IBEHS 3P04 – Health Solutions Design Projects III

Milestone 4 – Analysis, Outcomes, & Recommendations

Group 37

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Academic Integrity Statement

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Executive Summary

This report details the design controls, risk management plan, and economic analysis for a blister pack medication storage and management system. If the project is pursued further, it will span a 5-year period. The device consists of two physical components: a 3D-printed case that securely holds a blister pack, other electrical components of the system, and a spring-based “pill-puncher” that helps dispense a pill from its package. The device also has a hardware component that incorporates an MSP430 microcontroller chip to allow the user to track the number of pills remaining and set a daily medication reminder alarm. The primary goal of the device is to improve medication adherence by providing a medication reminder that is physically tied to the medication storage. Additionally, the device aims to help people with limited hand dexterity more easily dispense their own medication.

Several design inputs and corresponding design outputs were specified for this device. Design inputs include performance metrics for user interaction and the alarm functionality of the device, as well as design parameters such as product dimensions and longevity. In addition to mechanical sketches and material specifications, the key design outputs were the hardware and software components, which were the focus of design verification testing. The testing plan outlines the procedure for verifying one of the alarm-related design inputs: “notification/alarm always goes off within 1 minute of the specified time.” This design input was chosen for verification because alarm performance is integral to the overall goal of the device. The initial prototype used for verification consisted of an MSP430FR133 microcontroller, a peripheral buzzer, and a program written in C. The test involves device set-up, configuring the clock and alarm, and waiting to see if the alarm sounds within one minute of the set time. The outcome of the verification test was successful, indicating that there is potential to develop this device and pursue the project.

Failure modes and the effect of each failure were identified and classified by severity and probability of occurrence. The following failures were determined to be unacceptable due to their high severity: “user is notified more than the required amount,” and “medication is contaminated.” Since the device directly interacts with medication, failures that affect the medication itself or the frequency in which the user takes the medication could have life-threatening consequences. Adding a warning for users would reduce the risk of medication contamination to as low as reasonably practicable (ALARP). However, at this stage of development, the risk of over medication cannot be sufficiently mitigated, indicating that the project should not be pursued.

To further determine the viability of this project, three economic models were considered and analyzed, in comparison to the option to do nothing (i.e., not pursue the project). The reference model involves in-house fabrication of the device and wholesale distribution. The first alternative includes in-house fabrication but uses a retail sales method. The second alternative is to outsource fabrication and sell the device wholesale. A present worth comparison was used to determine which business model would be the most profitable. After considering that 30% of the company value will be returned to the investor, the group profits for the reference, alternative I, and alternative II were $166,646.93, $484,497.51, and -$10,654,010.73 respectively. The group profit if the project it not pursued is $14,000. Alternative I is the most profitable because in-house fabrication reduces production costs while retail sales increase the price point and revenue per unit. However, the assumptions made in the economic analysis are over-simplified and optimistic, so this is not enough evidence to support pursuing the project.

Based on the risk and economic analysis results, the project should not be pursued. In addition to the unacceptable risk the verification testing is limited in scope and does not guarantee that the project would be successful. Additional design inputs would require verification to conclusively demonstrate a viable device. As well, the economic analysis relies on hypothetical values, particularly the sales revenue. Therefore, the recommendation of this report is that the project should not be pursued.

Design Controls

Design Inputs

The design inputs for the smart pill case were developed based on the customer requirements that drove device development. Both the design inputs and customer requirements are summarized in Table 1.

*Table 1: List of design inputs and their associated category and customer requirements. Design inputs that have been since updated/added from Milestone 2 are labelled with an ** and can be found in the latest edition of the QFD table within the DHF.*

Design Input	Category	Matched Customer Requirement
Device is suitable for blister packs with dimensions up to 10x8.5x1.5 cm	Design	The device can be applied to various blister pack medications and designs
Notification/alarm always goes off within 1 min of specified time	Performance	The device notifies the user to take their medication at a user-defined time
Alarm buzzer must produce a sound of 75 dB or higher	Performance	The device notifies the user to take their medication at a user-defined time
Communicates with a cell phone (yes/no)	Performance	The device implements a secondary method of notification if user does not take their medication
Recognizes when a pill has been taken with 95% accuracy	Performance	The device can track if medication has been taken
Hardware can receive and store 1 gigabyte of data	Design	The device accepts user input for pills per pack and number of packs
**Case has three buttons for user to navigate the LCD program	Design	The device accepts user input for pills per pack and number of packs
**Case displays pill counter, warning for low pill count, and alarm	Performance	The device notifies the user when a prescription refill is required
User is notified for medication refill at 10 doses remaining	Performance	The device notifies the user when a prescription refill is required

Design Input	Category	Matched Customer Requirement
Product is fully functional for at least 5 years	Design	The device is long lasting and durable
Product does not exceed 12x9x3 cm	Design	The device is portable and lightweight
Product weighs no more than 200 g	Design	The device is portable and lightweight
**Amount of force user must apply does not exceed 120 N [1]	Performance	The device is accessible for people with numerous dexterity levels.
Device can apply 30.5 N of force to the blister pack [2]	Performance	The device can open an individual cell of the blister pack
Device can successfully remove 1 pill from the blister pack	Performance	The device can open an individual cell of the blister pack
Medication remains physically intact and drug efficacy does not decrease	Performance	The device does not alter medication
Incidence of injury is less than 40% in preliminary testing [3]	Performance	The device reduces the risk of injury for blister pack medication opening

Design Outputs

The design outputs were developed to fulfil the design inputs provided in Table 1. Table 2 outlines all design outputs as well as their corresponding design input(s). Initial drafts as well as final representations of the design outputs are included in Figures 1-5 below.

*Table 2: List of design outputs along with their associated design inputs. Design outputs labelled with an ** have been updated/added after Milestone 3.*

Category	Design Output	Matched Design Input(s)
Hardware Components **(see Figure 1)**	x1 MSP430FR4133 microcontroller [4]	Encompasses all design inputs
	x1 Buzzer	Alarm buzzer must produce a sound of 75 dB or higher
	x1 Pin layout for necessary connections	Communicates with a cell phone (yes/no)
Software Components **(see Figure 2)**	x1 *main()* function	Encompasses all inputs related to software components
	x1 Pill counter function	Recognizes when a pill has been taken with 95% accuracy
		Case has three buttons for user to navigate the LCD program.
		Notification/alarm always goes off within 1 min of specified time
		User is notified for medication refill at 10 doses remaining
	x1 LCD display function	Notification/alarm always goes off within 1 min of specified time
		User is notified for medication refill at 10 doses remaining
		Case displays pill counter, warning for low pill count, and alarm
	x1 Buzzer deactivation function	Notification/alarm always goes off within 1 min of specified time
		Alarm buzzer must produce a sound of 75 dB or higher
	x2 Functions for setting clock and alarm	Notification/alarm always goes off within 1 min of specified time
		Case has three buttons for user to navigate the LCD program
	x1 Flowchart for sending notification to a cell phone	Communicates with a cell phone (yes/no)
Mechanical Sketches **(see Figures 3-5)**	x1 Casing component	Amount of force user must apply does not exceed 120 N Device is suitable for blister packs with dimensions up to 10x8.5x1.5 cm
	x1 Pill dispenser	
	** x1 Preliminary CAD models of device	
	** x1 Preliminary 3D prints of device	
Material Specification	x1 Outer casing	Amount of force user must apply does not exceed 120 N
	x1 Pill dispenser	

Category	Design Output	Matched Design Input(s)
Other	Instruction manual explaining how to navigate the software using the push buttons.	Case has three buttons for user to navigate the LCD program

