Feb 21, 2018

Andrew H. Rawicz
School of Engineering Science
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Re: ENSC 405W Requirements Specification for PharmaSort's Axis

Dear Dr. Rawicz,

I am writing to you to review PharmaSort's *Requirement Specifications* document for the *Axis* platform. Our goal is to create a prescription pill sorting machine that, for personal or professional pharmaceutical use, can accurately identify many different types of prescription pills from their bottles and sort them accordingly for consumption.

Attached, this document will explain the system overview, delving into the separate modular sections of *Axis*, such as the software, mechanical, and hardware requirements of the integrated system. In addition, this document will cover the engineering standards, responsibilities, safety, and sustainability considerations that the team will follow to ensure a refined product that will prove to be both economical and professional.

This document will follow the development life cycle of the product, and classify requirement specifications according to the delivery stages (such as proof-of-concept, prototype, and final product), while keeping in mind the relative priorities of the system.

PharmaSort features five engineering students: Francis Tran, Hazel Monte de Ramos, Freddy Kooliyath, Mirac Chen, and Ananth Prabhu. With all team members bringing very diverse (yet standardized) skill sets, the team is confident that the requirements of this project can be met.

Please do not hesitate to contact us via our designated contact person, Hazel, for any questions or concerns you may have. You can reach her at hmontede@sfu.ca.

Sincerely,

Francis Tran
CEO

Enclosed: *Requirements Specification* for PharmaSort Axis

PHARMA SORT

Requirements Specification for the **Axis***:* A Prescription Pill Sorter and Dispenser

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Abstract

Increasingly so, prescription drug use is a large factor in the health maintenance of many Canadians, serving as the second highest expenditure in healthcare with a cost of $29 billion in 2013 [1]. Among the age demographic of medication users, seniors rank the highest [1], and adversively can also be prone to the highest risks. Drug noncompliance occurs irrespective of age, but seniors - who tend to suffer from vision and memory impairment- often fail in adhering to their medication with greater likelihood. Whether it be overuse or underuse, or simply failure to read the fine print on labels, consequences are evident- and they can be severe.

The following requirement specification document addresses the details of a possible solution to this issue: Axis. Our aim is to minimize the drug noncompliance in seniors and other potentially disadvantaged demographics (such as rural or Aboriginal communities [2]) by designing a device that can effectively determine and administer the correct pills and dosage at the appropriate day for a single week. This will be accomplished using a fully integrated system of software, hardware, and mechanical sections working in harmony. From a rudimentary level, the system features camera sensors and a character recognition API to extract required information from the prescription label. The internal mechanical structure will be designed to sort the pills by day, pass any excess medication for that week, and dispense accordingly, while the hardware will provide the brains for joining the software and mechanical functionalities.

This document splits up and specifies each domain of requirement, in order to narrow down the implementation priorities and methodologies of the diverse system parts. However, there are also general, and integration requirements which will be covered; this way, there is no doubt that the system can function on both unit and integration levels. Additionally, this document will cover the specifics of engineering standards, responsibilities, and sustainability of this project.

Considering the fact that this project calls for a seamless integration of very different domains of engineering, PharmaSort is confident that their team, all hailing from the diverse core options of Engineering Science, will be able to tackle the requirements laid out in this document.

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Glossary

Term	Definition
API	Application Programming Interface: a set of functions for interfacing with the underlying software system
PDL	Prescription Drug List: a comprehensive list compiled by the Canadian government for drugs for the treatment of humans
eCFR	Electronic Code of Federal Regulations: an online listing of federal regulations adhered to by the government
IEC	International Electromechanical Commission: an international agreement on standards pertaining to electronic and mechanical specifications

1 Introduction

1.1 Background

We live in a society with an increasingly disproportionate age pyramid, skewed towards the elderly. No doubt, many developed societies have this same occurrence, and many are wrestling with the consequences: the lack of sensory capacity that comes with age. When taking medicine, it can be difficult for an elderly patient to make out the dosage and quantity, especially if handicapped by deteriorating eyesight or lack of dexterity. These issues, however, are not exclusive to the elderly. Drug non-compliance is a severe issue in rural and Aboriginal communities, too. Small print on prescription labels dictating dosage can prove difficult to read, and needing to recall which medication to take, can be a hassle to remember. Furthermore, with about 29.9% of Canadians aged 65 to 79 taking 5 or more types of medications [1], the need to organize, manage and remember multiple pills can become much more cumbersome.

