Operator’s Manual
Accessible Incontinence Control Device

Team 8:
Erica Kramer
Yamalia Roberts
Zack Smith

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

- READ THIS OPERATOR’S MANUAL BEFORE USE OF THE ACCESSIBLE INCONTINENCE CONTROL DEVICE.

- Because this device includes a surgically implanted component be sure to discuss details of the device carefully with a physician before making the decision to purchase and use the Accessible Incontinence Control Device.

- Avoid dropping or mistreating the user remote unit, or else automated control of the implantable sphincter may be affected.

- DO NOT pass a catheter through the urethra while the artificial sphincter cuff is inflated. Make sure the cuff is relaxed first, or else damage can be caused to the device and the user’s urethra.

- Keep user remote away from water, extreme temperatures, and high amounts of static electricity.

- Avoid trauma to the pelvic and abdominal area from such activities as contact sports.
- **Parts and Accessories:**

- Artificial Sphincter
  
  1. Artificial Sphincter Cuff

  ![Artificial Sphincter Cuff Image]

  2. Artificial Sphincter Fluid Reservoir

  ![Artificial Sphincter Fluid Reservoir Image]

  3. Micro pump

  ![Micro pump Image]

- Device Housing

- Implant stretch sensor
• User Remote with Touchscreen LCD

• Optional Modifications/Accessories
  1. InterStim® Sacral Nerve Stimulator (for use by patients with urinary retention problems)

  2. “Smart” phone programmed to function as the user remote
Features:

The Accessible Incontinence Control Device is unique from any other device currently available for incontinence treatment:

- The artificial sphincter is automated, allowing the user to void urine with the touch of a button instead of manual pumping.

- The implanted stretch sensor provides the user with on-demand indication of the status of the bladder.

- The user remote unit provides a clear and simple display with large lettering that makes it easy for the user to read.

- The LCD touchscreen of the user remote is sensitive and responsive, eliminating the need for large amounts of strength in pushing the buttons.

- The status indication is accurate to 25%, starting at 0%. This is an improvement over the human brain, which doesn’t recognize fluid in the bladder until it is about half full.

- The device is discrete and can provide the user confidence in social situations.
Table of Contents:

1. Introduction
   1.1 General Overview of the Device
   1.2 Operating Instructions
      1.2.1 Powering Device and Preparing for Use
      1.2.2 Status Indication
      1.2.3 Urine Control
      1.2.4 Manual Pump
      1.2.5 Miscellaneous
         1.2.5.1 Using the remote unit clock feature
         1.2.5.2 Resetting the clock time
         1.2.5.3 Using the calendar
         1.2.5.4 Resetting the date
         1.2.5.5 Changing the font on the LCD screen
         1.2.5.6 Using the calculator

2. Maintenance
   2.1 User Remote
      2.1.1 LCD Screen
      2.1.2 Back-up Battery
      2.1.3 Wireless Transceiver
   2.2 Artificial Sphincter
   2.3 Environmental
      2.3.1 Water
      2.3.2 Temperature

3. Technical Description
   3.1 Microprocessor
   3.2 Micro pump
   3.3 Stretch Sensor
   3.4 Implant Power Supply
   3.5 Wireless Transceivers
   3.6 LCD Screen/User Remote

4. Troubleshooting
   4.1 User Remote/ LCD Screen
   4.2 Implant

Appendix A. Description of Surgical Implant Procedure
   A.1 Information for Patient
   A.2 Information for Surgeon
      A.2.1 Troubleshooting

Appendix B. Information Regarding Optional Modifications to the Accessible Incontinence Control Device
   B.1 Interstim® Sacral Nerve Stimulator
   B.2 Smart Phone as User Remote Unit
1. Introduction

The objective of the Accessible Incontinence Control Device is to provide incontinence control to a wide range of patients and to additionally be able to provide the user with real time bladder status. The device consists of two separate units to accomplish this, an implantable unit and an external user remote. The user remote allows the user to have simple control over the implanted portion with the push of a few buttons.

This section describes the general overview of the device part by part. It also includes directions on how to use the device.

1.1 General Overview of the Device

The Accessible Incontinence Control Device has an implantable portion and an external user remote unit. The implantable portion is multifaceted. It is mainly composed of a stretch sensor and an artificial urinary sphincter. The implantable unit of the Accessible Incontinence Control Device is shown below in Fig. 1.

