June 14, 2020

Dr. Andrew H. Rawicz
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Simon Fraser University
Burnaby. BC, V5A 1S6

Auto-Pharm Tech.

RE: ENSC 405W/440 Requirements Specification for an Automatic Medicine Supplier

Dear Dr. Andrew H. Rawicz,

This documentation is prepared by Auto-Pharm Technology to review the requirement specification of our automated medicine supplier product, Auto-Pharm. Our target is to remind the elderly to take medicine when their children cannot supervise the elderly. They do not need to memorize the medicine and the operation of the instrument.

The following document will cover the feature requirements of Auto-Pharm's Proof-of-concept, Prototype and the Final product. We will detailly provide the requirements and justifications of Hardware, Mechanical, Electrical and Software. Then, review the Safety & Sustainability concerns and Engineering Standards that Auto-Pharms should address.

Auto-Pharm consists of five creative senior engineering students, coming from three different engineering majors. Our team has extensive Co-op working experience in software and hardware to help us complete this project.

Thank you for taking the time to review our requirements specifications. If you have any questions, advice, or comments regarding the document, please contact our Chief Communications Officer Yu(Hazel) Yang at yya168@sfu.ca.

Regards,

Richard Dong
Chief Executive Officer

Requirements Specification for Auto-Pharm

Automatic Medicine Supplier

Auto-Pharm Tech.

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Abstract

This document will specify the multiple types of requirements of the automatic medicine supplement system: Auto-Pharm. Firstly, the document will introduce the background purpose of the Auto-Pharm, and given a simple overview of the Auto-Pharm's functions. Secondly, the document will go into detail about the project's general, software, and hardware requirements. This document will also list the Engineering Standards, Sustainability, and Safety factors that Auto-Pharm will meet. The purpose of this document is to provide the readers with a detailed understanding which is the functions and operations of the Auto-Pharm.

The system contains two parts: the first one will be the User Online Website, which can be used to set the dosage of each medication, the time of taking medicine, etc. The second part is the physical machine which is able to provide the pill on schedule, the machine will be placed in the elderly's home and will provide the medicine they need to take. More detail will be provided in the main body.

Moreover, we will conclude our planned proof of concept, which will be shown in August 2020.

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Glossary

CSA	Canadian Standards Association
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
IEEE	Institute of Electrical and Electronics Engineers
W3C	World Wide Web Consortium

Contents

1. Introduction

1.1 Background

Despite the rapid changes in the field of medicine due to the development of science and technology, it is undeniable that there has been no fundamental change in the way people take medicine. The mainstream way of taking medicine is still oral and infusion, and in today's society, nutrition and health products also play an increasingly important role in people's daily lives. Because of the decline in the physical function of the elderly, the phenomenon of taking medicine has become more common. In the U.S.A, the ambulatory elderly need to fill between 9-13 prescriptions a year, and the average elderly patient is taking more than five prescription medications [1] and at the same time, many older adults will suffer from memory impairment and worse vision. This implies a lot of problems, for example, they need to take many types of medicines every day and it is hard to memory all the dosage of each medicine; Also, many elderly people failed to distinguish two kinds of the pill if the outlooking are similar and all of these situations will cause the medical accident. Also, their children are bound to worry about the elderly taking the wrong medicine or overeating pills when children cannot care for their parents. Therefore, how to help the elderly to reduce accidents caused by medication errors is a topic worthy of attention.

1.2 Basic information about the Auto-Pharm

The automatic medicine supplement system: Auto-Pharm is a solution to reduce the possibility of medication errors in the elderly and other above concerns. Auto-Pharm, which has the same name as the company, can remind the elderly users to take their medicine on time and interact with their children in real-time.

It provides a pills box in which multiple kinds of medicine can be stored. The children can set the time for taking medicine through the user interface. And the number of pieces as needed is given by the device directly. The device also included an alarm clock which will remind the elderly to take medicine at the time specified by setting through the website. Also, the emergency message will be sent to children if it keeps alarming for a while.

