PillOne Dispenser

MCEN 5055 Final Report
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Section 1 - Executive Summary

This report presents a feasible design and prototype for a medication dispenser for individuals with early stage motor skill disorders such as Parkinson's disease and arthritis. The market for pharmaceuticals has never been higher with nearly 4 billion prescriptions filled at pharmacies nationwide [1]. An estimated $250 million is spent by pharmacies on pill bottles, which is offset by the amount paid by retailers for prescription medication [1,2]. Along with this, the number of people diagnosed with conditions that affect their motor skills is expected to grow from an estimated 40 million people by 3 million every year. Arthritis alone is the most common cause of disability in the United States. Most pill containers are not designed with these patient's points of view in mind. In particular, those with impaired motor skills often struggle with certain tasks involving these containers, such as opening the lid and extracting precise pill dosage. Their need for a better designed pill bottle is paramount to increase their independence and overall quality of life [2,3,4,5]. Through multiple design iterations, extensive user testing, and feedback from individuals with motor control impairment a robust and functional prototype was conceived and built.

Section 2 – User Point of View

Motor skill disorders such as Parkinson's disease and arthritis, even their early stages, often make simple tasks extremely difficult to execute. One of the most crucial and challenging daily tasks that these people must perform is taking their medication. The fine motor control and different forces that must be exerted make opening the bottle an onerous task. After the struggle of opening, comes the next step: dispensing their medication. As the individual tries to get their pill, three or four pour out of the prescription vial into their hand or onto the floor. Now the individual must retrieve the pills and put the extras back into the vial, requiring additional fine motor function. Depending on the condition, these individuals suffer from tremors, joint stiffness, and muscle weakness so they cannot be expected to perform such a difficult process to complete a necessary task. The PillOne Dispenser will allow people with motor skill impairments to easily and precisely dispense medication from a prescription pill bottle.

Section 3 - Background

A vastly increasing number of prescription drugs have been sold in the United States in recent years. While medications and vitamins are an integral part of many American lives, most pill containers are not designed with the patient's point of view in mind. In particular, those with impaired motor skills often struggle with certain tasks involving these containers, such as opening the lid and extracting precise pill dosage. Their need for a better-designed pill bottle is necessary to promote independence and increase overall quality of life. [2,3,4,5]

Section 3.1 – Market Dynamics

The PillOne team investigated the market to ensure that the market size is large enough to fulfill a product. The PillOne is a product which anyone in the United States of America who takes ingestible medication or supplements would be able to benefit from. In 2014, the US population filled more than 4 billion prescriptions with retail chains accounting for half. These prescriptions total a cost of $320 billion with $49 billion not accounted for by insurance. [6,7]

Based on research the PillOne team performed at pharmacies in Boulder, CO, the team found that the pharmacy generally pays an estimated $0.08 per bottle to wholesale distributers [2,5]. Coupled with the 4 billion prescriptions filled in 2014, this totals to an annual addressable market of $320 million, without any retail markup. To quantify the population of people the PillOne is specifically catered towards, that is, people with early to late stage motor skill disorders, the team gathered data regarding cerebral palsy, multiple sclerosis, amyotrophic lateral sclerosis, arthritis, diabetes, Parkinson's disease, Alzheimer's disease, Huntington's disease, and combined it to obtain the addressable market and annual growth rate, around 40 million users with growth of 3 million each year. Please refer to Appendix A for detailed plots and detailed numbers regarding the addressable market and growth rate.

Section 3.2 – Existing Products

There is no lack of pill bottle solutions that already exist for people who have difficulty opening or retrieving their pills from the prescription medicine vials. However, none of these products are fully successful at appeasing the user's needs. Many of these solutions set out to fulfill multiple needs of the user outside of opening and dispensing, such as the CleverCap, which adapts to existing pill bottles and uses electronic sensors to dispense an accurate pill count which is programmed by the pharmacist [8]. It also reminds the user to take their medicine by sending a reminder to their phone. While this product solves the issue, the CleverCap costs over $100.00. The Sabi Shake uses a simple shaking mechanism with a small opening that only allows one pill to come out per shake but this solution is only available online [9]. The existing solutions shown below range in price from $5.00 to $100.00, are not widely available, and many do not function reliably.

