MEDSense: A Portable Pill Dispensing Device

By
Ashley Martin
Christopher Falkner
Ryan Pogemiller
Timothy Coons

Rehabilitation Engineering Research Center
Dr. John Enderle
jenderle@bme.uconn.edu
860-486-5521

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Executive Summary

This proposal outlines the development and production of a pill cap designed to dispense and cut medication for persons with disabilities. This project is being done for the Rehabilitation Engineering Research Center on Accessible Medical Instrumentation (RERC on AMI) competition headed by Dr. John Enderle. The driving goal in designing this device is to provide a means for persons with disabilities to access vital medication when traditional pill caps prove to be increasingly difficult. Certain difficulties associated with the prospective clients' disabilities will be discussed later in the proposal. Also, more specific requirements relating to the programming and mechanical performance of the project will be outlined.

The idea of an accessible pill cap has been successfully implemented both in previous RERC on AMI and NSF projects as well as in industry. A description of these projects and their similarities to this proposed device will be explained within this proposal. The group plans to use successful elements of past projects as well as new ideas to improve the overall performance of the device. Within the discussion of previous projects done in this area will be an outline of patents currently held on similar projects. Research on patents allows the group to create a unique design that will not infringe on any current patents.

Following the summary of past work done on similar devices, a detailed explanation of the project and its requirements will be provided. This will explain both the objectives of the project as well as how the group plans to implement the device. A preliminary budget is also included within the proposal. This budget includes the prices of the proposed major components of the device. The goal is to create a low cost prototype that could be manufactured at an affordable price to be sold to persons with disabilities. This proposed device will provide a better means of both reminding people to take their medication and dispensing their medication than currently available products.

I. Introduction:

i. Background

During a series of scientific innovations sparked by a neo-classical rebirth of interest in the human body around the 17^{th} 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" (Prescot, Microbiology). 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.

Although there are multiple devices on the market that are capable of reminding patients when to take their medications or that dispense pills at certain intervals or that can easily cut pills in half, no one device sufficiently addresses the needs of modern patients. Many pill dispensing instruments are bulky and expensive despite their ability to dispense multiple medications at once. Others are compact and portable but difficult to use for elderly patients and those with physical disabilities. Additionally, while there are many manual pill cutting devices on the market, there are few that are automatic and easy to use, another serious problem for elderly and physically challenged patients. Finally, there is not a single device on the market that is capable of performing all the necessary aspects of pill monitoring in one easy to use affordable unit, thus resulting in an incredible demand for a fully automated device capable of addressing the modern patient’s varying needs.

ii. Clients

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.

iii. Current Market

Although many facets of the pill dispensing process are provided by currently marketed devices, each has significant oversights with respect to the modern patient's needs. Additionally, many devices accurately approach only one aspect of the pill dispensing process, leaving the patient to do the rest of the work, often an infeasible demand.

For patients on a budget, there are many devices available that act as static systems that allow patients to place medications in individual compartments that will unlock at the programmed dispensing times such as the Pill Reminder which is compact, affordable, and easy to use. Although such devices do not satisfy all of the market demands, when combined with other inexpensive static or manual devices, they could cumulatively address all of a patient's medication needs. The E-Pill Vibrating Countdown Timer and Alarm, for example, could supplement the Pill Reminder as a portable device that hangs around the neck and acts as a portable alarm clock. To address elderly patients with hearing loss, the device is capable of vibrating in addition to sounding an alarm to ensure

Fig 1. Although inexpensive and portable, many devices such as these do not meet the demand of the modern market. From left to right A) Pill Reminder B) E-Pill C) EZ-Swallow Pill Splitter

that the patient is clearly notified. The E-Pill device also features a countdown that will remind patients well in advance that there is a medication time approaching. Lastly, a pill cutting device such as the EZ-Swallow Pill Splitter, by American Medical Industries, provides patients with an easier way to cut pills for half dosages. Although the device is manual and requires the patient to have mild use of their fine motor skills, the well designed lever system allows the patient leverage to quickly and easily crack pills into halves. While a combination of these affordable devices certainly addresses many of the market demands, in a rapidly modernizing world, it is desirable to have fully automated devices that reduce the number of individual devices down to one device that performs all tasks.

