MEDalarm Design Document

Medication Storage and Scheduling Device

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Table Of Contents

Client/Customer Definition

Many individuals face challenges in managing their medications, particularly with taking the correct dosages at the correct times, leading to missed doses, consuming incorrect medications or overdosing/underdosing. This issue is highly prevalent in elderly with chronic illnesses, out of which 55% do not take medications according to their doctor's prescription, a result of forgetfulness and difficulty in reading labels [11]. For elders with complex medication regimens and chronic health conditions, these oversights can result in increasing healthcare costs, ineffective treatment, health complications and death [12]. Furthermore, as our end-users are based in Belize, the limited availability of residential homes, care homes, and nursing homes as well as the general need for improvement in elderly care services pushes the need for effective medication management [13]. To reiterate, our defined client/customer base possesses the following attributes:

- Demographic:
    - Our design is catered to address the challenges of elders with chronic illnesses/diseases.
- Geographic:
    - In order to fit the required scope of the defined client/customer base to be a group of 10 to 100,000 people, Belize was chosen as there are approximately 21,525 elders with chronic illnesses/diseases in Belize who would benefit from our product[14][15].
- Economic:
    - The country is classified to be a developing country, due to low economic performance [16]. This low economic performance reflects on the state of elderly care in Belize: it is both scarce and expensive [13]. While it does not improve economic performance, the design of the MEDalarm offers an inexpensive alternative to improve elderly care in Belize.

The key challenges experienced by our targeted customer base include

- Medication Non-Adherence:
    - Forgetting to take medications or taking incorrect doses.
- Complex Medication Regimens:
    - Managing multiple medications with different dosages and schedules.
- Dependence on Memory:
    - Relying on memory alone for medication management which can be unreliable for seniors.
- Lack of Oversight:
    - Limited visibility for caregivers or healthcare providers to monitor medication adherence.
- Physical Limitations:
    - Older adults may find it difficult to open medication bottles and read small labels, thus affecting their ability to take prescribed medications.
- Lack of Sufficient Elderly Care:
    - Although residential homes, care homes, and nursing homes are available in Belize, they are limited and quite expensive [13]. This leads to a need for sufficient and quality care, and such a need can be fulfilled by providing proper medication management with the MEDalarm [13].

The MEDalarm aims to develop an innovative solution which addresses these challenges faced by our end-users, allowing for effective medication management. The final product aims to be

user-friendly and simple to use. To ensure that users can operate the product with minimal technical expertise, it will require the client to simply input their medicine and set a timer for their medications. Evidently, as the MEDalarm aims to rectify the challenges above that our customer base experiences, our clients will solve their issues associated with the management of their respective medication and regimens. In conclusion, the intricate design of the MEDalarm will allow medications to become easier and perhaps enjoyable for the end-user to consume, thus improving their quality of care and overall medical state.

Competitive Landscape

Ingestible Sensors:

The technological system of ingestible sensors [19], also referred to as digital pills [22] or digital ingestion monitoring devices [23], addresses the challenges of medication non-adherence and lack of oversight. The technological system includes the following in order to address/solve the challenge: ingestible microsensors, an external monitor that is attached to the abdomen, and a mobile app [19]. The ingestible microsensors and medication are encapsulated together into one capsule, with the medication surrounding the microsensor.[19] Once the digital pill is dissolved by stomach gastric juices, the activation of the microsensor from the contact with gastric fluid will transmit a unique signal to the external monitor on the abdomen [19]. The ingested event is then also transmitted to a mobile app, which will upload the time of the ingestion as well as several other physiological measures of the user to a central server [19]. This particular technological system allows medical practitioners to directly observe the medication ingestion as well as offering real-time medication adherence monitoring of the patient/user [19]. This eliminates the challenges of medication non-adherence and lack of oversight. Healthcare practitioners no longer need to monitor their patients closely to ensure their patients are remembering to take their medications with the correct doses. Additionally, healthcare practitioners are now able to receive data by accessing the central server and observe if the patient took their medication, eliminating the lack of oversight challenge. Although digital ingestion monitoring devices are an advantageous technological system to address medication non-adherence, there are

multiple shortcomings associated with these devices. For example, as the microsensors within the capsule are meant to be ingested, there are concerns in terms of patient privacy and autonomy as a result of these devices' invasive nature [19][24][25]. Additionally, patients/users have reported skin irritation due to the adhesive external monitor that is worn on the abdomen [19][26][27]. Further, there is a possibility of sensor retention associated with the devices generating potential risks related to a patient's health and safety [19][28].