Figure 1 - Existing Products, From Left to Right: Sabi Shake, CleverCap, Pill Dayplanner, Target Rx Bottle

Section 4 – Customer Requirements

After interviewing a variety of people from different demographics, specifically focusing on people with motor skill disorders, and investigating the overarching problems that individual users have with the design of prescription medication vials, the team was able to define a list of necessary requirements [2,3,4,5,10,11,12,13].

- **Easy opening:** The bottle must eliminate the need or be easy and painless to open and close. People with dexterity issues have trouble opening and closing existing pill bottles.
- **Easy and accurate dispensing:** The bottle needs to effortlessly and accurately dispense medicine. Many individuals who were interviewed for market research expressed a desire to immediately ascertain the correct dosage.
- **Intuitive for primary users:** It must be usable with minimal instruction.

- **Compliance with FDA, CPSC, and CDC standards:** There are numerous FDA, CPSC and CDC standards required by medicine containers to ensure the safety of users. [14,15]
- **Inexpensive**: Based on research, it was found that these bottles cost approximately $0.08 at pharmacies. Based on batch injection molding cost, the prototype developed should not cost more than $0.30. [16,17]
- **Cannot compromise the integrity of medication:** The pills cannot sustain chemical or physical damage during storage or extraction.
- **Must resist everyday wear and tear:** Resist any form of everyday damage that could affect the container, i.e. impact through dropping, fatigue through regular use, etc.
- **Cost effective manufacturing**: The prototype design must be manufacturable via injection molding. Otherwise, this prototype will not be a market viable solution.
- **Pharmacy Friendly**: Compatible with pharmacy filling equipment and existing medication bottles.

It is important to note that keeping the design childproof is only an optional requirement because people who suffer from motor skill impairment struggle with childproof pill containers [3,4]. Additionally, pharmacies like Walgreens provide customers with non-childproof containers on their request [2,5].

Section 5 – Design Conception and Evolution

Section 5.1 – Design Concepts

To create the best product for people afflicted with motor skill disorders, the team began brainstorming. The concept map shown below is a summary of the ideas that the team initially examined for design concepts to move forward with. This concept map specifically focuses on mechanisms to dispense medication accurately and with minimal effort.

Figure 2 - Concept Map for Dispensing Mechanisms

In the concept map, the goal is shown in the middle, with three main concepts branching out. These are to redesign the entire bottle, redesign just the lid for existing medication bottles, or create an insert for existing medication bottles. From these, some specific mechanisms were determined such as the button, twist, shake, and pull-out. While brainstorming, no idea was deemed impossible or too wild so that all ideas would be considered. From these 34 initial concepts, 10 ideas were chosen to prototype based on considerations such as cost, complexity, and intuitiveness.

Section 6.2 - Pretotyping

The goal of pretotyping was to choose a suitable and useful mechanism for dispensing medication. These 10 concepts were: Flip & Shake, Flip Spout, Tic-Tac Container, Wheel, Spout/Funnel, Matchbox, Pez Dispenser, Hatch/Pull-Out, Retractable Pen, and Lotion Bottle. Most of these pretotypes were fashioned using the "Minimum Viable Product", "Pinocchio", and "Re-Label" approaches by using existing products to model the basic mechanism for dispensing [18]. Several also eliminated the need for opening through bypassing the process altogether. For pictures and descriptions of the function of each pretotype, please refer to Appendix B.

Since there were several concepts the team wanted to move forward with, extensive user testing was conducted to find out which mechanisms were best. The team interviewed forty-two healthy individuals, one amputee, and eight people impaired with Parkinson's disease (P.D.) at a support group that convenes monthly. The healthy subjects were asked to wear modified gloves, which inhibited joint movement and feeling in the fingertips to mimic hand disabilities. Thirty-two of the healthy individuals and all eight of the Parkinson's disease patients were asked to pick their top three mechanisms based on intuitiveness, comfort, and ease of use. More weight was given to the responses of the people with Parkinson's disease but the results were reasonably similar to those of people without disability. It was found that the three favorite mechanisms were the Wheel, Pen, and Flip & Shake.

