

Dr. Andrew Rawicz
School of Engineering Science
8888 University Drive
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 440, Functional Specification for a medical dispensary and reminder device

Dear Dr. Rawicz

The attached document is the Functional Specification for the PillPal medical dispenser. The highlighted functions will be implemented to offer a complete automated pill dispenser. Our design targets the senior market, who often are required to adhere to complex medical regimens, and is intended for use primarily in a home environment. The goal is have the PillPal become a common product in all homes and to be used by patients of all ages.

The Functional Specifications described in the following documentation will provide a high level overview of deliverable functions in our product. In addition, the Functional Specification document will describe the various stages of development we will go through, such as: testing phase, prototyping phase, and finalizing phase. To thoroughly describe each function, our specifications are divided into categories and subcategories with the high level items, hardware and software functions, followed by in depth analysis of specific functions. Through this, we can distinguish which phases the functions are expected to be implemented. To further assist ourselves, this document will guide our team in the research and development process as well to serve as a test base to begin our preliminary hardware and software implementation.

Our diverse team of 4 senior computing and electronics engineers are dedicated to the development of this device. Please feel free to contact us at igl@sfu.ca or 440-cc@sfu.ca with questions or comments regarding our enclosed documentation or our product.

Sincerely,



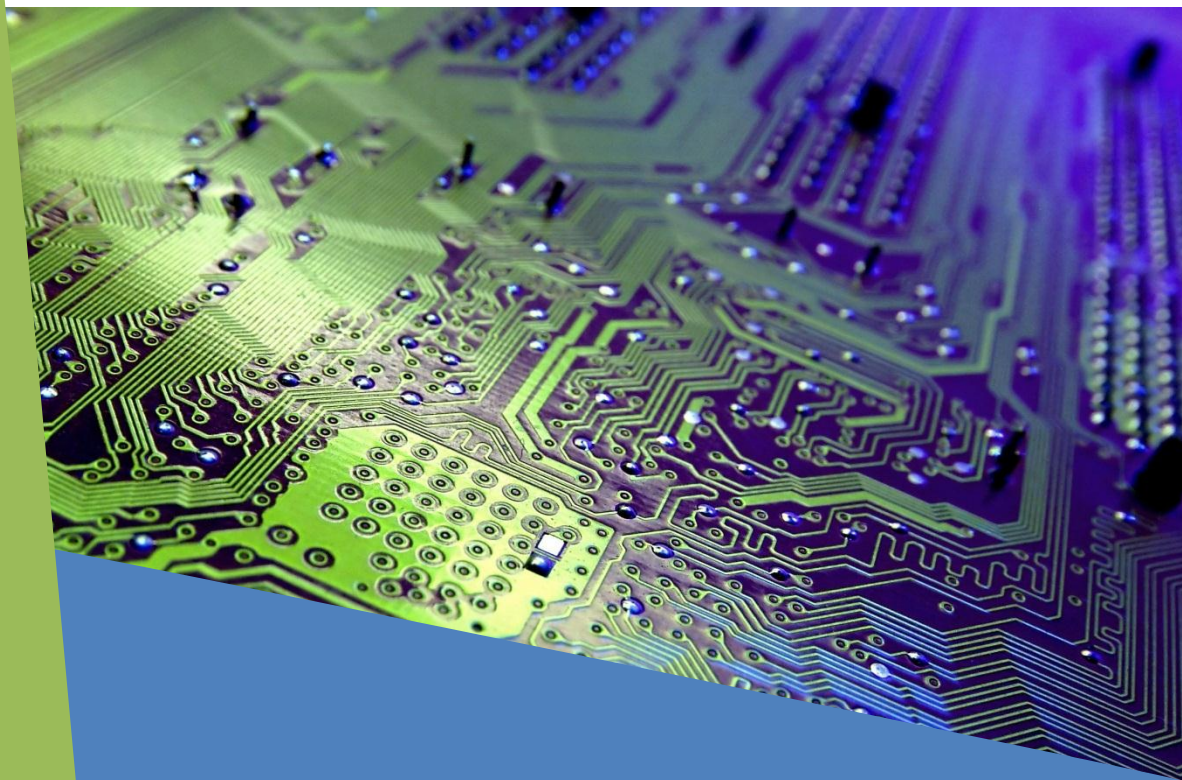
Izaak Lee
CEO
Capsule Corp

Functional Specification for PillPal

Charanpreet Parmar, Izaak Lee, Gurinder Dhaliwal, Clark Hsieh

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Revision 1.0



**CAPSULE
CORPE**

Executive Summary

In the last five years, Canada has experienced a 14.1% growth in senior populations. [1] [2] [3] Unavoidably, this has led to an increase in chronic and degenerative illnesses [4]. We understand that adhering to a medication schedule of a wide assortment of medication can be complicated and frustrating. Often, full time staff is dedicated at a senior home to perform daily medication dispensing, thus consuming a large amount of resources. Our solution to simplify the complicated and time consuming process of medication allocation and reminder is the PillPal Medical Dispenser. This device can be used in a home environment as well to provide assurance and peace of mind for the loved ones and caretakers of our senior members in the society.

