Final Design Report for RERC-AMI Competition

MEDSense: An Accessible Pill Cap Dispensing/ Cutting Device

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1. Introduction

a. Background

During a series of scientific innovations sparked by a neo-classical rebirth of interest in the human body around the 17th century, medical research was revolutionized as scientists began to understand how the body functions. Long before the crucial technique of magnification was conceived, the concept of microorganisms, for example, was limited to ambiguous and mysterious descriptions, often referred to as "invisible living creatures." Needless to say, when Antony van Leeuwenhoek discovered, in 1673, that observing samples through a series of lenses unveiled an entire world of interacting cells, the field of microbiology was truly born. Soon the entire world became fascinated with the autonomous microcosm of life within the human body and doctors began to study the science behind accepted medical techniques to the point where they were capable of understanding the details of common illnesses and disease. As the focus of medical research around the turn of the 19th century turned away from holistic methods emphasized by the pioneers of cellular biology, it transitioned towards an analytical approach that allowed scientists to map out detailed rationalizations to explain the causes and effects of common sicknesses. Such a deductive approach to medical research would later lead to multiple discoveries of the power of man-made chemical composites in fighting commonly fatal diseases such as polio and smallpox. Eventually, to address high demand for these composites, ingredients were process into pills or capsules of varying sizes and colors and mass-produced and distributed to the public. Thus, the pharmaceutical company was born.

Today, modern pharmacological establishments spend billions of dollars each year on advertising due to the exponentially growing supply of competing prescription medications. Patients now find themselves in a world where dangerous conditions and diseases are easily managed by relatively affordable medications. Although a remarkable increase in life expectancy of the American population over the past fifty years could additionally be attributed to an increased awareness of daily health issues, it could easily be argued that the primary culprit is the ubiquity of pharmaceutical products. As the number of available medications increases, however, patients are finding themselves reliant on a growing number of daily medications. Ultimately, many individuals accumulate an unmanageable number of medications, a problem that could potentially lead to unintentional neglect of prescribed schedules and dosages. Busy mothers trying to balance the hectic schedule of multiple children, elderly individuals with chronic memory loss, and patients with mild or severe physical limitations are all inconvenienced by complex medication schedules. Additionally, many prescriptions require half dosages, demanding that patients take the time and effort to cut pills into halves and to count out the correct dosages. Many patients, however, are physically incapable of cutting a small pill and calculating the correct dosage or perhaps too busy to take the time to cut each pill, all of which can lead to miss-consumption of important medications.

b. Clients and Disabilities

The benefits from the progress of the pharmaceutical industry can only be felt if the people consistently take the medication prescribed. For some people the seemingly simple task of taking pills is complicated due to various disabilities. This project was designed for the clients below, so that every person, regardless of their disability, would be able to use this device effectively.

Phylis is an energetic 77 year old woman that has rheumatoid arthritis. This condition causes joint pain and loss of hand strength. She also has macular degeneration and hearing loss but is resolute to staying active and healthy. She has difficulties with using complex interfaces and wishes that the design of the device is simple.
Aaron is a war hero from Iraq, with an amputation of the arm above the elbow, neck pain and recurring head aches. Although he has a prosthetic limb, he sometimes does not use it and improvises by only using one hand. Due to the many aliments, he has a number of medications to take.

Keisha just recently had a stroke which caused her to loose function in her dominant right hand. Due to the recent stroke, she also has memory loss and has to rely on her family to remind her of when to take her medication. She also has minor hearing loss that is progressively getting worse. She also deals with the challenges of incontinence.

Jerry is an 82 year old man that has Parkinson’s disease. This disease causes him to have tremors, stiffness, and a decrease range in motion. Also he has been experiencing symptoms of Dementia.

Jamie is an active basketball player and has to use a wheelchair because of her spinal cord injury. She wants to stay active while controlling her urinary problems.

Violet is a mother of three who has blood pressure medication to take. She wants a device that will dispense her medication as well as keeping the medication away from her children.

This very diverse group of people provided a construct for the design process. The device had to have a multi-modal alert system that would allow persons with visual and hearing impairments to be notified to take their medication. The device should also be easy to use for persons with limited hand control. This would include making the device as small as possible as well as excluding any elements that would necessitate fine motor skills. The result of focusing on these clients’ various difficulties was a device that could be successfully used by persons with many different disabilities.

c. Features

The main features of this product are designed to aid the patients in their medication routine. The multi-modal alert system lets patients know when it is time to take their medication with both visual and auditory alarms for patients with hearing loss or vision loss. The automated cutting mechanism accurately cuts pills in half if a half dose is required for patients with macular degeneration or a missing limb. The reminder to order a new prescription when the old prescription runs out is designed for elderly patients, patients with Dementia or memory loss, or busy patients who don't have a lot of time to think about their medication. The offsite alert system, which notifies a family member, nurse or doctor offsite if a dose is missed by the patient, is a built in safety device so a responsible party is notified if something happens to the patient and they miss their dose. An easy-to-use interface is needed since many elderly persons are intimidated by technology and so the device is simple and user-friendly.

2. Alternative Design

a. Dimensions and Materials

The design concept for the device is to use two compartments; one area will consist of the cutting and dispensing of the pill and the other area will be where the notification and alert systems are housed. The rectangular design of this unit will ease the user when gripping the device. The medication bottle will be placed on top of the device on the side of the cutting and dispensing area. The use of two compartments to hold the necessary equipment will ease in the replacement of new medication, because the user will only need to bring the cutting and dispensing area back to the pharmacist. The use of a wider shape will ensure that the user has a firm grip on the device while in operation. It is critical that the device be placed on a hard surface with good support so that the mechanisms that are cutting the pill do not cut a different size. The size of the device will have a maximum dimension of 6 cm by 12 cm by 6 cm to ensure easy portability and to act as a bottle cap. An average medication bottle is about 6.35 cm in height by 2.5 cm in width with a diameter no larger than 2.54 cm.

The ability to return half of the device to the pharmacist greatly increases the convenience of this device. This also alleviates a bulk of the device so the pharmacist and user do not have to carry around any extra weight then necessary. To cut the pill in half there will be a motor with a linear actuator; this motor will be no larger than 22 mm. Within the center of the linear actuator there will be a blade that will accurately slice the pill in half. The blade will be non-toxic, non-corrosive, and inert to all forms of medication. Single-edge blades are 0.023 cm thick and are 2.54cm in height by 1.27 cm in width. Because of the size constraints the normal blade will have to be modified to a smaller dimension. For the blade itself, stainless steel has been chosen because of its great mechanical properties; these include large tensile and compressive forces and good hardness properties. Also stainless steel is a very bio-inert material thus not reacting to any of the medication.