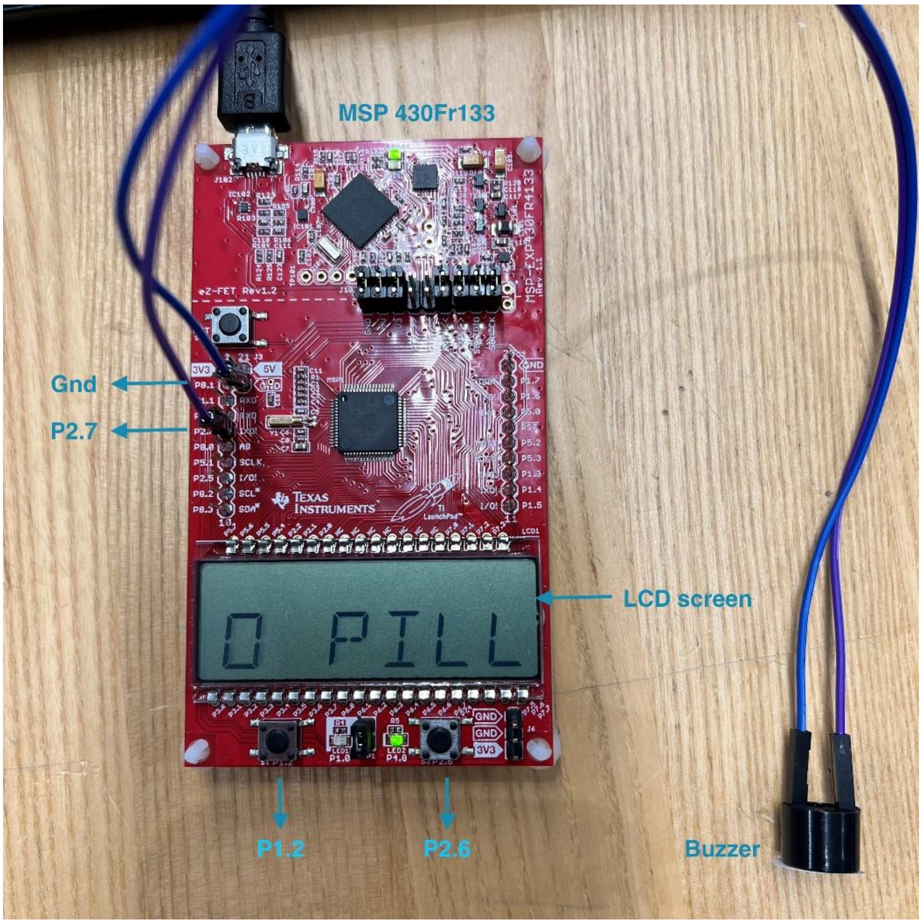

Figure 1: Picture of the MSP430FR4133 microcontroller. There are three onboard push buttons (P1.2 and P2.6 are labelled) and an LCD screen. The LCD screen is used to display the user interface in which the user uses the onboard push buttons to navigate. The ground pin and one of the GPIO pins are used to connect to the buzzer for alarm functionality.

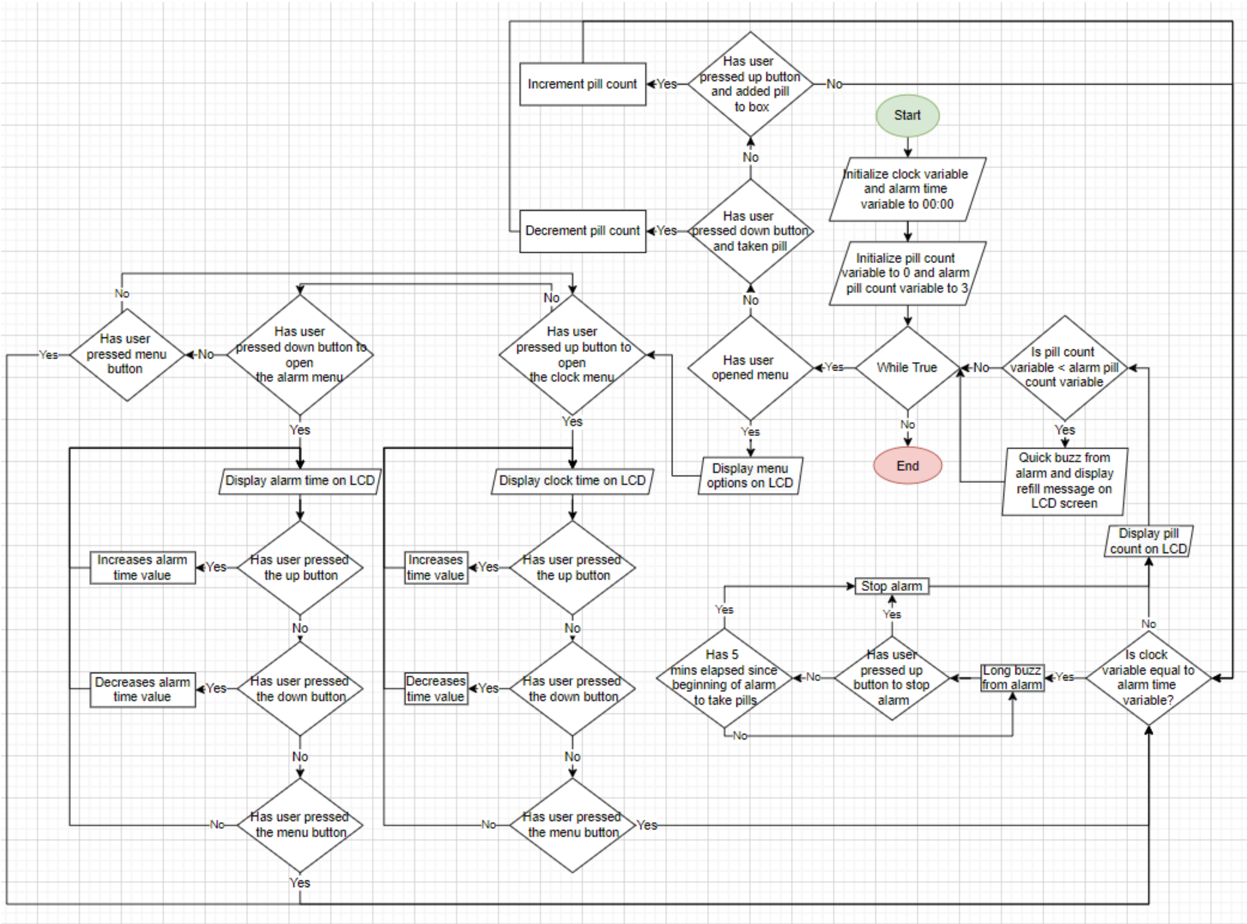

Figure 2: Preliminary flowchart for general use of the device. This implements the software and hardware design outputs.

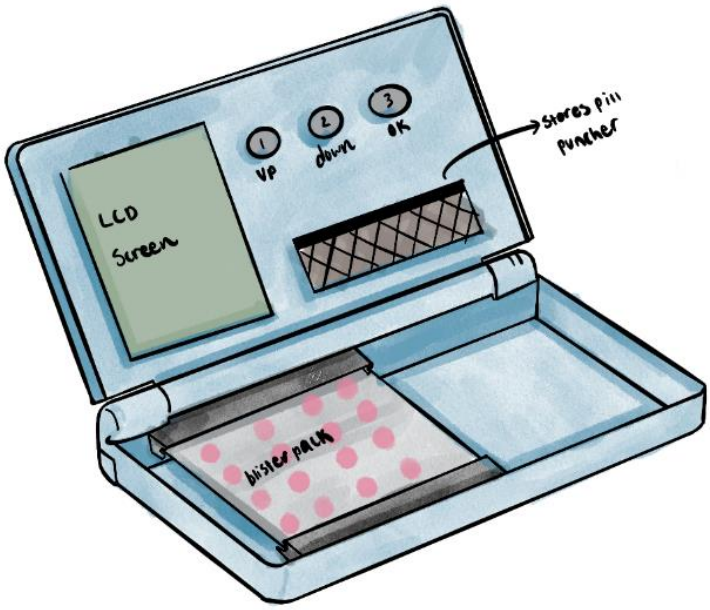

Figure 3: High-level sketch of the device (mechanical sketch design output).