![Image of implantable phase of Accessible Incontinence Control Device](image)

The stretch sensor provides the user with information about how full their bladder is. As the bladder fills it stretches the stretch sensor and the resistance across the sensor increases. These increased resistance values are used to estimate the volume percent of urine in the bladder.

The artificial sphincter has four components. The artificial sphincter cuff wraps around the urethra and compresses it to prevent unwanted urine flow. When the fluid is removed from the artificial sphincter cuff then urine can pass through the urethra. The micropump is used to move
fluid in and out of the sphincter cuff. The micropump is controlled by wireless signals from the user remote. When fluid is pumped out of the cuff it is stored in the fluid reservoir. The fluid reservoir is self-regulating and after a short time lapse will deflate, sending fluid back into the cuff to compress the urethra. There is a manual pump included with the artificial sphincter. The manual cuff functions as a safety feature. If the user remote or micropump malfunctions the manual pump can be used to allow the patient to void urine.

The external component of the Accessible Incontinence Control Device is the external user remote. The user remote is a touchscreen LCD that allows the user to get bladder status readings and control the automated artificial sphincter.

![User remote unit.](image)

**1.2 Operating Instructions**

**1.2.1 Powering Device and Preparing for Use**

The user remote will need to be plugged into a wall power socket when ready for use. (Note: this is only true in cases where the original remote unit is being used. A cell phone or smaller portable remote options may be purchased separately from the Accessible Incontinence Control Device and programmed to control the implant).
1. Plug the power cable into the user remote unit.

![Fig. 3. Plugging the power cable into the user remote.](image)

2. Plus the other end of the power cable into the wall.

![Fig. 4. Plugging the power cable into the wall socket.](image)
3. This turns the remote on, and it is ready for use.

![Fig. 5. The user remote ready for use.](image)

1.2.2 Status Indication

The status indication feature of the Accessible Incontinence Control Device should be used when
the user wants to know how full their bladder currently is. This will help determine whether or
not it is an appropriate time to void urine. This feature will help in managing daily voiding
patterns and gaining better control over incontinence. Note: If the status has been checked
previously and the status indication screen has not been exited, the most recent value will be
displayed on the screen. This value will not update automatically. In order to obtain the most
recent and accurate volume percentage the following procedure must be completed.
1. Touch the menu option at the top of the remote screen that reads “Status”. A list of options will appear.

![Fig. 6. “Status” menu.](image)

2. To obtain a numerical representation of the volume of your bladder (in terms of a percentage) touch the menu option that reads “Numerical”.

![Fig. 7. Obtaining a numerical bladder volume.](image)
3. To obtain a graphical representation of the volume of your bladder (in terms of percentage) touch the menu option that reads “Graphical”.

Fig. 8. Obtaining a graphical representation of bladder volume.

4. To obtain an audio output of the volume of your bladder (in terms of a percentage) touch the menu option that reads “Audio”.
**Urine Control**

The urine control portion of the device allows instantaneous voiding of urine when desired by the user.

1. Touch the menu option at the top of the remote screen that reads “Controls”. A list of options will appear.

![Fig. 9. “Controls” Menu.](image1)

2. To void, touch the menu option that reads “Relax”. (This is the second option on the list). This will send a wireless signal to the implanted portion of the Incontinence Control Device and the micropump will be activated. This will relax the cuff of the artificial sphincter and urine will be able to flow out of the urethra.

![Fig. 10. Relaxes the artificial sphincter.](image2)
3. When voiding is complete, press the menu option that reads “Contract” to ensure the artificial sphincter cuff is re-engaged.

Fig. 11. Relaxing the artificial sphincter.

1.2.4 Manual Pump

The manual pump of the implant is included in the event that the user remote of the implanted micropump experience failure. If the automated sphincter relaxation function is not working, then the manual pump can be used to provide the user with voiding ability until the device can be fixed, or if necessary replaced. IF THE MANUAL PUMP NEEDS TO BE USED TO VOID URINE A PHYSICIAN AND/OR THE ACCESSIBLE INCONTINENCE CONTROL DEVICE MANUFACTURER SHOULD BE CONTACTED AS SOON AS POSSIBLE.
1. For a male user the manual pump will be located under the skin of the scrotum. For a female user the manual pump will be located under the skin of the labia.