PharmaSort aims to help those who are in their time of need, particularly by dispensing pills in a professional grade matter -- though from the comforts of their homes. The product, Axis, provides an efficient and reliable method to dispense pills based on the dosage scanned from the label. In this manner, one does not have to worry about reading the labels, or making mistakes when it comes to taking several prescription medications.

Alternative solutions currently exist in the market, however they do not provide the exact qualities that the Axis will demonstrate. Hospital dispensers and pill counters are not readily available to the general public for purchase, and blister packages can still suffer from human error. The Axis concept will be made attainable for homeusers, but still possess the technological capability that surpasses manual pill organizers. To ensure accuracy, it will utilize a camera sensor to capture the prescription label of the bottle and use a character recognition API to extract the required information. The entire bottle is emptied into the device which will then correctly allocate the required number of pills for a week, passing the excess amount to alternate route to later be returned back. Finally, it will organize the pills by day and dispense accordingly. The entire process will prevent the risks of misreading instructions, and ensure medication is not forgotten.

Following is a document that will outline all required specifications to make the Axis possible. These requirements will involve the functionality of the device- general, hardware/electronics, software and mechanical requirements- as well as the requirements to ensure the device follows the proper engineering standards, responsibilities, sustainability and safety.

1.2 Requirement Classifications

PharmaSort's requirement classification will be as follows:

[Domain-Req#Priority]	*Requirement statement*

Where domain is the type of requirement, as seen in Table 1 with its corresponding abbreviations:

Domain of requirement	**Abbreviation**
General	GE
Hardware	HW
Mechanical	ME
Safety/Sustainability	SS
Software	SW

Table 1: Requirements Encoding

And the priority is:

H High: Needed for basic functionality of the product, most likely in the proof-of-concept
M Medium: Needed for more optimal and complete performance of project; prototype
L Low: More refined features, needed for professional grade performance; final produt

For example:

[SW-19H]	The Python engine must be running on a back-end server at all times

Would be the 19th requirement, which happens to be in the software domain, and high priority.

2 System Overview

2.1 Scope and Functionality

The system will take a digital input; namely, a photo of the bottle's label. The system will parse the information found on the tag via its software engine, and with that information, will dispense pills according to the dosage and frequency specified on the tag. The project harmonizes both a sophisticated software back end which identifies the medicinal dosage with a mainly mechanical hardware front end which dispenses aforementioned dosage into compartments. Meanwhile, excess pills will be poured back into the bottle.

2.2 Proposed Design

The system functions as a true IoT device, with the front and back ends connected by WiFi/3G. On the software side, this Wi-Fi (or a 3G/4G network in the event of unavailable internet access in rural areas and technologically unequipped residences), and use Google's Cloud Vision text recognition API to parse the necessary information from the labels. This will provide instruction to a mangOH microcontroller [3] which will appropriately manipulate the mechanical portion of the system on how and when to dispense and sort each prescription pill.

