and transmission to the microprocessor in the user remote control. The implantable locations and anatomy can be seen clearly in Figure 45 below. The pressure transducer connection will consist of two wires: one will transfer the power to operate the pressure transducer and the other will transfer the pressure reading to the amplifier located in the implantable device housing. This connection will run parallel with the tubing connecting the micro pump to the inflatable cuff. All of the connections will be concealed in a biocompatible conduit.
2.2.9. Micro Pump

To transfer fluid from the inflatable cuff to the fluid reservoir the device will use a micro pump. The pump will be housed in the implantable device housing and will connect to the cuff and the fluid reservoir through silicon tubing. The micro pump that will be used in this design will be the M100-S Micro Pump from TCS Micro Pumps. The pump can be seen in Figure 46 below. The pump will be connected to a battery power supply in the device housing and will be operated through wireless transmission via the user remote control. The advantage of the M100-S micro pump is its small size and low power consumption. The dimensions of the pump are 14 mm x 14 mm x 28 mm (.55 in x .55 in x 1.1 in). The micro pump has an operating voltage range of 3.0 – 4.5 volts, and only draws 0.28 – 0.42 amps of current. This results in total power consumption between 0.84 and 1.89 watts. The micro pump also operates at a temperature range that includes normal body temperature. The pump has an operational temperature range of -20° C to 150° C, which is well within the normal temperatures of the body. The micro pump requires the use of 2.4 mm bore tubing for the input and output connections to the pump. The micro pump also includes an optional vent connection which will not be necessary for the design of this device. One of the advantages of using a micro pump to transfer fluid from the fluid reservoir to the inflatable cuff and back is that the pump will produce very little heat in the process. This is a very important aspect, as the implantable device will not be able to significantly increase the temperature of the surrounding tissue, as this would cause tissue death and implant rejection.
2.2.10. Power Supply

As stated before the pump will operate at a voltage range between 3.0 and 4.5 volts. The normal operating voltage for this design will be maintained at the minimum operating voltage of 3.0 volts. While the pump is operating at 3.0 volts, the pump will produce a flow rate of 250 milliliters per minute. The fluid reservoir of the artificial sphincter only contains 2 milliliters of fluid. So the time of contraction and relaxation can be calculated by dividing 2 milliliters by 250 milliliters per minute and converting this to seconds. This calculation results in an approximate contraction time of 0.48 seconds. For power supply analysis purposes the contraction time will be increased to 1.0 seconds, doubling the actual time of contraction. By doing this the calculations will be simpler and the power consumption will be larger than the actual power consumption which will help to account for power leaks or the possibility of longer contraction or relaxation time. The total power consumed by the pump will be 0.84 watts per second for calculation purposes. This is a result of the pump drawing 0.28 amps of current while operating at 3 volts.

The average person empties their bladder between 4 and 6 times daily. For power analysis, again we will use caution and calculate the power consumption under the assumption that the device will be used the maximum amount of 6 times per day. The time for contraction and relaxation of the cuff will be 1 second each for a total of 2 seconds per restroom visit. With this logic the pump will only consume power for a total amount of 12 seconds per day. The power supply for the micro pump will consist of a combination of two 3 volt Lithium-Manganese Dioxide Non-rechargeable batteries. The two batteries will be placed in series and connected to a reed switch to make sure that the battery is only being used when the device is in operation. The two batteries are specifically the U10004 Thin Cell batteries from www.ultralifebatteries.com. The battery and its overall dimensions can be seen below in Figure 47 and Figure 48 respectively. The batteries have a nominal discharge of 1.5Ah (amp hours). The nominal discharge of a battery is simply a decreasing function of the discharge rate. By connecting the two batteries in series, the total nominal discharge will be a sum of the two discharges of the individual batteries, resulting in a total nominal discharge of 3 Ah. With the pump only drawing a current of 0.28 A, the total lifetime for the batteries will be the result of 3 Ah divided by 0.28 amps, thus 10.714 hours. This is then easily converted into 38570.4
seconds and then divided by the total time of usage per day, 12 seconds, which gives the result of a battery lifetime of 3214.2 days or approximately 9 years. As stated before this is an approximate lifetime for the battery supply since the time of pump operation was increased from the actual time. The batteries have a 0.5% power loss per year even when there is no current draw. There is also the possibility of occasionally the switch may stick resulting in extra power consumption. Also, the device could be used more often than 6 times per day for many other reasons. All of these instances will account for a shortened lifetime of the batteries. The overall lifetime of the batteries will be better estimated once the prototype is complete and testing can be performed to determine a more accurate lifetime. Even then the lifetime cannot be an exact function as the daily usage will vary greatly between patients. A better estimate of the lifetime of the power supply, considering all possible reasons for increased power consumption, would be somewhere in the range of 3-5 years. The batteries will be easy and accessible to replace with a quick outpatient procedure, similar to changing the battery of a pacemaker.

Figure 47 – U10004 Thin Cell Battery

Figure 48 – U10004 Dimensions (millimeters)
All of the components to control the power supply triggering the micro pump to function will be contained in the implantable device housing. The process for urination will begin with a reading from the pressure transducer. Once the pressure transducer takes a pressure reading in the urethra the signal is then sent to the microprocessor and is then converted to a bladder volume percentage and displayed to the patient. Once the percentage in the bladder reaches a certain level the patient will be notified through an alarm, either audio or vibration. The patient will then be able to empty the bladder in a timely manner. To induce sphincter relaxation the user will simply navigate to the urinary sphincter relaxation screen on the user remote and then with the simple press of a button activate relaxation. Once the button is pressed the microprocessor processes the user input signal and then sends a signal via the transceiver in the remote control to the transceiver in the implantable device housing. The transceiver in the housing will then sends a voltage to the reed switch resulting in the closing of the switch and current flowing to the micro pump from the batteries. The micro pump then turns on and pumps fluid from the cuff to the reservoir. Once the fluid is completely transferred into the reservoir the switch will again open shutting off power to the micro pump. Once the patient has completely emptied the bladder they will then use the remote to initiate urinary sphincter contraction. The microprocessor again sends the user input signal via the transceivers which again closes the switch resulting in the pump turning on and pumping the fluid back into the cuff. Once the cuff is completely filled the switch returns to its open position cutting off power to the pump. A simple diagram of this system is depicted in Figure 49 below.