Although the pretotypes were simple, they divulged a wealth of knowledge that was incorporated in the final design. The most apparent takeaways from the user testing were that users preferred to avoid using fine motor skills and that the design must consistently dispense a precise amount of medication. Additionally, customer's experiences varied greatly based on the severity of their conditions. The team also found that the expected price range for the design was lower than expected at approximately $1.00 for the product. The most excited responses came from the Parkinson's disease patients, which proved to the team that there is a definite need for the product. [3,4]

Moving forward, the PillOne team focused on developing prototypes using the button mechanism of the retractable pen and the Flip & Shake. The hatch/pull-out mechanism was also moved into the prototyping phase since the team felt that it showed promise for consistency despite not being a popular design among users.

Section 6.3 – Human Factors Research

In order for the PillOne to be as user-friendly as possible, various anthropometric data was collected regarding the target market. This included average hand size & range of motion statistics as well as max grip diameter for those with disabilities (Appendix C). A maximum force to eject a pill was then calculated using pen and pencil springs that the target market could use easily without pain. (Appendix D)

Section 7 – Initial Prototyping and User Feedback

After the initial user testing that the PillOne team performed, the team returned to the drawing board to refine the designs and produce functional prototypes. The team ultimately 3D-printed three lid prototypes that were adaptable to pill bottles using a threaded interface.

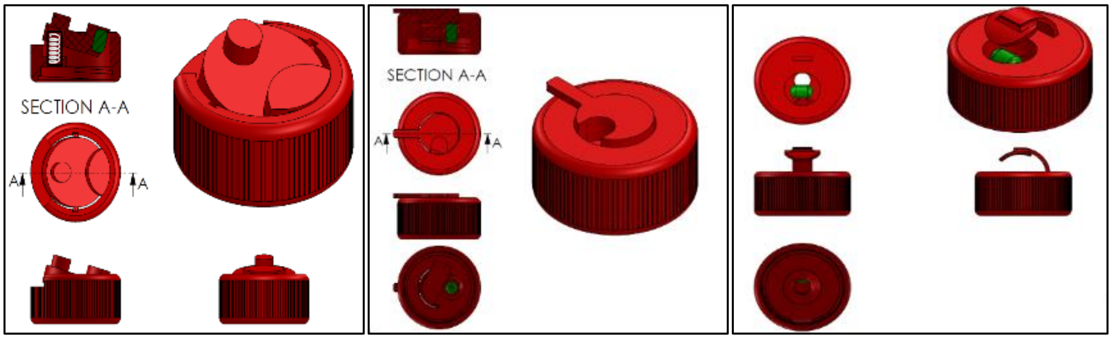

Figure 3 - SolidWorks Renders of the Button, Hatch, and Shake Prototypes, respectively

Figure 4 - User Testing Initial Prototypes with Gloves

The button prototype, shown above left, uses a linear spring that is compressed by a finger using a button. By pressing the spring down, the opening is revealed and pills can be dispensed through it. The hatch prototype, shown above middle, has two holes which create a reservoir for the pill. By rotating the mechanism using the lever, the holes align and the pill can be dispensed. The shake prototype, shown above right, has a funnel-like hole which allows one pill to enter a reservoir at the top of the lid. The cover is then lifted and the pill is retrieved. These three prototypes were tested with 23 healthy individuals and 1 person with P.D. During these tests, the healthy individuals wore the impairment-simulating gloves.

The team found that the Hatch and Shake prototypes dispensed a single pill consistently due to the reservoir built into each. However, the mechanisms to operate them were significantly less intuitive than the Button prototype. The person with P.D. stated that the "Shake is natural for me" [3]. Additionally, the team noticed that amongst all of the users, each one of them held and operated the prototypes in different ways. The most common piece of feedback that came out of testing was that the prototype mechanisms should be combined so that it could consistently dispense pills with the button.

Section 8 – Final Prototype Design and User Testing

The final design of the PillOne was derived from the user recommendation to combine the best aspects of each prototype into one design; the consistent one-at-a-time dispensing of the Hatch, the simple, intuitive functionality of the Button, and the natural motion of the Shake. Users dispense pills by turning the bottle approximately 45 degrees downward from horizontal, shaking it so a pill enters the reservoir, then depressing the button on the PillOne to dispense a pill into their opposite hand or onto a clean surface.