The PillPal is an assistive device to help people adhere to complex medication regimens, and it will use intelligent software to automatically process and collect relevant data. To complete the automated dispensing process, it will utilize mechanical components to perform the manipulation, storage and dispensing of the medication and the capturing of the label information. The mechanical components are guided by electronic circuitry controlled via a microcontroller. Development of the Capsule Corp PillPal will have two distinct phases.

For the first phase we will include the reading of the pill labels, dispensing of pills, and the physical Vacuum Arm Manipulator (VAM). The critical features included will be:

- Character Recognition software to scan our medication labels
- Store our medication into sorted containers.
- Interaction with immersive and simple UI
- Ability to correctly allocate and dispense the proper mix of medication
- Mechanical Components directly related to sorting and dispensing medication

The four-month development cycle of this prototype will result in a working prototype to demonstrate our ideas and is scheduled for completion on April, 12 2013.

The second phase of our development cycle, the PillPal will be redesigned with portability in mind by making it smaller and easier to handle. The final design will have internal backup battery packs to ensure continued operation of certain functions during power outages to communicate to others of the current power situation. It will have advance communication features such as WI-FI, Ethernet connectivity, modem connectivity, cellular network connectivity. Last but not least, the PillPal will conform to all safety regulations set by overseeing bodies such as the IEC 60601, which standardizes all medical electrical equipment.

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Glossary of Terms

AC - Alternating Current

VAM - Vacuum Arm Manipulator

GUI - Graphic User Interface

UI - User Interface

Wi-Fi - Wireless Fidelity

UPS - Uninterruptible Power Supply

ISO - International Standards Organization

IEEE - Institute of Electrical and Electronics Engineers

FDA - Foods and Drugs Association

CSA - Canadian Standards Act

MDA - Medical Device Agency

IEC - International Electrotechnical Commission

HID - Human Interface Device

RoHS - Restriction of Hazardous Substances

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1 Introduction

The PillPal is designed to dispense standard medical pills for patients who require multiple medications on a daily basis. The objective of this product is to correctly remind users to take medication on time. To achieve our goal, the PillPal will be able to generate medication schedules for multiple patients and optionally can be further customized to fit their daily routines. Capsule Corp will implement a wide variety of different reminder schemes to suite the general audience. This includes:

- **Local reminders:** An audible reminder for patients around the device
- **Electronic Reminders:** Emails, text messages and phone calls for patients who can't hear the local reminder
- **Service Reminders:** Electronic reminders to alert caretakers, medical professionals or loved ones

Multiple options coupled with numerous customization options make this product superior when compared to other similar pill dispensers. Figure 1 as shown below demonstrates the prototype design.