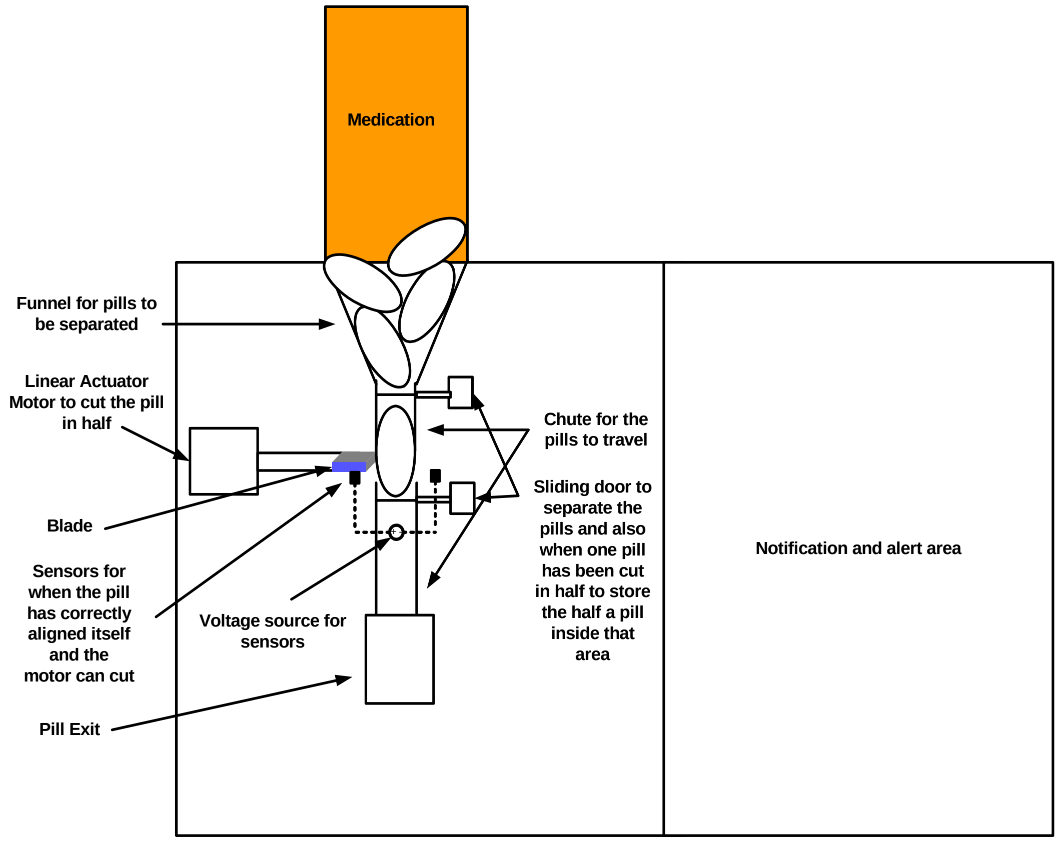

Figure 1 - Diagram of Overall Design Including Mechanical Elements

This device needs to have a chute just large enough to hold a single pill so that no other pills will be able to fall into the chute. The material used for the funnel and the chute will be the polyether plastic that is the same material used for the outside casing.

The notification and alert systems area will be able to be removed from the cutting and dispensing area of the device. In this area will hold the power source, PCB board, and the microchips for the LabVIEW program and the alerts. This part will also be able to be recharged when it is disconnected from the other half. The material used for this part will consist of the same plastic casting as the cutting and dispensing half; this will allow for this part to be waterproof, durable and capable of resisting moderate heat. The dimensions of this side will be 6 cm by 6cm.

For the exterior of the cutting and dispensing part, a plastic casing will be used. Plastic will be a lightweight comparison to some other materials such as aluminum. Because this device will contain important materials, the casing needs to be durable and waterproof. Both of these requirements are satisfied by using a plastic casing. A Polyether Polyol and Polymeric plastic mixture will be used because of its low cost, high strength and resistance to heat. Plastic can be molded into many shapes and sizes, so this also helps with design an efficient and cost effective device. On the exterior of the device there will be, an activating button which will be large enough of the user to see, a "ready" light to alert the user when the pill has fallen correctly into the position, an exit window for when the pills are dispensed, and an opening to place the cap-less medicine bottle. The exterior will have a port were the medicine bottle will be placed. The operation of the device for the pharmacist will be as follows: 1. removing the cap of the user's medicine bottle, 2. inverting the entire device and placing it over the bottle and securing it as one would with a regular medicine bottle cap, 3. invert the now connected bottle and set the device upright on a hard surface (note: the original medicine bottle will be upside down), 4. pushing the "button" to activate the system once the jamming light has gone off.

b. Cutting Mechanism

The group did extensive pill testing to determine the minimum amount of force needed to cut a pill as well as the optimum blade speed. After many trials the group determined that the minimum amount of force needed to cut the pill was 3.9 lbs (17.35 N) and the speed of the motor should be no less than 20 in/min. The stainless steel blade will be welded onto the end of the linear actuator motor. A small but powerful linear actuator motor with a speed of greater than 20 in/min like the Danaher Motion Digital Linear Actuator 42DBL20C2B-L will be used. This motor has a diameter of 42 mm and consumes 10 watts of power. The maximum force applied is 16.25 lbs (72.28 N) and maximum travel distance is 2.4 inches (0.061 meters) with a maximum speed of 36 in/min.

The MEDSense pill dispenser will use gravity to dispense the tablets. When the alarms alert the user that it is time to take their medication, the user will invert the system so the pill cap is towards the ground. The pills will flow through a funnel just below the pill bottle. At the bottom of the funnel, a chute will be present with a width just large enough for one pill to fit through. One pill will move through the funnel and down the chute. The size of the funnel will depend on the type of pill being dispensed, so this device will be pill-dependent. There will be a different size device for the different size tablets used. The pill will be stopped by a sliding door below the chute so exactly half the pill is exposed out of the chute. The pill will then be stabilized in the chute. Another sliding door will close above the pill inside the chute. The cutting blade will come from one side and cut the pill in half. The bottom sliding door will then open and release the half pill to the patient. When the next half pill is needed, the blade will retract and the other half of a pill will be released to the patient. If a whole pill is needed, the blade will not move and an entire pill will be released to the user. A sensor will be used under the chute to ensure that the pill is in the correct position and ready to be cut. In the case of a jam or that the pill is not in the correct position, the sensor will send a signal to an LED alert which will warn patients that the pill cannot be cut. If this is the case, the patients will be told to re-invert the device so the pills can be re-aligned in the chute.

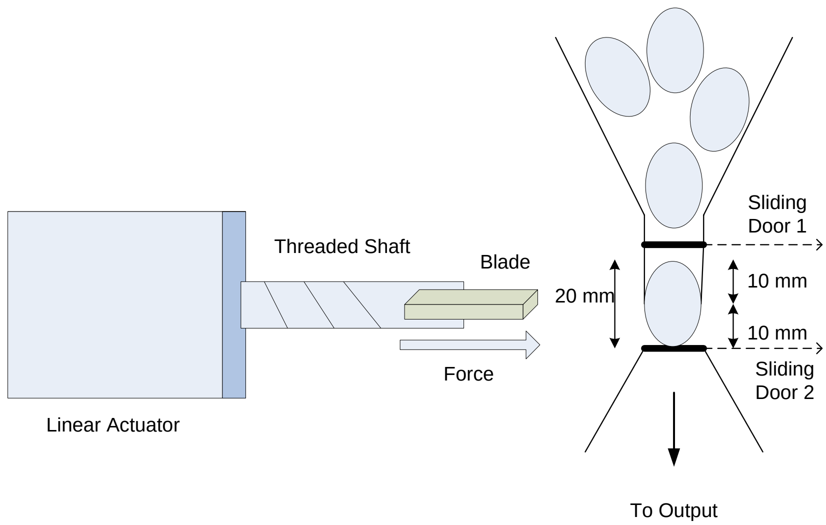

Figure 2- Alternative Design Cutting Mechanism

This design can be used to dispense ½, 1 or 1 ½ pills. In order to dispense 1 ½ pills, first one pill will be dispensed then a half pill. At the next medication time, first a half pill will be dispensed then one pill using the same process described below. The motors that will be used to control the two sliding doors will also be linear actuator motors but only have to produce enough force to open and shut the doors. Therefore, very small motors can be used, such as the Danaher Motion Digital Linear Actuator 20DAM40D1U-K. This motor is only 20 mm wide, consumes 5 Watts of power, and produces a maximum force of 1.88 lbs (8.34 N). All the motors used in this device will be controlled by the microprocessor.