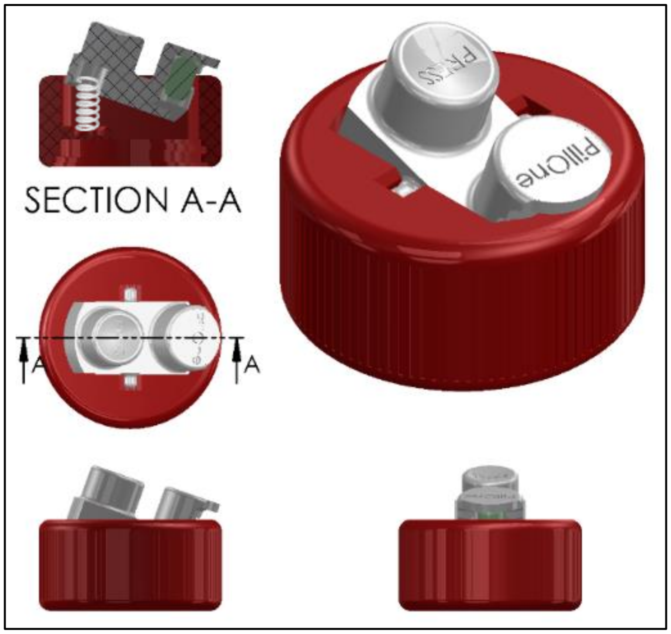

Figure 5 - Final Prototype Design

Only a single pill is dispensed with each use because the volume of the internal reservoir only accommodates one pill in its vertical orientation. Once the button is depressed, the interior hole becomes too small for other pills to pass through preventing additional pills from exiting the bottle. The button shown in Figure 5, right, integrates into a specially made lid. This lid can retrofit onto existing bottles, since the bottom $1/3^{rd}$ of the lid is specifically for integration (threads, hooks, etc.), with top 2/3rds accounting for the dispensing mechanism. The current design will work for capsules and caplets that are similarly-shaped to Tic-Tac's. Vitamin D and amantadine capsules were both successfully dispensed using the PillOne with no damage to the pills.

The final prototype was put through rigorous testing through a competition that the team set-up. The challenge: to dispense as many pills as possible in 25 seconds using the prototype while wearing the motor-skill impairing gloves. Each participant got a 10 second demo of the prototype, and then was allowed three successes with the device before they competed. With over 50 participants, the team was able to gain some insight into how people use and interact with the prototype. The time limit forced people to resort to their first instincts and use it in different ways than the team had seen previously. However, in all cases, the prototype worked and no participant was able to get more than one pill out with any attempt. This meant that the prototype was versatile and could be successful for people to use with minimal instruction.

Additionally, Team PillOne also visited the Parkinson's disease support group with the prototype in hand. The team has withheld the names of the individuals at the support group at their request. The team had six patients and a caregiver try the bottle. Three of the P.D. patients were able to successfully use the prototype, said that they would definitely use it, and that they liked the PillOne. One of the individuals stated, "I take too many different pills" and that this would not work for them. Another individual was too shaky to hold the pills once they were dispensed into his hands, but was able to successfully dispense pills. The last individual had trouble determining which side to press, which prompted the team to add an engraved “PRESS” to the final prototype.

Lastly, the team gave the prototype to two individuals, a 52 year old male with P.D. and a younger person with rheumatoid arthritis. Team PillOne asked them to use the prototypes for a few days, as part of their daily routine and provide feedback. The person with P.D. was able to use the prototype effectively with an 80-90% success rate, but did experience lock-up failures in which the pill becomes jammed between the reservoir and the lip. He would buy it if available at a pharmacy but only if consistency is improved [3]. The individual with arthritis however, had more trouble using the PillOne due to deformities in her wrist and fingers. She noted that while there is much improvement to be made for it to compete with existing pill bottles, specifically in regards to the lock-up failure, she supports the project and believes that it would help a lot of people if it were to go on market [4].

To produce prototypes, the team spent a total of $58.00 for printing high resolution PillOne prototypes on the Objet 3-D Printer in the ITLL.