Radio Frequency Identification (RFID)-based Medication Adherence Intelligence System (RMAIS):

The technological system, RMAIS, addresses the challenges of managing complex medication regimens and dependence on memory. The device is made of several components including an RFID reader, microcontroller, scale, liquid crystal display (LCD) panel, and a motorised rotating platform [19][20][21]. The device operates by utilising an RFID tag, where one tag is attached to each user's pill bottles, which stores information regarding the name of the medication as well as the appropriate dosage [19][21]. When it is time to take a scheduled dose, the RMAIS will produce an audio reminder to indicate to the patient to take the dose. Afterwards, the RMAIS will rotate the corresponding pill bottle towards the patient, allowing the patient to retrieve their medication easily [20][21]. At the designated time for taking medication, the pill bottle is weighed by the scale in the RMAIS and the medication's information is displayed on the RFID reader for the patient/user to read [19]. Once the patient/user opens the pill bottle, the scale will measure the weight of the pill twice (before retrieving medication and then after) and determine if the patient/user took the appropriate dose from the bottle [20][21]. If the scale measures the same weight, the device will alert a healthcare practitioner or family member [20][21]. The RMAIS allows patients/users with complex medication regimens to easily manage their medications as the device tells the patient/user which medication to take, at what time and the number of doses, addressing the challenge of complex medication regimes. Further, the user is not required to remember any details regarding when to take their medication, how to take it, and how much of it to take. This eliminates the challenge of depending on unreliable memory to drive medication

memory. However, a shortcoming of the RMAIS is that it is not able to confirm if the administered medication is ingested once retrieved from the device [19]. This shortcoming indicates that, although the system is able to prevent non-adherence to some extent, the device is still considerably limited in this particular area [20].

ReX (DosentRx Ltd)

The technological system, ReX, addresses the challenges of medication non-adherence and physical limitations. The device, ReX, includes the following components: mobile app, disposable cassette, reusable drug dispensing unit, and a Dose-E Analytics cloud system [19][29]. As the patient's medication is stored within the device, the patient simply needs to bring the device to their mouth at the designated medication administration time, and the medication is dispensed directly into their mouth in the accurate dosage [19][29]. Once dispensed, the mobile app allows data to transfer from the ReX to the Dose-E Analytics cloud system, where healthcare practitioners can access the data uploaded [19][29]. This transfer of the patient's medication adherence data from the device to the cloud system allows for real-time medication adherence monitoring of the patient [19][29]. This monitoring allows the challenge of medication non-adherence to be reduced as healthcare practitioners can easily monitor if their patients are taking their medications accordingly and correctly. Furthermore, the challenge of physical limitations faced when taking medication is partially solved (as the challenges of physical limitations are too large in scope to address fully) by the following device/technological system. This is a result of the precise dispensing mechanism included in the device, where medication is always dispensed in the correct dosages at the correct times [19][29]. This partially eliminates the challenge of physical limitations as the patient does not have to open any medication bottles and read small labels indicating what the correct dose is and how often to take the medication. However, it is imperative to mention the shortcoming associated with the ReX device. The device is limited to strictly dispensing the medication in the correct dosage and at the correct time. It does not monitor if the patient ingested the medication, thus cannot confirm if the patient/user is adhering to their medicine regimen [19].

Requirement Specifications

Overall, the medicine box is catered to be operated with minimal technical expertise, allowing the end-users to simply input their medicine and set up a schedule for their medications. In order to achieve this in our final product, we have taken into account multiple requirements to ensure the MEDalarm is user-friendly, simple to use, and resolves all of our customers' challenges.

Firstly, our targeted customer base, elderly with chronic illnesses/complex medication regimens in Belize, experiences medication non-adherence due to reliance on memory. To ensure that our clients are taking their medications at the correct time(s), the design includes a 5V active buzzer in order to act as an alarm to remind the user to take their medication. A 5V active buzzer was chosen as it produces a minimum of 70 dB (decibels) and a maximum of 105 dB [1][2]. The reason we chose an 70dB-105dB buzzer is because this is a sound level slightly louder than a car, which ensures the user is alerted to take their medicine.