![Fig. 12. Placement of manual pump in male patients.](image)

2. You will be able to locate the manual pump by feel. The raised button is obvious to the touch.

![Fig. 13. Manual pump with raised button.](image)

3. Once the pump is located, press the raised button.

4. Squeeze the bulb of the manual pump. This will relax the artificial sphincter cuff and allow urine to pass through the urethra.

5. The system will self-regulate and the sphincter cuff will re-inflate itself, sealing off unwanted urine flow. Note: There may be a time delay, and it may take up to 5 minutes for urine flow to be completely sealed off after use of the manual pump.
1.2.5 Miscellaneous

1.2.5.1 Using the remote unit clock feature

1. Touch the menu option at the top of the LCD screen that reads “Etc”. A list of options will appear.

Fig. 14. “Etc” menu.

2. Touch the menu option that says “Time”.

3. The current time will be displayed on the screen in military time as hours, minutes, and seconds.

Fig. 14. Clock screen.
1.2.5.2 Resetting the clock time

1. Touch the menu option at the top of the LCD screen that reads “Etc”. A list of options will appear. (Refer to Fig. 14 above.)

2. Touch the menu option that says “Time”.

3. To set the hour correctly, touch the box on the left labeled “HH”. Use the up/down arrows to change to the desired hour. Note: The clock is set in MILITARY TIME.

Fig. 15. Setting the hour.

4. To set the minutes correctly, touch the box labeled “MM”. Use the up/down arrows to change to the desired minute time.

Fig. 16. Setting the minute.
5. To set the seconds correctly, touch the box labeled “SS”. Use the up/down arrows to change to the desired value.

   ![Fig. 17. Setting the second.](image)

6. When the time has been set to the desired values, press the box labeled “Set”. This will then start the clock with the appropriate time.

   ![Fig. 18. Setting the time.](image)
1.2.5.3 Using the calendar

1. Touch the menu option at the top of the LCD screen that reads “Etc”. A list of options will appear. (Refer to Fig. 14 above).

2. Touch the menu option that reads “Calendar”.

3. The calendar screen will appear. The current date will be highlighted on the calendar and also displayed on the bottom of the screen in the format yyyy/mm/dd.

Fig. 19. Calendar screen.
1.2.5.4 Resetting the date

1. Touch the menu option at the top of the LCD screen that reads “Etc”. A list of options will appear. (Refer to Fig. 14 above).

2. Touch the menu option that reads “Calendar”.

3. Using the boxes labeled “YY” with up/down arrows, set the calendar to the correct year.

4. Using the boxes labeled “MM” with up/down arrows select the correct month.
5. When the correct month’s calendar appears touch the current date.

6. Touch the box labeled “Set”.

![Fig. 22. Setting the date.](image)
1.2.5.5 Changing the font on the LCD screen

1. Touch the menu option at the top of the LCD screen that reads “Etc”. A list of options will appear. (Refer to Fig. 14 above).

2. Touch the menu option labeled “Font”.

3. An example of the current font will be displayed on the screen.

4. Touching the menu option labeled “Font” will scroll through the various font options.
1.2.5.6 Using the Calculator

1. Touch the menu option at the top of the LCD screen that reads “Settings”. A list of options will appear.

![Fig. 24. “Settings” menu.](image)

2. Touch the menu option labeled “Calculator”.

![Fig. 25. The calculator.](image)
3. Use the touchscreen calculator as you would any basic calculator.

4. Press “Enter” to perform the calculation you have selected.

Fig. 26. Using the calculator.
2. Maintenance

2.1 User Remote

2.1.1 LCD Screen

Using your finger on the LCD touch screen will result in smudges and fingerprints on the screen. To prevent the majority of these smudges, using an object other than your finger to touch the menu options is recommended. For example, using the back end of a pen to press the LCD screen is one option. Regardless of whether you touch the screen directly with your finger there will be situations in which the screen will need to be cleaned. Consider the following instructions when cleaning the screen:

- Make sure the user remote unit is turned off before cleaning. This will make it easier to identify areas that are dirty, as well as ensuring that none of the controls such as relaxing the sphincter are accidently engaged.
- Filtered water, diluted isopropyl alcohol, or diluted vinegar may be used as cleaning agents. (The diluted cleaners should be at least 50% water).
- Apply the cleaning agent directly to a soft cloth. Do not use paper towels because they can scratch the screen.
- Clean by wiping across the screen in one direction, from top of bottom.
- You may also opt to purchase an LCD screen cleaning kit, such as the one shown below in Fig. 27.