Section 9 – Future Work

In order to ensure the future success of the PillOne, there are multiple considerations that need to be taken into account. One of the biggest considerations moving forward is the manufacturing and material selection for the PillOne. The prototype shown in this report was printed from ABS plastic using a MakerBot 3-D printer. However, the PillOne would need to be injection molded to be a cost effective solution. Using an injection mold cost estimator, the team projects the manufacturing and assembly costs per PillOne to be no more than $0.30 per part if produced in batches of 1 million with high density polyethylene (HDPE). HDPE was chosen primarily because it is already used in pill bottle manufacturing [source]. Additionally, it is favorable to other plastics, such as ABS, for this application because it is more compliant, due to a lower Young’s modulus, and cheaper. The increased compliance minimizes lock up failures as mentioned above. The cheaper manufacturing cost of HDPE also allows PillOne to be profitable is sold in the $1-2 price range, which potential users indicated they would be willing to spend. [16,17,19]

Another considerations are the wide variety of different size capsules and tablets that are available. Different reservoir sizes need to be designed in order to comply with most pills. Based on preliminary research, no more than ten different reservoirs should be sufficient to accommodate almost all pill sizes. More extended user testing and larger scale market research are necessary to provide a suitable product to the target market. The team has made connections that will enable us to conduct user testing with various senior centers throughout Colorado. The final PillOne design should include a torsion spring instead of linear spring. Based on failure analysis, we have concluded that the button press is not a linear motion, leading to possible spring deformation or failure. Sanitary factors are also a concern, so the design needs to be fully sealed, potentially by using a rubberized or plastic cover. The PillOne is well on its way to becoming a viable product to improve the lives of anyone who takes prescription medications.

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Appendices

Appendix A – Market Dynamics

This table was used to calculate the addressable market for our redesign.

	Cerebral Palsy	Multiple Sclerosis	Amyotrophic Lateral Sclerosis	Arthritis	Parkinson's	Diabetes	Huntington's	Total
Market	764000	400000	12000	22700000	1000000	21000000	30000	45906000
Adjusted Market	764000	400000	12000	17025000	1000000	15750000	250000	35201000
Growth (Yearly)	10000	10400	5000	3000000	60000	250000	1500	3336900