![Figure 49 – Implantable Device Circuit Diagram](image-url)
The circuit, Figure 50 above, will use a Reed Switch. Specifically the RI-02 Dry Reed Switch from Coto Technology. The reed switch is miniature, only 46 mm in length and 0.071 mm in width. The reed will remain in the open position until it is activated by a current produced from the wireless transceiver output. The output will produce a current that will allow the switch to close and allow power to flow through the reed switch. The reed will only remain closed for about a second, enough time to allow for the micro pump to completely transfer the fluid from the reservoir to the cuff and vice versa. The reed switch has an operating temperature range of -55° C to 125° C which is well within normal body temperature. The switch has a minimum lifetime expectancy of $2 \times 10^6$ operations. The switch would operate on average 12 times daily (6 average trips to the restroom x 2 operations). This results in a lifetime of approximately 39 years, well beyond the life expectancy of the implantable device.

One of the important factors in the implantable device is heat generation. As discussed before the micro pump will produce little heat through its operational cycle. The power supply will also be a source of heat in the device. While increasing the lifetime of the power supply is the major purpose of using a switch to control power to the micro pump, another important function will be decreasing heat levels created by power drainage of the batteries. As batteries produce power heat is generated from the chemical reactions within. Since the circuit will contain a switch, the batteries will never be operating for a long period of time. This will keep the production of heat to a minimum and will keep the device from creating a significant temperature increase that would create harm to the tissue surrounding the device. Heat could also be contained by selecting a material for the housing that would help insulate the heat generated by the device components and not allowing heat to propagate into the surrounding tissues.
2.2.11. Device Housing

The implantable device will have to contain the thin cell batteries, micro pump, fluid reservoir, the wireless transceiver, pressure transducer amplification components, and the circuit components for regulating the power supply. The dimensions will be approximately 90 mm x 72 mm x 30 mm (3.54 in x 2.83 in x 1.18 in). The dimensions of the device housing were approximated from the dimensions of the components themselves. The housing itself would need to be made out of a biocompatible material; probably the best fit for this device would be a material such as titanium. Titanium would be able to provide a solid structure that would be able to withstand the common impacts that could be received in the abdomen while still providing biocompatible implantable properties. For the purpose of this prototype it is not necessary to use a biocompatible material such as titanium or even a biocompatible material at all. The reasons for avoiding the use of a material like titanium would be the cost and the difficulty in fabricating a compartment for the device from this material with limited resources. The housing of the prototype will be created from a simple plastic material that will provide a sturdy support but still be easy to work with to create an adequate enclosure for the components of the design. The device housing also needs to have relatively good insulation properties. In the event that a component would overheat and increase the internal temperature of the device, the housing material should be able to keep most of that generated heat concentrated in the device and not transmit the heat to the surrounding tissue. A model of the enclosure and the components it will contain can be seen in Figure 52 below.

![Figure 52 – Implantable Device Layout](image-url)
3. Final Design

3.1. Objective

The purpose of the device is to assist any patients with a dysfunctional bladder by controlling the flow and release time of urine from the body. This device will be designed so that the patient or caregiver will be able to control their urine flow, by the push of a button on the LCD screen of the remote. The device is broken down into many different components, but there are two major components to the device; the artificial sphincter and the remote control. The first component is the artificial sphincter that will be automatically operated through the use of a micro pump. This automated system will ensure that the device will be easy to use by a patient or caregiver and will be major improvement over the current implant method, which is operated manually by the patient. Urinary sphincter contraction and relaxation will be simulated simply by the push of a button on the LCD screen of the user remote. The remote will then send a signal through Bluetooth transmission to implanted device signaling the micro pump to either contract or relax the artificial sphincter. This will control the flow of urine out of the body and provide the patient with the control over their bladder that they are seeking. The implantable portion of the design will also contain a microprocessor and Bluetooth wireless transceiver.

The second component is the user remote control that will be able to completely control the entire device. The remote will consist of the liquid crystal display (LCD), Bluetooth transceiver, and a microprocessor which will provide the digital logic for the device. The remote will output all the necessary information to the patient through the use of the LCD and audio alerts. Since the device is implantable and automated, a manual pump will be connected to the device using Y connectors in case the automated pumps fail so that the patient can void when necessary.
Figure 53 - Block Diagram of the Device Function
Figure 54 – Device overview

Figure 55 – Photograph of completed device
3.1.1 Remote Control (LCD Screen)

A liquid crystal screen (LCD) was used because it consumes very little power, allowing for long battery life. The LCD displays a numerical representation of bladder volume in volume percent, a bar graph illustrating the volume percent of fluid in the bladder and other text outputs for the patient. The LCD screen also has a calendar and time clock which may be helpful for the patient in managing their voiding patterns. This design will use Comfile CuTouch LCD screen (Comfile Technology, CA, USA). This LCD screen is blue with white text and is capable of displaying graphics and characters. The LCD screen is touch screen, which will enable the patient or caregiver to input any information they would like to receive regarding the status of the bladder with minimal pressing force. With the LCD screen the patient or caregiver will be able to visualize what is when the bladder is contracting or relaxing as shown in the figures below.

![Figure 56 - Main Menu of the LCD Screen](image)

Figures 57 and 58 below display the numeric and graphical bladder statuses, respectively that the patient can choose between.
A main positive feature of the user remote unit, from a patient point of view, is the ease with which the menus and options can be navigated. There are four main menus displayed at the top of the LCD screen, each with their own dropdown menu. Each menu option is described and visually shown below.
The “Status” menu drops down into a three option menu. The options are “Numerical”, “Graphical”, and “Audio”. Each option can be selected to provide the user with a different output mode for their bladder status. The “Status” menu is shown below in Figure 59.