In order to meet the need of adhering to medication schedules, the MEDalarm must be able to keep track of time precisely and accurately. This is done by the use of the microcontroller's onboard clock and a timer programmed into the device. The NUCLEO F401RE has a 32 kHz oscillator which is dedicated to RTC (real-time clock) purposes, meaning the timer must synchronise the frequency of the microcontroller's oscillator and an external time source to remain accurate over an extended period of time [18]. This timer must also be customizable by the user in order to be personalised to their particular medication schedule and must be simple to operate.

The medicine compartment must also be accessible and large enough to contain the average number of pills easily, which is approximately five for seniors [11]. This requirement has two aspects, the overall size of the compartment and the servo's rotation to reveal the MEDalarm's contents. Firstly, the MEDalarm should have dimensions that account for the different sizes of pills, which can get very long or wide. The compartment must then also be large enough for anyone, regardless of the size of

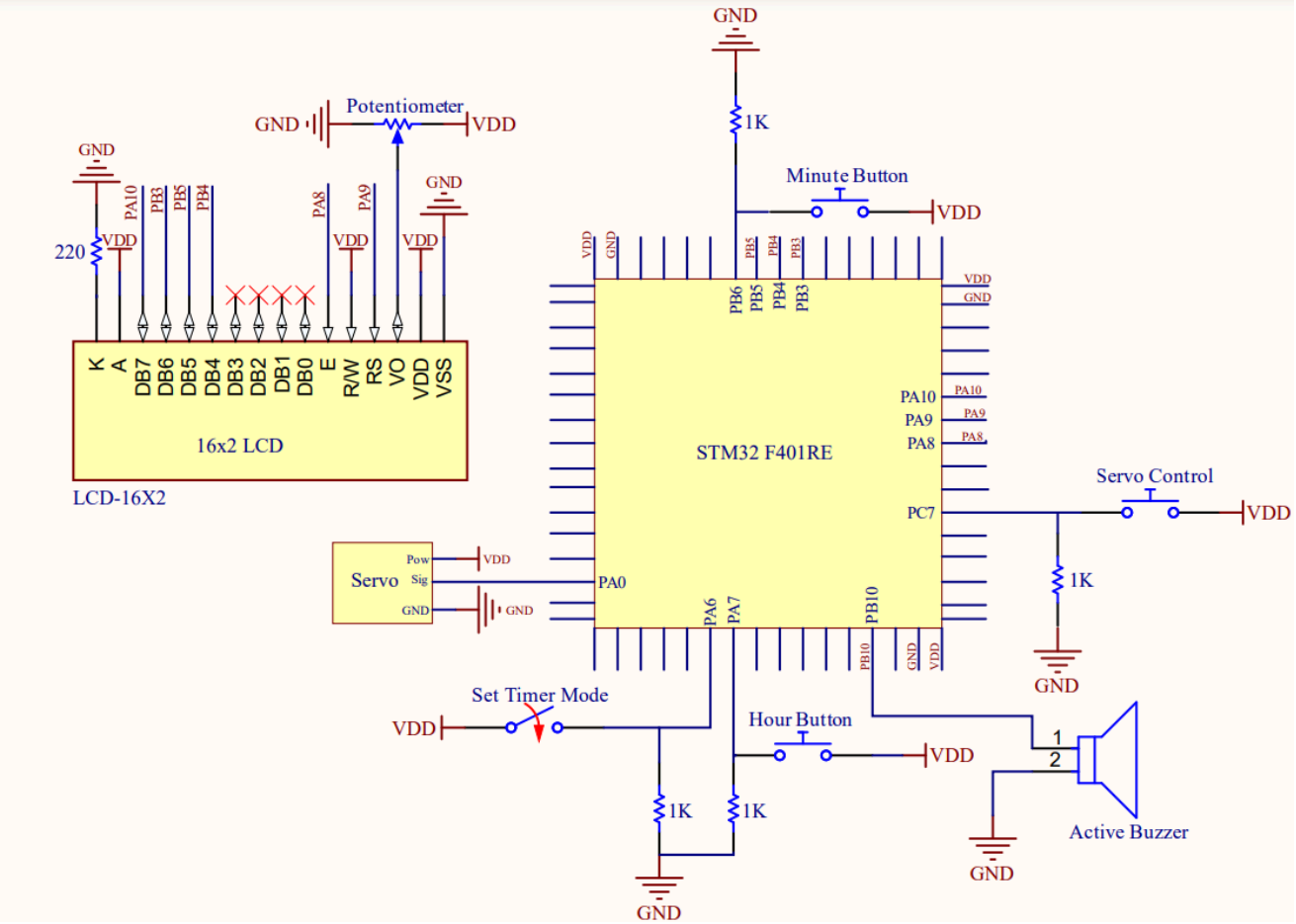
their hands, to be able to remove a pill. The average width of a finger and thumb are 2 cm and 2.5 cm respectively [17]. As such, the resulting width and length of the storage area should reflect these factors. Additionally, the servo must rotate the lid enough to fully reveal the medications and not be in the way as the user removes their pills. This is to ensure mechanical integrity of the MEDalarm and to reduce frustration for the end-user.

