Improvement of Prescription Medicine Adherence through the Development of an Intelligent Pill Organization and Dispensary System “Claire”

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SUBMITTED TO THE DEPARTMENT OF MECHANICAL ENGINEERING IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF BACHELOR OF SCIENCE IN MECHANICAL ENGINEERING AT THE MASSACHUSETTS INSTITUTE OF TECHNOLOGY JUNE 2012

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ABSTRACT

Incorrect medication adherence is one of the costliest problems in the United States. In addition to the thousands of people who die each year due to accidental drug administration, the nation spends over $100 billion annually on health care costs directly related to incorrect medication adherence. Most medication non-adherence is caused by unintentional mistakes, especially among the elderly (65+ years old) with multiple regular prescriptions. This thesis describes the design process, preliminary design and test mockups, a preliminary business model associated with a new product concept developed for this costly problem, “Claire.” Claire is a Compact, Low-cost, Accurate, Intuitive, Reliable, Easy medication management system that automatically sorts, dispenses, and tracks pills. By simplifying the pill-taking process, Claire will improve medication adherence among elderly patients with multiple prescriptions and reduce anxiety among their caretakers.

Thesis Supervisor: David Wallace
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Section 1 Introduction

1.1 Team Formation

The team was formed in the fall semester of 2011 for MIT's 2.009: Product Engineering Processes. During this class, a team of thirteen students created Phil\(^1\), an intelligent faucet attachment for commercial kitchens; however, an idea similar to Claire was considered early on in the design process. Ten of the original thirteen team members continued to work on Phil over January of 2012 with an incubator called Concept-2-Company\(^2\), based in Cambridge, MA. During the Spring of 2012, six members decided to continue working together on other hardware product start-up ideas. During brainstorming, the pill-sorting product considered during 2.009 was brought up again, and the subject for four of the team member's theses was chosen.

1.2 Background

Approximately one half of elderly who take at least one medication find adherence challenging,\(^3\) and average adherence decreases from approximately 80% in patients taking medication once daily to 50% in those taking medications 4 times a day.\(^4\) When doctors ask their patients why they have issues with adherence, their patients usually site one of the following reasons: regimen complexity, cost of medication outweighing the benefits, or cognitive decline.\(^3\) Medical non-adherence not only costs the U.S. health care system approximately $290 billion in avoidable medical spending annually, but also puts patients at risk for further illness. A study published by the New England
Healthcare Institute in 2009 on diabetes and heart disease patients found that mortality rates in patients who did not adhere to their medications were nearly double the rates of those who did.\(^5\)

The team felt that these were issues that could be remedied with a low cost, easy to use pill dispensing system, and that if they were able to improve medication adherence among this group, if even slightly, it would have a large impact on individual lives and society as a whole.

However, before the team was able to begin designing, they had to consider the products currently offering similar service. By researching products like traditional pillboxes and other electronic pill dispensary machines, the team was able to choose the correct path for their product. While pillboxes are extremely cheap, they often require a manual dexterity to open that most elderly people do not possess. Additionally, the patient, or their caretaker, must sort their medications themselves, often daily, which can be time consuming and frustrating. Traditional pillboxes, however, allow the user to take a large amount of doses with them, which is a characteristic the team wanted to incorporate into their design.

Research into existing home electronic pill dispensary systems led to three main results: they are extremely expensive (most ranging in price from $395- $895), difficult to program, and don’t allow users to easily take multiple doses with them.\(^6\) These observations led the team to design an inexpensive, easy to use pill sorting machine, with removable pillboxes.
1.3 Product Overview

The subject of this thesis, Claire, is a medical management device designed for a user of any age, but with elderly consumers in mind. Claire consists of multiple integrated systems: pill loading bins, singularization and distribution subsystems, an intuitive user interface, and removable pillboxes. The singularization system has each of the prescribed pills in their assigned bin, and a small vibration motor in each bin helps guide pills one by one through a chute into a centralized hub. Sensors are installed to ensure only one pill falls into the distribution system at a time, where the pill will be held and dropped to its proper pillbox compartment via an actuated pill holding device. The wheel-shaped device holding the pill is driven to its destination through an actuated x-y table aligned above the seven removable pillboxes. Users program their prescription schedule into Claire through the user interface, which controls both the singularization and distribution subsystems.

1.4 Statements of Personal Contribution

As a four-person team working in parallel to complete this project it was essential to communicate and divide work responsibly. The members of the team divided tasks up into four main categories. These consisted of pill singularization, pill delivery, user interface, and overall form factor. These are not exhaustive categories of the work involved with prototyping Claire, but gave the team, as individuals, clear areas of focus throughout the semester. They
were assigned to individuals based on their enthusiasm and experience with the content as demonstrated in the prototyping of Phil during 2.009.

1.4.1 Brent Boswell

Brent Boswell’s responsibility was the pill singularization component of Claire, the system that begins at accepting the user’s pills and ends at dispensing the pill that Claire requests to be sorted into the medicine box. He began by researching current pill and object sorting systems and searching patents for inspiration. With the specific target of an in-home, countertop product and our user’s needs in mind, he developed prototypes at both the sketch model and mockup level to align and individuate pills from a group. Drawing on experience from the 2.009 development process, he iterated to an alpha prototype that meets the needs of the intended users without being as prohibitively expensive as the products currently available.

The product development process requires that the designer both delve into the mind of the user and look at the broader picture, mixing practicality with creativity. This process has altered Brent’s view of everyday goods and sparked interest in previously overlooked design and manufacturing fields. Through the development of Claire he strengthened his ability to work as a team member, engineer a solution under specific parameters, and design a product that improves the life of the user.
1.4.2 Jared Darby

Jared Darby was directly responsible for designing and building the pill distribution system. Because the system was influenced by where the pills would leave the singularization system, he worked with Brent Boswell on making the transition between their designs as smooth a process as possible. He also worked closely with Jessica Iacobucci; the user interface would provide the ability to easily control the pill distribution system, so they brainstormed and designed the most effective solution for users to communicate with Claire.