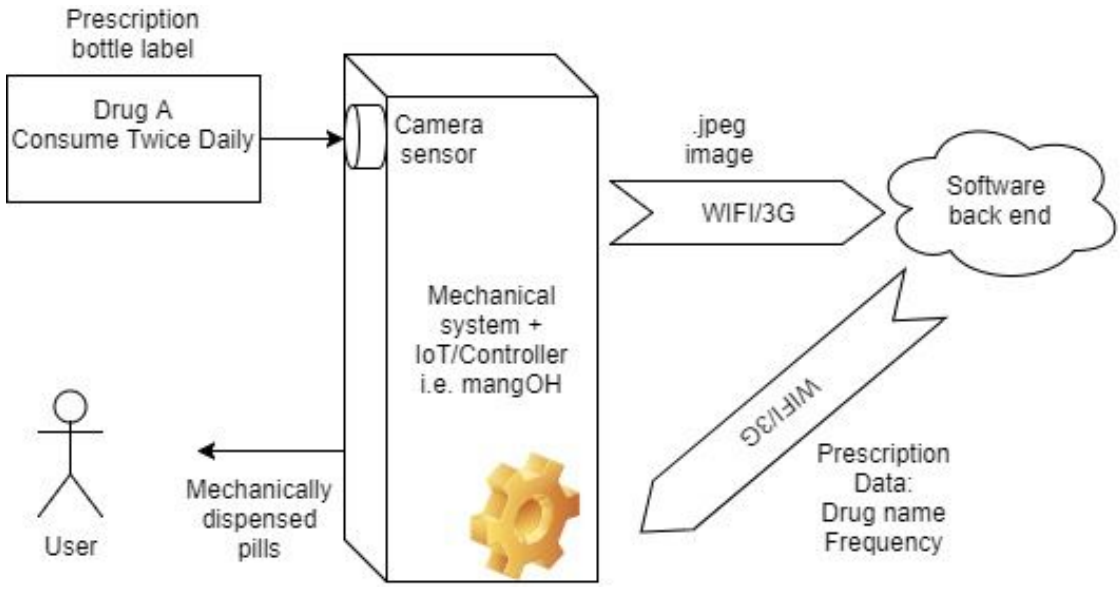

Figure 1: High level system diagram

2.2.1 Mechanical/Hardware Front End Overview

The final proposed design would have the entire system housed inside a spherical combination of pentagons. The structure of the pentagons arranged in a sphere will transfer the impact forces uniformly throughout the structure to minimize shock damage to the system.

The pills will enter the device through a rectangular hopper that narrows down to a square, abstractly depicted in Figure 2. This prevents the pills from being crushed by distributing the forces gradually when being fed into the sorting operation.

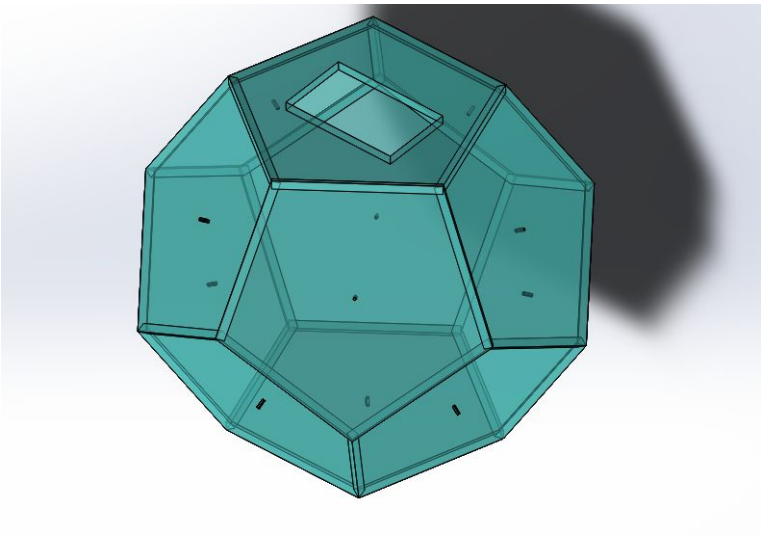

Figure 2: Pentagonal structure of the Axis shell case

The first operation would be to separate the pills one by one to determine what day the patient will have to take the given dosage. The entire bottle of pills is deposited into the rectangular hopper and collected into a square shaped funnel. The narrowing structure will allow the pills to condense and ensure the force of gravity is the predominant factor acting in the depositing of the capsules. A slider, controlled by a linear motor, will serve to sift the pills in order to obtain a singular piece. Figure 3 shows an example of this, as based on the Alogryx method [4]. There will be flaps which will control the side that the pills will go down. If there are an excess amount of pills, then the flaps controlled by servo motors will route the pills to their respective destinations. The excess pills tube would lead the pills back to the original bottle which the user will be instructed to place under the dispenser before starting the sorting process.