c. Notification System

It is necessary that the pill dispensing device has a mean of notifying users of various points of interest. To address the needs of a universal audience, the notification systems must stimulate multiple senses. MEDSense will feature visual alarm systems to accommodate users that are hard of hearing and auditory systems to accommodate users that are blind. Additionally, the device will vibrate when there is a notification to ensure that patience with both poor eyesight and hearing are clearly informed. Most importantly, the device will notify the user of when to take their medications. A microprocessor will be programmed with various command strings that remind the user to take their medications at certain time intervals. These strings will be input to a text to speech module that will verbalize the command. Selected times will be specific intervals before medication is dispensed, as selected by the user. The user can, for example, select that the device notify him/her every ten minutes before pills are dispensed to ensure that they are nearby and able to take their medications at that time. For a user with a busier schedule, selecting that the device notifies him/her half an hour before dispensing medications could be more convenient. Additionally, the user can select that the device notify him/her multiple times before dispensing pills. When the medications are dispensed, an alarm will sound and the “release” button will flash. Once the release button is pressed and pills are dispensed, a voice command will notify the user of consumption parameters specifying what medium to take with the pills (i.e. take with food, take with water, etc.). There will also be a volume control to ensure that all users are clearly notified.

In order to accomplish speech capabilities, the device will be installed with a text to speech synthesizer, a Devantech product distributed by Acroname Robotics. This compact module is 1.57 inches in length in 1.57 inches wide making it more than acceptable in size for the estimated design. The device runs on a 5V power source with a tolerance of approximately 10 percent. The standby current required is 20mA and the active speech current is 80mA. Additionally the device features an audio amplifier, an imbedded PIC processor, a Winbond WTS701 speech chip, and a 40mm speaker. The speech module has the ability to repeat 30 different text strings, each containing a maximum of 81 characters. A total of 1925 characters can be programmed.

Visual notification systems will include a series of LEDs that will notify different occurrences. A static red LED will indicate that medications are not to be taken. When there is no action or response required (ie not prescribed medication time) the red LED will be constantly on. When there is a response required from the user a green blinking LED will be triggered and will continue to trigger until the user responds. At medication time, for example, the green LED will be blinking, notifying the user to press the pill release button on the side of the device. When the button is pressed, the blinking LED will no longer blink and the pill will be dispensed. The triggering of these LEDs will be programmed into the microprocessor.

Additional visual notifications will include a PC mount LED array that will act as a low battery indicator. A full battery charge will show all bars illuminated with one bar deactivating as the battery loses its charge. The LED array will feature a total of ten illuminating bars, thus, each bar will represent 10 percent of the total charge. As a device that relies heavily on the ability to keep time, a loss of power by depleted battery charge could lead to a loss of exact regulation of prescription times. A battery level indicator will clearly notify users of when to change the batteries in their MEDSense unit.

The trigger switch that will ultimately release pills will also feature a visual notification. By using an LED pushbutton switch from Honeywell, the user will be clearly notified of what action to take when it is time to dispense pills. The switch will feature pushbuttons, paddles, rockers, solid state indicators as well as electronic key locks with LED, incandescent and neon illumination.

While creating the auditory and visual notification systems are relatively straightforward, notifying the user through their sense of touch proves to be a more difficult task. Similar to the E-Pill vibrating reminder device, the MEDSense will feature a vibrating device designed and constructed by the group that will trigger at programmed medication times.
A simple rotational dc motor will be stabilized in a sturdy plastic container. Attached orthogonally to the rotational end of the motor will be a small plastic gear that will rotate clockwise when the motor is activated. Attached parallel on the perimeter of the plastic gear will be a small weight. Due to the rapid rotation (100 to 150 RPM) of the system,

the rotating weight will rapidly change the center of mass of the system causing a “wobbling” motion.

Additionally, it is important to have a failsafe notification in the event that there is a jam in the pill dispenser. Although the funnel device described in previous sections is the most efficient method to ensure that only one pill passes through the system at a time, there is a slight possibility that the device jam at the funnel output due to the random orientation of pills. A simple optical system will be installed at the funnel output to detect a jam in the pill dispensing funnel. At the second trap door where the pill will rest vertically before being cut, there will be a simple photodiode LED on one side of the pill and a photodetector on the other. The photodetector diode used will be a QSB363 Subminiature Plastic Silicon Indrared Phototransistor from Fairchild Semiconductors. When there is a pill resting vertically, the path of the photons will be blocked and the cutting and dispensing process will continue as programmed in the PIC microprocessor. When there is no pill however, the photodetector will be excited and the process will not continue. This case will suggest that there is no pill in place due to a jam in the funnel. The optical system will be programmed into the same PIC microprocessor that controls the entire system as an “If, Then” type program. *IF* the photodetector is not excited, for example, *THEN* system will continue to function as programmed. On the other hand, *IF* the photodetector is excited, *THEN* the microprocessor will activate a notification LED on the external shell of the device. The external LED will signify to the user that they need to shake the device. The “shaking” motion will immediately reorient the pills in the reservoir in such a way that one will fall through the funnel exit. Rough simulations of the effects of this motion on a jammed funnel have been performed using One a Day: Women’s vitamin pills and a simple plastic funnel. Due to the random orientation of the pills in the static reservoir, it is likely that there will be a jam blocking any pills from exiting the funnel to be cut. From the rough experiment performed, however, even the slightest amount of motion is sufficient to reorient the pills, making it very unlikely that the user will need to apply a significant amount of energy or force to shake the device.

d. Offsite Alert

Not until now has the technology been readily available to allow a small pill dispensing device to communicate wirelessly to an emergency contact. Therefore, the ability of MEDSense to use Bluetooth technology to immediately contact a third party member when medications are not taken correctly or when the device is tampered with will be a hallmark of this design. The pharmacist could program any phone number can be programmed into the device allowing a wide variety of users to take advantage of the offsite alert feature. While elderly individuals might choose to have the device call their doctor or pharmacist, a busy mother could have the system call her own cell phone as a double reminder in case the notification systems do not successfully catch her attention. It is crucial for the safety of the patient to take their medication on time, and the offsite alert is a failsafe system to maximize the safety and health of the patient. If they miss a dose, the third party member is alerted and can respond however they feel fit. The MEDSense dispenser will be a wireless device using Bluetooth technology. There will be a Bluetooth module in the dispenser that will send a short-range signal with a frequency in the 2.4 GHz spectrum to a nearby computer with Bluetooth technology that is also connected to the internet. The computer will in turn send a text message to a pre-programmed cell phone number of the assigned caretaker. This cell phone number will be programmed into the MEDSense dispenser with the other information. The device will send an alert offsite if the dose is not taken within thirty minutes of the start of the alarm. Therefore, if the button to dispense medication is not pushed within thirty minutes of the programmed dosage time, the caretaker will be alerted through a text message and be able to come to the aid of the patient.

The specific device that will be built into the MEDSense system is an RCM3100, EmbeddedBlue eb506-AHC-IN Bluetooth Radio Module from A7 Engineering and distributed by Rabbit Semiconductors. This particular model features fully implemented components on the board to ensure that no additional code is required. Additionally, the embedded UART interface will automatically search, connect, and communicate with other Bluetooth devices nearby. Once it is located, connection to another Bluetooth device is designed to mimic the appearance of a serial connection so that users do not need to have a full knowledge of wireless communication protocol. The rabbit Bluetooth module also requires a low driving current, which should ultimately prolong the system's battery life. A standby current of 3mA and a data transfer current of 25mA is required. The driving voltage is also low at a value of only 3.3 Vdc.