One very important factor to consider is the safety of the stored medication. This means that whatever the materials of the MEDalarm are, they must be able to safely store the medication within the box as it is likely subject to falling since it is made to be handled by seniors with physical limitations as well. Thus, the material of the MEDalarm must be durable and able to withstand large quantities of force. As such, the material must have a high impact resistance (ability to absorb shock or impact energy without breaking, measured in joules per metre) and be as least brittle as possible.

Finally, since the users are relying on the automation of the MEDalarm to provide them access to their medicine, the mechanical components must be very durable to account for physical limitations [11]. For example, the lid of the medicine compartment is controlled by a servo. As such this lifting mechanism must be durable enough to function continuously for multiple cycles while being consistent with how far the lid is lifted.

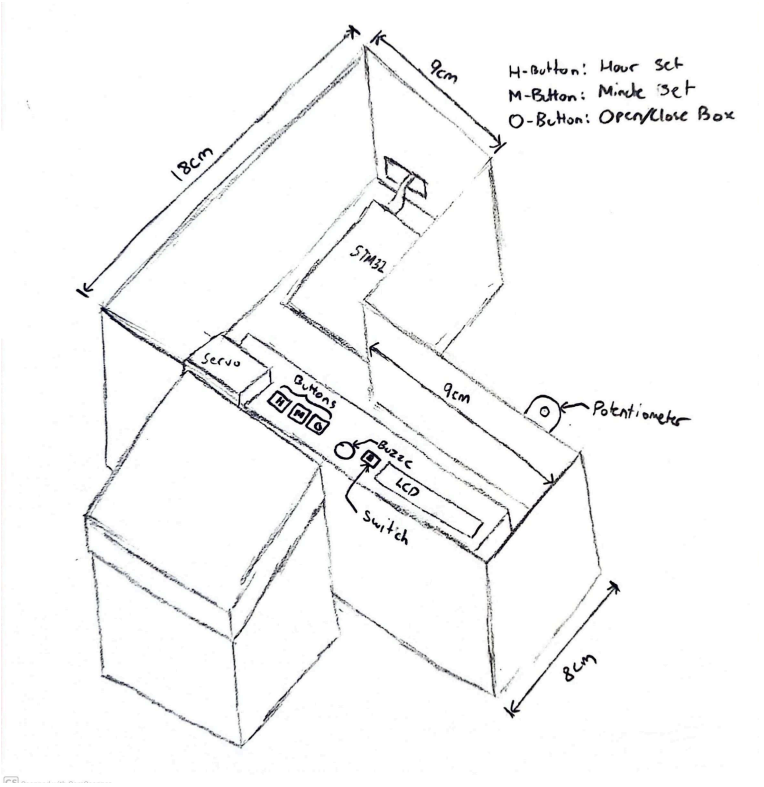
Design

Circuit Schematic:



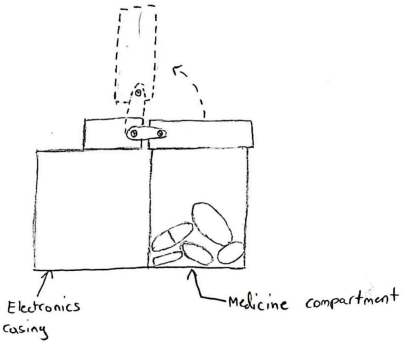
The diagram above demonstrates the connections of every electronic component in the MEDalarm. The buttons and switch are connected to the digital pins on the microcontroller as they only output a digital high or low (5V or 0V). They are all connected in the pull-down resistor configuration, which makes the default button output (not pressed) 0V. The LCD's V_0 pin (contrast) is connected to a potentiometer. This contrast is not to be adjustable by the user and is set during manufacturing to reduce the complexity of the device.