1.3 Scope

This document outlines the requirements of Auto-Pharm, this includes the general functional requirements that the entire system must meet; As well as the software and hardware requirement specifications. All of these requirements will be categorized by three stages of development, which is: proof of concept, prototype, and finished product. The document also outlines efforts to comply with engineering standards and sustainability/safety.

1.4 Intended Audience

This document will be considered as Auto-Pharm's requirement specifications for the members of Auto-Pharm Technology, Dr. Andrew Rawicz, Dr. William Craig Scratchley, teaching assistant: Mohammad Akbari and Chakaveh Ahmadizadeh, the project potential clients and partners. Please note: Future revisions and other related documents will draw on the framework detailed in this document.

1.5 Requirement Classifications

All requirement IDs in this document will be written in the following format:

< Req.Section.Subsection.Requirement Number.Stage of Development >

The short-writing for each stage of development will following the below table:

Short-writing	Stage of Development
C	Proof of Concept
P	Prototype
F	Final Product

Table 1.5-Short-writing with Stage of Development

Based on the displayed table above, the requirements of the stage: Proof of Concept, should be met by the end of ENSC 405W; The the requirements of the stage: Prototype should be eventually achieved by the end of ENSC 440; For the Final Product stage's requirements, it lists all the requirements that must be satisfied when the device is in production.

2. System Overview

Auto-Pharm is a senior-friendly and easy-use device that helps and assists the seniors to take medication safely and on time. The Auto-Pharm is designed for those who face a memory problem, have difficulties to remember taking medicines on schedule but with abilities to take care of themselves in daily life. With simple set-ups, it is a lower-price and easier-to-use device to assist the seniors' daily life.

This device is triangular prism-like which has about 30cm for side length and 35cm in height. The user needs to power it and set-up following the steps. With using a user interface on a simple website, the young contactors of the seniors can set up the medicine schedule and dose for the seniors. After matching the medicine storage boxes and the amount of the medicines, Auto-Pharm will be ready to use. It will automatically start to provide the needed amount of medications by the schedule. Further, it contains an alarm to remind if it is time to take

medicine, and has the ability to send an email to the seniors' children or other contactors if the alarm was activated for too long.

The Auto-Pharm's hardware was chosen to perform as a feedback system. Powered by a Raspberry Pi 4 (2GB memory), the Auto-Pharm will be able to control actions such as opening the door for the medicine, alarming for taking medicine, or powering the motor to rotate the storage boxes. It also has the ability to collect data, such as sensing the existence of the medicine, checking the scheduled time, or warning for refillings. Additionally, if we have enough time, we will modify the self-checking part, which allows the machine to check whether every medicine storage box has medicine. Given the information about Raspberry Pi 4, we should use a 5V 3A power charger. To control the 3 stepper motors, we need a small stepper motor driver to control the rotation degree. We also need a small servo motor to open and close the door for medication, an alarm to remind and some buttons with LEDs to show the signal and the status of the machine.