![Fig. 27. Commercial LCD cleaning kit.](image)
**Back-up Battery**

The user remote contains a back-up battery that stores the information contained in the remote when the remote is powered off. The remote comes with a 1.0 Farad capacitor that acts as a backup battery and will last about 30 hours.

![1 Farad Super-Capacitor](image)

This capacitor will eventually need to be replaced. The back will need to be removed from the user remote using a Phillips head screw driver.
By replacing it with a 10.0 Farad it will need to be replaced only 1/10 as often. An external backup battery can also be added to the user remote. If the back is removed from the user remote you can read a label that says “External Battery”. It is located below the super-capacitor. The area is also accessible when the back panel is still on, but the label is not visible.
2.2 Wireless Transceivers

Because the Accessible Incontinence Control Device relies on wireless communication to function, avoid using the device in environments that may result in high levels of wireless interference, specifically from devices that use Bluetooth technology. Also avoid using the Accessible Incontinence Control Device at the same time other wireless medical devices are being used. Some examples of common wireless devices that should not be used at the same time as the Accessible Incontinence Control Device are:

- Cellular Phones
- Wireless networking between PCs
- Wireless computer accessories such as the mouse, keyboard, and printer
- Nintendo Wii
- Sony Playstation 3

2.3 Artificial Sphincter

The maintenance required by the artificial sphincter is minimal since the sphincter is surgically implanted inside the user’s body. The following list summarizes important measures that should be taken by the user to maintain the artificial sphincter in top form.

- Urinary tract infection can damage the function of the implant. If symptoms of infection occur see a physician immediately to receive prompt treatment.
- Make sure that a catheter is not passed through the urethra unless the cuff is deflated.
- Regular appointments should be made with the user’s physician to periodically evaluate the condition of the implant. In some cases surgical replacement or repair may be necessary.
- Periodic cycling of the device using the manual pump is advised.
2.4 Environmental

2.4.1 Water

Since the device will be used frequently in a bathroom setting it is important to be careful not to get the user remote wet. The user remote is not waterproof and can be severely damaged if exposed to water. In addition, getting the user remote wet while it is being used can result in electrical injury to the user.

2.4.2 Temperature

Avoid exposing the device to extreme heat or extreme cold. Also avoid significant rapid temperature changes.
3. Technical Description

3.1 Microprocessor

The microprocessor used for the implant portion of the device is the CB220 from Comfile Technology. The functions of the CB220 are to receive wireless signals from the user remote and operate the micropump controlling the artificial sphincter, receive and interpret stretch sensor readings, and send data wirelessly to the user remote. The internal structure of the CB220 is summarized in the figure below.

![Internal Structure of the CB220](image)

The CB220 is a programmable logic controller (PLC) that supports both Ladder and Basic for use as programming languages. The CB220 can run Basic independent from Ladder, which differentiates it from other PLCs than can support both programming languages. In other words, the CB220 can multitask. For use in the Accessible Incontinence Control Device the CB220 was programmed completely in Basic.
Fig. 31. CB220 has the ability to multi task with Ladder and Basic.

Another feature that distinguishes the CB220 from other traditional PLCs is that it is an “on-chip” PLC. This distinction is summarized in the figure below.

<table>
<thead>
<tr>
<th></th>
<th>Traditional PLC</th>
<th>CUBLOC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Production</td>
<td>Din Rail Attachment</td>
<td>Din Rail or PCB</td>
</tr>
<tr>
<td>Labor Costs</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Mass Production</td>
<td>Difficult</td>
<td>Easy</td>
</tr>
<tr>
<td>Final Product Cost</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Final Size</td>
<td>Large</td>
<td>Compact</td>
</tr>
</tbody>
</table>

Fig. 32. CB220 and traditional PLC comparison.
The specifications of the CB220 are summarized below in Table 1.