Designing and building a system that can automatically sort pills was a difficult challenge; after doing a lot of research and brainstorming, he found that there were multiple ways to go about building it. He explored the most feasible options, and reiterated the most effective options before deciding on a final design. What he learned in 2.009 last fall became very useful this semester; brainstorming with his team on the design was the most important thing during the prototyping process. They were able to decide upon better design choices in a timely fashion, and as a result, able to build a better alpha prototype for Claire.

1.4.3 Jessica Iacobucci

Jessica Iacobucci was responsible for designing all aspects of the user interface. She learned a great deal about what is important to consider when designing a user interface through her work in 2.009 and applied this knowledge
to her work with Claire. Through talking to potential users and researching the causes of medical non-adherence, she went through many iterations before settling on a final user interface.

While user interface was her main responsibility, she worked closely with Jared Darby, whose responsibility was pill distribution, throughout the semester. Together, they brainstormed solutions for both of their problems, and found the design that allowed their two systems to communicate the most efficiently.

From working on product design projects throughout the past year, she has learned a great deal about how to make a successful product and what resources there are to grow a product design company. Most importantly, she has learned how to work with others, and how to make a cohesive product even while working independently.

1.4.4 Bennett Wilson

Bennett Wilson’s main responsibility lay in integrating the modules and sub-assemblies designed by his other team members. Specifically, he was in charge of the CAD work behind their design and overall form factor of Claire. Initially this involved form exploration as well as research into current devices. As his team members’ designs became more developed they chose an overall form based on several desirable pertinent characteristics and he worked to integrate their systems in a manner that upheld these qualities.

Through an agreement he made with Dassault Systèmes, the team was
granted license to CATIA for their work on Claire, in which Bennett’s final CAD modeling was done. This was a new software package for him and throughout the process he learned a great deal about sub-division modeling and direct editing tools standard in the automotive and consumer product industries. Although much of his focus was on the modeling of their design, he learned a significant amount about all of our sub-assemblies as well. Specifically, through collaboration with Brent Boswell, he learned about the complexities of mechanically isolating a single item based on the work Brent had done in his sketch model phases. The process is even more challenging when restricted to a limited footprint as he was in this product.

Most importantly, this project helped to reiterate how time and labor intensive the design process is. On a four-person team designing an alpha prototype each member had a significant amount of responsibility. It was essential to uphold team communication in order to ensure their time was put to good use in the window of time they had to design Claire.

1.5 Thesis Overview

This thesis highlights all aspects of the design process. First, the target user is identified as well as their requirements. Next, the brainstorming and initial ideation is shown for each of the four components of the product. The fourth section presents the alpha prototype with support for each design decision. Finally, a business case is included for bringing this product to market, as well as the team’s plan for the future.
Section 2  Intended User and Requirements

Analysis of the causes of unintentional medication non-adherence shows that the system has two fundamental flaws. First, for many patients, the costs of putting in extra effort to have 100% adherence are usually decoupled from the benefits. Second, the process from prescription to consumption is overly complex with too many potential failure points. One example is the step of sorting several prescriptions into daily doses, whether being performed by the elderly patient himself or by a care-taking family member (on a weekly to monthly basis). On the one hand, the patient’s potential lack of manual dexterity or mental coherence can cause errors during sorting. On the other hand, caretakers are less error-prone, on average, than elderly patients, but they often are not available to perform the sorting or do not want to be hassled by the sorting process.

Claire should therefore be a product that can be useful for both types of sorters. If the patient sorts the pills themselves, Claire needs to operate simply and intuitively, and the pillboxes should be easy to open and close. If care-takers are responsible for pill sorting, Claire should save the user time and frustration, and only require the care-taker to visit if something in the medication regime has changed, like the addition of a prescription. To make Claire accessible to all potential users, it is important that this product be designed and produced in order to keep the cost to the consumer low.
Section 3  Design Process

3.1 Initial Ideation and Idea Selection

Once a pill sorting device was chosen, different versions of the device were brainstormed in order to focus the design. Claire could sort pills daily, weekly, or monthly. Figure 3.1-1 shows what the user interface for a daily version of Claire could look like. With this design, users would pour all of their prescriptions into separate pill compartments when they return from the pharmacy. They would also write their prescriptions onto a list similar to the one shown in Figure 3.1-2 where they can designate when each medication is taken. When it was time to take their medicine, users would simply walk up to the machine and press which prescriptions were assigned for that time of day. The advantages of this design are a simple and uncomplicated user interface with few buttons, short programming time, and a machine with a relatively small footprint. One disadvantage is the inability to quickly take several days worth of pills with you since sorting is done every time you use the machine. Also, this design most likely doesn’t save the user much time and trouble, as it closely resembles how the user could take pills without the machine.
Figure 3.1-1: A user interface brainstormed for a daily design of Claire.

```
Prescriptions
1. ____________________ M A E N
2. ____________________ M A E N
3. ____________________ M A E N
4. ____________________ M A E N
5. ____________________ M A E N
6. ____________________ M A E N
7. ____________________ M A E N
8. ____________________ M A E N
```

Figure 3.1-2: Users would write down the name and time of day each prescription is taken. This list would be referenced each time the machine was used.

Figure 3.1-3 is the user interface for another daily sorting design. With this design, the user presses “Prescription” and pours their first prescription into Claire. They then designate what times during the day that medication is taken: morning, afternoon, evening, or night. After pressing “Prescription” again, they
can pour their second prescription into the second pill compartment, and designate when this medication is taken. This process is repeated until all medications are poured into Claire and programmed. The user can press and hold in “Prescription” for two seconds and all prescriptions are set. When it is time to take their medicine, the user just presses the button corresponding to what time of the day it is: morning, afternoon, evening or night. The advantages of this design include pushing one button to receive medication, and not having to remember your medication schedule once it has been programmed. Disadvantages of this machine are similar to the previously mentioned daily sorting machine. Additionally, with this design it is unclear what happens when the user receives a new medication or changes a medication. These are details that could complicate this presently simple user interface.