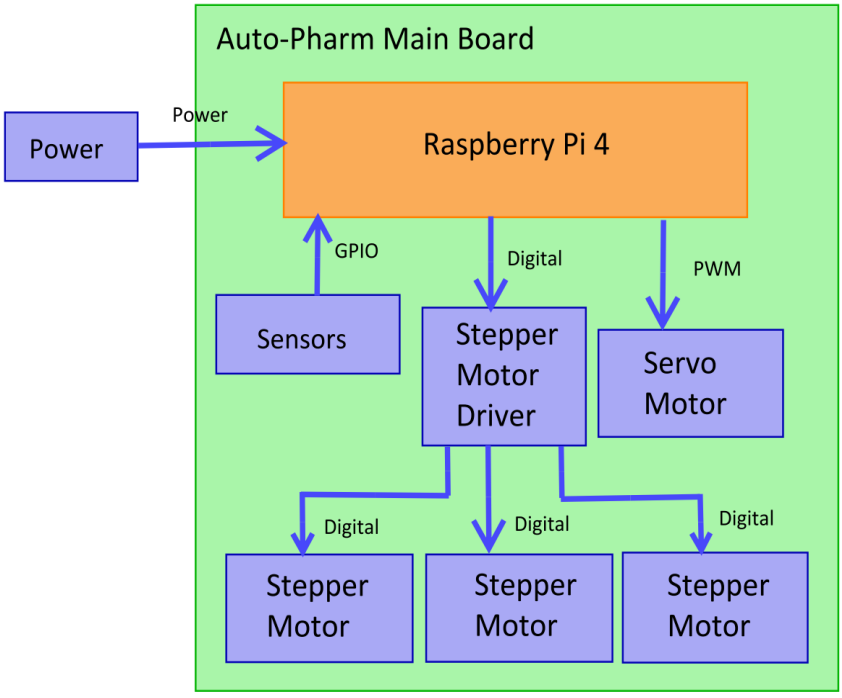

Figure 2.1-Auto-Pharm Hardware Block Diagram

The Auto-Pharm is a wise-designed and easy-use device. Our aim is to provide old people with a better life, decrease their suffering from life inconvenience, and improve their living conditions.

3.General Requirements

This section describes the general requirements for the system as a whole. The requirements for each component of the system will be detailed in the following sections.

3.1 System ReThe following table includes the general requirements for the system.

Requirements ID	Requirement Description
Req. 3.1.1 P	The system will consist of a microcontroller (Raspberry PI), three step-motors, a servo-motor, three gears, three timing belts, an audio output and a charger.
Req.3.1.3 P	The system must give the medicine on time.
Req. 3.1.4 C	The system will have an on/off button and a self-check button.
Req.3.1.5 C	The system will have four LED lights, which are power light, self-check light, medicine refilling light and a reminder light.
Req. 3.1.6 P	The size of the system will be within 30cm length, 30cm width and 35cm height triangular prism.
Req. 3.1.7 P	The price of the final product must be under $500.
Req.3.1.8 P	The system must send an email to the guardian when there is no one taking the medicine for a long time.
Req.3.1.9 F	The self-check process should be complete in 1 minute.
Req.3.1.10 P	The system should be able to detect whether the user takes the pillbox.

Table 3.1-System Requirements and Progress Requirements

3.2 Functional Requirements

The following table includes the general requirements for the system's functionality.

Requirements ID	Requirement Description
Req.3.2.1 P	The system will have a Wi-Fi module(or same function module) that can connect to the online server.

Req.3.2.2 P	The system must provide audio feedback to the user if the user does not take the medicine.
Req.3.2.3 F	The system will do self-check when refilling the pills.
Req.3.2.4 P	The system will flash the light and send an email to the guardian when there are not enough pills in it.
Req.3.2.5 P	The system can be controlled by an online website to set up the medical schedule.

Table 3.2-Operational Requirements and Progress

4. Software Requirements

Users can communicate with Auto-Pharm machine through the website. Our Website allows users to remotely send data and instructions to the Auto-Pharm machine. Users can set the time and dosage of the machine to release pills through the website. The number of pills will be monitored in real-time and displayed on the webpage. There is an alarm function which can send warning information if the user did not take the pills within the specified time. Also, we have the detection system to prevent human error when user supplement pills manually. With this function, a warning message will be sent to the user when there is a slot with an incorrect number of pills detected.

The Website will be hosted by firebase which is production-grade web content hosting for web development. Firebase hosting can provide a fast and secure hosting for the website which can ensure real-time data transmission between the Auto-pharm machine and the website.

4.1 General Requirements

The following table including the general requirements for the system software

Requirements ID	Requirement Description
Req.4.1.1 C	The website must be able to access on the basic desktop computer under stable network conditions
Req.4.1.2 C	Database storage must be large enough to store user data and machine data

Req.4.1.4 C	The website must be able to send the exact data of dosage set by the user
Req.4.1.5 C	The website must be able to send the exact data of medication schedule set by the user
Req.4.1.6 P	Email warning must be able to be sent if the user didn't take the pills for a while
Req.4.1.7 P	Warning email must be sent if the user doesn't take the pills within the specific time
Req.4.1.8 P	Warning email must be sent if the software cannot handle any exceptions
Req.4.1.9 P	Email must be able to send by Gmail