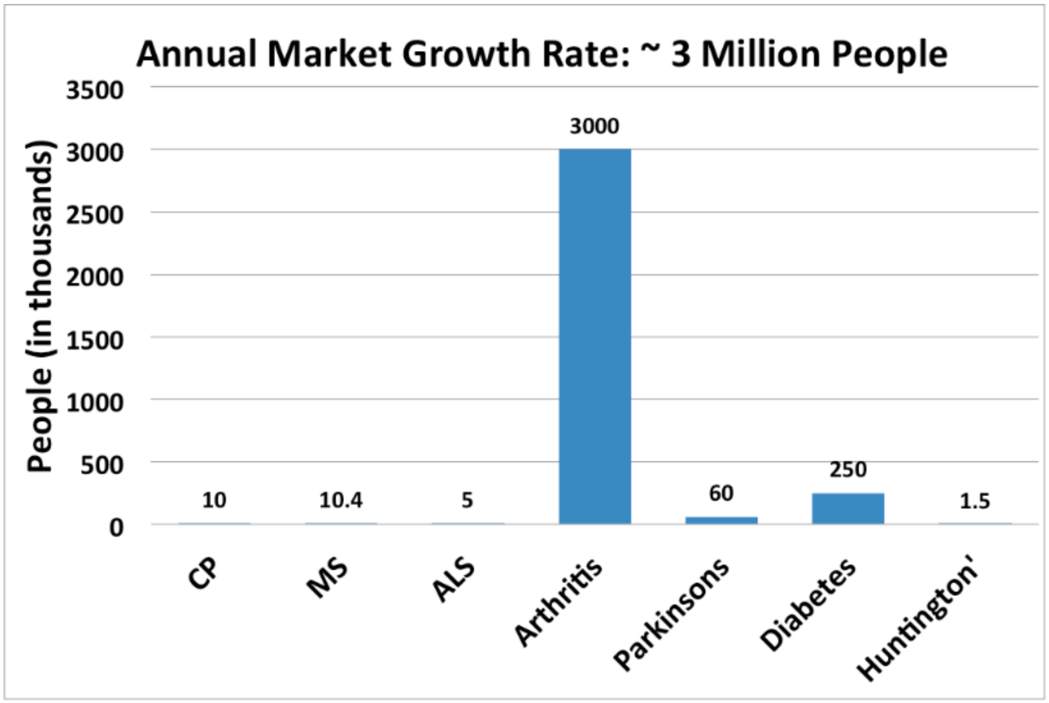


Figure 6 - Plot of Addressable Market Growth Rate

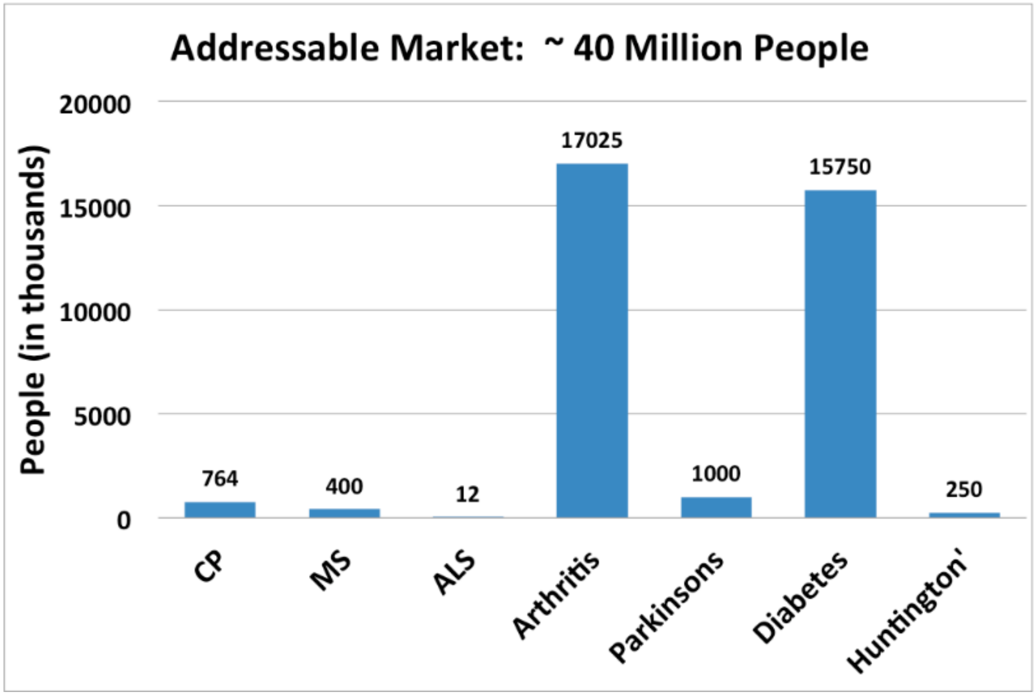


Figure 7 - Addressable Market Composition

Appendix B - Anthropometric Data and Operation Parameters

Appendix B.1 – Anthropometric Data

Hand anthropometry of non-disabled individuals.
(Sources: DTI, 2002; Ergonomics for Schools, 2008; RoyMech, 2008)

Dimension	Gender	5th percentile (mm)	50th percentile (mm)	95th percentile (mm)
Hand length	Male	173-175	178-189	205-209
	Female	159-160	167-174	189-191
Palm length	Male	98	107	116
	Female	89	97	105
Thumb length	Male	44	51	58
	Female	40	47	53
Thumb breadth	Male	11-12	23	26-27
	Female	10-14	20-21	24
Index finger length	Male	64	72	79
	Female	60	67	74
Hand breadth	Male	78	87	95
	Female	69	76	83-85

Figure 8 - Hand Anthropometry of Non-Disabled Individuals

Maximum grip diameters of individuals with and without dexterity disabilities. (Source: DTI, 2002)

	Gender	5th percentile (mm)	50th percentile (mm)	95th percentile (mm)
Non-disabled	Male	45	52	59
	Female	43	48	53
Dexterity-disabled	Male	34	40	47
	Female	34	40	48

Figure 9 - Maximum Grip Diameters of Individuals With and Without Dexterity Disabilities

Please refer to Additional Reference 11 for source.