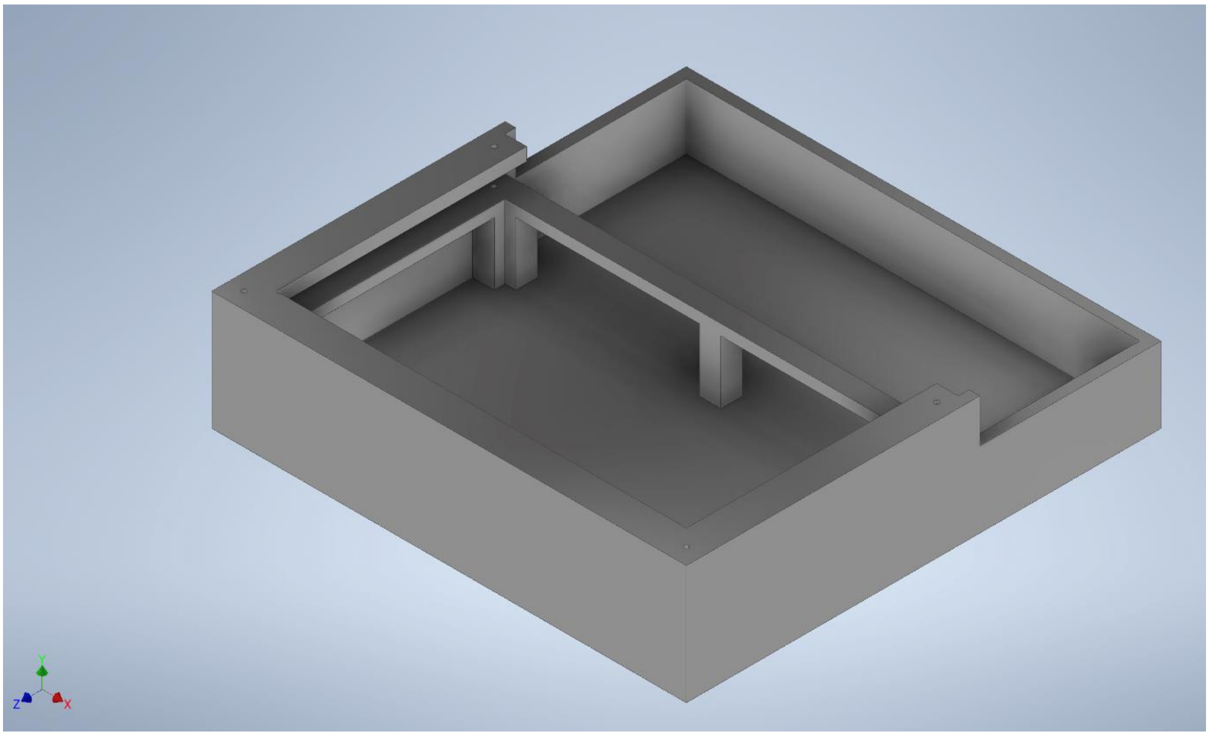

Figure 4: Preliminary CAD model of the device. This design output ensures that its associated design inputs will eventually be met after multiple prototypes.

Figure 5: Preliminary 3D printed model of the device. This design output ensures that its associated design inputs will eventually be met after multiple prototypes.

Design Verification and Testing Plan

The design input that the verification plan tests is that the device "notification/alarm always goes off within 1 minute of the specified time."

Purpose of Test

For many daily medications, the time of ingestion is an important component of adherence. Since the device is meant to improve adherence and reduce the burden of the user, an alarm that properly notifies the user when to take their pill is necessary. Moreover, proper functioning is necessary because missed medication can result in negative effects like reduced medication efficacy. Therefore, this test is necessary to confirm the device performs at the level outlined by the design input.

Experimental Apparatus

- A computer with *Code Composer Studio* (CC) downloaded [5].
- MSP430FR133 [d]
- An adapter with a micro-USB end to connect to the microcontroller and the other end to the computer (e.g., USB or USBC).
- Buzzer that can be connected to the GPIO pins of the microcontroller.
- Two female-to-female jumper wires to connect the buzzer to the GPIO pins of the microcontroller.
- ZIP file containing software to be uploaded to be flashed to the microcontroller.
- Stopwatch or any external time tracking device that tracks hours, minutes, and seconds.

The microcontroller and buzzer seen in Figure 1 are the ones used for implementing this experimental apparatus and are also part of the device prototype. The 3D printed case seen in Figure 5 is not part of the experimental apparatus but is solely part of the prototype.

The MSP430FR133 comes with two onboard push buttons that are used throughout the experimental protocol. Refer to Table 3 for the functions of each button before performing the experiment.

Experimental Protocol

1) Connect the MSP430 microcontroller to a computer using an appropriate adapter (specified above).
2) Open CC on the computer.
3) Un-zip the code and load the project to CC.
4) Connect the buzzer to the microcontroller with the positive labeled node of the buzzer to pin 2.7, and the remaining buzzer node to any pin on the microcontroller labeled "GND"
5) Run the code.
6) The buzzer will sound by default as the pill count is initialized to zero thus triggering the alarm. Press Button 1 at least five times to increment the pill count to five or more to stop the alarm (alarm will stop for any pill count greater than five).
7) Enter the main menu – refer to Table 3 for the specific buttons necessary to enter the menu.
8) Enter the clock setting menu – refer to Table 3.
9) Set device clock to current time. Note that if you are in AM and want to switch to PM (and vice versa), increase the hour to 12 to switch. Also note that the minutes reset to 00 if incremented past 59. Refer to Table 3 for specific button sequence.
10) Return to the main menu.
11) Enter the alarm setting menu – refer to Table 3.
12) Set the alarm clock to be one minute from the current time set in Step 9.
13) Wait for one minute for the alarm to sound using your time tracking device.

14) After one minute, the buzzer should sound. Make sure to raise the buzzer close to your ear if you cannot hear it at first as the one used for this experiment is not very loud.
15) Stop the alarm by decreasing the pill count – refer to Table 3.

Table 3: Functionality of the two onboard push buttons on the MSP430FR133 used for the experimental protocol.

<table>
<tr><th>Button(s)</th><th>Pill Counter
(Screen 1)</th><th>Main Menu
(Screen 2)</th><th>Setting Clock
(Screen 2a)</th><th>Setting Alarm
(Screen 2b)</th></tr>
<tr><td rowspan="2">Button 1 (P1.2)</td><td rowspan="2">Increments counter</td><td rowspan="2">Enter Setting Clock</td><td>(1) Increment hours</td><td>(1) Increment hours</td></tr>
<tr><td>(2) Increment minutes</td><td>(2) Increment minutes</td></tr>
<tr><td rowspan="2">Button 2 (P2.6)</td><td>Decrements counter</td><td rowspan="2">Enter Setting Alarm</td><td>(1) Sets hours and transitions to minute setting</td><td>(1) Sets hours and transitions to minute setting</td></tr>
<tr><td>Stops alarm from sounding</td><td>(2) Sets minutes and returns to Main Menu (Screen 2)</td><td>(2) Sets minutes and returns to Pill Counter (Screen 1)</td></tr>
<tr><td>Button 1
&
Button 2</td><td>Enter Main Menu</td><td></td><td></td><td></td></tr>
</table>

Outcome and Analysis

In the design demonstration, the MSP430FR133 was already connected to the computer with the buzzer connected and the code loaded to it prior to the actual demonstration to save time. When code was flashed to the microcontroller, the alarm went off as expected since the pill counter is set to 0 by default. When the pill counter is incremented, the number can be seen increasing on the LCD screen.

As well, the hours and minutes can be seen on the LCD screen when setting the desired clock and alarm times. An external iPhone stopwatch was used to track the seconds between the time between setting the alarm and the alarm going off as the seconds cannot be inputted using the experimental apparatus. One minute later, the MSP430FR133 successfully triggered the buzzer, and a sound was emitted.

The outcome of this experiment during the design demonstration showed that the current prototype of the device is correct in that it satisfies the design input “notification/alarm always goes off within 1 minute of the specified time.”

Recommendations

The recommendation based on the outcome of this experiment and the underpinning question of "what should we do?" is that this device is worth pursuing further. The assigned design input "notification/alarm always goes off within 1 minute of the specified time," is one of the most important controls associated with the smart pill box design. The improvement of prescription adherence is one of the central customer requirements outlined in the development of the project idea. Therefore, the successful implementation of this design input in the current prototype as verified by the test plan suggests it is reasonable to recommend moving on to the next step of verifying more design inputs and to continue developing the prototype.

One limitation of this verification testing plan is that the user cannot input seconds for the clock or alarm as the LCD screen on the MSP430FR133 is limited in the number of symbols it can display. As a result, it is not possible to know if the alarm activates in exactly one minute of setting it. The resulting error in measurement can be mitigated by including a display for the number of seconds or displaying a counter that goes down until the alarm is activated for testing purposes. Another limitation of this verification testing plan is that there is a mechanical debounce from the button presses that results in the microcontroller treating one button press as two separate presses, causing an unwanted function call to occur. This error can be mitigated by including functions to wait however many seconds it takes for the mechanical debounce to occur before performing the button's desired task. A limitation in the nature of the verification plan was the inability to test the 24-hour alarm repeatedly. The limited time for verification rendered this test unachievable. The repetitiveness of the alarm is another key feature; however, this limitation is not of significant concern because it can be included in test plans further along the project development timeline.