3. Prototype

The prototype was constructed based on an optimal design that was chosen after three previous designs were submitted. The following discussion is of both the design of the device and its construction. Appendix A shows the budget for the prototype. This includes all elements that were part of the prototype.

a. Client Testing

The overall goal of the device was to allow for persons with various disabilities to use this device to take their medication. Upon completion of the MEDSense device, testing occurred to allow the group to determine the extent to which the device accomplished tis goals.

The first qualification that needed to be addressed was if a blind person could use the machine. The subject was not allowed to open their eyes throughout the test to make the test as realistic as possible. Using only the auditory alarms the subject was able to find the device effectively. Before the test had occurred the subject was told that there was a pushbutton on the top of the device that would dispense the medication. The subject was able to find this button with little difficulty and the motor sequence commenced. The subject also noted that there was a change in the sound pattern when a pill was not in the correct position. The subject was told this change meant that a pill was not in the correct position. The subject then inverted the bottle and a pill successfully went in the holder. The subject then found the hole on the side of the device where the medication was dispensed and successfully retrieved the pills.

The second qualification is to address if a deaf person can operate the device. When the device lights up with both the LEDs (red and green), this is alerts the user that it is time to take their medication. When the LEDs go red this alerts the user that the device has not detected a pill within the system. Once the system has found a pill it will stop blinking and the system will begin. The various alerts were explained to the user before the test. After the device has dispensed the medication, it will blink green LEDs to alert the user that the medication is ready.

Figure 3- Alarm LEDs

The third trial is was where the user has fine motor skills. This test was conducted by using the side of the subject's hand. This would show that one finger is not necessary to press the button. The pushbutton was successfully pressed with the side of the hand. Also the user with a lack of hand control was able to invert the device so that a pill would fall into the correct position.

Overall the device accomplished the initial goals. This device could successfully be used by various persons with a wide range of disabilities. The effectiveness of the device would be increased as the device became smaller. During the manufacturing process the device would undoubtedly become smaller and thus easier to use.

b. Mechanical Elements

After careful consideration of all options for motors the group decided that a servo motor will be used to push the blade to cut the pill. The servo motor produces a torque to a blade backing. A piece of acrylic is attached to the blade for increased stability. The blade slides along a cutting track and cuts the pill. Two springs mounted to the blade backing then pull the blade back when the servo motor retracts. An intensive force analysis was done to ensure that the torque provided by the servo motor would be sufficient to cut the pill and oppose the forces provided by the springs. The lever arm also had to be long enough to provide the correct force. A diagram of the cutting mechanism can be seen below in Fig. 4.

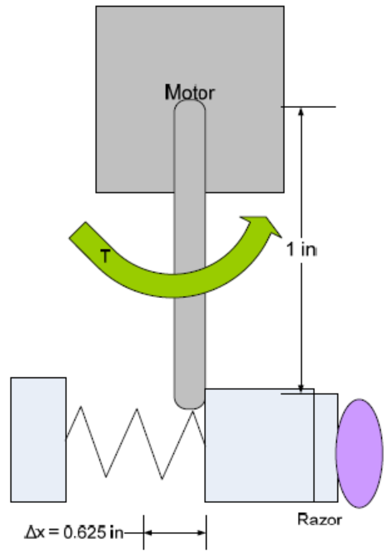

Figure 4- Cutting Mechanism Diagram

The two springs are attached to the razor blade stabilizer and work to retract the blade after the pill is cut. The springs are in parallel, so the spring constants, which are equal for the two springs, may be added together in order to calculate the total force provided by the springs, which is F_s.

Using Hooke's law, with a spring constant of 0.26 lb/in and a length of 0.625 in. the group determined that the springs provide 0.325 lbs of force in the direction opposite of cutting.

From previous testing, we found that the maximum force needed to cut the pill was 3.9 lbs. To ensure that the pill is cut the group planned for a force of at least 5 lbs to cut the pill. The force provided by the motor is in the form of torque:

From the specifications of the motor, the HiTec HS-645MG Ultra Torque, the stall torque provided by the motor is 106.93 oz/in, which equals 6.68 lbs/in. With a lever arm of one inch, the force provided by the motor, F_m, is 6.68 lbs.

We know that the force provided by the motor has to be greater than the force provided by the springs and the force necessary to cut the pill. Using a simple free body diagram and force analysis the group determined that the motor would more than be able to cut a pill successfully.

The servo motor that is being used is the HiTec HS-645MG Ultra Torque. This motor is 1.59" x 0.77"x 1.48" and weighs 1.94 oz. It operates at 4.8-6.0 Volts and requires a 3-5 Volt Peak to Peak square wave pulse with a current of 8.8mA (idle) and 350mA during no load operating. Its operating speed is 0.24sec/60° at no load and torque is 106.93 oz/in.

It was also decided that a servo motor would be used to rotate the discs. With a servo motor, there is much more precise control over the placement of the discs. Servo motors use error-sensing feedback to control movement. This negative feedback controls the input position to the actual position of the mechanism as measured by a transducer. The position is inputted in degrees. The motor has home position at zero degrees and as different values are input, the motor rotates to that location. The positions are sent as pulse-width modulation signals to the servo. A DC motor rotates the servo to the correct position, which is indicated by a potentiometer that reaches a value that corresponds to the indicated position. The motor used for the rotation of the discs is the HiTec HS-422 Deluxe.

The basic concept of our design was to make it look as accurately like a pill cap as possible. However, we realized that we could not make the prototype the same size as a real pill cap so we have scaled it up in size. The cap is about 4.5 times larger than an actual pill cap. A schematic of the pill cap drawn in Autodesk Inventor Professional 2008 can be seen below in Fig. 5.

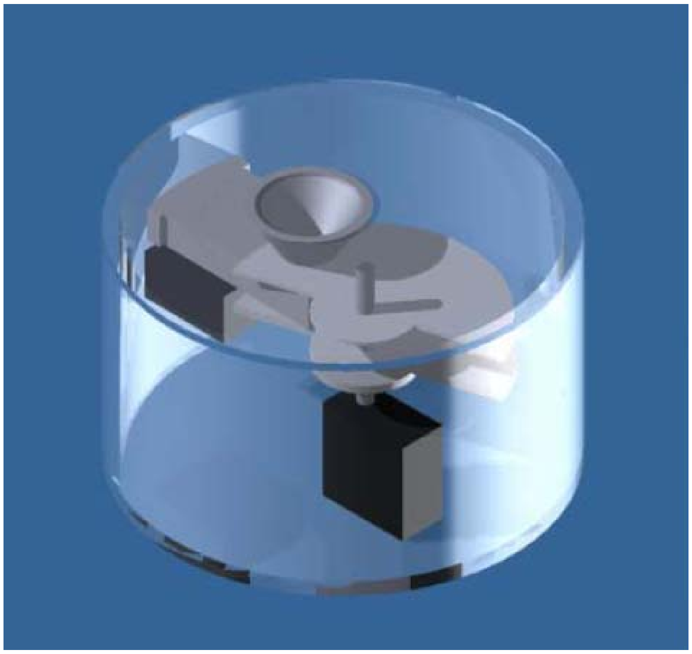

Figure 5- Pill Cap Schematic

The layout of the actual pill cap is very similar to the one envisioned. The parts are in the same place in the prototype, with the addition of the electrical components, including the Bluetooth module, the Text-to-Speech module, the PCB, LEDs and batteries. A picture of the final product can be seen in Fig. 6.

Figure 6- Pill Cap

In order for the pill cap to look as realistic as possible, we also designed a pill bottle to go with it. We also scaled the bottle up so its dimensions would be relevant to the dimensions of the pill cap. A picture of the MEDSense pill cap and bottle can be seen below in Fig. 7. The picture of the MEDSense pill cap has been shrunk down to see the similarities between it and a real pill cap.