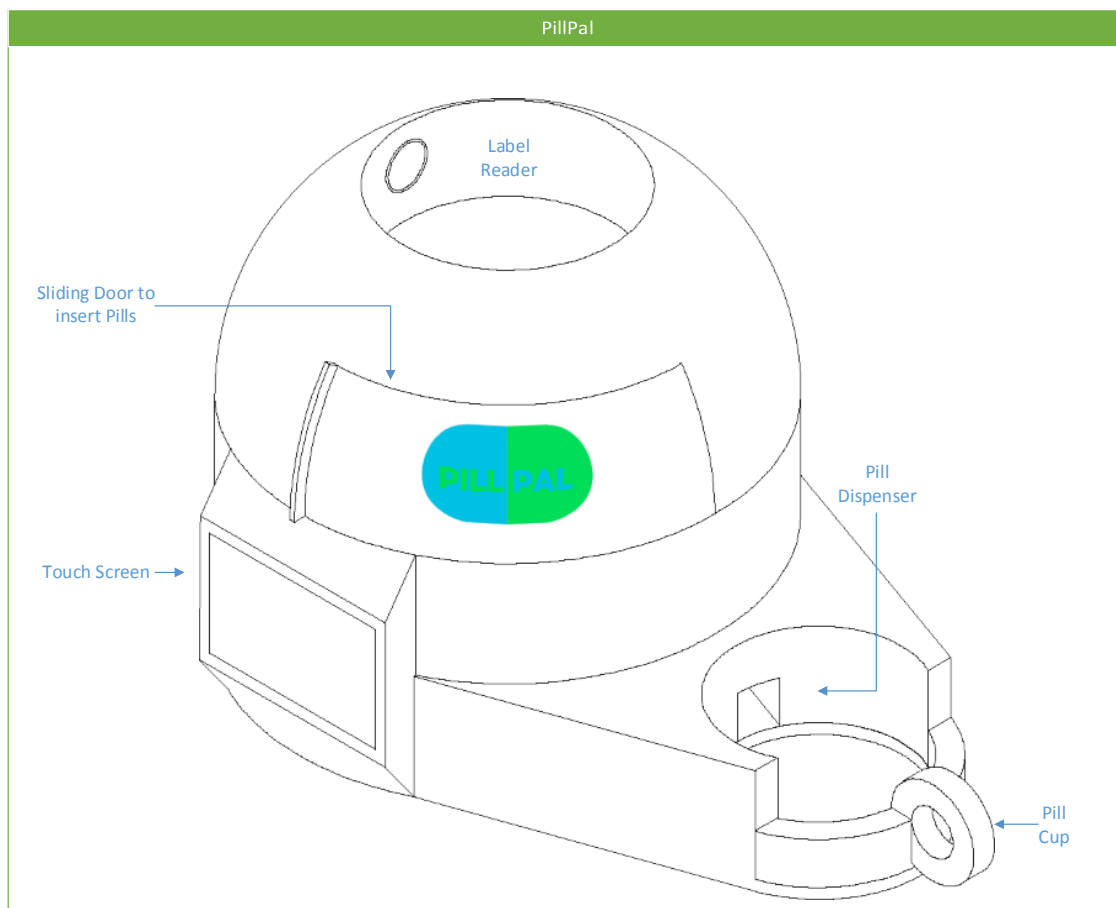


Figure 1 Complete system

1.1 Scope

This document highlights the functionality of the PillPal medication dispenser and also emphasizes the adherence to the medical standards in North America. We also include the list of functions of which will be implemented on our design of the PillPal. The following information and documentation shall serve as a guide and reference for all future modifications and upgrades to the PillPal device.

1.2 Intended Audience

The Functional Specification is created by and for Capsule Corp's engineering design team. This document highlights all functions to be employed in the PillPal. Included within the document is a list priority functions required for the prototype.

The design teams are to develop a functional prototype meeting the minimum functions listed. Following this document, the design team is also required to complete the system test plan as listed in the sections below.

1.3 Classification

In the following section of this document, Capsule Crop has prioritized functional development of the PillPal using abbreviations. Below represents the standard adhered by Capsule Corps:

[R#-Px]

R# = Denotes the section number and the features number

Px = Priority Level, a number ranked 1 - 3 designating the priority of the function

Priority 1 - Signifies a feature which must be implemented into the testing and prototype. The function of the design may be dependent on the outcome of this feature.

Priority 2 - Signifies a feature which is unnecessary but may be implemented if time permits. The feature is deemed useful, but the project may move on without it.

Priority 3 - Signifies the feature is not important and is a luxury item deemed by the engineers. If time permits, this feature will be implemented into the final product.

2 System Requirements

2.1 System Overview

The PillPal is a highly intricate device which works agilely to dispense the precise medication to each of its subscribed patients, and it can be broken down to four simpler modular devices:

- I. Pill Dispenser
- II. VAM
- III. Label Reader
- IV. Control GUI

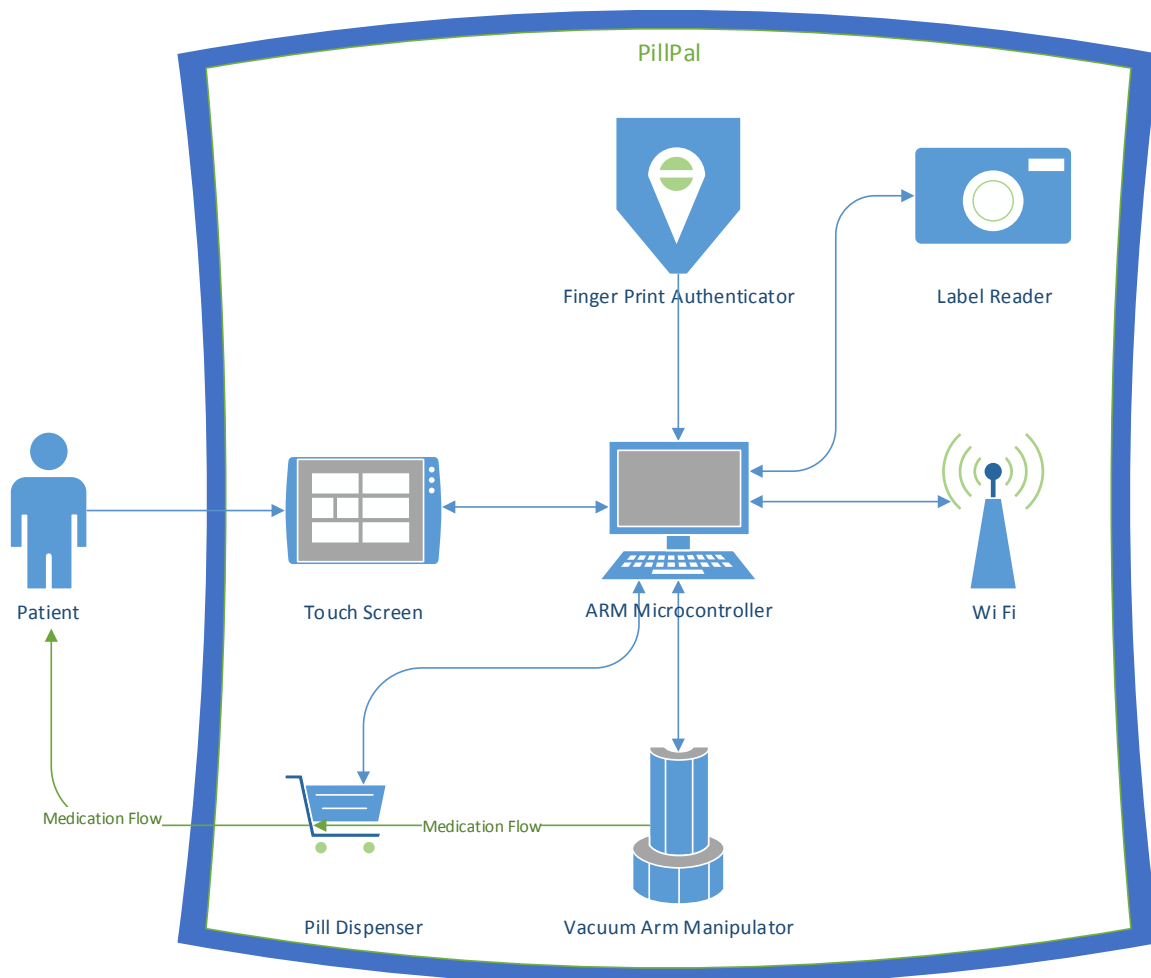


Figure 2 System Diagram

These individual modules, shown in Figure 2, work in unity to deliver medications to patients in a safe and timely manner. The goal of the PillPal is to be a device that is the most simple and intuitive as possible while performing all the necessary actions flawlessly. The label reader is designed to automatically read and record the label image. Once completed, the image is displayed on a 10.1” touch screen for user confirmation. The screen prompts users to make changes or customize the generated medication schedule. Once the schedule and medications are confirmed, the pills are automatically stored into a designated container where it will be dispensed at the correct time. The fingerprint reader shown in Figure 2 on the previous page is an optional implementation for additional security and authentication purposes.

One goal of the PillPal is to simplify the user experience as much as possible. To accomplish this, we require an intuitive GUI and accompanying software to act as the brain of the PillPal. With simplicity in mind, we hope to make the PillPal accessible to users of all ages.

2.2 System Requirements

General Requirement

[R2.2.1-P1]	Shape of pill containers shall be designed such that pills will converge at a single point
[R2.2.2-P1]	Power outages does not disrupt stored data
[R2.2.3-P1]	Sufficient storage of pills and capsules
[R2.2.4-P1]	User should only require simple actions to acquire pills
[R2.2.5-P2]	Sensors and motors should be invisible to the user
[R2.2.6-P3]	Consumer cost must be below \$800
[R2.2.7-P3]	Should complete pill allocation before the alarm goes off
[R2.2.8-P3]	Eight pill containers
[R2.2.9-P3]	Capable of storing pill bottles

Physical Requirement

[R2.2.10-P1]	Cup for dispensed drug to situate
[R2.2.11-P2]	Should fit on counter top
[R2.2.12-P2]	Should have screen in position for easy reading and touching
[R2.2.13-P2]	Should be simple to load the pills
[R2.2.14-P2]	Easy setup of physical unit
[R2.2.15-P3]	Fingerprint scanning for user confirmation
[R2.2.16-P3]	Have side panel to access internals of machine
[R2.2.17-P3]	Organized wiring inside
[R2.2.18-P3]	Light enough for one person to carry/lift
[R2.2.19-P3]	Ergonomic design

Electrical Requirement

- [R2.2.20-P1] Will run off the wall 110/120 V at 60 Hz AC
- [R2.2.21-P1] Power cord should be detachable
- [R2.2.22-P1] Power supply should be sufficient to power all required components
- [R2.2.23-P1] Safe and compliant with medical standard for electrical devices
- [R2.2.24-P1] Make sure things are terminated properly for safety (ground)
- [R2.2.25-P2] Have ports to easily measure voltages for motor diagnostics
- [R2.2.26-P3] Make it spill proof/water resistant
- [R2.2.27-P3] Back-up power (UPS)

Performance Requirement

- [R2.2.28-P1] Will allocate pills within 3 minutes
- [R2.2.29-P1] Optimize motor speed and efficiency
- [R2.2.20-P2] GUI touch screen should be almost lag free
- [R2.2.31-P3] User authentication required for actions

3 Hardware

3.1 Hardware Overview

The PillPal is required to be as reliable as possible. As such, the parts chosen and the design must be fine-tuned to expect near perfect performance in terms of reliability. Due to the nature of the product, there must also be failsafes to avoid overdosing and dispensing incorrect medication to maintain hardware accuracy and repeatability. An exploded view of the dispenser and VAM system can be seen in Figure 3 below.