Mechanical Design:



The MEDalarm's body consists of two sections, one being the electronics case and the other being the main medicine compartment. Both are made of a plastic material as it is non-toxic for storing medications.

All of the electronics and controls for the medicine box are embedded within the electronic case to ensure that none of the internal circuitry is disturbed and the MEDalarm is aesthetically pleasing and neat. Labelled slots for the buttons, switch, LCD, and buzzer allow for easy and clear control of the medicine box. The size of the electronic case is based on the dimensions of a standard breadboards (5.5cm × 17cm) and the STM32 F401RE microcontroller (7cm × 8.25cm).



The servo is to be attached to the top of the electronics case using an adhesive. The arm of the servo is also screwed into the lid of the medicine compartment and rotates up and down as show by the image to the right.

The medicine compartment (Figure 1B) is designed to be large in order to account for various hand/finger sizes which ensures that whoever uses this product does not have trouble taking their medication. The lid of the medicine box (Figure 1A) is 0.5cm longer and wider than the medicine compartment with one overhang being cut off as the servo needs to be able to slide the lid off the compartment with ease.

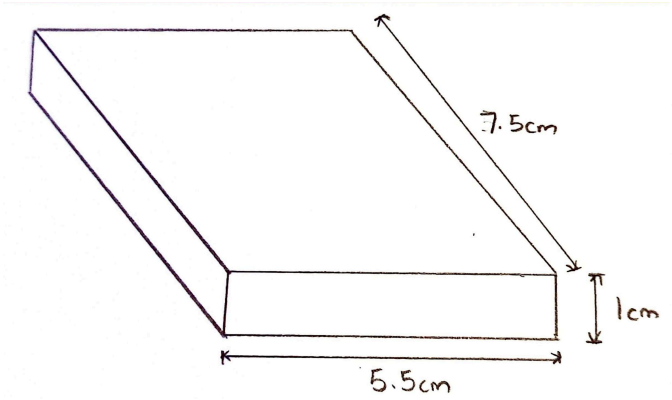


Fig 1A: Lid Dimensions

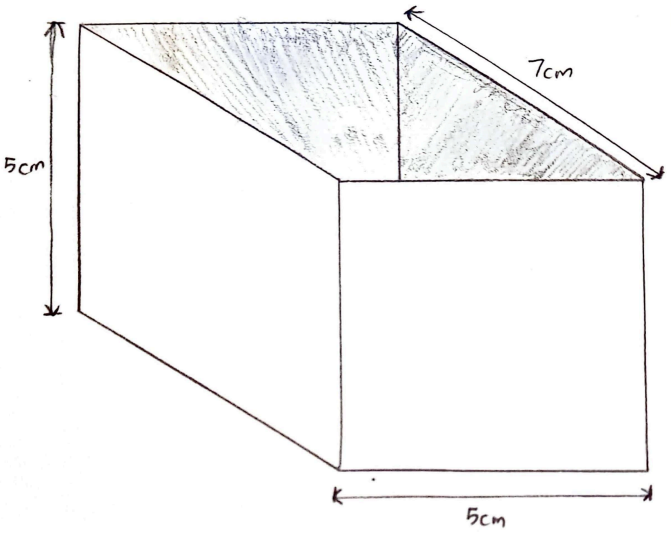


Fig 1B: Medicine Compartment Dimensions

Mathematical/Scientific Principles

Mechanical Design

➔ Determine the optimal volume/dimensions for the medicine compartment by comparing the average size of a human finger and thumb . This is done in order to minimise the amount of material required to create the container and provide easy access to its contents.

- Volume of compartment is given by: $Length \times Width \times Height$ [9]
- Average width of finger: ~2cm [17]
- Average width of thumb: ~1 inch = ~2.5 cm [17]

➔ Determine the appropriate angle that the servo motor must rotate in order to fully make the

contents of the box accessible using trigonometry [9].

- Pythagorean theorem for describing the movement of the servo: $a^2 + b^2 = c^2$
- Trig Ratios (sin, cos, tan) for calculating the angle.

Power Distribution:

➔ Calculations related to power requirements and power efficiency would be necessary to ensure the device functions reliably and safely [10].