![Figure 59 – User Remote “Status” Menu](image)

The “Controls” menu allows the user to control the micro pump of the implant and thus control the artificial sphincter cuff and their ability to void urine. There are two active options in the “Controls” menu. The “Relax” option empties the sphincter cuff allowing the user or patient to void their urine. The “Contract” option ensures that the sphincter cuff re-engages after urination is complete to avoid unwanted urine. The “Controls” drop down menu is shown below in Figure 60.
There are accessory menus that are available for the user to supplement the “Status” and ‘Control” menus, which are the only two menus relevant to the function of the Accessible Incontinence Control Device Implant. These two menus, “Settings” and “ETC” contain a calculator, a calendar, a clock, and a font changing option. They are shown below in Figure 61.
The LCD screen is backlit (controlled by software) which will make it easy to read in many various lighting conditions. In order to program the LCD RS232C communication must be used. The display has three independent layers that can be separately programmed. The code generated for the programming mostly sample code or code referenced from the user manual, with modifications to suit our purposes. The code was written using Cubloc Studio and the programming language Basic. The total coding for the LCD user remote, which outputs graphics and text and establishes wireless communication with the implant totaled approximately 47 pages in length. A brief example of the code written for the LCD screen is shown below.

**Sample Code for the Touch Main Menu Screen:**

```basic
Dotsize 0,0
Layer 1,1,0
Color 1
Low 18
CURRENT_MENU = 0
TX1 = Getpad(2)
TY1 = Getpad(2)
Boxclear 3,33,319,239
If Menucheck(0,TX1,TY1) = 1 Then
  Pulsout 18,300
If MENU_STATUS(0) = 0 Then
  Menureverse 0
MENU_STATUS(0) = 1
End If

Graph_Out
Clear 1
Clear 2
Cls
MENU_STATUS(0) = 0
MAIN MENU
On Pad Gosub TOUCH_MAIN_MENU
Return
End If
If Menucheck(2,TX1,TY1) = 1 Then
  Pulsout 18,300
If CUBLOC_MENU_STATUS(0) = 1 Then
  Menureverse 0
CUBLOC_MENU_STATUS(0) = 0
End If
If CUBLOC_MENU_STATUS(1) = 1 Then
  CUBLOC_MENU_STATUS(1) = 0
End If
```

The specifications for the CuTouch used for the user remote unit are shown in Table 1 on the next page.
### CUTOUCH Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microprocessor</td>
<td>Dual Core Atmega128</td>
</tr>
<tr>
<td>Program Memory (Flash)</td>
<td>80 KB</td>
</tr>
<tr>
<td>Data Memory (RAM)</td>
<td>24KB (Basic) + 4KB (Ladder)</td>
</tr>
<tr>
<td>EEPROM</td>
<td>4KB</td>
</tr>
<tr>
<td>Program Speed</td>
<td>36,000/sec</td>
</tr>
<tr>
<td>General Purpose I/O</td>
<td>82 I/O lines</td>
</tr>
<tr>
<td>Serial Ports for Communication</td>
<td>2 high-speed serial ports</td>
</tr>
<tr>
<td>Analog Inputs</td>
<td>8 channel 10-bit ADCs</td>
</tr>
<tr>
<td>Analog Outputs</td>
<td>6 channel 16-bit PWMs</td>
</tr>
<tr>
<td>External Interrupts</td>
<td>4 channels</td>
</tr>
<tr>
<td>High Speed Counters</td>
<td>2 channel 16-bit counters</td>
</tr>
<tr>
<td>Power</td>
<td>9-24 V DC</td>
</tr>
<tr>
<td>RTC (Real Time Clock)</td>
<td>Yes</td>
</tr>
<tr>
<td>Timers</td>
<td>1 user-configurable timer</td>
</tr>
<tr>
<td>Data Memory Back-up</td>
<td>Yes, 1F super-capacitor included</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>0-70°C</td>
</tr>
<tr>
<td>Package</td>
<td>Integrated Touchscreen Panel</td>
</tr>
<tr>
<td>Size</td>
<td>7.17x5.17x0.98 inches, 4.5x3.4 inch viewing screen (touch sensitive)</td>
</tr>
</tbody>
</table>

Table 1.

A schematic and description of input/output ports is shown below in Figure 62.

![Figure 62 - CUTOUCH I/O ports.](image-url)
A schematic of the back of the CUTOUCH is shown below in Figure 63.

Figure 63 - CUTOUCH back view.
3.1.2 Microprocessor

A CUBLOC microprocessor (the CB220) was used to run programs to monitor data from the device’s sensors, communicate with LCD display and control the device’s micro pump. The CB220 is shown below in Figure 64.

![CB220 Microprocessor](image)

Figure 64 – CB220

The major tasks of the microprocessor are to:
- Converts resistance from the stretch sensor to voltage using a voltage divider, and then input to volume percent with the output displayed on the LCD
- Controls the artificial sphincter using the micro pump
A schematic of the CB220’s internal structure is shown below in Figure 65.

![Figure 65 – CB220 Internal Structure]

Programs will be written using BASIC language and the Cubloc Studio software. The CB220 is a programming logic controller, or PLC. The main advantage of CUBLOC over other PLCs is that it fills Ladder Logic’s weaknesses with BASIC language. Ladder Logic is good enough to replace sequence diagrams, but to collect data, print graphics, and process complex tasks is too complex for Ladder. Another advantage over other BASIC processors is that CUBLOC is able to separate the amount of work and programming between Ladder Logic and BASIC as necessary. The user is able to debug easier by having two processes work together, instead of trudging through lines of BASIC codes. The CB220 can multitask whereas most PLCs cannot separate their Basic and Ladder commands. This comparison between CB220’s ability to multitask and traditional PLCs is illustrated below in Figure 66.
The CB220 is packaged in a 24 pin DIP package, as shown below in Figure 62. Sixteen of the 24 pins on the CB220 are input/output pins, but far fewer than 16 were needed for our purposes in the Accessible Incontinence Control Device. The pin assignments for the Accessible Incontinence Control Device are also included in Figure 67.
Pin Number | Assignment
---|---
5 | Input from the stretch sensor circuit
10 | Output to control the micro pump
15 | RX
16 | TX
23 | Ground
24 | Power

Figure 67 - CB220 pin assignments for the Accessible Incontinence Control Device.

The specifications of the CB220 are summarized below in Table 2.