Certain requirements such as the volume of speakers and the max noise level of our device are derived from references to commonly identified noises such as the ‘jackhammer’ or ‘speech in a quiet room’. Research identified that hearing problems are not limited to seniors and thus we should consider the sound levels and frequencies to best suite their environment and users. [5] [6]

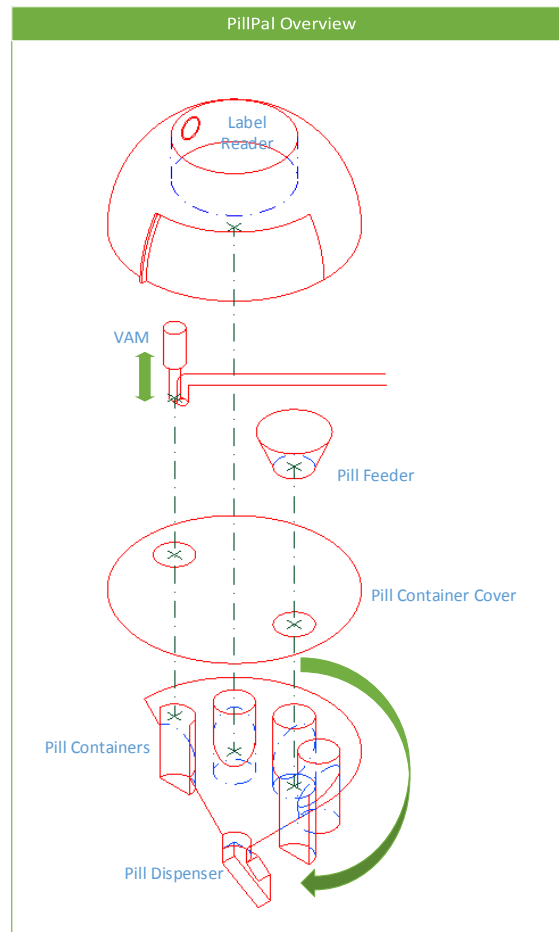


Figure 3 Hardware exploded view

3.2 General Hardware Requirements

General Requirements

[R3.2.1-P1]	Speakers to alert users with minimum volume of 90 dB [7]
[R3.2.2-P1]	Touchscreen for GUI interaction
[R3.2.3-P1]	Provide light for camera
[R3.2.4-P2]	Dispose of drugs not taken after set time
[R3.2.5-P3]	Keep track of number of pills dispensed
[R3.2.6-P3]	Verbalized Alerts

3.3 Pill Dispenser

The function of the pill dispenser is to ensure that the correct medication is dispensed and then ensure it is taken. Thus, it needs to keep track of the position of each medication containers and maintain tracking accurately.

Pill Dispenser Requirements

[R3.3.1-P1]	Rotate dispenser in both directions
[R3.3.2-P1]	Be sufficiently accurate for repeatability
[R3.3.3-P1]	Capable of self-calibration
[R3.3.4-P1]	Calibrate on boot-up
[R3.3.5-P1]	Safety feature to prevent damage during operation
[R3.3.6-P1]	Check if pills have been taken
[R3.3.7-P2]	Assign unique identification number to each pill container
[R3.3.8-P2]	Keep track of number of remaining pills

3.4 Vacuum Arm Manipulator

The VAM is the mechanical device that physically obtains and allocates the medication according to the patient information for each dispensing period. This mechanical action is crucial for the operation of the device, thus is required to be very accurate as to only pick and place a single pill at a time to guarantee repeatability and user safety. Not only are we concerned with the repeatability of the VAM action, but also with its ability to manipulate pills or capsules of various shape and sizes. We shall design and test vacuums and nozzle shapes to meet our requirements and allow for leakages in our design to maintain continuous pill manipulation capability. Figure 4 below displays the proposed design of the VAM.