One such model that has received attention is the Med-Time Automatic Pill Dispenser, by the American Medical Alert Corporation, a small circular device that automatically rotates at given time intervals to make the appropriate pills available at each prescribed time. While the device is certainly compact, weighing in at only 17 ounces when empty, its small size actually inhibits easy use by many patients. Elderly patients often have not only poor eye sight, but also an inability to manage simple small motor skills such as programming a device with small buttons or loading and unloading the pills at the beginning of each month. Although the system allows the patient to tip the device upside down to easily release the appropriate pills, there is no doubt that sorting and dispersing multiple medications into each day's position would be a burdening task. Therefore, the market demands a device that is certainly compact, but also that provides large displays and easy to use buttons and voice commands. Additionally, there is a need for a device that automatically separates different medications from individual easy to fill reservoirs and that is capable of cutting them into halves before dispensing.

Another popular device on the market, the Monitored Automatic Pill Dispenser MD2, by e-pill Medication Reminders, has benefits addressing needs not addressed by the Med-Time device, but once again falls short of satisfying all of the market demands. Unlike the Med-Time device, the MD2 is bulky and expensive. In addition to the unit's ability to dispense predetermined pill dosages at given time intervals, the MD2 features a voice command option that will verbally instruct patients when and how to take their medications. In addition, there is an off switch that the patient must hit when taking their

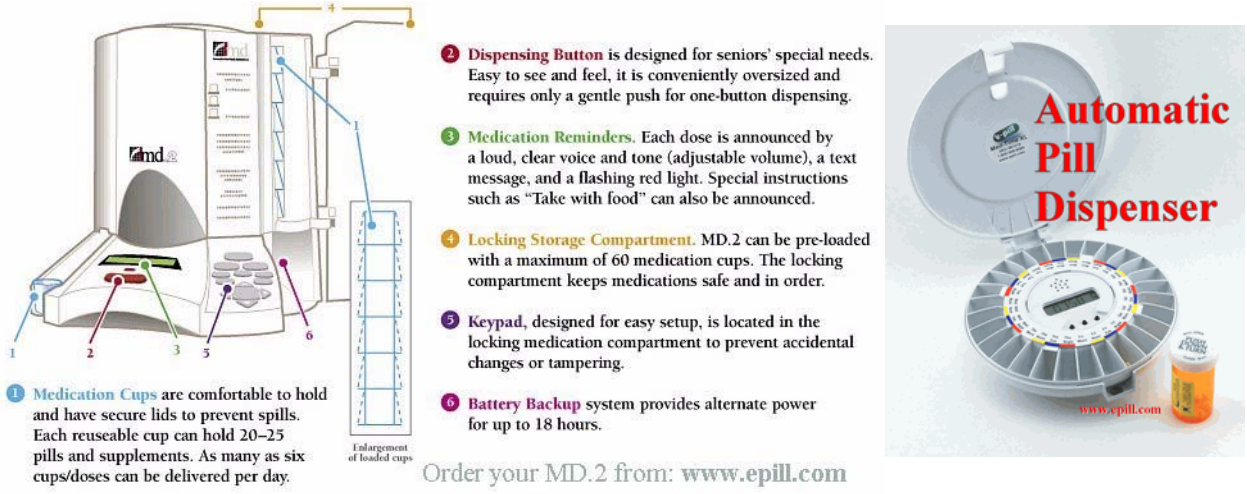

Fig 2. Many automated devices on the market address many but not all of the requirements for a universal pill dispensing device. From left to right A) Monitored Automatic Pill Dispenser MD2 with details B) Med-Time Automatic Pill Dispenser

medications to turn off the alarm system, which also acts as a fail safe method. If, for example, the alarm is not turned off, the MD2 will call a selected caregiver to inform them that their patient has not taken their medications. Although this is a convenient design for elderly patients with chronic memory loss, it is a feature that would turn away younger patients who may remember to take their medications but who do not have access to the device at exactly the prescribed dispensing times. While the MD2 certainly addresses many of the markets demands for a pill dispensing device it, as with the Med-Time device, is also incapable of cutting pills in half before dispensing them, a serious problem as previously discussed.

iv. Existing Patents

CASSETTE FOR DISPENSING PILLS (7,225,597): This device has many cassettes, each filed with a supply of pills and positionable over a target location. The device has a platen beneath the target location with receptacles configured to hold both vials and blister packs. The platen or the cassette is movable so that any blister of the blister pack or the vial can be positioned under the target location to receive a quantity of pills from a cassette.

PILL DISPENSER WITH REMINDER (6,581,797): A programmable vitamin and pill dispenser that is capable of storing multiple pill groups. The dispenser provides reminders to an individual when it is time to ingest the next serving. The serving is dispensed into a cup upon depressing a dispenser button. By loading the individual compartments specific to each serving, an individual does not have to create the serving each time.