### CB220 Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Memory</td>
<td>80KB</td>
</tr>
<tr>
<td>Data Memory</td>
<td>2KB (Basic) + 1KB (Ladder)</td>
</tr>
<tr>
<td>EEPROM</td>
<td>4KB EEPROM</td>
</tr>
<tr>
<td>Program Speed</td>
<td>36,000 inst./sec.</td>
</tr>
<tr>
<td>General Purpose I/O</td>
<td>16 I/O lines</td>
</tr>
<tr>
<td>Serial Ports</td>
<td>2 serial ports</td>
</tr>
<tr>
<td>Analog Inputs</td>
<td>8 Channel 10-bit ADCs</td>
</tr>
<tr>
<td>Analog Outputs</td>
<td>3 Channel 16-bit PWMs</td>
</tr>
<tr>
<td>External Interrupts</td>
<td>None</td>
</tr>
<tr>
<td>High Speed Counters</td>
<td>2 Channel 32 counters (Up to 2MHz)</td>
</tr>
<tr>
<td>Power</td>
<td>5 to 12 V, 40 mA</td>
</tr>
<tr>
<td>RTC (Real Time Clock)</td>
<td>No</td>
</tr>
<tr>
<td>Data Memory Backup</td>
<td>None</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>-40 to 120°C</td>
</tr>
<tr>
<td>Package</td>
<td>24-pin DIP</td>
</tr>
<tr>
<td>Dimensions</td>
<td></td>
</tr>
</tbody>
</table>

Table 2.
The computer program written for the CB220 of the Accessible Incontinence Control Device established wireless communication, took stretch sensor readings and converted them to volume percentage values, and controlled the automated micro pump. Selections of sample code are shown and explained below.

Below is the code for the main function of the implanted CB220. The device is initialized and the microprocessor is commanded to scroll through each of the subfunctions in a loop. Also, the appropriate port is set as an input to receive stretch sensor readings.

```
Const Device = CB220
Input 0
Dim Resistance As Integer
Dim Percent As Byte
Dim Relax_Var As String
Dim Relax As Integer
Dim W As String
Dim Z As String
Main
Sub Main ()
  Delay 1000
  Gosub Connect
  Do
    Gosub Get_Volt
    Gosub Get_Relax
    Gosub Release
  Loop
End Sub

The “Get Volt” subfunction is used to collect 10 readings from the stretch sensor and average these readings. Then the stretch sensor reading is converted to a volume percent.

Get_Volt:
  Resistance = Tadin(0)
  If Resistance < 525 Then
    Percent = 0
    Putstr 1,"0", Cr
  ElseIf Resistance < 540 And Resistance >= 525 Then
    Percent = 25
    Putstr 1,"1", Cr
  ElseIf Resistance < 552 And Resistance >= 540 Then
    Percent = 50
    Putstr 1,"2", Cr
  ElseIf Resistance < 565 And Resistance >= 552 Then
    Percent = 75
    Putstr 1,"3", Cr
  ElseIf Resistance > 565 Then
    Percent = 100
    Putstr 1,"4", Cr
  End If
Return
```
The “Connect” subfunction establishes a wireless connection with the user remote.

Connect:
Opencom 1,9600,3,30, 30
Putstr 1 "con 00:0C:84:00:06:A3" Cr
Return

The “Get Relax” sunfunction followed by the “Release” subfunction is the function that controls the micro pump. A high signal is sent to turn the pump on, and a low turns the pump off.

Get_Relax:
Relax_Var = Getstr(1,1)
Relax = Val(Relax_Var)
Release:
If Relax = 0 Then
Delay 100
Elseif Relax = 1 Then
High 5
Delay 3500
Low 5
End If
Delay 3000
Bclr 1,2
Return

3.1.3 Wireless Transmission

A finished medical implant device would need to use radio frequency, or RF, wireless transmission. The FDA has approved the use of RF transmission on certain wavelengths for medical implant uses. The wavelengths which are approved are able to penetrate body tissue without causing damage. The RF ISM bands that could be used are 325 MHz, 433 <Hz, 868 MHz, and 915 MHz.

For ease of use in this prototype, this prototype will use Bluetooth wireless transmission to communicate between the user remote and the implantable device. The wireless transceiver being used is the Embedded Blue 505 (eb505) serial Bluetooth module. The eb505 will provide direct connection between the remote and the implant. The eb505 module is shown on the next page in Figure 68.
Wireless technology is being used to prevent the patient from having to wear a device close to their body at all times so that data could be transmitted by wires. It is impractical to use an implant with wires. Running wires from inside the body to outside opens up the possibility of electrical injury to the patient, electrical failure of the device, and infection. Wireless technology is the more efficient and most practical way to convey information about the bladder to an external source. It also makes the device more attractive and marketable than a device that requires wires to transmit data. Bluetooth was chosen for this design because it is easier for electronic devices to communicate with each other using short range radio frequency. Also, Bluetooth utilizes the frequency method of a spread spectrum which uses several radio channels to reduce interference and increase security and reliability of the device. The signal is rapidly switched from channel to channel many times per second in a sender receiver pattern. This pattern provides recovery of any errors that may have been caused by interference from another radio source at a specific frequency. With Bluetooth, the data stored is usually more secure as it is not possible to receive more than a fraction of the data unless the particular programmed pattern between sender and receiver is established. The eb505 Bluetooth uses frequency in the 2.4 GHz radio band and transmits information between sender and receiver at rapid speed with a raw data range of about 1Mbps. The eb505 module supports a maximum sustained bidirectional data speed of 230.4kbps.
The wireless transceiver in the user remote will send the user input signal to the transceiver in the implantable device which will trigger the micro pump to turn on and off to allow the patient to release urine when desired. This will result in sphincter contraction and relaxation and thus resulting in the prevention and release of urine from the body. The wireless transceiver in the implant unit will be able to send the volume percentage values to the wireless transceiver in the remote unit, and these values will eventually be displayed on the LCD screen. This transfer of volume percentage data between the implant and the user remote occurs only on demand. The initial paper design for this device called for regular scanning and transmission of bladder status whether the user desired it or not. Although this was supposed to be implemented to alert the user if they have allowed their bladder to get too full, this constant stream of data being sent between the two units places an unrealistic and inefficient demand on the implant’s power source. In an effort to conserve battery life, data will be transmitted wirelessly only at the request of the device user.