Relevant Equations For Power Management and Circuit Design:

➔ Ohm's Law for calculating current/voltage [9]

- $E = IR$, where E = voltage in volts (V), I = current (A), R = resistance (Ω)
- Determine the appropriate resistance required to ensure the LCD is not overloaded. This is imperative to check as if the LCD is overloaded, the image may be distorted with reduced contrast and brightness, fail to display content, or cause image retention.
  - LCD light: Let: $E = 5V,\ I = 25\,mA = 0.025A$
  - As: $R = \frac{E}{I} = \frac{5V}{0.025} = \sim 220\Omega$
- To determine the voltage/current (using Ohm's Law or Kirchhoff's Law) at input pins, a pull-up resistor can be used in conjunction with a voltmeter/ammeter. Calculations of the current and voltage at the input pins are essential as it ensures that the input signals are within acceptable ranges/meet the design specifications.
  - Let: $E = 5V,\ R = 1000\Omega$
  - As: $I = \frac{E}{R} = \frac{5V}{1000} = 0.005A = 5\,mA$

➔ Rules for calculating voltage, current and resistance in a parallel circuit design for ensuring the total current/voltage is appropriately distributed across the servo, buzzer, LCD, and LEDs

as they all share the same voltage source [9]:

- $\frac{1}{R} = \frac{1}{R1} + \frac{1}{R2} + \frac{1}{R3}$, where R, R1, R2 and R3 = resistance (Ω)
- $I = I1 + I2 + I3$, where I, I1, I2, I3 = current (A)
- Voltage remains constant

➔ Calculate the total wattage of the device to ensure it fits within the established safety limit of 30W [45]

- Given: $P = EI$, where P = Power (W), E = voltage (V), I = Current (A)
- $I = \sim 200\, mA = 0.2\, A,\ E = 5V$
- $P = EI = 5(0.2) = 1\, W$

Time Keeping Operations:

➔ Unit conversion (e.g. seconds to minutes/hours) to inform the user of their next medication clearly and while providing the correct units to the microcontroller [18].

- E.g. timer set for 6 hours, 1 hour = 3600 seconds = 3600000 milliseconds

  6 hours = 6(3600000) = 21,600,000 milliseconds (read by the MCU)

➔ Experiment with the timer constants to ensure the countdown of the clock aligns with the frequency of the internal clock of the microcontroller for maximum precision [18].

➔ Use arithmetic operations and digital logic for the countdown timer and to set off the buzzer when a certain time condition is reached [18].

Manufacturing Costs

Component Name	Component Manufacturers	Component Vendors/Distributors	Cost (per component)
Standard 16x2 LCD	Adafruit Industries (United States) [31]	Distrelec (Switzerland), Opencircuit (Netherlands), 3DMakerWorld, Inc (United States), Makersify (United Kingdom), The Pi Hut (United Kingdom), Mouser Electronics (United States), Core Electronics (Australia), Digi-Key Electronics (United States) [31]	$9.95
3-Terminal Potentiometer (PDB181-K420K-503 A2)	Bourns Inc (United States) [36]	Digi-Key Electronics (United States) [32]	$2.23
Micro-servo - TowerPro SG92R	Adafruit Industries (United States) [30]	HQ Elektronika Kft. (Hungary), SEMAGEEK (France), MicroControleur Hobby (Belgium), Pakronics (Australia), Digi-Key Electronics (United States), Nano Tech Elements (Canada), Mouser Electronics (United States), BerryBase (Germany), Core Electronics (Australia), AndyMark (United States) [30]	$5.95
4-Pin Push Button (HP0315AFKP2-S)	NKK Switches (United States) [33]	Digi-Key Electronics (United States) [32]	$1.64
3-Pin Slide Switch (SS12SDP4)	NKK Switches (United States) [33]	Digi-Key Electronics (United States) [32]	$4.28
5V Active Buzzer (CMI-1295IC-0585T)	CUI Devices (United States) [34]	Digi-Key Electronics (United States) [32]	$1.98
STM32 Nucleo F401RE	STMicroelectronics [35]	Digi-Key Electronics (United States) [32], W Store (Canada)	$21.39

1k Ohm Resistors (CF14JT1K00)	Stackpole Electronics Inc [37]	Digi-Key Electronics (United States) [32]	$0.16
220 Ohm Resistor	Adafruit Industries (United States) [38]	Mouser Electronics (United States), Little Bird Electronics (United States), kjdelectronics (United States) [38]	$0.75
PC (Polycarbonate) filament	3DGence (United States), Raise3D (United States), CreatBot (China) [47]	Shop3D (Canada), DigitMakers (United States), DigiKey Electronics (United States)	$10.00

Implementation Costs

Installation Manual and User Guide:

Overview:

The MEDalarm smart medication storage system is a product designed to promote medication adherence and simplify complex schedules. The device consists of a slide switch, two push buttons (minute and hour) for setting the timer, a box-control button, a liquid crystal display (LCD), and an alarm.