Appendix B.2 – Operation Parameter Experiment Results

Spring Force Data & Calculations:

<u>Procedure:</u>

1. Measure "Push Down Distance" (Distance the spring compresses during pen activation)
2. Fix spring to vertical mount
3. Measure initial length of spring
4. Attach 200g mass to bottom of spring
5. Measure final length of spring
6. Calculate distance the spring moved
7. Calculate spring constant (k) from (SpringConstant=Force/DistanceMoved)
8. Using "Push Down Distance"(1), calculate the force required to activate the pen

Weight Used: 200g = 1.962N
Using $F = k * \Delta x$, and assuming no other external forces

UNIBALL 207

Initial Length	**29.13 mm**
Final Length	**38.86**
Total Displacement	**9.73 mm = .00973 mm**
Weight	**1.962 N**
Spring Constant	**201.644 N/m**
Push Down Distance	**6 mm**
Force Required	**1.2096 N = 0.272 lbf**

PILOT G2

Initial Length	**25.11 mm**
Final Length	**31.29 mm**
Total Displacement	**6.18 mm**
Weight	**1.962 N**
Spring Constant	**317.476 N/m**
Push Down Distance	**7 mm**
Force Required	**2.222 N = 0.4995 lbf**

MECHANICAL PENCIL

Initial Length	**16.37 mm**
Final Length	**20.44 mm**

Total Displacement	**4.07 mm**
Weight	**1.962 N**
Spring Constant	**482.06 N/m**
Push Down Distance	**3 mm**
Force Required	**1.446 = 0.325 lbf**

Weight of Bottles

KING SOOPERS

Cap	**3.3g**
Bottle	**9.4g**
Total	**12.7g**

RAPID PROTOTYPE

Cap	**14.0g**
Bottle	**20.2g**
Total	**34.2g**

Anatomical Movements

Dispensing Hand

- **Arm/Elbow Flexion: ~90º**
- **Hand Pronation: ~90º**
- **Thumb Flexion: ~1in**

Receiving Hand

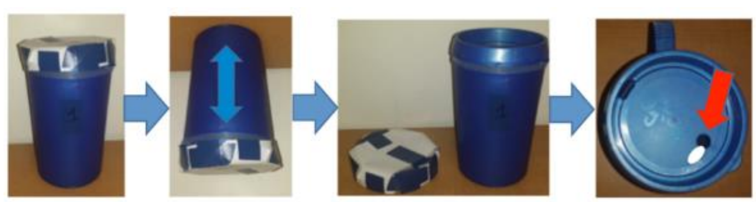
- **Arm/Elbow Flexion: ~90º**
- **Hand Supination: ~90º**

Appendix C – Pretotypes

Appendix C.1 – Pretotype Pictures and Descriptions

Flip & Shake

This idea is making a small reservoir at the top of the lid. The flip and shake motion can make the pill fall out from the little hole at the top into the reservoir and finish the dispensing. It is not very intuitive but people can use it well after instruction.



Flip Spout

This idea comes from water bottle. The spout can be made as other kinds of switch to control the pill dispensing. It is very easy to design only a lid which can be back and forth by simple push and pull.

Tic-Tac container

Tic-Tac lid inspires to develop some similar mechanism that uses friction force to redesign the bottle lid. It is very easy to use and it is widely welcomed by the low cost for manufacturing.

Wheel

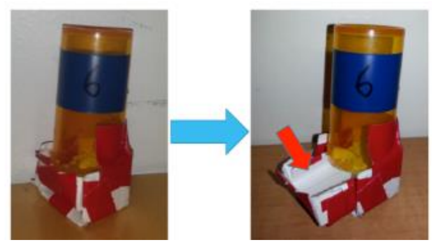
This concept has a good interpretation of how wheel rotation can dispense a pill. At first, the little hole on the side of the wheel can store one pill and during the rotation the little hole will come to the other side and then dispense.

Spout/Funnel

The funnel can limit the flow of pills and can control the dispensing when people try to pour small amount of pills.