Figure 69 below diagrams the transfer of information to and from the implanted wireless transceiver.

Figure 69 - Information flow via wireless transceivers.
As seen above in Figure 64, the eb505 has 2 20-pin connectors. The pins are arranged in 10x2 blocks with 0.1 inch spacing. Pin assignments are given in Table 3 below.

<table>
<thead>
<tr>
<th>Pin</th>
<th>Function</th>
<th>Type</th>
<th>Description</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>CN1 - 2</td>
<td>GND</td>
<td>Ground</td>
<td>Ground</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 4</td>
<td>TX</td>
<td>TTL</td>
<td>Serial Transmit line from eb505; TTL</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 6</td>
<td>RX</td>
<td>TTL</td>
<td>Serial Receive line to eb505</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 8</td>
<td>Status</td>
<td>TTL</td>
<td>Bluetooth connection status</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 10</td>
<td>Mode</td>
<td>TTL</td>
<td>Command/data mode toggle</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 12</td>
<td>RTS</td>
<td>TTL</td>
<td>Request-to-Send used for hardware flow control (0 = not signaled, 1 = signaled)</td>
<td>Optional</td>
</tr>
<tr>
<td>CN1 - 14</td>
<td>CTS</td>
<td>TTL</td>
<td>Clear-to-Send used for hardware flow control (0 = not signaled, 1 = signaled)</td>
<td>Optional</td>
</tr>
<tr>
<td>CN1 - 18</td>
<td>On/Off</td>
<td>TTL</td>
<td>Powers the eb505 up or down (0 = off, 1 = on) weak internal pull-up</td>
<td>Required</td>
</tr>
<tr>
<td>CN1 - 20</td>
<td>VCC</td>
<td>Power</td>
<td>Power</td>
<td>Required</td>
</tr>
<tr>
<td>CN2 - 19</td>
<td>GND</td>
<td>Ground</td>
<td>Ground</td>
<td>Required</td>
</tr>
</tbody>
</table>

Table 3.

The dimensions of the module are given below in Figure 70.

![eb505 dimensions](Figure 70 - eb505 dimensions)
The operating parameters are summarized below in Table 4.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmit Power</td>
<td>4dBm (max) class 2 operation</td>
</tr>
<tr>
<td>Open Field Range</td>
<td>eb505-AHC-IN (surface mount antenna) – 10 meters (32 feet)</td>
</tr>
<tr>
<td></td>
<td>(Actual range is dependent upon location and environment.)</td>
</tr>
<tr>
<td>Receiver Sensitivity</td>
<td>-85dBm</td>
</tr>
<tr>
<td>Operating Temp.</td>
<td>-15° to 70°C</td>
</tr>
<tr>
<td>Supply Power</td>
<td>5 to 12VDC</td>
</tr>
</tbody>
</table>
| Current Consumption    | 115.2kbps data transfer: 35mA  
                         | 38.4kbps data transfer: 30mA  
                         | 9.6kbps data transfer: 25mA  
                         | connected and idle: 8mA  
                         | no connection: 3mA                                             |
| Interfaces             | 5V TTL UART                                       |
|                        | Baud rate 9.6k – 230.4k                           |
|                        | Flow control: RTS/CTS or none                     |
| Connector              | Two 10x2 20 pin 0.1” headers                      |
| Antenna                | Matched internal surface mount                    |
| Bluetooth Support      | Version 1.2 compliant with profiles L2CAP, RFCOMM, SDP, SPP |
| Firmware               | Upgradeable via PC application with RS232 adapter. |

Table 4.

3.1.4 Bladder Status

The bladder status indication portion of the device has been changed from using a pressure transducer to a stretch sensor. This change was made because the stretch sensor was readily available and was more ideal for the status indication. Cost was also a deciding factor between the two status indication methods. Also using the stretch sensor, in replacement of the pressure transducer reduces the amount of power supply that would be needed to operate the device, and would eliminate the need for signal amplification that was necessary to operate the pressure transducer. Although the pressure transducer would give a more precise reading of the bladder status regarding the accuracy of the volume percent of fluid in the bladder, the stretch sensor would be sufficient as the brain itself does not usually recognize the volume of the bladder until it is approximately 50% full. A urine bag shown below with stretch sensor placed across was used to measure the resistance across the bag as it was filled with fluid for purposes of testing the device and establishing ranges of resistance values to corresponding with each volume percentage. Resistance ranges were measured with the urine bag was 0%, 25%, 50% 75% and 100% full. These resistance values are then converted to voltage which is then calculated to output a volume percent by the remote control on the LCD screen. An example of the urine bag setup with the stretch sensor across it is illustrated below in Figure 71.
3.1.4.1 **Stretch Sensor**

The bladder status indication portion of the device will be accomplished by the use of a stretch sensor STRX-04. In theory the stretch sensor will be placed between the urethras, and as the bladder expands, the stretch sensor will measure the resistance, which will then be converted to voltage readings by the microprocessor. The voltage readings will then be converted and output bar volume and numeric percentage of the bladder. An illustration of the stretch sensor across the urethras is shown in Figure 72 on the next page.
Figure 72 - Stretch Sensor placed between the urethras

Using an implantable stretch sensor for clinical applications is possible because large quantities of information are known about bladder dimensions and distortion as the bladder fills. It is known that the length between the ureters is about 2 inches when the bladder is empty and the length stretches to about 4 inches, or double the initial length, when the bladder is full.

For our design setup, obtaining resistance reading from the stretch sensor when placed between the urethras was not practical so a few adjustments were made to ensure that the set up works. For the design setup, a urine bag with maximum volume of 1000 mL was used to test the design specifically for the status of the bladder as shown in Figure 71 above. The stretch sensor was also mounted across the middle of the bag instead of the top surface. The stretch

The stretch sensor is a part of the implant portion of this device. As it will be implanted in the body in theory, the material must be biocompatible and not illicit any inflammation and any damages to surrounding tissues. The ideal material for the stretch sensor should be one that is biocompatible, flexible, non biodegradable and durable. The material that would be best suited for the stretch sensor is the polymer PTFE. PTFE, has been used in many biomedical applications and is also FDA approved. It has been reported that it does not cause any adverse effect when comes in contact with body fluid and tissues. The only problem that has been reported is its stability, which can affect its full functionality in some medical applications.
The STRX-4 stretch sensor is implanted across the ureters of the patient’s bladder. The STRX-4 is a 4 inch stretch sensor with a resistance of 1000Ω per linear inch, or 4000Ω total, when relaxed. At 50% stretch the resistance approximately doubles. The stretch sensor has a diameter of .060 inches.