ONE DOSE AT-A-TIME PILL DISPENSER AND CONTAINER HAVING SAME (7,100,797): A device for dispensing pills one at a time or one dose at a time includes a unit chamber fittable within/integral with the rim of a bottle. The unit chamber includes a plurality of radial projections which project inwardly to define discrete pill holding areas. The distance between adjacent radial projections is slightly larger than the width of the pill sought to be contained and dispensed by the container. As the bottle is inverted, pills will fall into the pill holding areas, one pill or dosage amount per area. A dispensing cap

is rotatable relative to the unit chamber. A single pill-width window in the cap is positionable opposite the pill holding areas of the unit chamber. When a pill is meant to be dispensed, the bottle is inverted or angled downward, and a single pill in the pill holding area opposite the window falls out of the bottle.

II. Project Description

i. Objective

This product is an accessible pill cap that dispenses the correct amount of medication at a set time for elderly patients or patients with disabilities. It is difficult for some patients to remember when to take their medication, as well as how much medication to take. It may also be a problem for the patient to cut a pill in half if a half dosage is prescribed. The diverse disabilities of the patients for whom we are designing this pill cap include vision loss due to macular degeneration, hearing loss, loss of or decreased strength and motion in one hand or arm, memory loss and Dementia. Some minor problems that affect these patients that must be kept in mind while designing this pill cap are being in a wheelchair, loss of legs, neuropathy in the hands, hand tremors, having small children and being easily intimidated by high-tech machines.

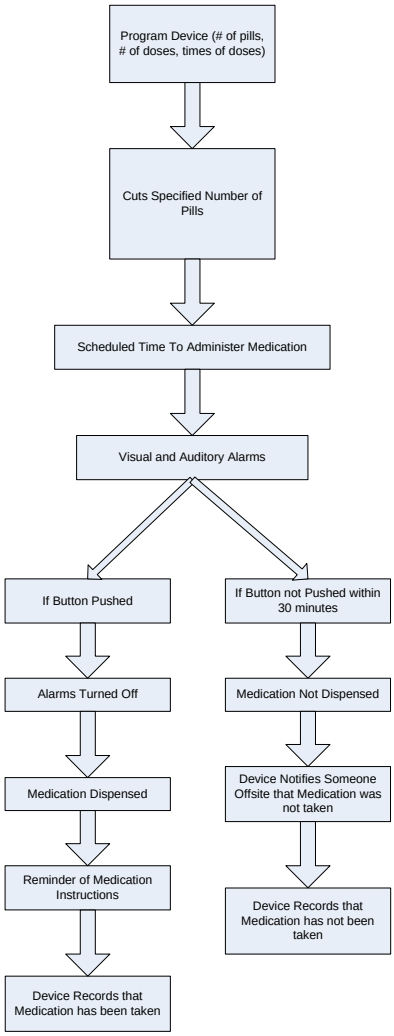

Fig 3. Programming Flow Chart

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.

Other features that are not required but that will add to the accessibility of the product will be implemented. Patient safety is a huge concern for the project plan, so the designers of the device will put the patient's safety as their number one priority while designing the pill dispenser. A security device should be installed to ensure that third-

party members do not tamper with the schedules or amount of dosage programmed into the pill dispenser since this could seriously harm the patient if an incorrect dose is taken. This device should also be waterproof since many medications are taken with water. Water can cause electrical damage and malfunctioning of electrical equipment. A major safety concern for this product is that it is childproof. Children often mistake medicine pills as candy and will unknowingly consume pills that are left lying in a tray. Therefore, it is important that this design ensures the safety not only of the user, but also of any unsuspecting third party members.

This pill dispenser can be broken into six major components. The first component is the scheduled dosage system. A simple front panel will be used and how many pills per dose and the times the pills should be taken will be programmed into the device. The next component is the alarm system. It will include both visual and audio alarms that remind patients each time their pills should be taken, which reads from the previously programmed schedule provided by the user. The user interface is the third component in this device. It should be simple so the patients aren't intimidated by it and the patients will use this to program in the required information about their medication. The next component is the pill transport mechanism. This mechanism will be used to transport pills from the reservoir at the top of the device to the cutting mechanism to the area where the pill is dispensed. The cutting mechanism is the major component. The blade used to cut the pill in half will be powered by a motor. The pill will be stabilized and accurately cut in half by the blade. The last important component of this product is the offsite alert. A wireless system will be used to alert a third party if the medication has not been taken within a specific time frame to ensure the safety and health of the patient.