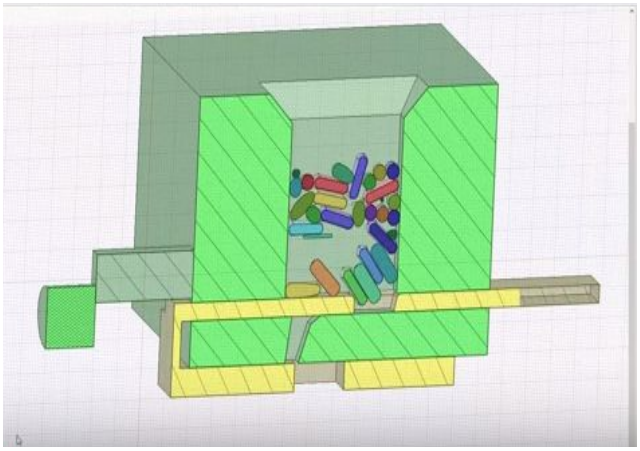

Figure 3: Simulation of dispensing single pills (From Algoryx) [4]

As the pills are deposited one by one, they are guided to fall into a circular surface. The pills are sorted by day on this circular surface, which lies at the bottom of the structure. This surface is partitioned into seven sections for each corresponding day of the week, with each section acting as a separate tray. A servo motor will be used to rotate a nozzle in order to align the deposited pill's pathway to the corresponding day on the tray. The tray is expected to be pulled out in a sliding fashion by the user. Figure 4 depicts the mechanical system diagram.

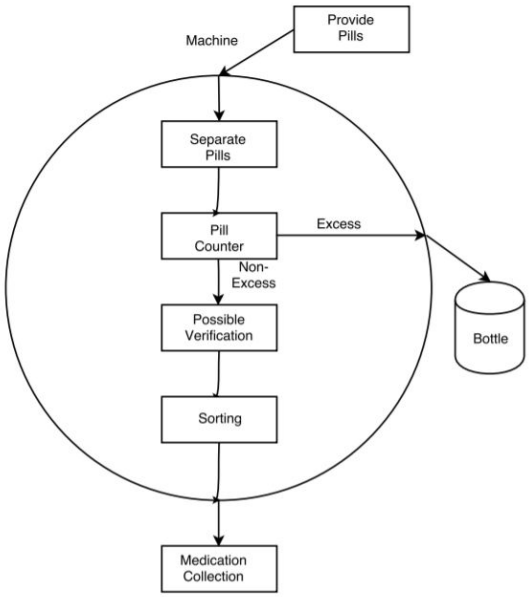

Figure 4: Mechanical System Diagram

2.22 Software/Back End Overview

In terms of software, the over-encompassing function is to create a method that is able to identify characters on the bottle label. The first step is to obtain two or more different angle shots of the label on the target prescription pill bottle. This is due to the fact that the label is adhesively attached onto the curved surface of the logo, making a profile photo difficult to obtain. The photos will be sent to a photo stitching API which will combine the photos into one final image. After the final image is obtained, the system will use Google Cloud Vision API to generate text from the input image. From this data, the system can parse the necessary details such as prescription liabilities and frequency of consumption. This functionality will be implemented using a Python script running on PharmaSort servers to connect to Google's Cloud Vision API and synthesized using an Arduino or mangOH microcontroller.

Figure 5 shows an in depth system diagram focusing on the software aspect of the system:

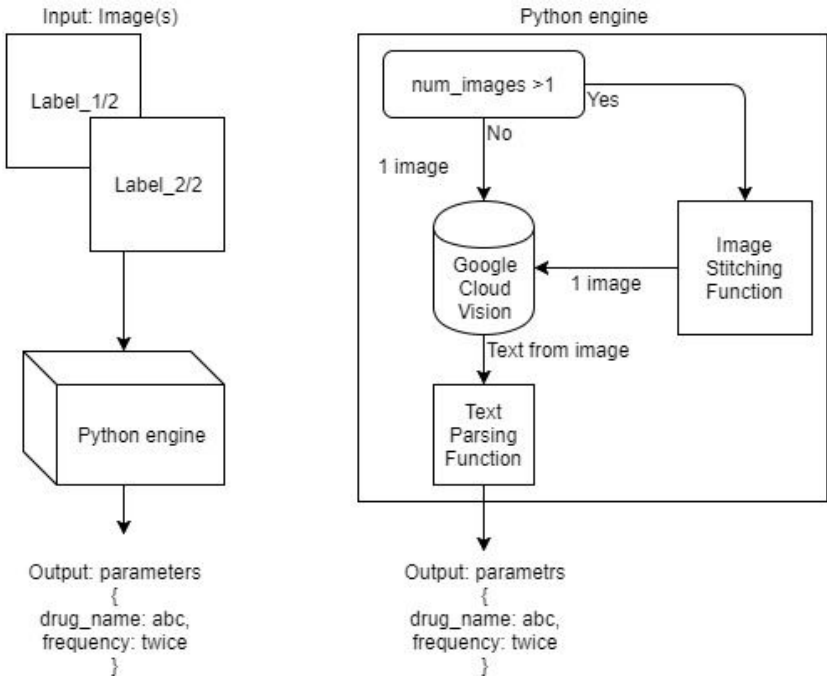

Figure 5: System software flow chart

3 Requirements

3.1 General Requirements

The following requirements are classified as general requirements and shall be adhered to when designing the prototype system. The purpose is to ensure the functional requirements are met during the development of the project.

[GE-1H] Axis shall dispense pills based on the information of the prescription label
[GE-2H] The system shall be expected never to make an error in dispensing the pills
[GE-3H] The system shall sort the pills for a single week as intended by the seven partitioned circular tray
[GE-4H] In the case that the system is knocked over, it shall maintain structural integrity to avoid damaging internal hardware
[GE-5M] The user interface is simplistic and straightforward to accommodate an older audience
[GE-6L] Axis is designed to be used indoors to avoid outdoor extremities damaging device
[GE-7L] The outer shell shall have a pentagonal structure to ensure strongest protection for the prescription pills
[GE-8L] The input prescription pills must be intended for humans (not pets)
[GE-9L] The system shall dispense pills quickly and efficiently, not taking longer than 10 minutes
[GE-10L] Each Axis product shall not be shared among users

3.2 Hardware/Electronics Requirements

These requirements shall be used as a guideline when designing the electronic and hardware components of the system.

[HW-11H] mangOH platform must be able to send images to back-end server
[HW-12H] mangOH platform must be able to interface with camera sensor
[HW-13H] mangOH platform must be able to interface with system actuators
[HW-14H] System must be able to dispense from preset (hard coded) dosage profile
[HW-15H] System must be able to receive dosage data from back-end server
[HW-16H] System must be powered by a single wall AC/DC adapter
[HW-17L] User must be able to connect to home Wi-Fi network
[HW-18L] User interface must be intuitive, as will decided by user testing

3.3 Software Requirements

The following requirements shall be used as a guideline when designing the software of the system. They will be adhered to in order to ensure the necessary software functionality.

[SW-19H] Python engine must be running at all times on back-end server
[SW-20H] Python engine must receive images from microcontroller platform
[SW-21H] Python engine must stitch images if necessary
[SW-22H] Python engine must upload final label photo to image hosting service (i.e. imgur)
[SW-23H] Python engine must prepare JSON object to be sent to API
[SW-24H] Python engine must receive JSON output from API
[SW-25H] Python engine must parse output into tokens
[SW-26H] Python engine must parse tokens into appropriate output containing dosage of drug
[SW-27H] Python engine must send output data back to microcontroller platform
[SW-28H] Python engine must correctly calculate the dosage for the user
[SW-29M] Python engine must feature reentrant code to ensure safe processing

3.4 Mechanical Requirements

The following requirements are guidelines for the mechanical specifications of the system.

[ME-30H] Sorting station for deposited pills must be a square funnel to allow gravity to be central pulling force in pill depository
[ME-31H] System must have a slider beneath the square funnel to be able to deposit one pill at a time
[ME-32H] System must have a restriction on the slider during the sorting process to avoid damaging the drug
[ME-33H] System must dispense correct number of pills for each day to ensure safe usage
[ME-34H] System must have correct alignment with the pill sorting mechanism and the dispensing tray to ensure pill is deposited on the correct dispensing day tray
[ME-35H] System must have a servo motor to rotate dispensing tray to appropriate day of week to retrieve the pills
[ME-36H] System must have a seperate slider and holding compartment to be able to seperate all excess pills
[ME-37M] The rectangular opening for pill depositing must be appropriately sized to prevent spills
[ME-38M] Dispensing trays must be slidable for easy user accessibility to dispensed pills
[ME-39M] System must interface with the electronics and software
[ME-40M] System must provide minimum delay to ensure overall usability

4 Engineering Standards & Responsibilities

The team will follow Google's coding standards for Python, C, and all other programming or scripting languages used in the software modules [5]. This standard is appraised as one of the most excellent in industry, and ensures clean code that is reusable, modifiable, and efficient.