### 3.1.4.2 A/D Circuit

The relationship between the stretch of the space between the ureters as the bladder fills (the length about doubles from an empty bladder to a full bladder) and the changing resistance of the stretch sensor is used to provide the user with the status of their bladder. The resistance across the stretch sensor is passed through an A/D conversion circuit before entering the CB220. This circuit is seen below in Figure 73.

![A/D conversion circuit for stretch sensor readings.](image)

The Zener diode is used to protect against voltage surges. The A/D converter converts the voltage that passes across it to a value between 0 and 1024. It is these A/D values that are used to estimate bladder volume.
3.1.5 Artificial Sphincter

An artificial sphincter will be used to control the flow of urine out of the body; the design will use a surgically implantable artificial sphincter to replace the incorrectly functioning urinary sphincter. The artificial sphincter can be altered and used by both sexes. The artificial sphincter in our device, AMS 800 was designed and given to us by American Medical Systems (AMS). A nondisclosure agreement was signed, and any additional information cannot be disclosed regarding how it is manufactured. The artificial sphincter is biocompatible and reliable in its application. The sphincter consists of three main parts: an inflatable cuff, a fluid reservoir, and a mechanical pump. The pump is implanted into the scrotum of a male patient, and in the labia for women. The manual pump usually controls the flow of fluid from the reservoir to the inflatable cuff. The manual pump in our design will be used as a back up manual system, as our device will be automated by using a small micro pump which will be activated by the circuitry discussed below in the following section. The automated pump will be more convenient to the patient and also should provide a more discrete operation of the device, but the manual backup is an important design feature in the event of electrical or mechanical failure of the micro pump. An implantable medical device should always have safety features that allow for normal bodily function in the even of device failure. In this case, the manual pump will allow normal voiding of urine in the event of device failure. The artificial sphincter from AMS prior to modifications is shown below in Figure 74.

![Figure 74 - Artificial Sphincter](image)

3.1.6 Micro Pump

For our design we use an automated micro pump to transfer fluid from the inflatable cuff to the fluid reservoir. The micro pump that is used in this design is the M100-S Micro Pump from TCS Micro Pumps. The micro pump is the same model as the one chosen from last semester. The pump will be connected to a battery power supply in the device housing and operated through wireless transmission via the user remote control. The micro pump also operates at a temperature range that includes normal body temperature.
The pump has an operational temperature range of -20° C to 150° C, which is well within the normal temperatures of the body. The micro pump will be implantable in the abdomen and will be controlled by a wireless remote control. This will provide for an easy to use interface for controlling the flow of urine. By eliminating the manually operated pump from the design, the device will provide a better control system for individuals with disabilities and poor motor skills. Patients also will not have to try and operate a mechanical pump in an undesirable location. This design will be more convenient to the patient and also should provide a more discrete operation of the device.

The pump can be seen in Figure 75 below.

Figure 75 - TMS M100S Micro pump

Figure 76 on the next page shows the micro pump connected to the artificial sphincter cuff in a test set-up.
Figure 76 - Inflatable Cuff and Micro-Pump Setup

Figure 77 below shows a schematic of micro pump control of the artificial sphincter.

- Receive Signal from Wireless Remote
- Micro Pump is Activated
- Fluid Reservoir Inflates
- Sphincter Relaxes
- Urine is Released
- LCD Screen Return to Main Menu Mode
- Fluid is Retuned to the Fluid Balloon preventing urine flow
- Fluid Reservoir Deflates
- Micro Pump turns off

Figure 77 - Flow Chart for Micro Pumps
The specifications of the M100-S at 3 volts input, which is the input voltage applied to the pump in this device, are summarized below in Table 5.

### Micro pump Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Input Voltage</td>
<td>3 V</td>
</tr>
<tr>
<td>Current Draw</td>
<td>0.28 A</td>
</tr>
<tr>
<td>Power Usage</td>
<td>0.84 W</td>
</tr>
<tr>
<td>Pressure Head</td>
<td>700 mm</td>
</tr>
<tr>
<td>Pressure</td>
<td>69 mBar</td>
</tr>
<tr>
<td>Free Flow Rate</td>
<td>250 ml/min</td>
</tr>
<tr>
<td>Weight</td>
<td>9 g</td>
</tr>
<tr>
<td>Operating Temperature</td>
<td>-20 - 150°C</td>
</tr>
</tbody>
</table>

Table 5.

The pump body is made of aluminum and the push on connectors for 3/32” tubing are made of stainless steel. An engineering drawing of the pump is shown below in Figure 78.

![Figure 78 Micro Pump](image-url)
3.1.7 Device Housing

The implantable device will contain the thin cell batteries, micro pump, fluid reservoir, the wireless transceiver, and the circuit components for regulating the power supply. The dimensions of the implantable device are 4.724 inches in length, 3.543 inches in width and 1.968 inches in height. The device housing was ordered from okwenenclosures.com. The device housing that is currently used to for the implantable portion of our device is not made of biocompatible material and would need to be smaller in theory. The best suited material for the implantable device housing will be made of titanium as it is a biocompatible material which has a relatively low modulus of elasticity and does not include any elements which have been shown or suggested as having short term or long term potential adverse effect from a standpoint or biocompatibility. Titanium is also completely inert to human body fluid. The reasons for avoiding the use of a material like titanium in our actual design are to eliminate the difficulty in fabricating a compartment for the device from this material with limited resources. The housing of the prototype will be created from a simple plastic material that will provide a sturdy support but still be easy to work with to create an adequate enclosure for the components of the design as shown in Figure 79. Titanium will be able to provide a solid structure that would be able to withstand the common impacts that could be received in the abdomen while still providing biocompatible implantable properties. The device housing also needs to have relatively good insulation properties to prevent body fluids from entering the device housing that could possibly damage the circuitry and cause damage to the patient cells and surrounding tissue. In the event that a component would overheat and increase the internal temperature of the device, the housing material should be able to keep most of that generated heat concentrated in the device and not transmit the heat to the surrounding tissue. A model of the enclosure and the components it will contain can be seen in Figure 80 below.