<table>
<thead>
<tr>
<th>CB220 Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program Memory</td>
</tr>
<tr>
<td>Data Memory</td>
</tr>
<tr>
<td>EEPROM</td>
</tr>
<tr>
<td>Program Speed</td>
</tr>
<tr>
<td>General Purpose I/O</td>
</tr>
<tr>
<td>Serial Ports</td>
</tr>
<tr>
<td>Analog Inputs</td>
</tr>
<tr>
<td>Analog Outputs</td>
</tr>
<tr>
<td>External Interrupts</td>
</tr>
<tr>
<td>High Speed Counters</td>
</tr>
<tr>
<td>Power</td>
</tr>
<tr>
<td>RTC (Real Time Clock)</td>
</tr>
<tr>
<td>Data Memory Backup</td>
</tr>
<tr>
<td>Operating Temperature</td>
</tr>
<tr>
<td>Package</td>
</tr>
<tr>
<td>Dimensions</td>
</tr>
</tbody>
</table>

Table 1.
The CB220 PLC is in a 24 pin DIP package. 16 of these pins are input/output pins. A schematic of the CB220 pins, and each pin’s assignment in this device is shown below in Fig. 33.

<table>
<thead>
<tr>
<th>Pin Number</th>
<th>Assignment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Input from the stretch sensor circuit</td>
</tr>
<tr>
<td>10</td>
<td>Output to control the micropump</td>
</tr>
<tr>
<td>15</td>
<td>RX</td>
</tr>
<tr>
<td>16</td>
<td>TX</td>
</tr>
<tr>
<td>23</td>
<td>Ground</td>
</tr>
<tr>
<td>24</td>
<td>Power</td>
</tr>
</tbody>
</table>

Fig. 33. CB220 pin assignments for the Accessible Incontinence Control Device.

The program for the CB220 of the Accessible Incontinence Control Device was written, and the CB220 was programmed, using Cubloc Studio. The program for the CB220 includes sub-functions that convert readings from the stretch sensor to volume percentages, turn the micropump on and off, and send and receive data from the user remote. Sample code from these subfunctions are shown below.
The following sample code is the sub-function that gets a voltage reading from the stretch sensor and converts it to a volume percentage.

```plaintext
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
```

The code that turns the micropump on thus allowing the user to void their urine is shown below.

```plaintext
Release:
    If Relax = 0 Then
        Delay 100
    ElseIf Relax = 1 Then
        High 5
        Delay 3500   'Relaxation time
        Low 5        'Ends Relaxation
    End If
    Delay 3000
    Bclr 1,2
```
Micropump

The M100-S micropump from TCS Micro Pumps Limited is used in the Accessible Incontinence Control Device to control the artificial sphincter cuff. The sphincter cuff has fluid in it that is pumped out by the micropump to allow the user to void urine. 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 2.

<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 2.

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 Fig. 34.
3.3 Stretch Sensor

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 $1000\,\Omega$ per linear inch, or $4000\,\Omega$ total, when relaxed. At 50% stretch the resistance approximately doubles. The stretch sensor has a diameter of .060 inches.

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 Fig. 36.

![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.
3.4 Implant 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 37). 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 38. 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.
Fig 38 Power Supply Circuit

Fig 39 PCB Layout for Implant Device
3.5 Wireless Transceivers

The Embedded Blue (eb) 505 wireless transceivers from A7 Engineering were used to establish wireless communication between the implant and the user remote. The device is set up in such a way that there is a connection that is established between the eb505 module in the implant and the eb505 module in the user remote. However, an eb505 module can establish a connection with any standard Bluetooth v1.1, v1.2, or v2.0 device, which allows the implant to be controlled by wireless devices other than the default user remote, for example a smart phone. The operating parameters are summarized below in Table 3.

<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><em>(Actual range is dependent upon location and environment.)</em></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>
<tr>
<td>Current Consumption</td>
<td>115.2kbps data transfer: 35mA</td>
</tr>
<tr>
<td></td>
<td>38.4kbps data transfer: 30mA</td>
</tr>
<tr>
<td></td>
<td>9.6kbps data transfer: 25mA</td>
</tr>
<tr>
<td></td>
<td>connected and idle: 8mA</td>
</tr>
<tr>
<td></td>
<td>no connection: 3mA</td>
</tr>
<tr>
<td>Interfaces</td>
<td>5V TTL UART</td>
</tr>
<tr>
<td></td>
<td>Baud rate 9.6k – 230.4k</td>
</tr>
<tr>
<td></td>
<td>Flow control: RTS/CTS or none</td>
</tr>
<tr>
<td>Connector</td>
<td>Two 10x2 20 pin 0.1” headers</td>
</tr>
<tr>
<td>Antenna</td>
<td>Matched internal surface mount</td>
</tr>
<tr>
<td>Bluetooth Support</td>
<td>Version 1.2 compliant with profiles L2CAP, RFCOMM, SDP, SPP</td>
</tr>
<tr>
<td>Firmware</td>
<td>Upgradeable via PC application with RS232 adapter.</td>
</tr>
</tbody>
</table>

Table 3.