**Figure 3.1-3:** An alternative user interface brainstormed for a daily design of Claire.
A user interface similar to the one shown in Figure 3.1-3 could also be used to sort pills weekly. In Figure 3.1-4, an additional button could help the user navigate seven pillboxes. With this design, the user would press “Prescription” and pour a prescription into the first pill compartment. The user would designate what times the pills were taken and press “Prescription” again in order to add and program the second prescription. When all prescriptions are added, the user can press and hold “Prescription” and the Claire would sort all pills for the next seven days.

An initial idea was to have the pillboxes on a round tray, which could rotate through to the pill sorting mechanism. To take the pills, the user simply had to walk up to the machine and grab the pillbox associated with the day of the week. If the day they wanted was unreachable, they would press rotate until that day was visible. The advantages of this design include a relatively simple user interface, and the ability to quickly take an entire day or weeks supply of pills with you since all sorting is done at the beginning of the week. Also, at the beginning of each successive week, the user would simply have to press and hold “Prescription” and Claire would sort another week’s worth of pills. The disadvantage to this design is sorting must be done more often than a monthly machine. This could be troubling if a caregiver for the patient is using Claire, and therefore they must visit the patient once a week to fill their pillboxes.
A design, which could sort a months worth of prescriptions at the beginning of each month, was the final version of Claire discussed. Figure 3.1-5 shows what the user interface would look like for this design. The user would pour the first prescription into Claire, press the “Program” button, and designate what time the pill is taken. After pressing “Program” again the user could do the same for the rest of the prescriptions. To assist the user in programming Claire, a screen displays instructions for each part of the process. When the user wants to take their pills, they press “Dispense” and a days worth of pills is dispensed.

The advantages to this design are that sorting is done once a month, which is ideal if sorting is done by a caretaker. This design also encompasses a screen displaying instructions, which could help older users operate the machine.

There are certain disadvantages to this design. A machine with this design would have to be very large, especially if it is holding a months worth of
pillboxes. Distributing pills to this many pillboxes would probably also require the pillboxes to move around within the machine in order to reach the sorting mechanism, which could complicate this design.

Figure 3.1-5: A user interface for a monthly version of Claire.

For the first proposed model of Claire's pill distribution system, the goals were to make it failure-proof while using the least amount of actuators or motors. This system's functions would be to 1) take the pill that comes from the singularization, 2) move it to its proper location in the pillbox, and 3) place the pill in its proper location. The first function was fairly easy to accomplish since the pill singularization would ideally take place above the pill distribution system, and essentially "drop" the pill into the desired place. The only factor that caused for concern was the chance the pill misses the target where it's supposed to be
dropped, and the possibility of landing into an improper part of the pillbox as a result.

The second and third functions were the more difficult because motorized parts would need to be used in order to complete the functions. Given that Claire would handle a week’s worth of the customer's medication schedule, the pillboxes would be modeled similar to those in the market already. Most weekly pillboxes are in the form of a rectangle: seven columns representing each day of the week, and each row representing the different times of day that one would take his/her medications. Thus, two actuators would be needed in order to have the capability of automatically moving a pill along the two axes of a rectangular pillbox, and possibly one more to place the pill into its proper compartment.

After brainstorming a way to do the same job using less than three actuators, it was found that only two actuators would be necessary if the rectangular pillboxes were arranged in a heptagonal tray. The pill would drop through a chute into a sitting “L”-shaped structure, that structure would be linearly actuated to vertical chutes aligned to the compartments of a daily pillbox corresponding to the different times of day, and the pills would be dropped into its proper location in a purely mechanical way. The tray would also be motorized to rotate around its central axis (like a circle) so it could rotate to be filled day-by-day.
Figure 3.1-6: Early sketches of the first iteration of the pill distribution system. The pillboxes are arranged in a heptagonal tray (top view).

Figure 3.1-7: Early sketches of the first iteration of the pill distribution system. The pillboxes are put beneath the above distribution apparatus (front view).
The pill holder in this model would be connected to a base that moves along a motorized leadscrew, parallel to the slots and pegs (as shown above in Figure 3.1-7). The pill holder would rotate along an extruded peg of the base, and it would be hinged to the base through a torsion spring. As it moved towards the slots, the top of the pill holder would hit the pegs, and as a result would be forced to compress the torsion spring hinge to prevent the pill from falling into the wrong slot. Once it reached its proper slot, the motorized leadscrew would spin in the opposite direction so the pill holder (the pill still held) would start moving back towards the chute. As the holder hits the first peg on its return, the torsion spring would stretch, and the pill would fall out of the holder due to gravity in its proper slot. The slot's dimensions were the same as each of the compartments in the pillbox, and there would be minimal clearance above the pillbox. Thus, there would be no chance of the pill going into the wrong compartment after it fell in the desired chute.

After weighing the advantages and disadvantages of each design, it was decided that a machine that could sort pills weekly would allow for testing the pill singularization and distribution systems, while most adequately serving the intended user.

3.2 Mock-Ups and Sketch Models

3.2.1 Pill Singularization

To sort a user's prescription into dosages, the pills need to be removed individually from the group. While this problem is solved for pharmacy pill
sorters, Claire demands a solution appropriate for an in-home, countertop size product. The primary consideration in this step is reliability, though size, weight, noise, and cost are also important factors in choosing a singularization method.

The process of pill singularization was addressed by reducing the number of axes in which the pills can travel. Two methods were considered for flattening the group of pills to a single plane: rotation and vibration. Rotating a hopper of pills at high speed will cause them to flatten out on the circumferential wall. Alternatively, vibrating a group of pills will fluidize them, allowing gravity to flatten out the group evenly.