Figure 79. Exterior of Implant Device Housing
3.1.8 Power Supply

The power supply for the implantable portion of the device is constructed of four small cell 3.7 volt Li-ion Polymer batteries (below if Figure 81). The four batteries are connected in parallel to provide optimum battery life for the device. The 3.7 volts is then passed through a circuit that converts the 3.7 volts to 5.0 volts to power the device. The circuit can be seen below in Figure 82. The circuit consists of the LM3224 a Step-up PWM DC/DC Converter from National Semiconductor. Since the device only needs five volts for operation, by connecting four 3.7 volt batteries in parallel we were able to keep the overall size of the device to a minimum and also create an adequate power supply. This same circuit is used again to power the LCD Remote, since it can operate of a 5 volt to 12 volt power supply.
For the actual implantable device a power supply similar to the pacemaker would be used. Since the components don’t need to be operating at all times power consumption can be minimized by turning off the eb505 Bluetooth device when it is not necessary for operation. Also there have been recent advances in powering implantable devices and research for uses of kinetic energy that would recharge implantable batteries as the patient performs simple tasks such as walking. The energy generated by the movement would recharge the implantable batteries and thus supplying the implant with virtually an everlasting power supply.
3.1.9 Optional Device Accessories

3.1.9.1 Interstim® Sacral Nerve Stimulator

The artificial sphincter of the Accessible Incontinence Control Device is designed to aid patients with urinary incontinence that leads to undesired voiding of urine. An artificial sphincter can treat patients with stress, urge, mixed, or functional incontinence. Overflow incontinence, which results from urinary retention, or the body’s inability to contract the bladder, cannot be treated by an artificial sphincter.

About 10-15% of all urinary incontinence patients experience overflow incontinence. The condition is more common in men, and causes include enlarged prostate, diabetes mellitus, spinal cord injury, damaged sacral nerve, and certain medications. Overflow incontinence can be treated with Interstim® therapy.

Patients who experience overflow incontinence should talk to their physician about replacing the artificial sphincter component of the Accessible Incontinence Control Device with the Interstim® Sacral Nerve Stimulator. The device will maintain its ability to control urination and provide the status of the bladder.
3.1.9.2 Smart Phone as User Remote Unit

Having the user remote computer program uploaded to a Smart phone, or other similar device, is a good option for Accessible Incontinence Control Device users who are active and spend a lot of time outside their home. This option provides the user with a portable user remote that can be easily used in public places without having to find a bathroom with a power socket in close proximity to the toilet. In addition, it is a smaller and more lightweight option than the included user remote, as well as more discrete.

4. 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 constraints 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. For this project a simulated testing environment will be created and used to test the device.

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.
5. Safety Concerns

A major safety issue for this device design is biocompatibility and host reaction to biomaterials. 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.
6. **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.

7. Life Long Learning

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.
8. Budget

8.1. Budget

The maximum budget we were allocated to complete this project was $2000. This funding was provided by the RERC on Accessible Medical Instrumentation (RERC-AMI) student design competition. As is shown in Table 6 below, of our total expenditures, our team spent $1551.66. There was $448.34 remaining that would have been available for our use had we needed it.

### Total Budget Expenses

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>MODEL/ PART NUMBER</th>
<th>QUANTITY</th>
<th>ITEM COST</th>
<th>SHIPPING COST</th>
<th>TOTAL COST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro Pump</td>
<td>M100-S</td>
<td>2</td>
<td>NA</td>
<td>NA</td>
<td>$196.49</td>
</tr>
<tr>
<td>Tygon Tubin (3/32&quot;)</td>
<td>57361</td>
<td>10</td>
<td>$0.80</td>
<td>$5.80</td>
<td>$13.80</td>
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<td>4</td>
<td>$5.95</td>
<td>$7.83</td>
<td>$31.63</td>
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<tr>
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<td>$402.00</td>
<td>$10.00</td>
<td>$412.00</td>
</tr>
<tr>
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<td>$34.00</td>
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<tr>
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<td>$23.45</td>
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<td>$32.48</td>
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<tr>
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<td>$69.00</td>
<td>$22.62</td>
<td>$160.62</td>
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<td>$12.85</td>
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<tr>
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<td>2</td>
<td>$4.50</td>
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<tr>
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<td>Misc. Parts</td>
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<td>$39.86</td>
<td></td>
<td>$39.86</td>
</tr>
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</table>

**Total:** $1,551.66

Table 6.
Since we had several design changes during the course of the semester we did not use all of the parts that we ordered. In addition, some of our budget went to developing a test set-up that could be used to evaluate the implant without being able to implant it. Table 7 below summarizes the cost of parts that were directly used to make the device. The total cost to build the device was $1129.40.

### Cost to Build Implantable Device

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>MODEL/PART NUMBER</th>
<th>QUANTITY</th>
<th>ITEM COST</th>
<th>SHIPPING COSTS</th>
<th>TOTAL COST</th>
</tr>
</thead>
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<tr>
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<td>NA</td>
<td>NA</td>
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<td>$5.80</td>
<td>$13.80</td>
</tr>
<tr>
<td>Thin Cell Battery</td>
<td>PL-052025</td>
<td>4</td>
<td>$5.95</td>
<td>$7.83</td>
<td>$31.63</td>
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<tr>
<td>CuTouch</td>
<td>U06003</td>
<td>1</td>
<td>$402.00</td>
<td>$10.00</td>
<td>$412.00</td>
</tr>
<tr>
<td>CB220</td>
<td>U01002</td>
<td>1</td>
<td>$34.00</td>
<td></td>
<td>$34.00</td>
</tr>
<tr>
<td>Stretch Sensor 4 inch</td>
<td>strx-4</td>
<td>1</td>
<td>$10.95</td>
<td>$12.50</td>
<td>$23.45</td>
</tr>
<tr>
<td>Power Supply Parts</td>
<td>NA</td>
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<td>$32.48</td>
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<td>BlueTooth</td>
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<td>Check Valve</td>
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<td>$4.50</td>
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<td>Reduction Coupler</td>
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<td>2</td>
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<td>PCB Board</td>
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<td><strong>Total:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>$1,129.40</strong></td>
</tr>
</tbody>
</table>

Table 7.