Throughout the entire design, the team intends to follow protocols for safe engineering methodologies laid out by the IEEE:

> "The IEEE Product Safety Engineering Society focuses on the theory, design, development and practical implementation of product safety engineering methodologies and techniques for equipment and devices. " [6]

In the software domain, the risk of safety does not come as obviously as the physical domains. In fact, there are several cyber threats that users must watch for, especially in the realm of privacy. The team intends to follow protocols, such as those laid out by Amazon [7], to ensure that the user data being used in the cloud stays secure and does not compromise the privacy of the users.

In terms of the pill bottles, we expect all labels to follow the Food and Drug Administration standard for labelling, prominence of labels, and symbols required in labels.

Food and Drugs Act (R. S. C., 1985, c. F-27) s9 (1) - Deception, etc., Regarding Drugs [8]
Food and Drugs Act (R. S. C., 1985, c. F-27) s11 - Unsanitary manufacture etc. of drug [8]
FDA eCFR- Title 21, Chapter I, Subchapter H, Part 801, Subpart A 801.15 [9]

Furthermore, steps will be taken to ensure that the pills that the user inputs into the device are verified to be safe for consumption, and are cross referenced with their legality in Canada. As well, to provide an integrated experience for the user, the system will refer to standardized medication listings provided by the Government of Canada wherein we require that all prescription pills input to the device must be found on the Canadian Prescription Drug List (PDL) [10].

Lastly our responsibilities also include following engineering standards regarding machine safety [11][12][13], which indicates that the device must have these given safety protocols in place to deal with the possibility of misbehaviour, further ensuring user safety. With regards to home safety, this device shall conform to following home safety standards set out by the federal government of Canada and the International Electromechanical Commission (IEC) [14].

[SS-41M] System will employ Amazon Cloud information standards [7] to protect user data
[SS-42H] System will adhere to USA FDA standards for medication labels [8][9]
[SS-43M] To ensure even more safety, system shall require all prescription pills inputted be available on the Canadian Prescription Drug List [10]
[SS-44M] System must adhere to IEC 62061:2005 machinery safety standards [11]
[SS-45M] System must adhere to CAN/CSA-C22.2 NO. 0-10 (R2015) electric code [12]
[SS-46M] System must adhere to IEC 61558-1 power safety standards [13]
[SS-47M] System must adhere to CAN/CSA C22.2 NO 60601-1-08:2008 - Medical Electrical equipment Part 1: General Requirements for basic safety and general performance [14]
[SS-48M] System must adhere to IEC 60601-1-11:2010 -Ed 1.0 - Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [14]

5. Sustainability & Safety

The product will adhere to all regulations in accordance to its sustainability and additional user safety. With an understanding of how to accomplish both, the following section will clearly describe how these will be achieved in the end design.

5.1 Sustainability Standards

It is the team's goal to construct a device that fits the cradle-to-cradle criteria, in order to keep the manufactured materials in a constant usable cycle. Table 2 illustrates the five categories towards the process of obtaining the cradle-to-cradle certification, which we have considered in creating our sustainability requirements.

Criteria	Description
Material Health	Material identification: either technological or biological nutrients, and understanding the chemical ingredients of which it is composed to ensure optimal safety in materials
Material Realization	The ability to return the technological nutrient back to the industry and the biological nutrient back to nature
Assessment of Energy	Assessing the energy required for the production of the device parts and subassemblies, requiring at least 50% of that energy to be renewable for the highest certification
Water	Appropriate management of water in manufacturing
Social Responsibility	Considers and assesses fair labour methods and operations in order to ensure a positive working environment for all labourers

Table 2: Criteria for the cradle-to-cradle certification process [15][16].

The initial step to the certification process is to identify the material health to be used in the device as either biological or technological nutrients. We aim to use a biological nutrient for the creation of the outer shell of Axis. In 3D printing, PLA is increasingly becoming a favorite. The environmental effect of PLA is far less than plastic counterparts [17]. The team will go to great extents to incorporate PLA into the design, and would prefer this for mass production. In addition, any 3D parts will be designed to reduce the amount of material needed.