Once the pills lie on a single plane they can be funneled into a single line. With a rotating hopper, the pills will go to the point radially farthest from the center. This rotating approach provides a fast and reliable method for concentrating the pills on a plane, but as an in-home product Claire places more value in cost and noise than in speed. Rotating each hopper of pills proved to be an expensive approach, but using one rotational element for all the prescriptions required that each prescription be put back into its bin after the pills for the period were removed. Using rotation to flatten out the pills was not a suitable approach for Claire.

A vacuum singularization system, seen in Figure 3.2.1-1, was tested as a sketch model in Fall 2011 2.009 Product Development. This system consisted of a hopper with an agitator to fluidize the group of pills. At the end of the hopper the pills rested against a wheel. The wheel was hollow and had a vacuum pulled inside of it. A small hole on the circumference of the wheel was drilled to suck a
pill from the group onto the wheel and hold it. After the wheel completed one half of a turn the pill was cleaved off.

Figure 3.2.1-1: Acrylic model of a vacuum singularization system.

The vacuum sketch model showed that the method is viable for pill singularization. Single pills were successfully cleaved from the vacuum wheel and sorted into a pill box. The system required several subsystems, though, that are ungainly for a countertop product. As with the rotating method, using a one singularization device is preferable from a cost standpoint but requires that pills be cycled from their bin to the device and back to their bin every time the pills are sorted. The vacuum system requires tight sealing, and running a vacuum pump is noisy.

Vibratory feeders are commonly used in handling large quantities of small objects. These feeders use vibration to move the objects up a chute one at a time. A bowl vibratory feeder, like the one pictured in Figure 3.2.1-2, is designed
to work from an AC power source and vibrates at the utility frequency of the power outlet, 60Hz in the USA. These feeders are tuned to this frequency. Since Claire is designed for the home, using a precision tuned bin for each prescription is restrictively expensive, and, once again, if one device is used for singularization of all the prescriptions the pills must be cycled to and from the device.

Figure 3.2.1-2: A vibratory bowl feeder handling small plastic parts.

The final approach to singularization, a vibratory chute, is a simplified system derived from a bowl feeder. Instead of moving the pills up a chute, they travel down a shallow incline. Vibration flattens the pills in the chute so that they feed through one at a time. A vibration motor at each bin is reasonably
inexpensive and allows each prescription to stay in its bin through the singularization process.

A foamcore model was used to test the vibratory chute method and determine the proper geometry. A chute made from a V-shaped length of foamcore held the candy “pills,” and a motor with an asymmetrically weighted shaft provided the vibration. Both capsule and tablet-shaped candies were used, and the pitch of the chute was varied to determine the optimal slope of the chute. It was important to test both single and multiple pills in this model since the last pill would not have the weight of any other pills pushing it down the chute.

The candy “pills” had different coatings as well as being different shapes. The tablet-shaped candy had a hard, slick shell, and the capsule-shaped candy was a gelatin. The hard-shelled tablets had no trouble moving down the chute, as they would roll down with little friction. The gel capsules had a more difficult time moving down the chute since their circular cross section was aligned perpendicular to the direction of travel, and the gelatin material was tacky. Since the gel capsule was much more resistant to motion down the chute, a pitch was chosen that ensured that the capsule would make it down the chute as a single pill. This angle was found to be around 3 degrees.

The foamcore model also tested vibrating a pile of “pills” located at the top and bottom of the chute. Figure 3.2.1-3 shows the results of vibrating a group of tablets at the bottom of the chute and capsules at the top of the chute. Both tests were successful in that the “pills” ended up in a line in the chute.
Figure 3.2.1-3: A demonstration of the effect of vibration on a group of pills in a chute.

After successful tests of the foamcore model, a solid model was constructed and 3D printed. The bin, seen in Figures 3.2.1-4 through 3.2.1-7, was designed to hold a full prescription of pills and line them up in a chute at the bottom of the bin. Baffles in the bin were inserted to direct the pills to the chute and to keep the full weight of the pills from resting on pills in the chute. The bin would have a vibratory motor attached to the bottom under the chute to localize the vibration where it was needed.
Figure 3.2.1-4: A cross sectional view of the first solid model bin.

Figure 3.2.1-5: Isometric view of seven bins as they would sit in Claire.
**Figure 3.2.1-6:** Bottom view of seven bins with a central hub pill selector.
To go along with the bins for each prescription, a device was needed to select which bin would be dispensing and to allow only one pill to feed out from the bin. A central hub selector, seen in Figures 3.2.1-8 and 3.2.1-9, rotates to the position of a bin and translates up to open the bin's chute, allowing the pill to feed out. A 360 degree servo motor provides a full turn of positional rotation for the hub, and the hub mounts to the vertically translating stage by this servo motor. In order for this selector to reliably allow one pill out of the bin chute a break-beam sensor is positioned at the bin chute opening. When the sensor detects a pill entering the hub it notifies the selector to stop translating upward. The pill is fed out of the bin into the hub, and when the pill is fully out of
the bin the selector lowers, closing off the bin. The sensor A test setup of this IR LED and phototransistor is pictured in Figure 3.2.1-10.

Figure 3.2.1-8: Hub pill selector with servo installed.

Figure 3.2.1-9: Detail of the chute-hub interface when open.
The first 3D printed iteration was tested with a variety of pill sizes, shapes, and textures, pictured in Figure 3.2.1-11, and though it successfully fed pills out of the bin chute, as seen in Figure 3.2.1-12, it did not perform reliably. Capsules tended to jam around the baffles in the bin. The 3D printed material was not finished smoothly enough to allow pills to flow easily through the bin. The smaller vibratory motor was not as effective at vibrating the chute as the one in the foamcore model, so the angles of the baffles and chute proved to be too shallow. The hot glue mounting of the motor on the bin is likely damping the vibration as well. The smaller vibratory motor did provide more consistent vibration, though, so with adjusted geometry the feeder is more reliable with the small motor.
Figure 3.2.1-11: Tablets and capsules used to test the 3D printed vibratory bin feeder.