The eb505 module is shown below in Fig. 37.
As seen above, 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 4 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></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></td>
<td></td>
<td></td>
<td>(0 = not connected, 1 = connected)</td>
<td></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></td>
<td></td>
<td></td>
<td>(0 = command, 1 = data)</td>
<td></td>
</tr>
<tr>
<td>CN1 - 12</td>
<td>RTS</td>
<td>TTL</td>
<td>Request-to-Send used for hardware flow control</td>
<td>Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(0 = not signaled, 1 = signaled)</td>
<td></td>
</tr>
<tr>
<td>CN1 - 14</td>
<td>CTS</td>
<td>TTL</td>
<td>Clear-to-Send used for hardware flow control</td>
<td>Optional</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(0 = not signaled, 1 = signaled)</td>
<td></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)</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>weak internal pull-up</td>
<td></td>
</tr>
<tr>
<td>CN1 - 20</td>
<td>VCC</td>
<td></td>
<td>Power</td>
<td>Required</td>
</tr>
<tr>
<td>CN2 - 19</td>
<td>GND</td>
<td></td>
<td>Ground</td>
<td>Required</td>
</tr>
</tbody>
</table>

Table 4.

The dimensions of the module are given below in Fig. 38.
3.6 LCD Screen/User Remote

The main component of the user remote unit is the CUTOUCH touchscreen LCD. The specifications for the touchscreen are shown below in Table 5.

CUTOUCH Specifications

<table>
<thead>
<tr>
<th>Dimension</th>
<th>inches</th>
<th>mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.54</td>
<td>39.00</td>
</tr>
<tr>
<td>B</td>
<td>1.77</td>
<td>44.90</td>
</tr>
<tr>
<td>C</td>
<td>0.17</td>
<td>4.23</td>
</tr>
<tr>
<td>D</td>
<td>0.27</td>
<td>6.78</td>
</tr>
<tr>
<td>E</td>
<td>1.02</td>
<td>25.90</td>
</tr>
<tr>
<td>F</td>
<td>0.45</td>
<td>11.40</td>
</tr>
<tr>
<td>G</td>
<td>0.67</td>
<td>17.00</td>
</tr>
</tbody>
</table>

Table 5.

Fig. 38. eb505 dimensions.
A schematic and description of input/output ports is shown below in Fig. 39.

Fig. 39. CUTOUCH I/O ports.

A schematic of the back of the CUTOUCH is shown below in Fig. 40.
The code to program the LCD touchscreen was written in Cubloc Studio. The code to program the touchscreen LCD was long and involved and mainly concerned with formatting the various layers of menus. A short sample of code is shown below. This particular sample codes for the display that occurs when the user wants the implanted sphincter cuff contracted. Figure 41 below the code shows the result when this particular section of code is used.
Gosub Contract_Display

Contract_Display:

   Relax Var = 0
   Font 7,1
   Style 2,0,0
   Glocate 92,80
   Gprint "Contracting...
   Font 7,1
   Glocate 90,120
   Gprint "Please Wait...
   Style 0,0,0
   
   Putstr 1,"0", Cr

End

End Sub

Fig. 41. Result of the above code.
4. Trouble Shooting

4.1 User Remote/LCD Screen

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>How to fix it</th>
</tr>
</thead>
<tbody>
<tr>
<td>User remote won’t turn on.</td>
<td>1. Power cable is not securely plugged in to either remote or wall.</td>
<td>1. Check to make sure the power cable has been pushed completely into the appropriate sockets.</td>
</tr>
<tr>
<td></td>
<td>2. Power cable is damaged.</td>
<td>2. Purchase a new power cable.</td>
</tr>
<tr>
<td></td>
<td>3. User remote is damaged.</td>
<td>3. If the user remote still will not turn on the remote unit may be damaged. In this case you should contact your physician.</td>
</tr>
<tr>
<td>Previous screen will not clear</td>
<td></td>
<td>Reselect the menu which you are working from and then reselect the function you want to use.</td>
</tr>
</tbody>
</table>
### 4.2 Implant