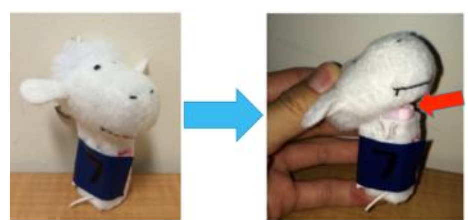
Matchbox

In this concept, the matchbox is installed under the pill bottle as a reservoir. When it is pulled out, the pills which fallen before will be taken out and when it goes back, pills will fill in again.



Pez-dispenser

Pez can precisely dispense one pill per time when the top lid is pressed so it will lever up the inside container by spring and then one pill come out from the top.



Hatch/Pull out

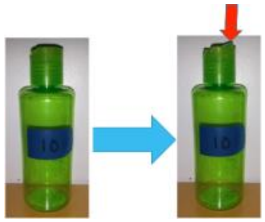
In this concept, a hatch controls the motion of the inner container. When it is pulled out, the hole in the container will be exposed and people can dispense the pills.

Retractable Pen

Retractable pen has the button mechanism that can be developed to an intuitive switch to control the open and close of the pill dispenser.

Lotion bottle

The lid of lotion bottle uses the button to lever up the other side of the lid that exposes the opening to dispense.



Appendix C.2 - Pretotyping User Survey Results

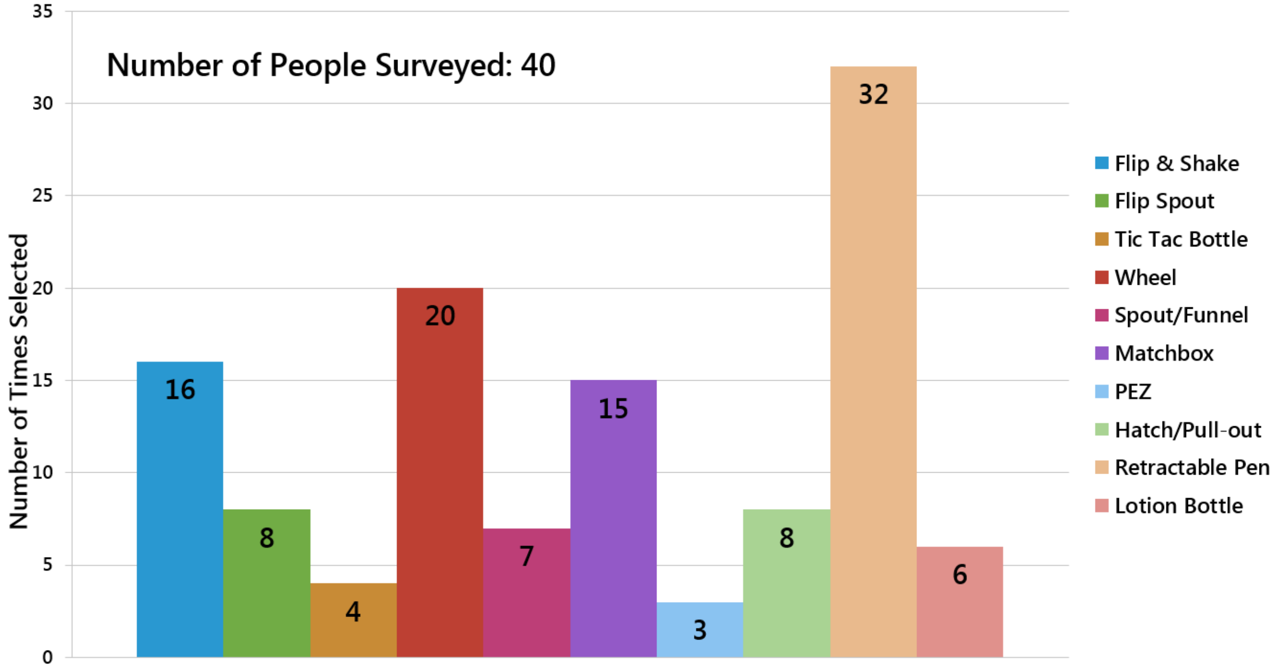


Figure 10 - Pretotyping User Survey Results