Figure 3.2.1-12: Pills aligned in the bin chute after vibration.
3.2.2 Pill Distribution

After early design sketches of the pill distribution system with only two motors, there were a few design problems that were foreseen to be difficult to solve. The mechanical method of the pill holder dropping the pill into its proper slot was complex, and needed proper relations of various effective lengths for it to work without failure. There were more degrees of freedom in the pill holder alone where the system could fail, which was far from ideal. The variations of pill shapes and sizes would also affect the size of the pill holder. The spring constant of the torsion spring, the speed of the stepper motor’s movement, the material of the pill holder, and even the size of the pegs would be crucially important for this very delicate design system to work.

The aforementioned difficulties showed that it would be much easier to build the distribution system if another motor was incorporated into the design. Despite the goal of reducing the total number of motors in the system as much as possible, there seemed to be a much better exchange between level of design difficulty and the cost of another motor. With the addition of a third motor, the design was much more common than what was brainstormed before. The team decided to design and build an x-y table, which is used in a variety of applications. It is used in CNC machinery and laser cutting, as well as in toy claw machine games, which was analogous to the first sketch model we completed.

The sketch model of the pill distribution system consisted of two leadscrews, three stepper motors, a slider drawer, a 3D-printed plastic arm for a stepper motor, and two 3D-printed plastic parts that travel along each of the
leadscrews (thus, one of the parts moved in two dimensions). This was held together in a rectangular structure that was made with laser-cut acrylic. Two of the stepper motors were placed outside the acrylic structure, and they were coupled to nylon leadscrews within the structure (through fitted holes). As shown in Figure 3.2.2-1 below, one of the 3D-printed parts moved along the leadscrew in the Y-direction, but was also connected to the end of the leadscrew in the X-direction. The X-leadscrew had a 3D-printed piece that had a cylindrical shell to hold pills, and an "L"-shaped guard beside it.

![Figure 3.2.2-1: SolidWorks models of 3D-printed lead screw parts. The Y-lead screw piece (left) helps move the X-lead screw piece (right) in two dimensions.](image)

The third stepper motor would sit on top of the X-leadscrew piece, as shown below in Figure 3.2.2-2. The stepper motor had an "arm" piece connected to it, which had bristles attached to the bottom of the arm. The X-leadscrew piece was the piece that resided over the desired pillbox compartment where a certain pill should be dropped. The motor arm would rotate and brush the pill out of the cylindrical container when appropriate, and the pill would fall through the guard (with the same dimensions as the compartment) into the pillbox.
While testing the model, there were a few things that needed to be modified on the spot. The stepper motor that moved the X-lead screw piece was placed on the opposite side of the Y-lead screw piece; due to the size and weight of the motor, the nylon lead screw did not have enough strength to slide the motor along with it when it moved. A slider drawer was placed underneath the stepper motor in order to accommodate this. This helped the stepper motor slide parallel to the Y-lead screw piece with minimal force. In order for the lead screw pieces to move without rotating with the lead screw, small pegs or extrusions were designed behind the parts; a small hook was designed on the Y-lead screw piece (as shown above in Figure 3.2.2-1) as well, where a rubber band would be hooked from there to a piece on the other side of the table that would slide with it. The rubber band provided enough resistance for the part to stay upright.
3.2.3 User Interface

One of the initial ideas for a weekly pill sorting machine was to arrange the pillboxes on a circular tray. While this arrangement would require a large tray, it would have advantages that outweighed its footprint. The pill singularization and distribution systems could be stationary and the tray could rotate the pillboxes to these devices. This would also allow the user to quickly access the pillboxes since only a few boxes would be covered by the pill sorting systems at a
time. Figure 3.2.3-1 shows what the tray would look like for this design. The tray would be labeled with days of the week.

*Figure 3.2.3-1: Circular tray to house pillboxes.*

Figure 3.2.3-2 shows the pillboxes that were designed for this tray. Each compartment would be labeled with M, A, E or N for morning, afternoon, evening or night. The dimensions for these trays were based off of current pillbox designs while incorporating how many prescriptions our design can sort, and pill dimensions for the largest pills manufactured.
Once this pillbox was designed in SolidWorks, it was observed that each pill compartment was very deep relative to the size of the compartment opening. It would be difficult for the user to reach in and remove the pills from the compartments. One idea was to design a lid that would enable users to dump the contents of the container into their hand. Users could slide the lid to reveal the pills for the morning, and dump those pills into their hand. When it was time to take pills in the afternoon, the same method could be used and only those pills would be dumped. Figure 3.2.3-3 shows how the pillbox was changed.
to incorporate this sliding lid, Figure 3.2.3-4 shows the sliding lid, and Figure 3.2.3-5 shows an assembled pillbox.

Figure 3.2.3-3: Early pillbox design which a lid can be slid onto.

Figure 3.2.3-4: Sliding lid for early pillbox design

These lids would be stacked next to Claire, and if users wanted to take a pillbox with them for the day, they could remove the pillbox from the tray and attach one of the lids.
While this design would keep pills protected from the environment and would allow users to take the pillboxes with them, it could still be improved. When talking to potential users, they expressed to us how cumbersome their current pillboxes were. They wanted a pillbox that could easily fit in their pocket without attracting attention. Additionally, this design could be improved if the lid could wrap around and was attached to the pillbox. Our final pillbox design was constructed with these ideas in mind.

3.2.4 Form Factor

Before settling on a final design based on the sub-assemblies discussed in the previous sections, several form factors were explored as part of the early design process. As the most critical module of the device, these designs focused on complimenting the singularization mechanism. In particular, it was
understood that this process would be greatly simplified by centralizing the active pill isolation location. This led to designs that utilized a circular pill loading stage in one form or another. Figure 3.2.4-1 shows some early concept sketches based on this notion.