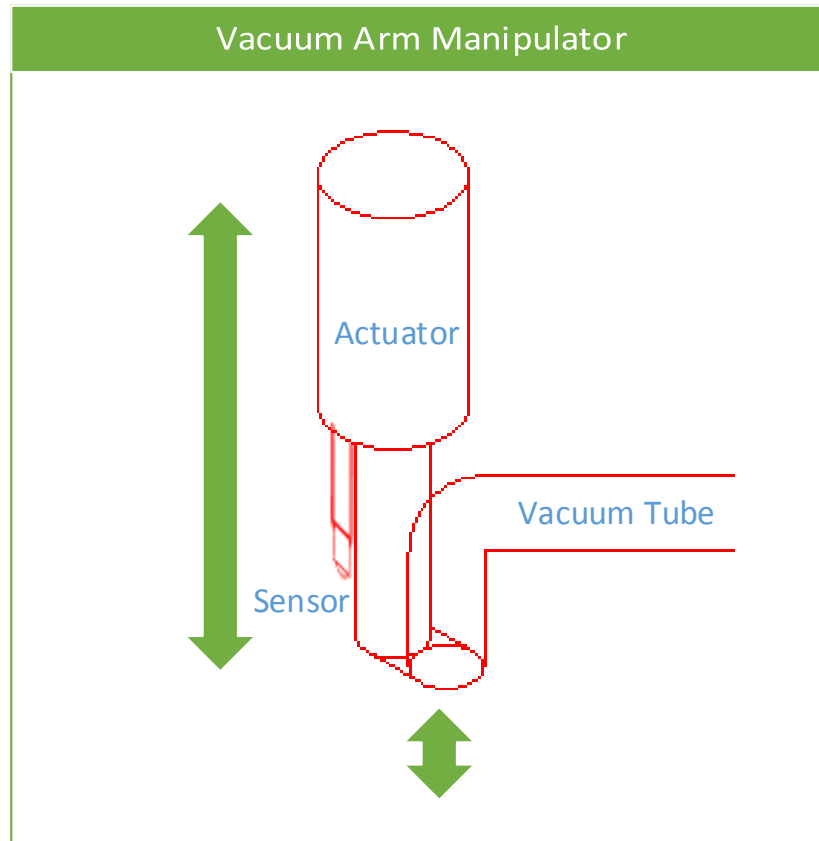


Figure 4 The Vacuum Arm Manipulator Module

VAM - Vacuum Arm Manipulator Requirements

- [R3.4.1-P1] Be sufficiently accurate for repeatability
- [R3.4.2-P1] Should not pick up multiple pills
- [R3.4.3-P1] Be able to drop pills in a predetermined location
- [R3.4.4-P2] Be able to pick up pills of various sizes and shapes
- [R3.4.5-P3] Minimum maintenance for user
- [R3.4.6-P3] Noise level to be below 60 dB

4 Software

4.1 Software Overview

The software provides the main control of the machine. It provides a high level abstraction between the user and the machine so that the user can easily control the machine without worrying about functional details. We want to minimize patient interaction as much as possible so this means the software needs to be intelligent enough to perform as many actions as autonomously as possible. To do this, we need an intuitive GUI as well as reliable software to control the hardware.

4.2 Software Requirements

General Requirements

[R4.2.1-P1]	Must run on embedded Linux OS or equivalent
[R4.2.2-P1]	Must control all hardware reliably
[R4.2.3-P1]	Must store relevant prescription and user information
[R4.2.4-P1]	Must determine schedule automatically
[R4.2.5-P2]	Provide relevant user statistics
[R4.2.6-P2]	Must be able to store multiple patient schedules
[R4.2.7-P2]	Capability of aborting operation
[R4.2.8-P3]	Web interface and able to view all prescriptions and schedule on web
[R4.2.9-P3]	Encryption of sensitive user data

Reminder System

[R4.2.10-P1]	Must send emergency emails and text
[R4.2.11-P1]	Must provide users with customized schedules
[R4.2.12-P2]	User confirmation of being reminded
[R4.2.13-P3]	Must send emergency calls
[R4.2.14-P3]	Vacation mode (dispense those times for user, will send phone text reminder appropriately)
[R4.2.15-P3]	Send out alerts/info to correct personnel (caretakers, patients)
[R4.2.16-P3]	Able to store sufficient / customized information of patient

4.3 Label Reader

The Label Reader module will take the pill bottle from the user, utilizing the standardized medical label, and then read in relevant data via an OCR software to determine the appropriate schedule for the medication dispensing. Figure 5 below illustrates the label reader.

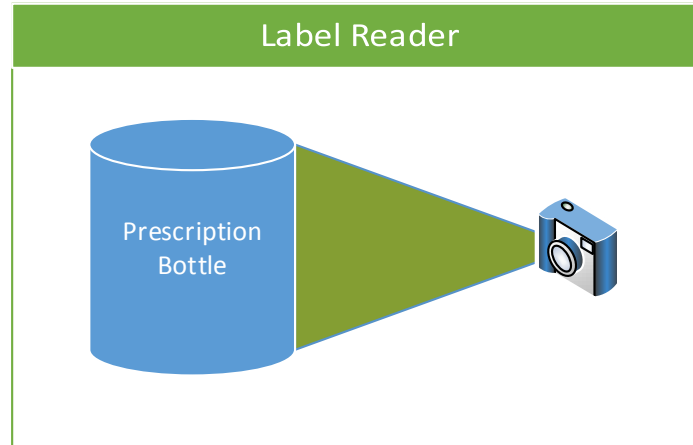


Figure 5 Label reader diagram

Label Reader

- [R4.3.1-P1] Camera Sensor must take clear Macro-Shots
- [R4.3.2-P1] Must stitch images together
- [R4.3.3-P1] Must translate stitched image to text
- [R4.3.4-P1] Rotate and take image of pill labels

4.4 Control GUI

The purpose of the GUI and the touch screen is to provide the user with means of interaction with the PillPal as a HID. It will allow the user to input desired settings as well as providing visual feedback for the current settings or states of the device in a clear and concise manner for the user.