In considering material realization, our initial prototype will intend to incorporate recycled parts, such as servo motors that other group members currently own. Any excess materials, scraps or

unwanted electronics will be returned accordingly to electronic recycling facilities in Vancouver. Looking ahead in terms of mass production, we would consider working with the Canadian Association of Recycling Industries (CARI) [18], who would be able to ensure the materials we use in the manufacturing of the Axis are all recycled accordingly.

In Canada, the largest source of renewable energy is derived from hydropower [19]. When the device is in the production stage, it will be an important goal for PharmaSort to seek facilities that can utilize hydropower for manufacturing. As well, the production of semiconductors requires the usage of water, which is considerably important [20]. Water stewardship is an essential aspect to consider, and so it will be an important factor to ensure that the production of our electronic components are being done so with proper water stewardship.

Lastly, in terms of social responsibility, the construction of the current prototype will be done so in a way that ensures a fair and proper team working environment. For future production, it will be a critical aspect to ensure that the labourers involved in the production of the Axis are treated fairly, and that the work environment is safe and follows the Workers Compensation Act, including the Occupational Health and Safety (OHS) regulation [21].

[SS-49M] System shall use PLA 3D printed structure for casing to comply with a biological nutrient [15][16]
[SS-50M] System shall use locally sourced parts for prototyping to ensure material realization
[SS-51M] Excess scraps and electronic materials will be brought to electronic recycling facilities to ensure parts are returned to the industry
[SS-52L] Production stage will consider the CARI for recycling materials [18]
[SS-53L] Hydropower will be sought for manufacturing facilities to encourage renewable sources of energy
[SS-54L] Assurance that water stewardship is appropriate for the production of electronic components, such as semiconductors [20]
[SS-55L] For future production, company will seek to follow the regulations laid out by WorkSafe BC [21]

5.2 Safety Standards

Of course, the system itself must be safe to use, on a fundamental user interaction level. This entails having proper procedures set in place to ensure that the chances that a user can accidentally harm themselves are brought to a minimum. Most of these requirements feature common sense safety protocols such as not exposing sharp or moving components.

[SS-56M] System exterior will not have sharp edges in order to reduce injury risk to user
[SS-57M] System will be encapsulated in case in order to reduce moving part injury risk to user
[SS-58H] System will only dispense pills which can be accurately identified in order to protect health of user
[SS-59L] Users shall be notified of recall procedures if life threatening or harming flaws are found
[SS-60M] System shall come complete with reference documentation to ensure safe usage
[SS-61H] System will alert user when their pills are deposited, as well as notifying them when they have been taken in case the user forgets

6 Conclusion

Age brings challenges, some of which can affect the overall quality of life. When medication becomes routine, and maintenance of one's health suddenly becomes more important, it shouldn't have to be a trial to simply to take one's pills. With the senior population rapidly rising in Canada and many other developed countries, there is a shrinking ratio of caregivers to medical professionals. Seniors reside in the latter portion of their lives, so it would be a welcome addition to not have to balance and manage multiple prescription medications. With vision impairment and memory loss almost inevitable aspects of aging, it is no surprise that so many seniors tend to be drug noncompliant. By reducing the factors that affect this, such as providing a means to compensate for failing eyesight and a fading recollection, we can consequently reduce the likelihood of noncompliance. This, of course, will have a positive effect on not just their health, but their quality of living. Maintaining their medication will give them more time to spend with family, and participate in things they enjoy without needing to worry about the routine of their pills. Additionally, seniors just so happen to be the most pressing demographic in need of Axis. There exist several rural and Aboriginal communities which would also benefit from a device meant to axe drug noncompliance.

Although primarily designed for home use, with further research and investigation, it may be possible to add a degree of complexity to the device. In particular, having a standalone device unreliant on internet connection would be an attractive feature. Furthermore, a machine of this type has a great potential to become a cheap and easy alternative to pill machines at the hospital or pharmacy. With enough innovation and effort, it may be possible to see such a device operational in a hospital environment. While hospital staff and doctors are trying their best to avoid error, there is no harm in redundancy when it comes to safety.

Combining the different skills and talents of each individual in our team, blended with our common goal to bring efficiency and helpfulness to society, PharmaSort hopes to transition the Axis idea to reality.

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