![Figure 3.2.4-1: Early concept sketches exploring form factor.](image)

The three most visually defining features of Claire are the loading stage, the main body where pill distribution occurs, and the removable pill boxes, so these were the main areas of focus. Before deciding on a form factor direction many shapes were explored in the context Claire would likely be used. In particular, they were examined in bedroom, bathroom, and kitchen environments. Figure 3.2.4-2 illustrates some of the concept designs that were explored.
As a medical assistive device, one of the themes deemed important for Claire to convey to users was health and well-being. After examining different shapes we concluded that a tapered base and large top and loading station was effective in communicating this message. The broad stance of these designs
can be seen in Figure 3.2.4-2 in concepts 2, 5, and 6. A square base was more desirable than a round one because Clair has a distinct orientation during use and needs to communicate this to users. However, as previously mentioned the loading bins were most space efficient in a circular orientation. For these reasons we chose to pursue a design similar to 6 as seen above.

Section 4 Final Design

4.1 Pill Singularization

The final pill singularization design addresses flaws discovered in the 3D printed mock-up: the path of the pills is smoother, the parts are better finished, the vibratory motor is more firmly secured and tuned to the bin, and the hub selector design is refined. The final design better addresses how to get the last pill in the bin to feed out and does not struggle with capsules.

The bin design is host to several changes that improve the reliability of feeding pills to the hub and ultimately to the distribution system. Instead of housing platforms to support the pills not in the chute, the final bin has a helical ramp that acts a chute for the entire quantity of pills. The ramp, seen in Figure 4.1-1, is sloped such that the pills rest against the cylindrical body of the bin. Encouraging the pills to rest on the outer diameter of the ramp effectively lengthens the chute, allowing it to hold the entire prescription’s worth of pills. A tilted platform at the top of the bin covers the deeper part of the ramp and guides the pills poured into the bin to the ramp entry. At the bottom of the bin, the
A helical ramp straightens toward the hub of the system. The exit chute is therefore offset to one side of the bin.

**Figure 4.1-1:** *The final bin incorporates a helical ramp to smooth the path to the exit chute.*

The problems encountered with feeding pills, especially the last pill, from the mock-up bin were largely due to the surface finish of the part combined with the small amplitude vibration. The final prototype bin, seen in Figures 4.1-2 through 4.1-4, is finely sanded to a smooth, slick finish, allowing the pills to flow more fluidly down the chute. The vibratory motor is also integrated into the part design to translate as much vibration as possible to the bin. The motor speed is tuned through testing to promote maximum excitation of the pills in the bin. As
seen in Figure 4.1-5, the final prototype, unlike the previous iteration, does not struggle to feed capsules.

**Figure 4.1-2**: 3D printed helical ramp.

**Figure 4.1-3**: View of 3D printed final prototype bin from above.
Figure 4.1-4: Bottom view of final prototype bin with vibratory motor installed.

Figure 4.1-5: Final prototype bin running a test feed of 30 capsules.
To integrate the hub pill selector into Claire the mechanism was redesigned with a support from the base instead of from the top. The selector rotates, driven by a 360 degree rotation servo motor, on a stage to the desired bin. Instead of translating the selector vertically, an actuated gate opens to allow the pill to be fed into the hub. Once the gate is opened the bin is vibrated, and an IR sensor tells the selector when a pill is fed into the hub. The pill drops into a funnel and ultimately into the pill distribution system wheel.

4.2 Pill Distribution

The final design of the pill distribution system was completed after acknowledging the design flaws that hindered the apparatus from achieving its main duties. With the former designs of the sketch model, there was a chance that the pill that dropped from the singularization system may land in the shell, and possibly fall out upon contact. There was also a chance that the stepper motor arm may not always be effective in taking the pill out of the shell, and properly placing it in its desired compartment. The weight of the stepper motor on top of the leadscrew may warp, alter, and maybe even halt the movement of the pill holder; these problems called for a redesigned model that was more precise, and used lighter objects to complete the intended goals.

The first thing that was changed was the pill holder. It was changed into a motorized “wheel” that would completely enclose the pill in its container, and release the pill at the correct moment for it to fall directly into its proper
compartment. The wheel design, shown below in Figure 4.2-1 & 4.2-2, was made of three 3D printed parts, and was controlled by a servomotor (which is significantly lighter than a stepper motor). The servo controlled the 180° movement of the wheel. The wheel had a capsule hole inside of it that aligned with its outer stationary shell when the entire piece was ready for a pill to drop. When the pill dropped, the hole was deep enough so it wouldn’t pop back out of the wheel. The piece that was driven by the leadscrew was connected to the outer stationary shell, and when it moved to its proper position, the servo rotated the wheel 180° for the pill to drop straight through the bottom hole of the stationary shell and directly into its compartment. After testing the wheel a few times, it was found to be much more effective and less prone to failure than any of the prior designs we had brainstormed.

*Figure 4.2.1: An assembled SolidWorks model of the pill “wheel”.*
The leadscrew alignments were also redesigned to accommodate the movement of the stepper motor that was on the slider drawer before. It was moved to the other side of the x-y table so that it would be much easier for the motor to move in parallel to the X-lead screw. In order to accomplish this, the Y-lead screw piece had to be redesigned so that both leadscrews would go through it. Because of the redesign, one leadscrew was placed slightly above the other. A slider drawer was also machined out of laser-cut acrylic and bearing balls, so the stepper motor can slide easily. The acrylic structure was designed so it would assemble together to create minimal necessary clearance for the pillboxes to slide beneath the x-y table. Both sides had approximately 1.5" clearance for symmetry, and the back has almost two inches of clearance because of the size of the wheel design.
Figure 4.2-3: The final SolidWorks design of the Y-lead screw piece. The X-lead screw will go through the tight-fit hole 0.5" below the Y-lead screw and connect to a stepper motor.
Figure 4.2-4: A hand-drawn top view of the pillbox design, and the calculated lead screw lengths and acrylic dimensions for the final design. This was based off of the lead screw pieces' interactions with each other, as well as their maximum necessary x-y range.
4.3 User Interface

After several iterations, the final user interface shown in Figure 4.3-1 was chosen because it is relatively simple, easy to use, and intuitive to program new or different medications.