- [R4.4.1-P1] Must have an on-screen keyboard
- [R4.4.2-P1] Home screen must display details of next scheduled pill
- [R4.4.3-P1] Home screen must have options for at least pill loading, prescription details, calendar view, and settings
- [R4.4.4-P1] All screens must have a 'back/home' option to return to previous and home screens
- [R4.4.5-P1] Must display confirmation when pill dispensing
- [R4.4.6-P1] Must display OCR results after pill bottle is scanned
- [R4.4.7-P1] Must have an option to edit OCR results before storing (becomes read only after storing)
- [R4.4.8-P1] Power saving must automatically turn off when a scheduled pill is close to being

- [R4.4.9-P1] dispensed and as long as the pill is not dispensed
- [R4.4.9-P1] Option for external alerts to store external contact information
- [R4.4.10-P1] About should list all relevant company information
- [R4.4.11-P2] Will be simple and usable so that seniors can use it
- [R4.4.12-P2] Keyboard will show up in all editable scenarios
- [R4.4.13-P2] Selecting the next scheduled dosage will take you to details of the prescription
- [R4.4.14-P2] Will have monthly/weekly/daily calendar views which show prescriptions at correct time
- [R4.4.15-P2] Will be able to view read only details of prescriptions from calendar view
- [R4.4.16-P2] Settings will contain Wi-Fi settings, user settings, brightness, power saving, date and time, alarms, outside alerts, help, about
- [R4.4.17-P2] Wi-Fi settings will contain options to list, select, and manually enter values (SSID, password, etc.) for wireless networks
- [R4.4.18-P2] Each patient will not be able to edit any other patient's settings and information
- [R4.4.19-P2] Configure date and time manually or automatically via Internet
- [R4.4.20-P2] Brightness settings will have a slider type of object to change brightness
- [R4.4.21-P2] Alarms settings will have options to change alarm volume and alarm type
- [R4.4.22-P2] Outside alerts will have an option to determine the delay between alarm and alerts
- [R4.4.23-P3] Will use colours, font, font size, etc. that ensure good visibility
- [R4.4.24-P3] Status bar on the home screen will display current user, time, and connectivity information
- [R4.4.25-P3] Selecting any of the items in the status bar will take user to its respective settings
- [R4.4.26-P3] Patient Management Settings (manage multiple patients)
- [R4.4.27-P3] Power saving will have options to turn on/off power saving (screen off, Wi-Fi off, etc.) and after how long to turn it on
- [R4.4.28-P3] Power saving will have vacation mode options
- [R4.4.29-P3] Alarms will have a preview option
- [R4.4.30-P3] Help Menu

5 User Manual

5.1 Overview

The user manual will only be written for the production model or the PillPal. The user manual must be clear, concise, and easy to follow with the general public as the intended audience. It shall be organized in a way such that the all critical information is easy to find. All instructions and descriptions must be easy to understand and have zero ambiguities.

5.2 User Manual Requirements

General Requirement

- [R5.2.1-P3] A User document shall be created to demonstrate the operation of this device
- [R5.2.2-P3] The document shall be simple and be understood by anyone with a high school level
- [R5.2.3-P3] Must contain pictures
- [R5.2.4-P3] Must be short and concise
- [R5.2.5-P3] Must have large lettering for those with deteriorating eyesight

Hardware Documentation Requirement

- [R5.2.6-P3] Demonstrate replacement and maintenance of parts
- [R5.2.7-P3] Demonstrate the device capabilities
- [R5.2.8-P3] Demonstrate device limitations

Software Documentation Requirements

- [R5.2.9-P3] Demonstrate user interface map
- [R5.2.10-P3] Instruction to store name and other options
- [R5.2.11-P3] Highlight important settings

6 Sustainability and Safety

The Engineers are not only responsible for ensuring international safety standards are met, but also perform due diligence to ensure safety systems are implemented to prevent human error. The PillPal has numerous safety inputs to prevent patients from taking wrong medications. Some safety features include:

- User confirmation of medication schedule
- Dispose of untaken medication
- User fingerprint scanning to prevent incorrect patient
- Pill sensor to detect pill presences

6.1 Reliability and Durability

Capsule Corp understands its responsibility and is dedicated to the delivery of a safe and reliable product. During the multiple stages of development, our engineers will determine the necessary components and algorithms to create a reliable product, as well as rigorous testing for durability. In addition to reliability, many standards are laid out by multiple organizations; therefore, not only shall we adhere to all safety measurement set by the ISO, IEEE, FDA, MDA, IEC and CSA, but we shall also be diligent to go above and beyond to ensure product reliability. [8] [9] To conform to standards, a testing schedule is developed to ensure that the PillPal meets and exceeds the expectation of users.