Table 4.1-General Software Requirements

4.2 Data Processing Requirements

The following table including the Data Processing requirements for the system software

Requirements ID	Requirement Description
Req 4.2.1 C	The database will use Firebase
Req 4.2.2 C	The database must be able to store the medicine names of the three storages set by the user
Req 4.2.3 C	The database must be able to store the medication and dosage set by the user
Req 4.2.4 C	The database must be able to update the real-time number of each type of medicine reported by the sensors in the machine
Req 4.2.5 C	The corresponding pills' number should be able to update in real-time based on the specific type of pill consumed or added
Req 4.2.6 C	The database must be updated automatically by the feedback of the sensor.
Req 4.2.7 P	The specified time period for the user to take pills should be able to change by the user.
Req 4.2.8 F	User's data must be secure and confidential.

Table 4.2-Data Processing Requirements

4.3 Detection System Requirements

The following table including the Detection System requirements for the system software

Requirements ID	Requirement Description
Req 4.3.1 P	The software must be able to detect the error number of pills in each slot with a 90% success rate
Req 4.3.2 P	The initial pill counts from the database must be synchronized with the number of pills after user supplementing manually.
Req 4.3.3 P	A warning email should be sent to the user if the number of pills in any slot is wrong.

Table 4.3-Detection System Requirements

4.4 Performance Requirements

The following table including the Performance requirements for the system software

Requirements ID	Requirement Description
Req 4.4.1 P	The software must be able to start up within 10 seconds
Req 4.4.2 F	Website response time must be less than 3.0 second
Req 4.4.3 F	The website must reach to 99% uptime
Req 4.4.4 C	The website can store data up to 1GiB

Table 4.4-Software Performance Requirements

5. Electrical Requirements

The core of the device is the Raspberry Pi 4 which works as a kernel to collect information and command each component. In this way, the hardware needs to be controlled by the software. The amount of medication and schedule to take medicine will be collected by the website UI and transferred to the Raspberry Pi, which means the board has to be connected through wifi for the whole day if possible.

For the proof of concept, please refer to the Appendix part. The prototype will have the necessary functions and circuits to efficiently run our software and have the ability to control the hardware.

5.1 General Requirements

The following table includes the general requirements for the system's electronics.

Requirement ID	Requirement Description
Req 5.1.1 P	Circuit well-connected and able to perform basic functionalities
Req 5.1.2 P	Circuit protection for all electrical components and hardware
Req 5.1.3 P	Circuit protection for electrical failures
Req 5.1.4 F	Neat wiring inside the machine
Req 5.1.5 F	3D printed project cover

Table 5.1-General Electrical Requirements and Progress

5.2 Power Supply

The following table includes the power requirements for the system's electronics.

Requirement ID	Requirement Description
Req 5.2.1 P	The Raspberry Pi 4 needs 5V 3A power supply to operate
Req 5.2.2 P	The stepper motor needs 5V stepper motor driver to control
Req 5.2.3 P	The servo motor needs 5Vto power and PWM signal to control
Req 5.2.4 P	The power button with LED needs 5V 20mA to light
Req 5.2.5 P	The refilling button with LED needs 5V 20mA to light
Req 5.2.6 F	The checking button with LED needs 5V 20mA to light

Table 5.2-Power Supply Requirements and Progress

5.3 Other Components

Requirement ID	Requirement Description
Req 5.3.1 P	The force sensor needs analog pinout to read

Table 5.3-Other Components Requirements and Progress

6. Engineering Standards

For designing and developing pharmaceutical products, following the correct standards is the ultimate directive. Thus, the standards published by acclaimed organizations and authoritative officials such as the Canadian Standards Association (CSA), International Electrotechnical Commission (IEC), International Organization for Standardization (ISO) and the Institute of Electrical and Electronics Engineers (IEEE) will guide Auto-Pharm Tech. to develop a quality and durable product. The operation and construction of Auto-Pharm shall comply with the following engineering standards.

6.1 Electrical & Mechanical

In the design, the power supply is utilized to operate the motors, therefore, the proper consideration of electricity and mechanical will be listed in the following table.