![User interface from the final design](image)

**Figure 4.3-1: User interface from the final design.**

The user opens the lid of Claire, dumps the prescriptions into separate bins, and then closes the lid. The user presses “Prescription” and the LED labeled “1” lights up to indicate to the user that they are programming the information for the first prescription. The users presses what time of the day this prescription is taken, and those buttons light up and remain lit. If the user made a mistake, they can press that time of day again, and the button light will go out. Once the user has the correct buttons pressed for this prescription, they can
press “Program” again, and the second LED will light up. The user programing continues with this process until all prescriptions are programmed into Claire. When all information is entered, the user can press “Fill” and the seven pillboxes will be filled.

When it is time for the user to take their medication, they can remove the pillbox, which corresponds to that day of the week. The user can take the pills for that time of the day and then put the pillbox back into Claire, or take the pillbox with them for the entire day. When a weeks worth of pills have been taken, the user can put all seven pillboxes into Claire and press “Fill.” Once again, the pillboxes will be filled, and the user can come back and remove whichever pillbox they need.

If the user’s medication regime changes in anyway, Claire is simple to reprogram. If the medication remains the same, but the time of day when it is taken changes, the user must press “Program” until the LED corresponding to that prescription is lit. The buttons will be lit corresponding to when the prescription is currently taken. The user can press these buttons until the new ones are lit. After that, the prescription will now be given at those times. The same process can be used if a prescription is replaced by a new prescription. Make sure the pills for the previous medication are removed from the container in Claire, and then fill that container with the prescription. Press “Program” until that prescription’s LED is lit and adjust the settings. If the user wants to remove a medication, they can press “Program” until the LED corresponding to that medication is lit. The user has to press the time of day
buttons until they are no longer lit, and then Claire will no longer sort that prescription.

The circuit board for this user interface was designed using a software called CadSoft EAGLE PCB Design Software. Figure 4.3-2 below shows the connections necessary between the back lit switches, the LEDs, and the I/O expanders.

![Circuit board layout designed with CadSoft EAGLE PCB Design Software.](image)

Figure 4.3-2: Circuit board layout designed with CadSoft EAGLE PCB Design Software.

The circuit board was assembled by hand and is shown in Figure 4.3-3 below. Once installed into Claire, button caps are added to each back lit switch in order to display the letters, which indicate the time of day.
4.4 Form Factor

Once we had decided on final directions for each of our sub-assemblies, we were able to integrate the designs into our product in accordance with the form factor direction we had chosen earlier. Because Claire was ultimately designed in CATIA for its industrial design tools and advanced surfacing capabilities this meant first remodeling the SolidWorks parts. This was done from the base up, starting with the pill box design. As previously discussed the goal of our pill box was to create a design less bulky than the current market standard. Figure 4.4-1 contains our final design. The cover design consists of a thin piece of sliding acrylic that can be opened and closed using the tab at the end. When closed it retracts into the front of the pill box. When the pill box is
inserted into Clair's loading dock the slide is automatically retracted as the tab interferes with the docking station. This ensures that the slots are open for the filling process whenever the pill box is in place.

*Figure 4.4-1: Pill box design and dimensions.*

The next step in Claire's design was to integrate the UI into the new form factor. Because we chose a design with a tapered base and smooth edges, it was necessary to add a new face on the body to mount the buttons and board. Additionally, this face needed to be angled towards the user instead of downward like the existing tapered face. Claire will typically be used on countertops, and the user will either be standing or sitting when interacting with it. Taking this into account we decided on an upward angle of 12 degrees between the UI face and the vertical as illustrated in Figure 4.4-2.
Figure 4.4-2: Angle between the UI face and the vertical.

After the addition of the UI face and buttons, the loading bins were modeled as seen in Figure 4.4-3. An initial test of these bins showed that some pills would get stuck during the filling process, so they needed to be redesigned. After Brent Boswell finished the bin redesign he passed on the design intent of the new shelving system and it was modeled in CATIA.
The new bin design utilized a helical shelf instead of two slanted ones in order to improve the pill dispensing reliability. The complexity of this design required extensive wireframe and surface modeling to generate the necessary geometry. The process is documented in Figure 4.4-4.
Finally the pill singularization system was integrated into the design. Because this system required a vibratory agitator, a seating component was also designed in which the bins would fit snugly, as seen in Figure 4.4-5. This shelf is decoupled from the rest of the body on rubber grommets to dampen vibration. If the user wishes to remove a bin to retrieve medication or for any other reason, they simply lift out the back of the bin tilting the top towards the center of the device and it comes out of its seating.

![Figure 4.4-5: Loading bin seating component](image)

After the addition of these components we arrived at our alpha prototype. A render of the completed Claire is shown in Figure 4.4-6 below.
In its current alpha prototype stage the lid to Claire is a basic lip-groove press fit. In the final design this will be hinged on the back and swing open during the loading process. Additionally, the clear plastic lid will have label locations to attach the prescription above the appropriate bin.
Section 5 Business Case

5.1 Market

The market for medication management devices is large and growing. 12 million seniors – 80% of who want to remain independent – currently take 5 or more medications. And that number will double by 2020 due to rising rates of prescriptions per person, increasing lifespans, and changing demographics. Figure 5.1-1 breaks down the population of U.S. seniors to project CLAIRE’s market penetration within the first 3 years of business.

![Figure 5.1-1: Segmentation of U.S. seniors to predict market penetration.](image)

There are several potential customers, such as the 20 million non-seniors with 5 or more prescriptions, assisted living facilities, and the seniors themselves. Nevertheless, seniors’ family member caretakers will be Claire’s initial target.
market because they represent the most penetrable segment. They crave convenience, demand premium care for their parents/relatives (often more than the patients themselves), and are prepared to pay more in the context of increasing health care costs. This tech-savvy population, moreover, is not afraid to deal with advanced interfaces.