9. Team Member Contributions

A majority of the work done over the course of the semester building the Accessible Incontinence Control Device was done as a group. Any decisions that needed to be made regarding a change in the design of the device were made as a group. A lot of the physical building the implantable portion of the device was also done as a group. Although much of the work was done together, the sections below summarize the main contributions of each group member.
Erica: Erica focused mainly on writing the code for the CB220 using Basic and Cubloc Studio. She created subfunctions that would control the micro pump and that would provide the user with bladder status. Erica also worked on the related circuitry for these subfunctions. An A/D converter circuit was needed for the stretch sensor and a control circuit was needed to turn the micro pump on and off. Erica also did some work attempting to establish wireless communication with the first set of transceivers that were used, the ACODE 300s. Erica also helped with laying out the circuit diagrams for the PCB boards.

Yamalia: Yamalia focused mainly on the test set-up. She built and tested a few different test set-ups, and had to spend some time in machine shop. It was Yamalia’s responsibility to make sure the test set-ups looked good for presentation purposes, as well as were functional for testing and troubleshooting purposes. Yamalia also researched which materials each component of the device would have to be made of for a final device that could actually be implanted since some of the materials used in our prototype would not be appropriate for implantation purposes.

Zack: One of Zack’s main tasks was programming the user remote unit. He was responsible for creating the drop down menus on the user remote and for programming the remote to display the status of the bladder in multiple ways. In addition, Zack worked on establishing wireless communication using the eb505 transceivers. This was an extremely important feature of our device and required a lot of troubleshooting to ensure it would work perfectly. Zack also built all of the electrical circuits that were required for power supply and wireless communication. Zack also converted the necessary circuit diagrams to PCB board layouts.

10. Conclusion

The accessible urinary incontinence device is composed of two major components; the bladder status indication system and the urinary control system. These two systems can further be broken down into different sub units and components. The status indication system is comprised of the stretch sensor, wireless transceiver, and the user remote control. The stretch sensor will be implanted across the top of the bladder between the ureters. The pressure in the urethra will be sent to the operational amplifier in the device housing. The voltage reading across the variable resistance stretch sensor will be sent through an A/D conversion circuit to the CB220 microprocessor where it will be converted to a volume percentage. The signal will then be sent wirelessly to the remote where it will be displayed on the LCD touchscreen. The user will then be able to make a decision about whether or not they wish to void urine.

The urinary control system can be divided further into sub units consisting of the artificial sphincter, micro pump, wireless transceiver, and the user remote control. Once the patient is ready to empty the bladder they will simply navigate to the sphincter relaxation option and with the press of a button be able to induce sphincter relaxation resulting in the flow of urine from the body. The remote sends a signal to the wireless transceiver in the device housing which will apply a voltage to the micro pump, turning it on. The micro pump will transfer the fluid in the inflatable cuff to the fluid reservoir allowing sphincter relaxation. Once the bladder has been emptied the patient will be able to navigate to the sphincter contraction option and press a button
and the micro pump will be activated again moving the fluid back into the inflatable cuff and thus causing contraction and preventing fluid flow. Alternatively, if the user forgets to re-engage the sphincter cuff, the fluid reservoir is self-regulating and should collapse thus refilling the sphincter cuff within 3 to 5 minutes.

The Accessible Incontinence Control Device should provide a superior treatment option for urinary incontinence. The design provides the patient with a discrete way to fully manage their incontinence. The device will allow patients restore their independence and allow them to complete their normal every day tasks without the worry of their incontinence issues. The device provides the user with a visual output of the percentage of urine in their bladder whenever they feel they need to know. The device has optional accessories that allow it to be modified to best suit each patient’s needs. The device should be as discrete as the patient wants. The device also will be very easy to use by patients of all ages and abilities. The remote control will be user friendly and simply designed so there is no confusion in the operation of the device. Overall the device will provide an affordable, practical, and user friendly solution to urinary incontinence to patients of all ages and abilities, as well as both sexes, and individuals with every type of incontinence.
11. References

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12. Acknowledgments

We would like to thank our sponsor the RERC-AMI for giving us this opportunity to process a design project and build our product.

Thanks to Dr. John Enderle for his constructive advising and criticism throughout the design process.

Thanks to Dave Price for his advice and feedback on our designs throughout the entire project.

A special thanks to Alan Wirbisky from AMS for supplying us with AMS 800 parts for the device.
13. Appendix

13.1. Updated Specifications

Technical Specifications – User Remote

Electrical
- **Power Source**: battery
- **Voltage Supply**: 12 volts
- **Battery Life**: at least 2 months

Display
- **Dimensions**: 320 x 240 pixels
- **Illumination**: backlit
- **Character Size**: 8 x 16 pixels
- **Contrast**: software controlled
- **Colors**: software controlled

Wireless Transceiver
- **Range**: 3 – 10 feet
- **Physical Path**: Through obstructions (body tissue)
- **Frequency**: 402-405MHz, 433-434MHz

User Ability
- **Dexterity Level**: Low
- **Range of Motion**: Limited
- **Strength**: Low
- **Button Size**: 30 mm in diameter

Environmental
- **Operating Temperature**: 5-110° F
- **Storage Temperature**: 65-85° F (room temperature)

Technical Specifications – Implantable Artificial Sphincter

Electrical
- **Power Source**: battery
- **Voltage Supply**: 5V
- **Battery Life**: 3-4 years

Wireless Transceiver
- **Range**: 5-10 feet
- **Physical Path**: Through obstructions (body tissue)
- **Frequency**: 402-405MHz, 433-434MHz

Implantable

Biocompatibility
- **Bio inert**: No tissue in growth
- **Biodegradable**: Non-biodegradable

Environmental
- **Operating Temperature**: 85-105° F (body temperature)