Standard	Description
IEC 61508-2 [2]	Req 6.1.1- F The instrument shall obey the rules in the standards – "Functional safety of electrical/ electronic/ programmable electronic safety-related systems- Part 2"
IEC 60950-1 [3]	Req 6.1.2- F The voltage supply utilized in the operation of Auto-Pharm shall conform to general standards- "Information technology equipment- Safety-Part 1: General requirements"
CAN/CSA-C22.2, No.100-14 [4]	Req 6.1.3- F The stepping motors with the driver must adhere to the safety list in "CAN/CSA-C22.2, No.100-14- Motor and generators"
IEC TS 60034-20-1: 2002 [5]	Req 6.1.4- F The action of stepping motors shall comply with the "Rotating electrical machines- Part 20- 1: Control motors- Stepping motors"
IEEE 2700- 2017 [6]	Req 6.1.5- F The sensor performance shall confirm the "IEEE Standard for Sensor Performance Parameter Definitions"
ISO 10218-1: 2006 [7]	Req 6.1.6- F The automatic instrument must adhere to the Part 3.2 "Automatic mode -- Operating mode in which the robot control system operates in accordance with task program"
IEEE C2 [8]	Req 6.1.9- F Auto-Pharm shall satisfy the "Preprint Proposals for the 2022 Edition of the National Electrical Safety Code (R) (NESC(R))"

Table 6.1-Electrical & Mechanical Engineering Standards

The installation and usage standards of electrical components and motors guide us to consider more safety issues, especially the elderly are our target market. The above table is a part of safety regulations about electrical and mechanical. The requirements for the safety of Auto-Pharm will be listed in the Safety & Sustainability section.

6.2 Software

There are standards about coding development and testing including design a website to lead Auto-Pharm more completely. To be more specific, the World Wide Web Consortium (W3C) published the standards about web design and the IEEE, ISO added serval programming regulations. Table 6.2 listed the requirements:

Standard	Description
W3C [9]	Req 6.2.1- F The website design in Auto-Pharm shall comply with the “WEB DESIGN AND APPLICATIONS”
IEEE 802.11ax [10]	Req 6.2.2- F The wireless communication in the website shall obey the “IEEE 802.11ax: High-efficiency WLANS”
ISO/IEC 22534: 2005 [11]	Req 6.2.3- F The relationship between the application and the controller must adhere to “Information technology -- Telecommunications and information exchange between systems -- Application session services”
IEEE 1016-2009 [12]	Req 6.2.4- F The software design description shall follow the standards in “IEEE Standard for Information Technology- Systems Design- Software Design Descriptions”
IEEE 1074.1- 1995 [13]	Req 6.2.5- F The software develop shall address the standard in “IEEE Guide for Developing Software Life Cycle Processes”

Table 6.2-Software Standards

These specifications help the development of logic about the software program includes the communication between the product and the network- Internet of Things (IoT) to become complete and reasonable.

6.3 Environment

The impact of the product on the environment is also a point that Auto-Pharm must be considered. So that we should confirm the environment and the life cycle requirements of Auto-Pharm in CSA and ISO:

Standard	Description
ISO 14040: 2006 [14]	Req 6.3.1- F Auto-Pharm shall be friendly to the environment because of the standard- “Environmental management- Life cycle assessment- Principles and framework”
CAN/CSA- C22.2 No. 60601-1-9: 15 [15]	Req 6.3.2- F The Auto-Pharm systems shall not violate standards in “Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design”
ISO/TR 14062: 2002 [16]	Req 6.3.3- F The development process of Auto-Pharm shall follow the “Environmental management -- Integrating environmental aspects into product design and development”

Table 6.3-Environment Standards

Environmental protection is a necessary factor for product development, especially utilizing some components that can be recycled will have ultimate value. The requirements for the Sustainability of Auto-Pharm will be outlined in section 7.