In summary, the recommendation to further pursue the device as students is based on the successful outcome of the verification test and the correctness of the current prototype in that it satisfies its assigned design input. The limitations outlined above have solutions that fall within the skill set of the team as does the remaining design inputs necessary to complete the device. The completion of this crucial component of the device has made the team feel capable of correctly and efficiently executing the remaining technical aspects of the project.

Risk Management

Possible failure modes and effects of failure are listed in Table 4. Each failure mode was classified based on severity and probability according to. or unacceptable risks, mitigation plans are listed in Table 5.

Table 4: Risk Classification and Reasoning.

Failure Mode	Effect of Failure	Severity, S	Probability, P	Risk Classification	Reasoning
User is not notified to take pill	User does not take their meds at the appropriate time	3	2	Broadly acceptable	The secondary notification will still prompt the user to take their medication and user can take medication on their own.
User is notified more than required amount	User overdoses on required medication	5	2	Unacceptable	Possibility of user blindly taking medication when the notification goes off. Over-medication could result in poor health or even death
Caregiver or user not notified of missed medication	User either does not take meds at appropriate time or at all.	3	3	ALARP	Low possibility: however, not being able to notify the caregiver is more serious than not notifying user. If the caregiver is not notified and the user is cognitively impaired, the user will have no way to be alerted to take medication.
Device fails to notify user that they ran out/are close to running out of medication	User does not refill their medication/is not able to take medication because they don't have any	1	3	Broadly acceptable	The blister pack design makes it generally easy to recognize when medication is low.
Device does not detect when pill is taken	Device provides secondary notification when not required	2	4	ALARP	If a caregiver is unnecessarily contacted, the user would be able to confirm that they did take their medication. If the user is notified that they missed their medication, they would know that they had just recently
Device mechanical components break due to excessive force	Medication rendered inaccessible or contaminated, user injured while	3	3	ALARP	The worst-case scenario is that the user is not able to access their medication however, it is more likely that the user is slightly inconvenienced when accessing their medication.

Failure Mode	Effect of Failure	Severity, S	Probability, P	Risk Classification	Reasoning
	interacting with device				
User is injured while using device	Patient is lightly injured when taking meds	2	1	Broadly acceptable	Any injury that a participant received from mechanical usage of a blister pack would not be very serious - at most it would be on the same scale as a papercut
Medication is contaminated	Patient is not receiving correct prescription, may become ill	5	1	Unacceptable	Contamination could, although unlikely, cause the medication to become severely harmful to the user, potentially causing death. Or participants will be taking their medication but not be receiving the full effects due to reduced effectiveness

Table 5: Risk Mitigation Plan

Failure Mode	Severity, S	Probability, P	Risk Mitigation Plan	Category
User is notified more than the required amount.	5	2	Include a check after the pill count is decreased to determine if more than one pill has been taken in the 24-hour time frame	Design change
Medication is contaminated	5	1	Inform consumers that improper use of the punching device or rough handling may result in damage to the packaged medication.	Warning

Recommendations

The risk mitigation plan, provided above in Table 5 attempts to mitigate the unacceptable risks identified in Table 4. The plan suggests that the most concerning risks of the device, over notification and medication contamination can be effectively controlled by a design change and warning. Concerning over notification, a condition in the software that recognizes a secondary medication alert via a secondary pill decrease would reduce the possibility of the user being notified. The plan, however, does not reduce the severity of the risk because the consequences of overmedicating remain the same. Thus, despite this risk mitigation plan, the failure mode remains unacceptable.

The warning applied to mitigate the risk of medication contamination would work to reduce severity to a four. By providing a warning, users would handle the device with more care and therefore the damages that may occur would be miniscule resulting in minimal to no contamination. Therefore, the "medication is contaminated," failure mode can be reclassified as ALARP.

Based on the results of the risk mitigation plan, it is recommended that the project not be pursued. The risk mitigation plan is unable to reduce the unacceptable risk of user over-notification from the classification of unacceptable therefore making it unwise to pursue the project. Moreover, the risk analysis suggests that this should not be pursued as a student project because of the likely complications that would arise from the unacceptable risks. Based on one of the target populations, elderly people requiring assistance with medication adherence, concerns such as memory and medication intensity must remain at the forefront of decision-making. The consequences of over notification could be life or death and the risk mitigation plan is unable to reduce the severity of this failure.

The risk mitigation plan is very definite, and lacks nuance compared to what might be considered by certification boards like the CFIA. Automated pill dispensing devices that have been brought to market would face this same risk, yet they have been approved. This is a direct result of the coarse assignment procedure of the risk management process. If the possibility of this over notification could be reduced to some significantly small number, then it is likely that the device would be approved and accepted on the market.

On the other hand, the risk mitigation plan presented is limited to the minds of the creator. A designer pictures the device being used how they intend but that is not often the case. Thus, there likely exist unacceptable risks that would present themselves during first product launch or in a focus group that would solidify that the project should be abandoned. These risks could not be mitigated until brought to attention therefore resulting in a limitation in the risk management process.

In the unlikely event that the device was to fail by causing the user to overdose or by contaminating the medication to the point its harmful to the user, the company could face a lawsuit. With the permanent damages that could be done to the user, the lawsuit could be detrimental to the company. The company would still be early in its development and would not have the resources to face major lawsuits. With the lack of legal resources, a lawsuit due to the device causing bodily harm or death could potentially cause the company to shut down.

Therefore, the risk mitigation plan provided above, in tandem with the limitations above, do not support the pursuit of this project by five full-time university students. The risk, at this stage of development, is unacceptable which would slow the project timeline and increase the possible personal risk of the students involved.

Economic Analysis

Assumptions

The following assumptions are held throughout the entire economic analysis (including project alternatives). Assumptions that are associated with a specific cash-flow alternative are outlined in its corresponding section.

1) The product would be on the market six months from the start of the project.
2) The project would use over $20,000 before the product reaches market therefore a loan is required.
3) A loan of $70,000 will be obtained with a nominal interest rate of 10% [7]
4) The cost per unit for each cash flow is consistent throughout the duration of the project.
5) A software developer is hired at $40.00/hr at the start of the project timeline at 10 hr/week and kept on throughout the complete timeline.
6) 25% of revenue goes toward overhead costs.
7) There is no app development throughout the project timeline.
8) There is no wet-lab space required throughout the project timeline.
9) There is no salvage value of any equipment purchased at the end of the project timeline.
10) There is a $4000 annual marketing disbursement.

Project Alternatives

Reference

As the baseline for comparing alternatives, this projection considers manufacturing the device in-house then wholesaling to retailers. As the units are being sold wholesale, the price per unit is $30. The assumptions for the reference cash-flow are listed in the tables below (Table 6-10) and a cash-flow diagram can be seen in Figure 6. All device production equipment will be acquired at the beginning of the project, while they will only be used at later stages when more labourers are hired to use it. While the equipment will be purchased early on, it will not lose much value as the unused equipment will be safely stored, ensuring that the equipment's functionality is not hindered by long-time usage.

Table 6: Initial cost assumptions

Initial Costs		
Expense	Cost	Purpose
Website Commission [8]	$20,000	The website will be used for purchase inquiries, partnership inquiries, advertisement, product description, hiring calls, and other relevant information about our company.
Sewing Machine (x4) [9]	$500 per machine	Sewing machines will be used to place the finishing material around the 3D-printed device to improve device aesthetics.
Soldering Kit (x4) [10]	$40 per kit	Soldering kits will be used to solder electronic components to the PCBs and to the device.
3D Printers (x5) [11]	$800 per machine	3D printers will print the main device storage unit and device cover. These parts will be covered with the surrounding fabric using the sewing machines.
Prototype Packaging [12]	$300	Prototyping will be necessary to determine what packaging materials and methods are necessary to properly package our device.
Hidden Equipment Costs	$2,000	This money will be allocated in case of equipment failure or injury while using equipment.