Figure 7- MEDSense Pill Cap and Bottle

Most of these parts were machined by our team members in the machine shop out of various materials. The enclosure is made out of PVC. It is the container for all of the other components of the device. The funnel ensures that only one pill goes from the bottle into the cutting mechanism at a time. This prevents jamming from occurring and ensures the smooth flow of pills through the system. This funnel is made out of polyethylene. The rotating discs control the movement of the pills through the device. The top disc rotates and the hole gets aligned with the funnel and pill stabilizer so that the pill can fall from the funnel into the pill stabilizer. The discs rotate and help hold the pill in place when it gets cut then the bottom disc rotates so that the hole lines up with the pill stabilizer and exit chute and the pill falls from the pill stabilizer into the exit chute. The discs are controlled with one servo motor. The rotating discs are made out of PVC. The rotating axis connects the two rotating discs to the servo motor. The motor rotates the discs to the correct position. The rotating axis is made out of steel. The rotating servo motor controls the position of the two rotating discs through the rotating axis. It is controlled directly by the microprocessor. The microprocessor sends signals and tells the servo motor where to rotate. The motor uses a closed-loop self-regulating system to ensure that it is in the correct position. This servo motor is the HiTec Delux HS-422.

The cutting mechanism itself is made up of many components. It contains a blade, cutting track, pill stabilizer, blade stabilizer, springs, and razor backing. A standard stainless steel razor blade is used to cut the pills in half. This razor blade is made by Stanley U.S.A. The cutting track stabilizes the blade so that it accurately cuts the pills in half. The blade slides along the track and through the pill stabilizer to cut the pill. The cutting track is made out of acrylic. The pill stabilizer holds the pill steady as it is being cut by the blade. The pill falls into the pill stabilizer from the funnel and out of the pill stabilizer into the exit chute. The pill stabilizer is made out of polyethylene. The blade stabilizer is attached to the back of the blade. It provides a larger surface area for the cutting servo motor to push against in order to move the blade and cut the pill. The blade stabilizer is accurately fitted so that it slides through the cutting track. This component is made of acrylic. The springs are used to retract the blade along the cutting track after it has cut the pill. The servo motor pushes the blade forward along the track and when it goes back to its original position the springs pull the blade back along with it. The springs are 302 SS Instruments Extension Springs from Small Parts, Inc. The razor backing holds the cutting track securely to the wall of the enclosure. This backing is rounded since the enclosure is a cylinder. The curvature of the backing directly matches the curvature of the enclosure to ensure a tight fit. The razor backing is made of acrylic.

The cutting servo motor is used to push the blade along the cutting track to cut the pill. Enough torque has to be provided to cut a pill. This servo motor is directly controlled from the microcontroller. The Hitec Ultra Torque HS-645 MG motor is being used for the cutting servo motor. The exit chute is positioned directly below the pill stabilizer. When the bottom rotating disc rotates so that the hole lines up with both, the pill falls through into the exit chute. The pill falls down through the exit chute and is dispensed out of the device. The exit chute uses the concept of gravity to move it through the device. The exit chute is attached to the wall of the enclosure. The exit chute is made out of Tygon Tubing.

The user is notified that it is time to take their medication by a multi-modal alert system. This alert system includes a visual alert, through LEDs, and an audio alert, through a Text-to-Speech module. The medication time is pre-programmed into the device so that the user does not have to worry about the programming. When the alerts go off, the device will announce that it is time for the user to take their medication and the LEDs will begin to flash.

The user then inverts the entire pill cap and bottle and places it on a flat surface. This device uses the concept of gravity to move the pill through the pill cap so it should not be touched or disturbed in any way while in operation.

The user then pushes the pushbutton located on the side of the device to start the cutting process. The pushbutton starts the process of cutting the pill. One pill falls through the funnel. The upper rotating discs will rotate so that the hole is aligned with the funnel and the pill stabilizer. One pill will then fall through the funnel and top rotating disc into the pill stabilizer. The pill stabilizer is only large enough for one pill to fit in at a time so jamming should not occur.

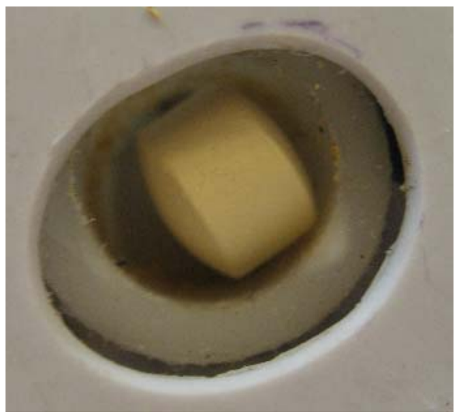

Figure -8 Pill in Pill Stabilizer

If a pill happens to get jammed and does not fall correctly into the pill stabilizer, an alert will be sent to the user to re-invert the device to move the pills around. The inversion of the bottle and cap shakes the pills up and allows them to fall correctly into the device. This jam is detected using infrared detectors located in the pill stabilizer. If a pill is correctly positioned in the pill stabilizer, the infrared light sent by the transmitter will not be detected by the receiver, and the cutting process will go as planned. If the receiver detects the infrared light, that means that the pill is not correctly positioned in the pill stabilizer. The user will then be notified that a jam has occurred and prompted to re-invert the device.

The rotating discs rotate again once the pill is in the pill stabilizer. If the pill is to get cut in half, they rotate to the middle of the discs, between the holes. The pill is held steady and the cutting servo motor is activated. The blade is pushed forward by the servo motor and the pill gets cut in half. The blade remains in the pill stabilizer.

Once the pill is cut all the way through, the rotating discs rotate again so that the hole in the bottom disc is aligned with the pill stabilizer and exit chute. The bottom half of the pill falls through the hole, through the exit chute and out of the device. Only one half of a pill falls through since the blade is still in the pill stabilizer, blocking the other half of the pill from being released. The second half of the pill will be released when it is the next medication time and the user pushes the pushbutton again. The blade will retract and then the second half pill will fall out of the pill stabilizer and into the exit chute and out of the device. Once the pill falls through the exit chute, the user is free to take their medication however it was prescribed by their doctor or pharmacist.

If the dosage prescribed is a whole pill, the device will skip the cutting process. Once the pill is in the pill stabilizer, the rotating discs will rotate so that the hole in the bottom disc is correctly lined up with the pill stabilizer and chute. Then the whole pill will fall out of the pill stabilizer, through the chute, and out of the device so that the user can take it as prescribed.

c. Hardware

The MEDSense is a portable pill cap that not only cuts and dispenses pills but also communicates wirelessly to any off-site source in the event of an emergency. Powered by one 9V battery, the MEDSense is capable of executing a multi modal alarm sequence to ensure that patients with varying levels of handicaps can comfortably use the device. The visual alarm system is accomplished using multiple LEDs that flash in a sequence when the patient is expected to take there medications. Additional LEDs act as “status” notifications that indicate different scenarios. An auditory alarm system that uses an SP03 text-to-speech module to verbally notify the patient that it is time to take their medication is also provided. Additionally, the text-to-speech module provides a series of instructions that remind the user of the correct use of the device. Lastly, a vibrating DC motor provides mechanical alarm system that will vibrate in a series of pulses when it is time for pills to be dispensed. The logic driving the MEDSense is handled by a PIC16F877 microcontroller as well as passive elements that include a SPDT Micromini 5VDC relay and a number of 1N4004 Diodes. In the event of an emergency, wireless communication will be accomplished via Bluetooth through an eb505 Bluetooth module.

i. Microcontroller

The PIC16F877 microcontroller is responsible for the majority of the logic and timing for each pill dispensing sequence. Connected to the controller are the cutting motor, rotational motor, SP03 text-to-speech module, eb505 Bluetooth module, real time clock module, switches and relays. By programming it to execute a set of commands, the microcontroller manages the function and timing of the cutting/rotational motor system, vibrating mechanical notification system, text-to-speech auditory notification, and the real time clock applications. There are also a number of passive devices attached to the microcontroller. These devices include a resistor at the MCLR/Reset pin, a 4MHz oscillator crystal, an npn transistor and a 5V voltage regulator.