ii. Methods

In response to the high demand for a fully automatic programmable pill dispensing device that addresses the needs of a universal audience, MEDSense will be a prototype pill dispensing unit that improves and revolutionizes those designs already on the market. It is of the utmost importance that MEDSense not only improve those tasks which are already accomplished by other dispensing devices, but also offer additional features that optimize user convenience. As a result, the design process will require a meticulously well planned vision of how all the device components will be integrated into one unit. The entire system will be divided, then, into a series of subunits that will be designed and conceptualized individually. Once all units are perfected, the overall device will be designed as an integration of each subunit. The seven selected subunits are 1.) the notification system 2.) cutting device 3.) schedule programming 4.) user interface 5.) transportation mechanism 6.) offsite alert and 7.) physical properties. A brief design synopsis of each subunit is provided below.

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. Most importantly, the device will notify the user of when to take their medications. A microprocessor will be programmed with various commands 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 medications. 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.

Cutting Device

The cutting device will likely be the most complicated subunit as it determines the accuracy of the final product. A custom made stainless steel blade will be used to cut the pills. Stainless Steel was selected because it is very strong, non-corrosive, and low cost. Also, stainless steel is an inert material that will not react with any of the medication ingredients. Driving the blade will be a small but powerful motor. Testing with a Tinius Olsen material testing device is necessary to determine the specific force required to successfully split various pill types. When splitting the pill, it is important that there is little loss of pill material and so the cutting device will ensure a weight loss of no more than 1% of the pills original weight. Stabilizing the pill will be accomplished by using a cone shaped funnel that will catch a pill. The pill will become wedged into the mechanism by gravity and the blade will crack the pill from above. The funnel will then separate into two pieces by a spring loaded system and a small motor, allowing the pill to fall. This design will accommodate a wide range of pill sizes and shapes.

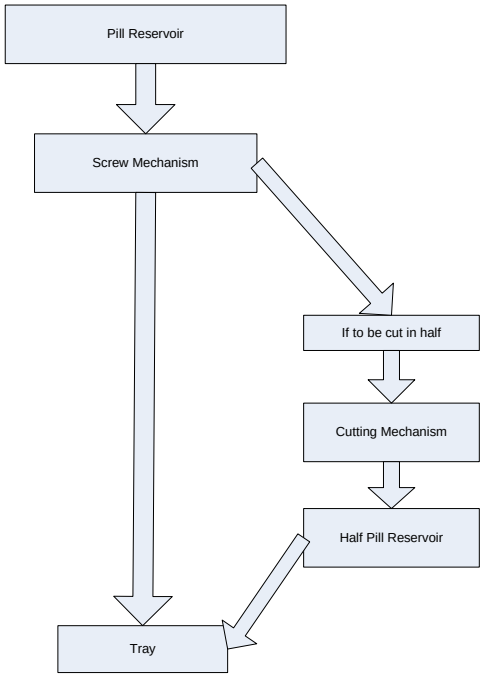

Fig 4. Mechanical Flow Chart

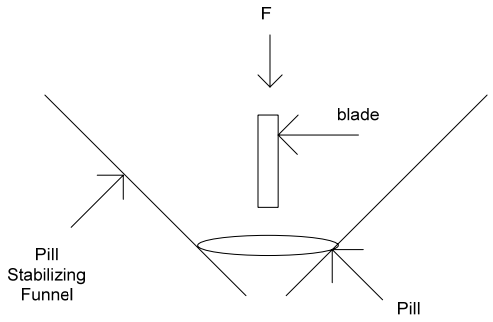

Fig 5. Pill Stabilization and Cutting Device

Schedule Programming

The schedule programming will primarily be executed by the user. An ergonomic front panel will be provided and the user will be prompted to answer basic questions about the medication dosages and times to be dispensed. The question prompts and displays will be programmed as a LabVIEW application that will input from an easy to use key pad and output to an LCD screen. The user will also have the option of adjusting the volume and frequency of the notifications as discussed previously. A possible addition is a barcode scanner that will read all of the medication's scheduling information right from the bottle and will automatically program the device.

User Interface

On the front panel of the device will be a numerical key pad including numbers ranging from 0-9 as well as a "*" and "#" key. The "*" and "#" keys will be programmed as "yes" and "no" to ensure that the user can easily answer prompted questions. Each key will be labeled with large numerical characters and Braille characters. Additionally, each key will be large and coated with soft grip material to accommodate patients with limited motor skills. All key strokes will be verbalized by a text to speech module to accommodate blind users. There will also be a backlight on the keypad to optimize visualization in all environments. Also on the front panel of the device will be a large LCD flat screen monitor that will visualize all prompted questions.