7. Safety & Sustainability

7.1 Safety

As a product, Auto-Pharm is plugged into the wall and operates electricity and motors. Meanwhile, most of the fundamental users interacting with the product are the elderly, so we need to increase the requirements of procedure to prevent accidental damage to the elderly. According to the engineering standards, requirements are outlined below:

Req 7.1.1- P	Auto-Pharm should have no sharp edges in order to prevent unexpected injury to the elderly
Req 7.1.2- P	The wires must adhere to be hidden into insulated shall to reduce the risk of electricity leakage
Req 7.1.3- P	The systems in Auto-Pharm shall not make the pills toxic to the security of the elderly’s life
Req 7.1.4- F	Auto-Pharm shall shut down the systems automatically once the risk factors occur such as overheating

Req 7.1.5- F	The system will alert the guardian of the elderly when there is not enough medicine in the instrument
Req 7.1.6- F	The motors shall not provide harmful noise and will not cause physical injuries to the elderly

Table 7.1-Safety Requirements

Safety is definitely our top priority when we design Auto-Pharm as our target customers are the elderly and their guardians. The previous engineering standards allowed us to perfect our safety requirements in order to protect the health of the elderly.

7.2 Sustainability

The qualification of Auto-Pharm should not only consider the safety and integration of functional implementations, but also components' service life. To explain more, there is a philosophy in the Cradle-to-Cradle (C2C) production system that all components can be used for the next process [17]. Based on this point, Auto-Pharm tech. listed the following requirements:

Requirement ID	Requirement Description
Req 7.2.1- C	Unnecessary packaging and spacers between pills should be avoided
Req 7.2.2- C	The microcontroller and motors can be reused to next process
Req 7.2.3- P	The command for stopping the operation of Auto-Pharm immediately shall not cause damage to the electrical components
Req 7.2.4- F	The power consumption shall not perform highly waste on energy

Table 7.2-Sustainability Requirements

The development and operation of the product should be sustainable with consideration of life and future generations. The environmentally friendly product will indirectly prevent the endangerment of the elderly.

8. Conclusion

The core purpose of Auto-Pharm is to reduce the risk of medical errors or safety hazards caused by medication errors/untimeliness by standardizing the safety of older people taking their medications. This medical aid device is designed to help children prepare their parents' daily needed medications more conveniently and effectively. The user concept of this product will be simple and easy to use, that is, users do not need to spend a lot of time reading the instructions of the product.

Also at the beginning of the design, the company adhered to the concept of providing convenience to the majority of the elderly group implemented strict control and supervision on product materials and technologies and tried to compress product costs to the minimum while ensuring product quality. To control the final selling price of the product, Auto-Pharm Technology will ensure that the product can be borne by most families.

Auto-Pharm Technology is committed to providing users with more concise and practical products. This product fully reflects the company's philosophy and brings real convenience to users. The engineering team of Auto-Pharm Technology will provide customers with excellent, reasonably priced products that meet all the requirements of this document.

9. Appendix

Acceptance Test Plan

Date:

Electrical & Mechanical Part	
1. The Turntable Works Ideally	comments
Rotation ☐Yes ☐No	
Speed and Direction ☐Yes ☐No	
2. Pills Moving Channel	comments
Pills can reach ideal place ☐Yes ☐No	
Channel Switch working ☐Yes ☐No	
3. Warning Alarm	comments
Sounding works ideally ☐Yes ☐No	
Response On-time ☐Yes ☐No	

Software Part	
1. Website	comments
Start-up Time: less than 10 secs: ☐Yes ☐No	
Up Time: less than 3 .0 secs: ☐Yes ☐No	
2. Software	comments
Able to receive feedback from sensor ☐Yes ☐No	
Able to interact with Stepper Motor Driver properly ☐Yes ☐No	
Able to interact with Servo Motor properly ☐Yes ☐No	

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[15] “CAN/CSA-C22.2 NO. 60601-1-9:15 (R2019) Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral standard: Requirements for environmentally conscious design (Adopted IEC 60601-1-9:2007, edition 1:2007 consolidated with amendment 1:2013, with Canadian deviations)”, CSA Group, 2015. [Online] Available: https://store.csagroup.org/ccrz__ProductDetails?viewState=DetailView&cartID=&portalUser=&store=&cclcl=zh_CN&sku=CAN%2FCSA-C22.2%20NO.%2060601-1-9%3A15.

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