Table 7: Annual annuity assumptions

Annual Annuities		
Expense	Cost	Purpose
Software Developer ($40/hr, 20 hr/week)	$41,600	One of the device's secondary functions is to communicate with a cellphone as another form of communication to the user/caretaker. This, alongside further development of the current alarm and pill count systems, will be implemented and improved by a software developer hire.
Physical Labourer ($16.55/hr, 35 hr/week)	$30,121	Physical labourers will be required to make the 3D-printed parts and assemble all the device's components together.
Electronics Labourer ($20/hr, 35 hr/week)	$36,400	When more complex and miniaturized systems are implemented in our device, an electronics labourer will be required to make fine additions to the device that the physical labourers will not be doing.
R&D Labourer ($30/hr, 35hr/week)	$54,600	An R&D labourer will be required to develop currently planned additions to the device, as well as implementation of future ideas into the device.
Website Maintenance [13]	$6,000	To ensure the website is up to date with current information regarding the company and is running with optimal software, website maintenance will be done throughout the project.
Fabrication Rental Space	$50,000	Space will be required to fabricate and develop the device. This space will be sufficient to run all company operations for the 5-year duration of the project.
Warehouse Rental Space	$20,000	To store materials, unused equipment, and packaged devices, a warehouse will be rented to store all these items.
Marketing Costs [13]	$4,000	Marketing will be done every year by the original team members. A yearly amount of money will be allocated for social media advertisement and communication with potential industry partners.
Loan Repayment	$5,142.83	The loan acquired at the beginning of the project will have to be repaid during its duration.

Table 8: Assumptions for material costs per 100 units

Expense	Cost	Purpose
Packaging Materials	$420	When the device is fully fabricated and ready to be sold, it will be packaged using bubble wrap and boxes.
Plastic Filament [14]	$130	3D printers will be used to fabricate the device. Plastic filament will be purchased in bulk from Prusa to ensure high quality of prints. The primary device housing unit, the device housing cover, and the pill puncher will all be printed.
Surrounding Fabric	$200	Quality fabric will be sewed onto the device to improve the device's physical appearance rather than just having the 3D printed plastic being visible.

Expense	Cost	Purpose
PCBs [15]	$100	PCBs will be custom-made using Altium and ordered in bulk. The PCBs will include a processor, IO, power, and ground pins for connection to peripherals (i.e. alarm, battery holder and other devices that may be added later), an LCD screen, and other necessary transistors.
Electronic Components [16]	$350	Some electronic components will be added to device to achieve its intended functionality. Some of these devices include an alarm, a battery holder, and wires.
Springs [17]	$6	The pill puncher will include a low-resistance spring to allow the puncher to return to the disengaged position after being used.
Total	**$1110**	

The number of sales made per period will increase as the project goes on. The wholesale project models will have a higher sales per quarter than the retail sales model as the wholesale models will be selling products in bulk.

Table 9: Quarterly production assumptions

Production Amount per Quarter	
Quarter	Number of Units
2-4	4,000
5-8	5,500
9-12	7,000
13-16	8,500
17-20	10,000

The hiring schedule for the reference cash flow is included in Table 10 below. In the reference cash flow, the highest rate of unit production is in quarters 5-8 where the two physical labourers are required to produce 209 units per week. In these quarters, some of the 10 hours per week dedicated by the team to the project would go towards production, reducing overall team productivity.

Table 10: Reference hiring schedule.

Hiring Schedule	
Worker	Quarter Acquired
Physical Labourer	1
Electronics Labourer	1
Software Developer	1
R&D Worker	9
Physical Labourer	9
Physical Labourer	13
Physical Labourer	17

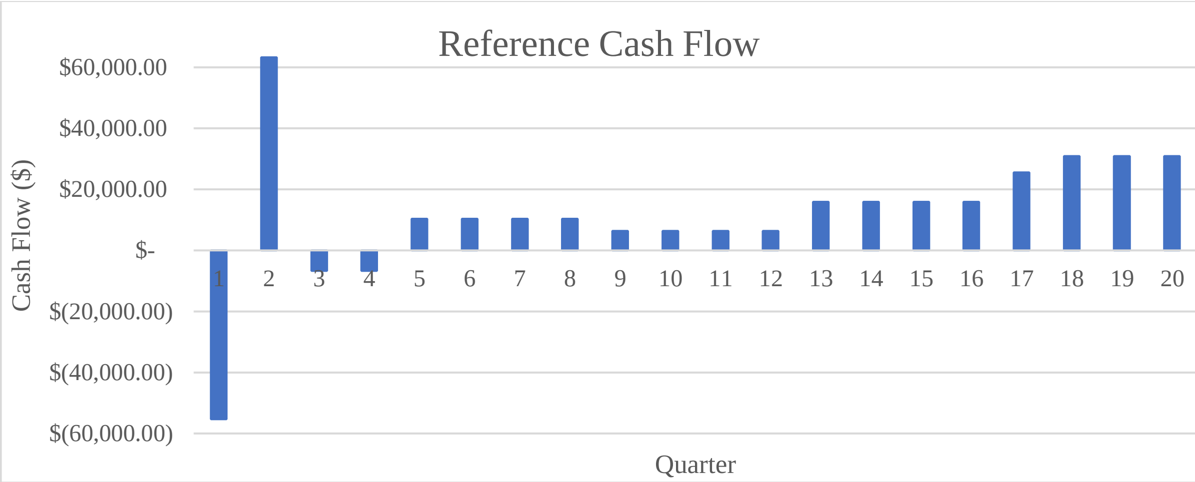

Figure 6: Reference cash flow showcasing single flows and annuities together.

Alternative I

Project Alternative I maintains the in-house fabrication of the device (same as the Reference) but the device is sold with a retail model instead of wholesaling. In this alternative, the retail price per unit is $45. The initial costs from Table 6 are identical to the ones for alternative 1 (Table 11) asides from quantity of machine differences. All assumptions from Table 7 and Table 8 remain the same for this alternative. Alternative I purchases less equipment at the start of the project and purchases additional equipment at period 4. This is summarized in Table 12. Alternative I also has a different hiring schedule than the baseline (Table 14) which is a result of the different approach when developing the cash flow. The same number of workers are hired, but the workers for alternative I are hired earlier with the mindset of skill development. The higher price point per unit allows an increase in hiring. The highest rate of production per week in alternative I is 145 per week per worker which comes many quarters after all workers have been hired. Thus, the student team is always able to dedicate the 10 hours a week to selling the device. This focus of student time on sales is more necessary for a retail model because there must be a constant effort to ensure people are exposed to the device. The assumptions for the production amount per quarter in Table 9 decrease since the devices are retailed. The corresponding cash-flow diagram can be seen in Figure 7.

Table 11: Alternative 1 initial costs.

Initial Costs*	
Expense	Cost
Website Commission [8]	$20,000
Sewing Machine (x3) [9]	$500 per machine
Soldering Kit (x3) [10]	$40 per kit
3D Printers (x2) [11]	$800 per machine
Prototype Packaging [12]	$300
Hidden Equipment Costs	$2,000

*The amounts are the same as those in Table 6, but the number of items differs

Table 12: Alternative 1 additional purchases.

Additional Purchases			
Expense	Cost	Quarter	Purpose
Website Overhaul [8]	$11,100	8	Necessary for the retail model because of the increased user traffic that comes with individual sales. Moreover, the website should be updated as the company does well to provide a better user experience
Sewing Machine (x3) [9]	$500 per machine	4	More equipment must be purchased to keep up with the rate of production.
Soldering Kit (x3) [10]	$40 per kit	4	More equipment must be purchased to keep up with the rate of production.
3D Printers (x2) [11]	$800 per machine	4	More equipment must be purchased to keep up with the rate of production.

The quantities per quarter section (Table 13) are lower in each case compared to the reference. This is a result of selling retail: by selling units at a higher price point, it is assumed that there would be fewer units sold

Table 13: Quarterly production assumptions for Alternative I.

Production Amount per Quarter	
Quarter	Number of Units
2-4	3,000
5-8	4,500
9-12	5,500
13-16	6,500
17-20	7,000

Table 14: Alternative 1 hiring schedule.