Transportation Mechanism

Pills will be stored in a main reservoir at the top of the device, which will feed into a rotating screw device that loads one pill at a time. The screw will be programmed to rotate a specific number of degrees to release one pill into the next compartment at programmed times. Pills will primarily move from one compartment to the next by gravity but will be directed by the horizontally moving screw mechanism.

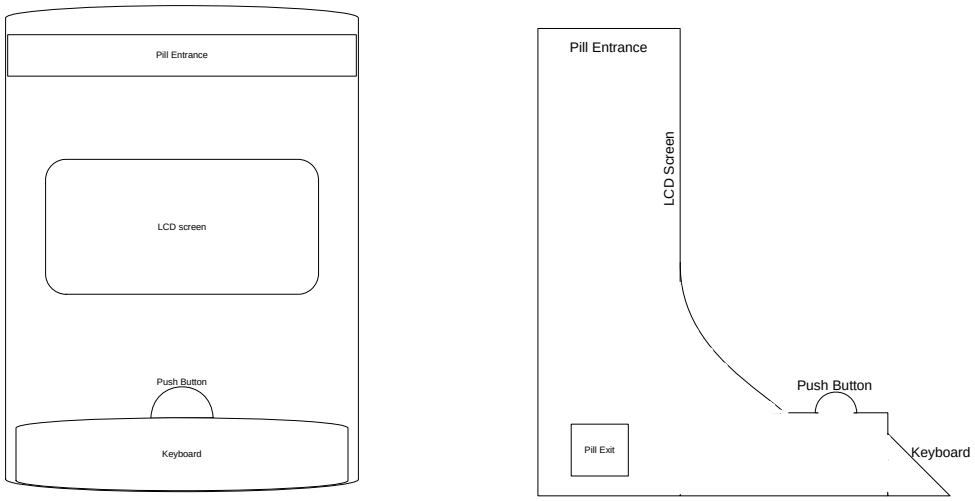

Fig 6. Conceptual Design. A) Front View. B) Side View.

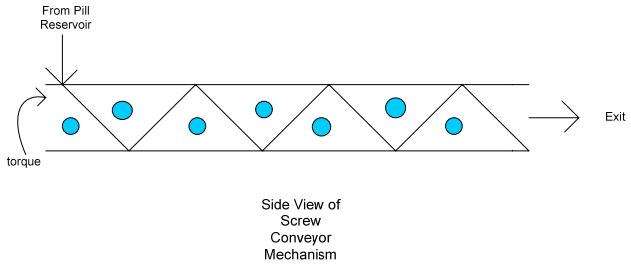

Fig 7. Screw Conveyor Mechanism (side view)

Offsite Alert

An offsite alert is needed to alert a third party member offsite in case a dose is missed. This third party can be a nurse, doctor, pharmacist or family member. It is crucial for the safety of the patient to take their medication on time, and the offsite alert is a safety 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.

Physical Properties

While the final goal for manufacturing the product is to fit it onto a pill cap, the prototype can be larger. The maximum proposed dimensions for this device are 2ft. x 2ft. x 2ft. The final design will undoubtedly be smaller than these dimensions but establishing maximum dimensions adds structure to the design process. The casing material used for this design will be plastic. Plastic encasings are light-weight which would make the device easier to transport. Also, the outer casing will be waterproof since many people keep medication in the bathroom. Another important component of the physical design is the durability of the device. The group proposes that the device should be able to withstand a four foot drop. This would more than account for a drop from a countertop or sink. The pill reservoir would be made of a transparent material. This would allow the user to see how many pills are left so that they know when the prescription is about finished.

IV. Conclusion

This device will provide a reliable way for dispensing the correct amount of medication, an easy-to-use scheduling system, and safeguards in case the medication is not taken. The device will alleviate uncertainty and anxiety amongst users with certain disabilities; these disabilities include being deaf and/or blind, arthritis, etc. This device will also be able to alert the user's caretakers via an email or text message if the user has not been taking their medication. If the prescription calls for ½ dosage of the medication this device will be able to cut and dispense the prescribed amount. For users with arthritis and other disabilities, the ability for a device to cut their prescription will lessen the hassle of taking their medication.

While many products on the market dispense the scheduled dosage, they do not accommodate the need to cut the prescribe medication. In addition to the cutting device, voice directions, brail, and alert lights will be added to accommodate the needs of the user's disabilities. This device will provide a solution to many patients that have disabilities and difficulties with properly taking their prescribe dosages.