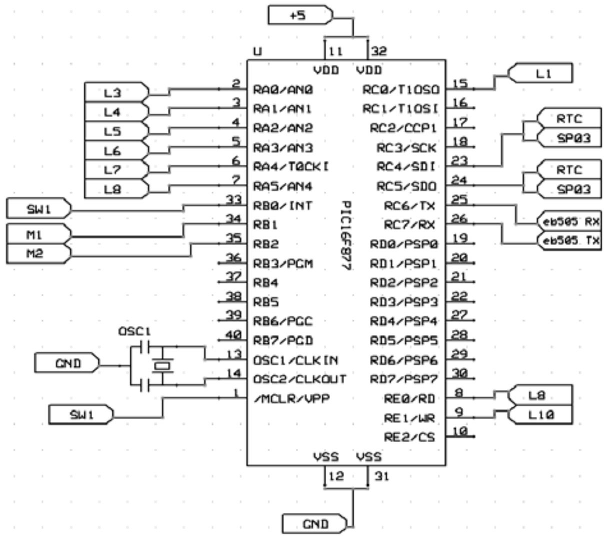

Figure 9- PIC16F877 Schematic with Peripherals

ii. Voltage Regulation

Although the device is powered by 9V batteries, the majority of the peripheral devices are capable of running on only 5 volts. A listing of the required voltages to drive each device on the network is seen in table [----]. An LM317T adjustable voltage regulator is used to reduce the voltage from 9 volts to 5 volts. This three pin regulator has a limited current (Cout) of 1.5amps and a maximum power dissipation of 15 watts. This output current is more than sufficient to drive all the devices on the network. The adjustable output voltage (Vout) ranges anywhere from +1.2V to 37V and is regulated by the values of R1 and R2]. The output voltage can be calculated as:

$$Vout = 1.25V*(1+R2/R1)$$

$$[@ Vout = 5V] \qquad 5 = 1.25V*(1+R2/R1)$$

$$[solving R2/R1] \qquad R2/R1 = 3$$

The ratio, then, of R2 to R1 must be equal to 3. For the [Medicator v.1], the values of R2 and R1 are 6.07Kohms and 2.2Kohms. It should be noted that a resistance of 6.07 is accomplished using a 5.6Kohm and 470ohm resistors in series and the principles of Ohms Law. Additionally, two capacitors connect Vin (pin 1) and Vout (pin 2) to stabilize the transient response of the output signal.

iii. Power Indicator

With any device that is designed to ensure a strict time dependent regiment such as pill dispensing, it is important that there is always power being delivered to the system. As a result, a battery life indicator has been included in the circuit. The battery life indicator is composed of four LEDs driven by a power source traveling at different stages through a series of diodes. The more diodes before a LED, the more power will be required to drive the LED because of their threshold voltage of about 0.7 volts. As a result, a green LED is connected at the end of 9 diodes, indicating that that battery is full. The voltage required to exceed the total threshold of the diode system is about 9V, which will be the voltage of the battery source. If the battery life is full, the 9V threshold will be exceeded and the green LED will be illuminated. With 8 diodes before it, a yellow LED will indicate that there is around 7.5 volts left in the batteries. There is also an orange a red LED to indicate lower battery lives:

Red LED: .7V*2 Diodes = 1.4 volts

Orange LED: .7V*7 Diodes = 4.9 volts

Yellow LED: .7V*8 Diodes = 5.6 volts

Green LED: .7V*9 Diodes = 6.3 volts

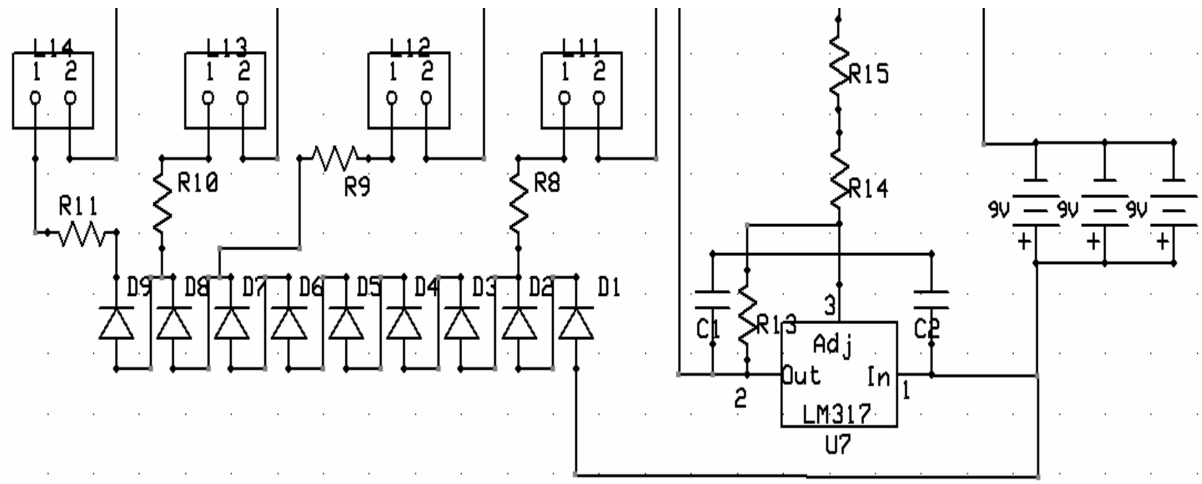

Figure 10- Battery Life Schematic

iv. Wireless Communication

The specific device that will be built into the MEDSense system is an RCM3100, EmbeddedBlue eb506-AHC-IN Bluetooth Radio Module from A7 Engineering and distributed by Rabbit Semiconductors. With advances in technology, many of the tedious programming requirements are no longer need because the devices come pre-programmed. This particular model features fully implemented components on the board to ensure that no additional code is required. Additionally, the embedded UART interface will automatically search, connect, and communicate with other Bluetooth devices nearby. Once it is located, connection to another Bluetooth device is designed to mimic the appearance of a serial connection so that users do not need to have a full knowledge of wireless communication protocol. The rabbit Bluetooth module also requires a low driving curent which should ultimately prolong the system's battery life. A standby current of 3mA and a data transfer current of 25mA is required. The driving voltage is also low at a value of only 3.3 Vdc.

v. Data Acquisition

The system that will be used to acquire data from the Bluetooth module is National Instrument's LabVIEW. An image of the final front panel and block diagram is seen below. On the highest level, the health care provider is prompted to input a series of parameters that will ensure that the data is received correctly from the wireless module. These parameters include: the serial communication port, baud rate, data bits, parity, stop bits, flow control and delay. While the program prototype will prompt the user to input these values each time communication is attempted, in actuality, these parameters will be constant for the device and can be input once and stored in the software memory. From here, the user has the option of reading data in from the microcontroller, writing data to the microcontroller, or executing both. Data written to the microcontroller is user defined and could be used, for example, to send a text string to the text to speech module as some kind of confirmation that data has been set.