Hiring Schedule	
Worker	Quarter Acquired
Physical Labourer	1
Physical Labourer	1
Electronics Labourer	1
Software Developer	1
R&D Worker	5
Physical Labourer	5
Physical Labourer	5
Electronics Labourer 2	5

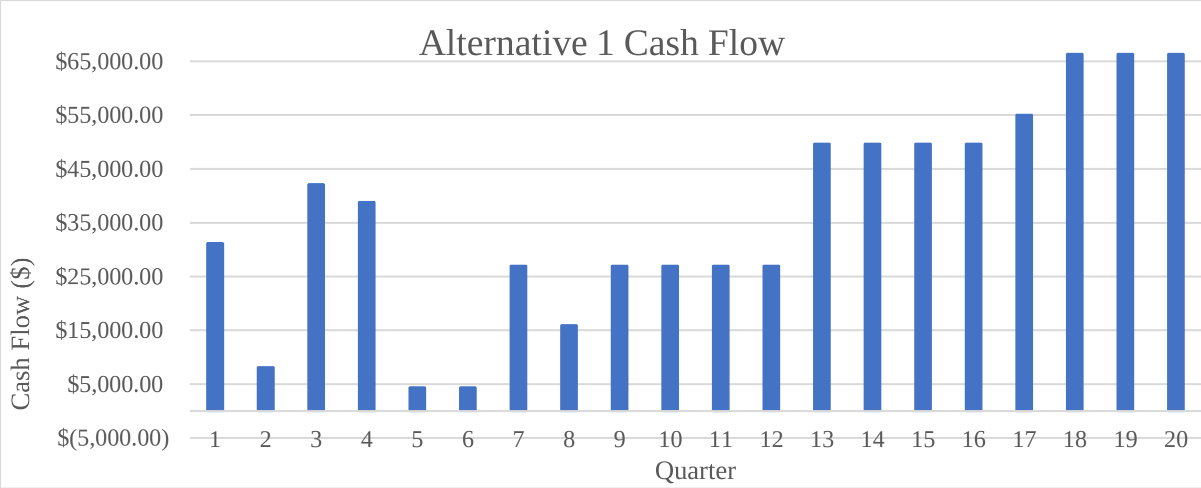

Figure 7: Alternative I cash flow showcasing single flows and annuities together.

Alternative II

Project Alternative II involves outsourcing the fabrication while wholesaling the device. With this alternative, the device is back to being sold wholesale as in the Reference but outsources production. The assumptions outlined in Tables 7 and 9 are the same as the Reference. From Table 6, only the website commission remains as no equipment is purchased. The material costs per 100 units as in Table 8 are transformed in Table 15 to outsourcing fees which account for both the outsourced labour and materials. The hefty outsourcing fees demands a higher loan intake than the Reference and Alternative I. The loan would increase from $70,000 to $100,000 with the same interest rate of 10%. The corresponding cash flow diagram can be seen in Figure 8.

Table 15: Assumptions for outsourcing fees per 100 units for Alternative II

Outsourcing Fees per 100 units		
Expense	Cost	Purpose
3D Printing [18]	$12,000	Instead of purchasing 3D printers, another company will be used to 3D print our parts for us.
PCBs [19]	$100	PCBs will still be manufactured as per the Reference project.
Sewing	$500	Instead of purchasing sewing machines, all sewing will be outsourced to another company.
Device Assembly	$500	Device assembly will not be done in-house.
Shipping	$200	Shipping for all outsourcing fees must be considered.

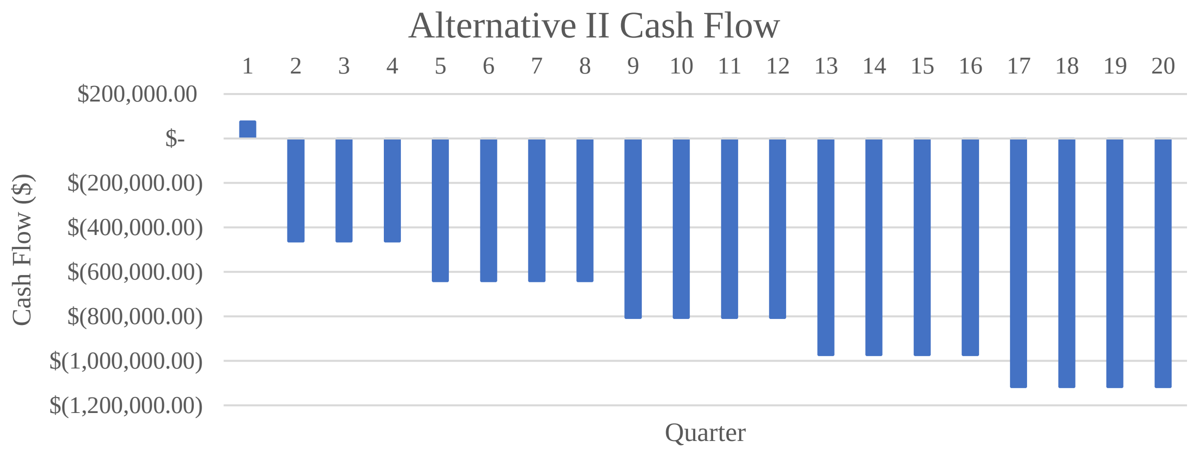

Figure 8: Alternative II cash flow showcasing single flows and annuities together.

Alternative III

The "do nothing" alternative, in which none of the $20,000 gift is utilized during the five-year plan. No investments were made, and no costs were drawn from the initial gift.

Figure 9: Alternative III cash flow showcasing single instance of the gift at period 1.

Revenue Justification

The price point per unit was based on the fabrication cost per unit. The cost to produce the device, for in-house fabrication, is $1110 per 100 units, not considering the associated cost of labour. Then, a baseline $3000 revenue for the wholesale of 100 units minus the 25% overhead stated in the assumptions corresponds with $1140 in profit per 100 units. For retail, that value is higher at $2265. The retail value was set higher because in a retail approach each unit is sold individually rather than to a reseller who will increase the price after purchasing in bulk.

Then, the number of units sold per period was determined as a conservative estimate of the approximate target population. One population of interest is people taking daily oral contraceptives. If, for the sake of approximate calculations, the population of women aged 15-34 was considered as the possible persons that would use contraceptives — that is a population of approximately 6 million people in 2023 [20]. Then, the literature suggests that 85% of women who are sexually active use protection and 43.7% of those women use oral contraception [21]. Therefore, these values suggest that approximately 2,228,700 people could have a use for this device.

The chosen number of units sold for wholesale sum to 136,000 units sold at the end of the 5-year timeline. This value would mean approximately 6% of the oral contraception population would need to purchase the device. However, the target audience includes more than just oral contraception users – it also targets audiences with reduced dexterity and elderly persons. Thus, the true percent of each population that must find interest in the device is lower. These calculations demonstrate the reasonableness of the number of units sold throughout the project timeline.

Comparison Method

The four possible cash flows were compared using the present worth analysis. This entails calculating the present-day worth of each cash flow to what would be labelled period 1, the initial period of the project. Present worth calculations were completed using the provided MARR, 8%. After calculating, the projection with the highest profit, for both the group and the investor, would be chosen as the ideal path forward.

Comparison Outcomes

Table 16: Comparison outcomes for the Reference, Alternative I, Alternative II, and Alternative III.

	Reference	Alternative I	Alternative II	Alternative III
Total Present Worth	$238,067.05	$692,139.30	-$15,220,015.33	$20,000.00
Investor Returns	$71,420.11	$207,641.79	-$4,566,004.60	$6,000
Group Profit	$166,646.93	$484,497.51	-$10,654,010.73	$14,000

Recommendations

A recommendation based on the economic analysis mainly considers the present worth value of each alternative present. The largest present worth value will be the most profitable and therefore the best business decision. Other considerations include the secondary benefits of the selected cash flow as well as the possible limitations.

The present worth of the four alternative cash flows are summarized in Table 16. The economic analysis supports the pursuit of the project specifically through the execution of alternative 1, in house fabrication with retail sales. This option generates the largest final group profit, $484,497.51. The in-house production reduces the cost of production – mainly because of the low 3D printing cost per unit, generates the highest quality devices, and allows the device to be priced at a higher amount. The greatest weakness of the wholesale approach was the low price point that accompanies bulk pricing. Moreover, the outsourced manufacturing approach costs far too much per 100 units to generate a profit with the assumed units per quarter.

Along with providing the largest group profit, the structure of alternative I offers other benefits such as quality control and consumer relationship. In house production would allow the team to closely monitor the control of the units sold allowing the company to maintain a strict quality assurance. In addition, the team would be able to ensure that all people working on the product are compensated properly and are well trained to do the work they do. By instituting a retail approach, the company has better opportunities to connect with the customers, hear their feedback, and approach new audiences.