5.2 Competition

Given this large opportunity, many products and services exist to help manage medication. Home pill management can be substituted altogether by personal nurses or assisted living facilities. In addition, product category rivals include online pharmacies, pre-sorted disposable packs at brick-and-mortar pharmacies, and dedicated reminder systems. Finally, product form competitors range from $2 plastic pill boxes to machines with sophisticated features for over $1000. Figure 5.2-1 maps just some of these product form competitors in the competitive landscape.
5.3 Competitive Advantage and Strategic Positioning

Claire delivers 3 significant advantages over existing devices in this crowded field: automatic sorting, flexibility, and affordability. That is, CLAIRE is the only product that offers the full functionality of higher-end devices, accommodates varying lifestyles and different pharmacies, and has a mass market price tag.

How can Claire be priced at a fraction of its high-end competitors while provide all of their features? In other words, if we can sell a sophisticated device for a lower price, why have current manufacturers not done so already? The answer lies in Claire’s comparatively lower cost and strategic positioning. Claire can be produced at a small variable cost due to its compact profile, simplicity, and minimal use of moving parts. That – coupled with minute research and development expenses – results in inexpensive per-unit costs.

Figure 5.2-1: CLAIRE's position within the competitive landscape of home medication management devices.
Furthermore, as a low-cost alternative to current options, CLAIRE will trigger a paradigm shift in the industry away from high-margin pricing. Current companies price their devices significantly above cost because they can; insurance coverage and customer naiveté allows the industry to maintain these artificially high prices. Once one company transitions to an aggressive pricing strategy, however, the rest of the industry will typically follow (albeit hopefully not quite to Claire’s low price). The key to success lies in exploiting the first mover advantage to gain market traction and trust.

5.4 Marketing Tactics

Claire will be brought to market in 3 phases. First, early adopters will be targeted through the crowd funding platform Kickstarter\(^1\), inbound marketing tactics, and primary care geriatricians. Second, as the network of geriatrician promoters grows and Claire gains widespread legitimacy, distribution channels will be expanded to pharmacies and promotion to a full-scale advertising campaign. Third, Claire will also be found in a variety of retail stores as its lifecycle matures.

Claire’s pricing scheme will either require a single upfront charge or involve a subscription model with monthly fees. In both cases, a delicate pricing paradox arises: Claire’s price must simultaneously connote a bargain (like $99.95) and avoid the stigma of cheapness, or unreliability (as a flat $100 does). $95 upfront or $9.50 per month represents a compromise between the two
extremes. In addition, a deluxe version will be introduced by the third phase to exploit price discrimination, and the foot-in-the-door technique of a 1-month free trial will increase adoption.

Because most consumers are unaware of the more sophisticated pill sorting options, the initial promotion will emphasize informing. While Claire offers a sufficient value proposition to remain a rational purchase, promotional material will employ emotional appeal for this highly emotional subject. Last, the price of the device will be disaggregated into a weekly basis in advertisements to reduce perceived price.

Section 6 Conclusion

Claire is a medical management device that is compact, low-cost, accurate, intuitive, reliable, and easy to use. The progress made in the alpha prototyping of Claire has shown that although difficult, the task of improving the ease of prescription is very possible. An integrated system was designed for Claire; it consisted of pill loading bins, singularization and distribution subsystems, a user interface, and removable pillboxes within an organically shaped outer form that embodies health and well-being. The singularization system has each of the prescribed pills in their respective bins, and a small vibration motor in each bin helps guide pills one by one through a chute into a centralized hub. Sensors are installed to ensure only one pill falls into the distribution system at a time, where the pill will be held and dropped to its proper pillbox compartment via an actuated pill holding device. The wheel-shaped
device holding the pill is driven to its destination through an actuated x-y table aligned above the seven removable pillboxes. Any customer's medical prescription schedule can be easily programmed in Claire through the user interface, which controls both the singularization and distribution subsystems.

Incorrect medication adherence is a very costly problem that needs an effective solution. Although there is certainly room for improvement, the development of Claire seems to be a promising option in the medication management industry. More specifically, it will improve medication adherence among elderly patients with multiple prescriptions, and reduce anxiety among their caretakers.

Section 7  Future Work

As Claire currently stands there are several areas for specific improvement. As the most critical module and most complex system, the pill singularization method needs additional work to improve it's reliability.

In the pill distribution system, there are multiple areas of the design that could be improved, given more time and resources. Even though the alpha prototype of Claire was accurate and precise, it wasn't completely failure-proof. In order to completely get rid of the chance of failure, Claire's pill distribution system would have to be built upon more precise dimensions. This would also minimize Claire's physical footprint, but the methods that would be used to make a machine with such detail would cost more than what we spent to build the alpha prototype. The design of the x-y table could be improved; instead
of using lead screws, timing belts and gears could have been used with the stepper motors. The stepper motors in our alpha prototype were much larger than desired, and there are definitely smaller ones that are found in certain printers or hard drives. By using smaller ones, and combining with timing belts, minimal materials would be necessary to build the table, and the process would run much smoother. The pill holder performed well in our final design, but it was much larger than anticipated as well. With a smaller servo and a more compact design, this would allow the process of filling the pillbox to run faster.

With a functional device, we will now need to undergo more user testing and potential customer feedback. This is particularly important for our user interface design, where feedback is the driving force for change and use flow of the device. Ideally, our design will eventually include a screen, which guides the user through the programming process. This will make Claire an even more ideal product for elderly who manage their own medication regimen, without the help of caretakers.

As an alpha prototype, this iteration of Claire was designed without the manufacturing process in mind. However, once these areas are refined the parts will need to be redesigned for manufacturing and assembly. The loading bin in particular requires some modularity as it is a very complex part and cannot be manufactured in ways other than additive machining such as 3D printing. Likely, this part will require two or three molded components that snap together during assembly. Similarly to the pill loading bins, the form factor will need to be redesigned to make machining it a feasible process. This will likely require
splitting the main body into two parts at the pull plane and adding some locating
and fastening features to each half. Although there are still many areas for
improvement, the alpha prototyping process was successful as a proof of
concept and as a team we have a clear direction moving forward.
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