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>How to fix it</th>
</tr>
</thead>
</table>
| Unable to void urine using the automated micropump | 1. Wireless connection not established.  
2. Air has gotten into the implanted system.  
3. Micropump is damaged. | 1. Check the corner of the screen for an indication that the wireless is connected. If it is not, try turning off the user remote, moving into an area without wireless interference, and turning the remote back on.  
2 and 3. If air has gotten into the implanted system or the micropump is damaged contact your physician. |
| Unable to void urine using the manual pump | 1. Manual pump is not prepared to function correctly.  
2. One way valve in pump tubing is allowing fluid to flow immediately back into sphincter cuff.  
3. Manual pump is damaged. | 1. Make sure the raised button has been pressed. Try holding it down during the first couple of pumps.  
2 and 3. If the one way valve or the manual pump are damaged they will need to be replaced. Contact your physician. |
| Urinary incontinence persists even after sphincter cuff has been engaged | 1. Wireless connection not established.  
2. Fluid reservoir is not self-regulating correctly.  
3. Sphincter cuff has slipped position or become unwrapped.  
4. Implant system has sprung a leak. | 1. Check the corner of the screen for an indication that the wireless is connected. If it is not, try turning off the user remote, moving into an area without wireless interference, and turning the remote back on.  
2. Try pushing gently on the area of the abdomen where the fluid reservoir is implanted to force some of the fluid out of the reservoir and back into the cuff.  
3 and 4. The sphincter cuff may need to be repositioned or part of the system may need to be replaced. Contact your physician. |
Appendix A: Description of the Surgical Implant Procedure

A 1. Information for the patient:

The surgical procedure to implant the artificial sphincter is performed under general anesthesia. The procedure can take from about 45 to 90 minutes. The basic procedure is as follows:

1. Your doctor makes an incision near the scrotum/labia and performs dissection to the urethra. Once the tissue around the urethra is cleared your doctor measures the circumference and selects the appropriate sized cuff. The cuff is then placed.
2. The fluid reservoir is then placed under the skin of the abdomen, along with the implantable device housing containing the micropump and wireless transceiver.
3. The manual pump is placed in the scrotum/labia.
4. Tubing is connected between each component and it is filled with saline solution.
5. The incisions are closed.

The device cannot be activated right away. The incision area must heal for 4 to 6 weeks before activation of the implant. During this time it may be necessary to use a condom catheter or absorbent pads to deal with your incontinence. You will be provided with care instructions and possibly pain medication from your surgeon when you are released from the hospital.

After 4 to 6 weeks you will have an appointment with your surgeon to check that the surgery is healing properly and to activate your implant. At this point it is a good precaution to have a caregiver or family member learn how to operate your Accessible Incontinence Control Device as well. As with any medical implant, make sure all of your health care providers are aware that you have received the Accessible Incontinence Control Device as this may effect medical care and treatments.
A.2. Information for the surgeon:

A.2.1. Troubleshooting:

<table>
<thead>
<tr>
<th>Problem</th>
<th>Potential Cause</th>
<th>How to fix it</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient experiences urinary incontinence when sphincter cuff</td>
<td>1. Sphincter cuff was improperly sized for patient’s urethra</td>
<td>1. Patient’s urethra will need to be re-measured and an appropriate size cuff will need to be implanted.</td>
</tr>
<tr>
<td>is engaged</td>
<td>2. Sphincter cuff or another part of the implantable system has sustained a leak</td>
<td>2. The leak need to be found and the damaged component needs to be replaced.</td>
</tr>
<tr>
<td></td>
<td>3. Fluid reservoir is not self-regulating</td>
<td>3. Fluid reservoir may be damaged or it may need to be moved to a high position in the abdomen.</td>
</tr>
<tr>
<td>Patient is unable to void urine using the user remote</td>
<td>1. Micropump is not functioning due to air in the system.</td>
<td>1. Purge air from implanted system.</td>
</tr>
<tr>
<td></td>
<td>2. Micropump is damaged.</td>
<td>2. Replace micropump.</td>
</tr>
<tr>
<td>Patient is unable to void urine using the manual pump</td>
<td>1. One way valve on pump tubing is not functioning.</td>
<td>1. Check valve and if it is not preventing backflow replace valve.</td>
</tr>
</tbody>
</table>
Appendix B: Information Regarding Optional Modifications to the Accessible Incontinence Control Device

B.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.

Fig. ?? Placement of the Interstim® therapy system.
B.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.