A wholesale approach reduces the company's ability to move the product around and focus on certain target audiences.

The economic analysis has numerous limitations that cannot be ignored. First, the projected sales used in all cash flows are fictional and do not have supporting evidence. Often, new products would be focus grouped and research would be conducted to determine the predicted population. While a conservative estimate was made concerning the possible sales amount, it does not account for the possibility that the price is set too high, or the demand just does not exist. Then, the group has a generally naive approach to an economic analysis. All values were determined with a best-case scenario mindset with regards to space rental, worker pay, and general costs of operation. Thus, there is a likelihood of larger expense that what was provided. The analysis is unexposed to numerous constant operating costs that exits for a real business-like taxes and insurance. Finally, time delays and fees concerning device approval were not considered. These limitations make it more likely that the business would not be as profitable as predicted by the reference or alternative I cash flow.

The answer to the underpinning question, should the project be pursued by a group of students, is no. A consideration of the limitations, in tandem with the results of the economic analysis, suggest that there will be more hardship than can be projected by the tools available. The project assumes ideals that are unreasonable to the current economic climate. Moreover, the number of unknowns concerning demand and operational costs greatly increases the possibility that the project will have success.

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Appendices

Appendix A: Team Charter

Team Charter

Team Number:	37

Please list full names and MacID's of all Team Members.

Full Name:	**MacID:**
Jacqueline Huo	huoj6
Rachael Bowman	bowmar9
Anthony Atalian	ataliana
Om Patel	patelo7
Maya Setrak	setram1

Roles and Responsibilities

In this section, you can identify who will be responsible for what roles in a team. At this stage, you should focus on the high-level administrative tasks (e.g., taking meeting minutes, submitting documents to Avenue, scheduling meetings, communicating with instructors, etc.). However, as the project progress roles may expand and become more specific. As needed, you can attach an addendum to this charter and submit with future deliverables (important: the original team charter should ***never*** *be changed once all team members have signed it.*

- Maya – Meeting Minutes Maker + Snacks
- Om – Submitter
- Rachael – Meeting Initiator + Room Booking
- Anthony – Prof Speaker
- Jackie – Reference + File Manager

Expectations of Behavior, Work Ethic, and Professionalism

Summarize what will be expected of all team members.

- *Examples can be found in Breakout Box 2.2 of [Chapter 2 excerpt from Biomedical Engineering Design](#).*
- Check the chat once a day end of day + be patient for full group reply
- Reach out as soon as possible – no later than a day if you think you can't meet a deadline
- Do your work, please 😊

    - Two repeat offenses that are recognized by the group (4-1 vote) lead to an intervention
- Straightforward conversations/provisions concerning feedback
- Open to change
- Slay (aim for 12)
- Work under the assumption that everyone is putting in their best effort

Communication and Documentation Management

This section is intended to outline the frequency of meetings, who is expected to attend each meeting, and the expected format for meetings (e.g., in-person vs. virtual). You should also describe where documents will be stored (e.g., OneDrive, Google Drive, MS Teams, etc.).

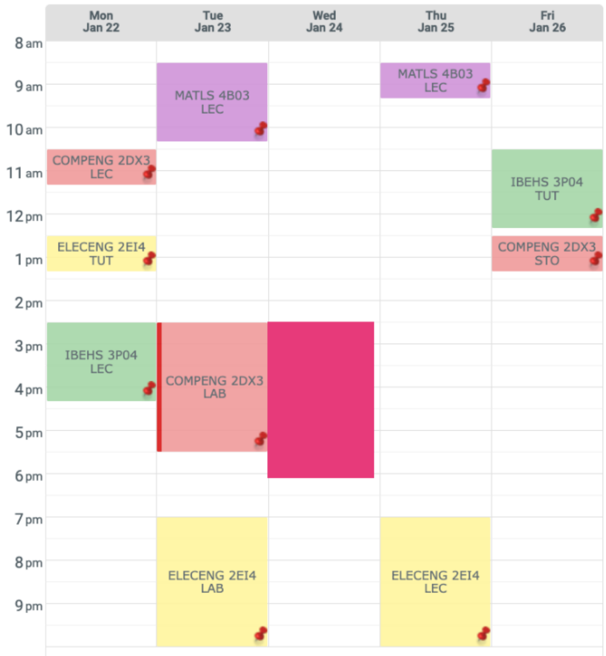
- Documents and files all stored in Teams
- Meet as necessary – medium free time that people are aware of but is flexible
- Full roster unless good reason or split meetings
- In-person meetings are preferred whenever possible
- Keep meeting minutes + if you miss meeting check meeting minutes --> you might be assigned to something to do within the meeting
- Agenda items can be added pre-meeting by the person who wants it discussed

Other Commitments

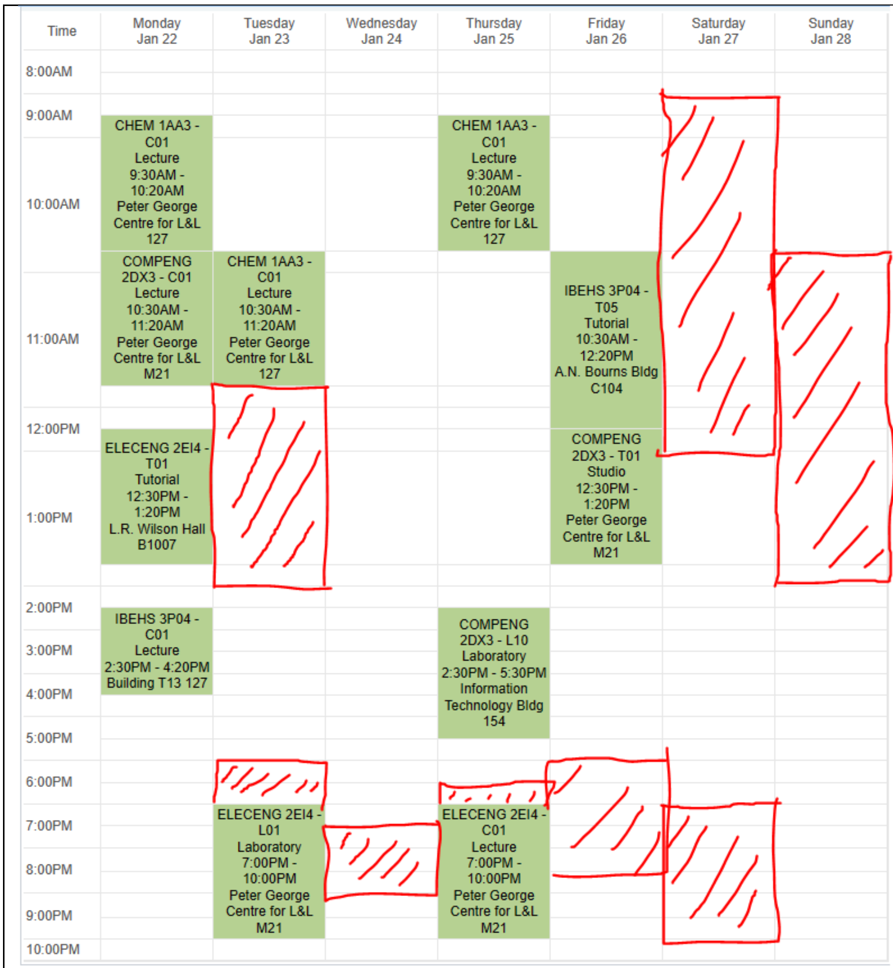
List anything team members should be considerate of when scheduling meetings, assigning tasks, or working towards deadlines. Examples include, but are not limited to, midterm schedules, work schedules, availability limitations due to weekend availability (e.g., due to commuting), scheduled time out of town, religious observances, etc.).