6.2 Sustainability

At its current stage of development, we are primarily using spare cardstock and cardboard salvaged from empty cereal boxes to build a preliminary design for our prototype. By doing so, we hope to minimize the use of non-recyclables during the prototype and proof of concept phase for our design, which we believe will in turn minimize waste during the design and production for our final product. We have also taken a test-before-buying approach to most of the electronic components required by using similar components, such as spare webcams and microcontrollers, before choosing suitable parts for the design. On top of doing so, we also ensure that the parts we must buy for testing have a suitable return policy to minimize expenditures and waste if they are not suitable for our needs.

By utilizing the prototype and proof of concept phase of the product to fine-tune the design, we hope to make our final product as efficient as possible in terms of the number of components used and consider environmental factors related to materials used for the enclosure and other mechanical parts. In the production version of the PillPal, we hope to utilize advance bioplastics for all our exterior components and enclosures to reduce our environmental impact of our product. [9] [10] Bioplastic will reduce the environmental footprint for products that has reached its end of life stage. [11] [12] Interior

components will utilize RoHS compliant electronics to eliminate the heavy metal and poisonous materials in our product.

We are considering of introducing a program for customers to return their used or broken products in exchange for a discount on our other products. This program allows us to ensure the proper disposal of our units as well as recycle materials such copper in wires and other metallic components. This program also gives customer incentives for their continued loyalty. Plastics and electronics that are deemed unusable shall be shipped off to contractors who specialize in material salvage and environmentally safe disposal.

7 System Test Plan

The System Test Plan section highlights a vigor test plan to ensure our device meets the international safety standards while accommodating our functional design. The PillPal is comprised of multiple mechanical and software systems; thus, our system test plan is divided into two sections. The first section of the test plan shall focus on the hardware while the second section shall highlight the software testing and debugging. Due to time constraints, the list is devised such that the design engineers are to be testing in parallel during the project's progression. The test plan can be generalized into three phases: testing of individual modules, testing of combined modules, and final testing.

7.1 Hardware Tests

Pill Dispenser

1. Locating empty container
2. Positioning of empty container
3. Allocating pills from bottle to Container
4. Labeling container

VAM

1. Positioning of VAM
2. Positioning of container
3. Movement of VAM
4. Sensor for level of pills
5. Gripping of Pills
6. Dropping of Pills
7. Releasing of pills into container

7.2 Software Tests

The software testing will be split up into two main categories, the GUI and the control of the microcontrollers. We will test the smallest modular portions of the code before integrating into a larger portion and then retest after integrating. This way we ensure that each module of the code works individually and as part of the larger program. This will also make it easier to debug the software when doing the final integration since we will know for sure that each individual component is functional. We will test the reliability of the code by feeding in bad data to ensure our software is able to handle errors. We will also test with data that ensures we cover all possible corner cases. Further details of each software categories are given below:

GUI

1. Each button goes to the correct menu
2. Correct wireless signal information is given
3. Correct time is displayed
4. Correct prescription information is displayed
5. Prescription information is writable when first loading pills and read-only after that
6. Calendar views are correctly displayed with correct prescription posted on its respective date
7. Make sure user is not stuck in any menu
8. Correct keyboard functionality
9. Images are stitched correctly
10. Image is correctly converted to text
11. All settings correlate with required functionality

Label Reader

1. Rotation of pill bottles
2. Understanding Typical Pill Labels
3. Devise Code to do image stitching
4. Autofocus coding
5. Time Rotation of pill bottle to image capturing
6. Testing Image Stitching
7. Testing of OCR Software

Embedded Hardware Control

1. Motors and webcam work as expected when loading option is selected
2. Motors work as expected when dispense option is selected
3. Connect to selected wireless network
4. Fingerprint authentication functions correctly

7.3 Integration Tests

Once the hardware and software are fully tested they will be integrated. The fully integrated system will be tested to ensure each hardware and software component dependent on each other work as fully expected. Each component of the system that worked under separate testing earlier will be retested to ensure no errors are created during integration. We will finish off with a User Acceptance Test of the overall product. We will refer to the functional specifications to ensure that each functional requirement is met without any errors. Each unique way to use the product will be tested from start to finish to simulate the intended user operating our product.

Label Reader + Pill Allocation

1. Timing to release pills into container
2. Confirmation prompt for users to release pills
3. Allow user to make change before pill allocation

Pill Allocation + VAM

1. Timing of pill dropping
2. Releasing pills after confirmation

Final Testing

1. Check to ensure customization is possible
2. Audible sound
3. Texting and calling is working
4. Finger scanning
5. Email
6. Ensure electrical circuitry is compliant to safety standards

8 Conclusion

The functional specification document highlights the expected deliverables in order specified by the priority. The priority of each feature will determine the probability of integration in the prototype. Capsule Crops will undergo testing to further determine the final features in the prototype and ultimately the final product. In addition to key features, this document demonstrates the rigors testing carried out by the Capsule Corp engineering team. The Design Team is expected to adhere to and address all functional specifications as demonstrated by this document by April 12, 2013.

9 References

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