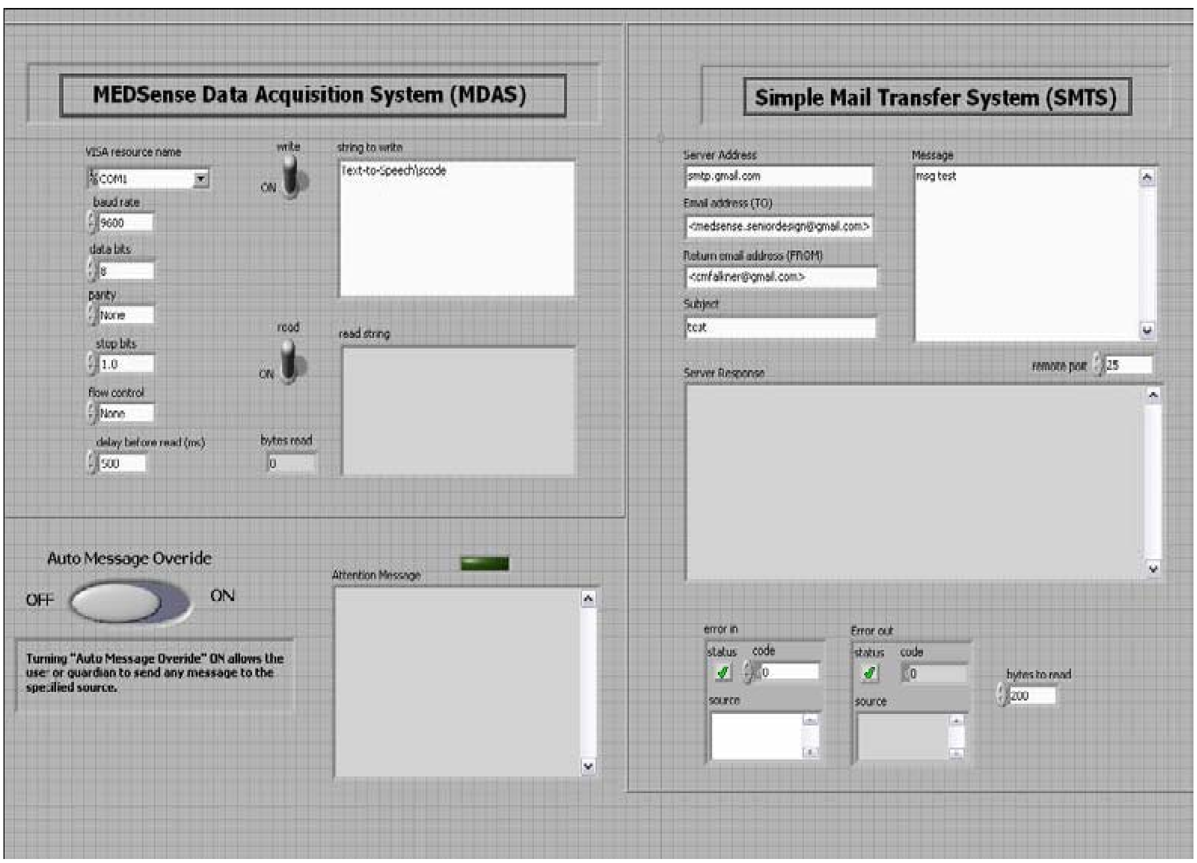

Figure 11- LabVIEW Front Panel

In the future, however, the ability to write material to the microcontroller wirelessly will allow the health care professional to send specific announcements to the user as reminders or notifications.

Once data is obtained, the software will automatically compose the information into an email and send it to an off site source, which can be programmed by the health care professional and stored in the software's memory. Parameters that must be defined include: server address, email address (TO), return email address (FROM), the subject of the email, and the body of the message. When data is collected it will automatically compile the messages into the correct format such that the data being read in from the device will become the body of the email. As such, there will be a pre-programmed message that will be sent as a confirmation that the device is working or as an error message that the device has malfunctioned. If, however, the user wants to override the standard message, he or she has the option of doing so by activating a toggle switch on the front panel. When this occurs, the user will be prompted by an LED to write their own message in the "Attention Message" box, which will then become the body of the email that is sent out. This option is available for those patients that want to communicate something specific directly to their healthcare provider. Although it is often difficult for elderly patients to manage technology and the Internet, the MEDSense data acquisition and email front panel will provide such patients with an easy all in one place to communication directly with a doctor or pharmacist in the event of an emergency.

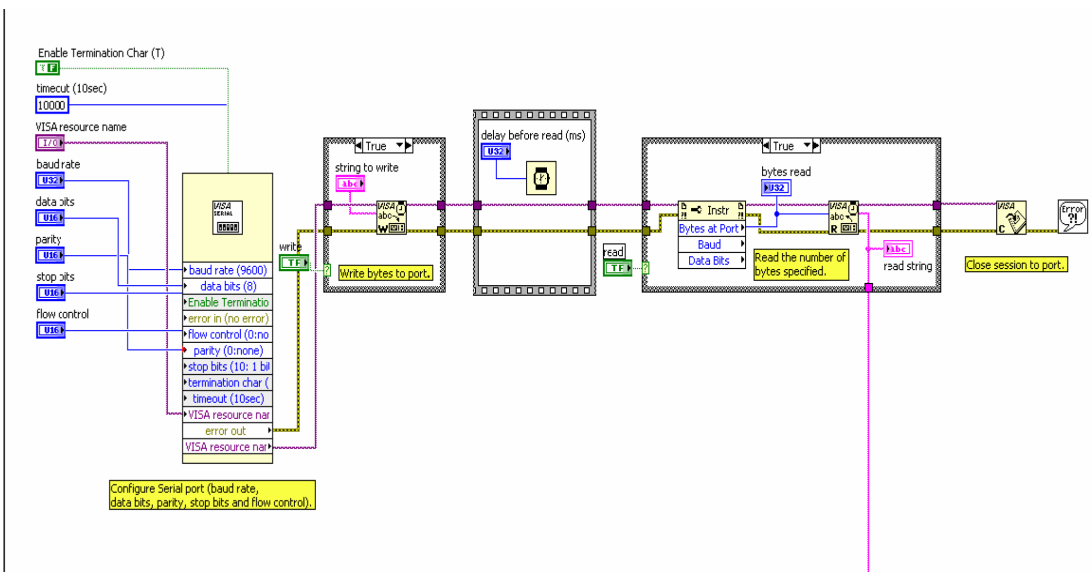

Figure 12- LabVIEW Logic Diagram

It should be noted, however, that the option of overriding the original message is password protected to ensure that the doctor or pharmacist has full discretion as to whether or not the patient should have the option available to them.

vi. Power Consumption

Table 1- Operating Currents and Voltages of Various Elements

Unit	Minimum Voltage (V)	Operating Current (mA)
Microcontroller	5	
Text-to-Speech	5	100
eb505 Bluetooth	3.3	idle: 8 data tx: 35
Motors	5	500
LEDs (all)	Variable	100
AverageRunning Total	5	150

d. **Software**

All programming for the prototype was done in C code. This is a high level language in which members of the group had had previous experience. It was also done in C to facilitate interaction between the computer and the microcontroller. The compiler from HI-TECH software allowed for the conversion of C code to program the microcontroller. Once the code was written the PIC16F877 was programmed using the MPLAB ICD2. The original plan was to use in circuit programming but there was a problem with this function in the ICD2. Instead the group used a development board to program the microcontroller.

There were seven major elements of the project that needed to be programmed individually. The visual alarms, the audio alarm, the vibrating motor, pill detection, the servo motors, the Bluetooth module and the internal clock were all essential to the functioning of the device.