Rachael: Monday (8:30 am to 7:30 pm)

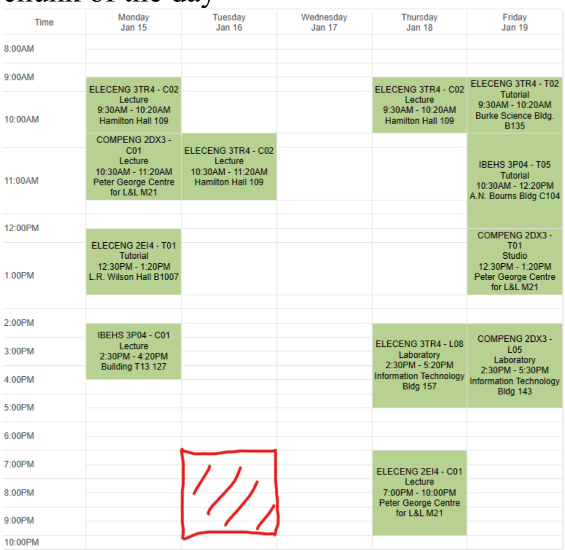
Maya



Anthony: Starting approx. first week of Feb, busy Wednesdays 5-9pm. Possible 30min weekly meeting to be scheduled Thursday morning



Om: Good for whenever I don't have classes; Can't do Mondays and Fridays for a good chunk of the day



Jacqueline: Cannot meet past 8:30 pm on Monday/Friday.

Time	Monday Jan 8	Tuesday Jan 9	Wednesday Jan 10	Thursday Jan 11	Friday Jan 12	Saturday Jan 13	Sunday Jan 14
8:00AM	ENGPHYS 3SM3 - T01 Tutorial 8:30AM - 9:20AM Burke Science Bldg. 120	ENGPHYS 3PN4 - C01 Lecture 8:30AM - 9:20AM Burke Science Bldg. 105	IBEHS 3P04 - C02 Lecture 8:30AM - 10:20AM L.R. Wilson Hall 1057	ENGPHYS 3PN4 - C01 Lecture 8:30AM - 9:20AM Burke Science Bldg. 105	ENGPHYS 3PN4 - C01 Lecture 8:30AM - 9:20AM Burke Science Bldg. 105		
9:00AM	ENGPHYS 3BB3 - C01 Lecture 9:30AM - 10:20AM Burke Science Bldg. 120						
10:00AM		ENGPHYS 3BB3 - C01 Lecture 10:30AM - 11:20AM Burke Science Bldg. 120			IBEHS 3P04 - T05 Tutorial 10:30AM - 12:20PM A.N. Bourns Bldg C104		
11:00AM	INDIGST 2K03 - C01 Lecture 11:30AM - 2:20PM L.R. Wilson Hall 1057						
12:00PM		ENGPHYS 3SM3 - C01 Lecture 12:30PM - 1:20PM Peter George Centre for L&L B131	ENGPHYS 3SM3 - C01 Lecture 12:30PM - 1:20PM Psychology Complex 155		ENGPHYS 3SM3 - C01 Lecture 12:30PM - 1:20PM Psychology Complex 155		
1:00PM							
2:00PM		ENGPHYS 3PN4 - L01 Laboratory 2:30PM - 5:20PM Burke Science Bldg. B101		ENGPHYS 3BB3 - L02 Laboratory 2:30PM - 5:20PM Burke Science Bldg. B101			
3:00PM							
4:00PM							
5:00PM							
6:00PM				MUSIC 1HW0B - C01 Lecture 6:30PM - 9:20PM Togo Salmon Hall 118			
7:00PM							
8:00PM							
9:00PM							
10:00PM							

Conflict Management and Accountability

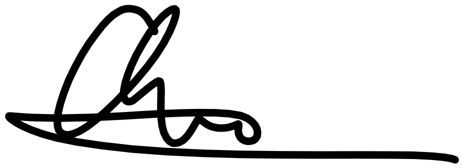
Explain how you are going to manage conflict should it arise. The focus here should be on resolution rather than punitive measures. Section 2.5 from the [Biomedical Engineering Design textbook] is an excellent resource that you are encouraged to review.

- 4/5 group members need to agree after attempts of compromise for an idea to move through
- If a team member stop doing work, reach out to course instructor or TAs for assistance
- Keep meetings open to all, let every member be heard
- Conflicts should be approached with a group-success oriented mindset

Action items to deal with conflict

1. Address core issue if possible
2. Engage in an open-minded discussion to focus on general behavior and not on an individual member
3. Listen to feedback, even if the discussion seems to be targeted or is unpleasant
4. Have reasonable work expectations and when it can be completed, or if it can be completed to then distribute better
5. Do not let emotions take over the problem, keep feedback objective to minimize personal conflict

By signing below, all team members certify agreement with the team charter as outlined below.

Full Name:	**Signature:**	**Date**
Jacqueline Huo		12/01/2024
Rachael Bowman		12/01/2024
Anthony Atalian		12/01/2024
Om Patel		12/01/2024
Maya Setrak		12/01/2024

Appendix B: Summary of Contributions

Team Member	Contribution
ANTHONY ATALIAN (ataliana, 400395321)	Milestone 1: Made the project Gantt chart. Small contributions to customer requirements Milestone 2: Worked on FMEA (table 2 and table 4b). Milestone 3: Made flowchart for device general functionality. Contributions to tabular outputs (table 3). Prototype: Made the pill housing and pill puncher. Design Demo: Explained background for verification. Economic Analysis: Made reference project. Small modifications to other cash flows. Project Presentation: Explained assumptions for cash flow. Presented reference cash flow. Report: Wrote cash flow reasoning. Added to risk mitigation plan recommendations.
RACHAEL BOWMAN (bowmar9, 400360862)	Acted as "Meeting location booker" and "Meeting Starter." Milestone 1: Contributed to project brainstorming. Contributed to the problem statement. Milestone 2: Worked on the FMEA (tables 2 and 4b). Contributed to QFD completion. Milestone 3: Wrote design verification plan 1 and contributed to the table of design input-output correspondences. Design Demo: presented the verification plan correlated with the design demonstration. Economic Analysis: Developed skeleton excels used to generate cash flow graphs and calculate the present worth of each alternative. Completed alternative I. Edited the cash flows for discrepancies. Project Presentation: presented cash flow alternative I Report: Completed the risk analysis section, contributed to the economic analysis recommendation, edited the report.
JACQUELINE HUO (huoj6, 400373489)	Acted as "reference and file manager" by maintaining the DHF organization and compiling citations for each milestone. Milestone 1: Brainstormed potential device ideas. Developed customer requirements for chosen design. Milestone 2: Contributed to design inputs and QFD table.

	Milestone 3: Helped ideate pseudocode and edit flowchart. Created a rough bill of materials for the prototype. Wrote a summary regarding prototype fabrication to answer milestone questions. Final Deliverables: Helped determine parameters and costs associated with the different economic alternatives. Looked into FSR for verification testing (not pursued). Helped format presentation slides and presented the introduction. Proofread cashflows and helped clarify discrepancies in economic analysis. Wrote the executive summary. Edited and formatted final report.
OM PATEL (patelo7, 400378073)	Acted as "Submitter" by submitting all project deliverables. Milestone 1: Brainstormed ideas for the project. Took notes for and formatted the first design review section. Helped with sections of the Gantt chart (brainstormed timings and action items). Milestone 2: Took notes for and formatted the second design review section. Itemized the design risks for the report. Helped with Table 2 of the FMEA, and completed Tables 3a and 3b of the FMEA, as well as adding some of the reasonings in Table 4b of the FMEA. Milestone 3: Added some expected design outputs for the associated design inputs. Completed the second verification plan for the device. Took notes for and formatted the third design review section. Developed the code for the prototype (microcontroller with LCD display) Design demo: Completed the code for the microcontroller to function according to design specifications. Carried out the interactive demonstration. Project presentation: Helped clean up slide formatting, talked about the "do-nothing" alternative, the recommendations section and the limitations associated with the project (conclusion) Economic analysis: Completed the do-nothing alternative section, did some quality checking for the other three alternatives to fix any inconsistencies. Report: Formatting, summarizing the cash flow reference and alternatives. Added appendices. Reviewed other sections to ensure they align with the rubric.
MAYA SETRAK (setram1, 400368295)	Acted as "Meeting Minutes Maker" by documenting all group meetings in the "Meeting Minutes" folder of the DHF. Milestone 1: Contributed to writing the project statement. Contributed to brainstorming customer requirements. Milestone 2: Contributed to brainstorming design inputs and assigning their category. Contributed to filling out the QFD table. Milestone 3: Made sketches of the prototype. Contributed to brainstorming design outputs and formatted the table.

	Design Demo: Contributed to the 3D-printing of the prototype for the pill case. Project Presentation: Contributed to making the slides for the presentation. Presented project alternative II. Economic Analysis: Developed the cash-flow for project alternative II using Jackie/Rachael's Excel template. Took on the "Design Controls" section of the Milestone 4 and helped with the "Economic Analysis" section.