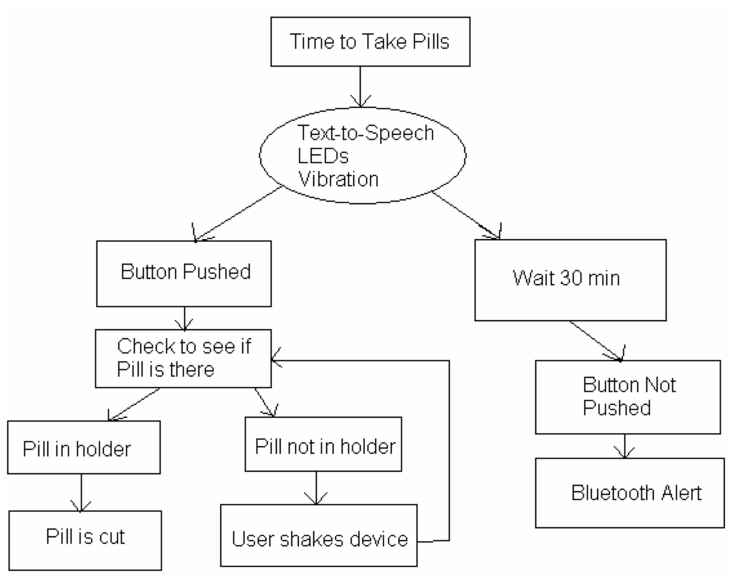

Figure 13- Flowchart of program

This is an overview of how the program will work with user interaction. The alarm will be set off at the correct time. This alarm will set off the text-to-speech module, the LEDs and the vibrating motor. If the button is pushed then the infrared detector will detect if there is a pill in the holder. If there is a pill in the holder the motor sequence will commence and the medication will be distributed. If there is not a pill in the device a status LED will light up and the text-to-speech module will notify the user that there is a problem and the device needs to be inverted to loosen the pills so only one pill could fall through. Once the pill is in the correct position the motor sequence will start. If the button is not pushed within a 30 min. time period the Bluetooth module will send an alert that the person did not take their medication. All of these elements need to work both individually and within the overall program of the device.

i. Visual Alarms

The programming of the visual alarms consisted of creating a program that would turn LEDs on and off at specific times. This can be accomplished by setting the pin on the microcontroller high when the LED should be turned on and low when the LED should be turned off. Another element of the visual alarms would be blinking LEDs. The program for the blinking LEDs used the same program as before but added delay functions. This allowed the certain LEDs to be on for a period of time and then turn off.

ii. Audio Alarms

The audio alarm used in this device was a buzzer. This is more like a cell phone alarm because it would only beep. This was more practical than a text to speech module because it is less imposing and more discrete. The elderly users of the device would not be intimidated by the buzzer which would not necessarily be the case with the text-to-speech module. The buzzer has two different frequencies of alerting the user. The buzzer emits a sound at a quicker pace when there is an error with the device. This would notify a person with vision impairment that there is a problem that needs to be addressed. The buzzer emits sound at a slower pace when just the alarm is occurring.

iii. Pill Detection

One potential problem with the design is that there was no way to ensure that a pill would fall into the holder. If there was not a pill in the holder the medication would not be dispensed and the user would not be able to take their medication. To combat this problem an infrared detector and an infrared emitter were placed on the sides of the pill holder. When there was not a pill in the holder, the voltage would be passed through the emitter to the corresponding pin on the microcontroller. When there is a pill in the holder the voltage would not be passed to the pin and it would register as a low.

The program for the device has a simple if statement. If the pin which corresponds to the detector is low the motor sequence will commence. If this pin is high there is no pill in the holder and the user will be prompted to invert the bottle by the text-to-speech module.

Also, a status indicator LED will also light up if there is a problem with the pill not being in the holder. This allows for both a visual and auditory alarm when there is a problem with the device.

iv. <u>Motors</u>

The motors are the most essential elements to the device. The motors are what cuts the pills and dispenses the medication. The motors used in this device are Servo motors. Servo motors are controlled by pulse width modulation. Each motor is controlled by a square wave with a frequency of 50 Hz. The angle to which the motor moves is determined by the Up-Time and Down-Time of the square wave. As the Up-Time is increased, which also means that the Down-Time decreases to maintain the same frequency, the angle to which the motor moves is increased. Reversing the motors requires a decrease in the Up-Time. Using this theory the group was able to control the motors.

The mechanical system was built before the motors were put in place because it is much easier to make corrections to the motor position than to the spring-blade system. The motors were then tested to achieve the optimum angle to cut the pill. Moving the motor too far could result in breaking the mechanical system while not moving the motor far enough would result in the pill not being cut. After many trials the group finally achieved the optimum angle which was then recorded.

The motor sequence involves first moving the rotational motor to 90 degrees. The hole in the top disc was set to correspond with 90 degrees on the rotational motor. Once the pill falls in, the motor will move to 45 degrees which is half way between the holes on the top disc and the bottom disc. The cutting motor will then move to cut the pill. The blade then stays in while the rotational motor moves to 0 degrees which is the location of the hole on the bottom disc. This results in one half-pill being dispensed. The rotational motor then rotates back to 45 degrees and the blade is then retracted. This would complete the process of dispensing the medication.

The next time the person needs their medication the rotational motor would rotate to the dispensing position which would then release the pill. Following the pill being dispensed the rotational motor will then rotate back to the original position of 90 degrees to allow another pill to fall into the holder.

v. <u>Clock</u>

The group initially attempted to interface with a real time clock but that proved to create more problems than it was worth. Instead of using an external clock, the group took advantage of the timing capabilities of the microcontroller. Using the fact that the frequency of the microcontroller is 40 MHz, a clock can be created using the fact that instructions are carried out every .025 ms. The device utilizes this and creates a clock that counts the instructions and converts it to time. From this an alarm can be set which is a comparison between the values in the time and compares them to the values set in the alarm. When these values match the device notifies the user to take their medication.

vi. Bluetooth

The Bluetooth module utilizes the USART capabilities of the microcontroller. The module was initially programmed using a serial cable to set values for the baud rate and to connect to the Bluetooth dongle. This was achieved through HyperTerminal by typing the commands and receiving ACK for a correct command and NACK for an incorrect command. Once the initial programming was completed the group connected the module wirelessly through a Bluetooth dongle in the computer USB drive using the microcontroller to send data. Using USART and a simple printf function the group was able to send to the computer that the person did not take their medication. This interaction was finalized and ultimately put into the overall program to only send alerts when the user does not take their medication.

e. Future Work

While the group tried to make this device as small as possible, there is some room for improvement. The ultimate goal would be to modify the design so that it could fit on an actual pill bottle. One way to accomplish this in the future would be to put all of the electronics onto one chip. The group purchased embedded devices for ease in programming and mounting but during manufacturing the microcontroller, Bluetooth module and all other circuit elements could be on one chip which would drastically reduce size. The major element that would need to be reduced would be the motors. This could potentially be done with materials such as shape memory materials. Using these materials would greatly reduce the size of the device and make it possible to fit onto a pill bottle.

4. Acknowledgements

The group would like to thank first of all thank the RERC on AMI competition committee for providing funding for this device. Without their financial support this project would not be possible. We would like to thank Dave Kaputa and Dave Price for input on design elements and support throughout the entire design process. We would like to thank Rich and Serge in the machine shop for all of their help in constructing the device. Finally we would like to thank Dr. John Enderle for his valued information on the design process as well as pushing the group to make continued improvements on the design.

Appendix A- Budget

Product	**Subtotal**
Infrared Emitter	$0.20
Infrared Detector	$0.13
Bluespoon USB Dongle	$39.99
PIC16F877 microcontroller	$6.15
Extension Springs	$7.38
Dip Sockets	$2.64
Push Button	$15.47
PCB Board	$44.99
LEDs	$5.00
Rotational Motor	$19.99
Cutting Motor	$35.99
Bluetooth Module	$69.00
Total	**$246.93**