Initial Setup - Setting up the Box and Timer:

1. When setting up the MEDalarm storage system, the user should first plug the device into power using the provided USB-A to Mini-B connector. This will immediately power on the device.

2. By default, the timer is set to 12 hours. When the box powers on, the countdown will automatically begin and display on the LCD. To change the timer, move the slide-switch to the “Set Time” position and use the hour/minute buttons to set a new timer. This will also open the medicine compartment.

3. While the box is open, place your pills into the medicine compartment then move the slide-switch back to close the box and begin the timer.

Accessing the Medications:

1. When the timer ends, the box will intermittently sound an alarm. This alarm can be turned off by pressing the “Open/Close” button. This will turn off the alarm and open the box to make its contents accessible.
2. When done removing medications, replace the medicine and press the “Open/Close” button to close the medicine compartment and restart the timer.

Changing the Timer:

1. At any time, move the slide switch to the “Set Timer” position. Similar to the initial setup, this will allow the user to set a new timer using the minute/hour buttons and will also open the medicine compartment
2. Once done setting the timer, move the slide-switch back to its default position to begin the new timer and close the box.

Energy Analysis

The IEC standard for medical devices (IEC 60601-2) states that the supply voltage must be in the range of 100-240V [10]. The standard output of wall outlets in Belize is about 110V [39] meaning this specification is easily addressed as the medicine box is designed to be plugged into a wall outlet using a wall adapter. When plugged in, the USB adapter would be used to lower the high voltage to a range between 5V to 9V (refer to picture). Our microcontroller unit (MCU), the STM32F401RE, operates within a safe voltage range of 3.3V to 12V, which means that any output from the USB adapter is sufficient.

Additionally, our project outline imposes a strict limit of 30W power consumption. This limit is comfortably met as the system has a maximum current of approximately 200mA and utilises an

on-board voltage regulator to step down voltage to 5V. Using the formula for power, P = IE (P = power in watts, E = voltage in volts, I = current in amps), the resulting wattage is approximately 1W.

As there are no components that contain materials dedicated to electrical storage used in the design (i.e. capacitors, batteries), the 500mJ storage limit does not apply. For example servos are made primarily out of plastic and some metal (aluminium) which can store/conduct electricity, however the electrical energy signal transferred from the STM32 to the servo is almost completely converted directly into mechanical and kinetic energy to rotate the motor. Any remaining unconverted electrical energy would be insignificant.

A hypothetical analysis of the current draw (as there are no physical systems to test at this time) reveals that the device expends about 1 J per second (according to the formula for electrical energy: $E = Wt$ where E is the energy, W is the power in watts, and t is the time power is expended in seconds). For instance, the LCD requires only about 25mA of current at 5V, the micro servo requires 100-200mA during movement [43], and the active buzzer averages 20mA at 5V [44]. Given these minimal current values (total of ~200mA at 5V) and considering the usage of the buzzer and servo only occurs for a few seconds each day, the maximum electrical energy expenditure is about 1 J for one second of usage.

Furthermore, in terms of mechanical energy, the system's design also minimises the hypothetical mechanical energy produced by the lifting of the medication compartment lid (~100 grams) and the minimal lift distance of just a few centimetres (no exact values as device is still in production but estimated to be approximately 5 cm). Using the formula for work, $W = F\Delta d$, where the force is the weight of the lid, $mg = 0.1(9.8) = 0.98$, then the energy expended is $0.98(0.05) = 0.049$ J.This design approach ensures compliance with project energy limits and underscores the safety and efficiency of the device.

Risk Analysis

Possible negative consequences on safety/environment from incorrect usage:

Safety: The MEDalarm can be used incorrectly in a variety of ways. Firstly, the user may potentially set the incorrect scheduling time to receive medication. If this is done, the user may suffer serious consequences related to their health as they are not adhering to their actual schedule. Secondly, the user may retrieve the incorrect medications when using the MEDalarm. It is imperative that the user understands which medication is required for them to take during the scheduled medication administration events. If the user potentially retrieves the incorrect medication, it can lead to severe consequences associated with their health. Thirdly, as stated in the requirement specification section, a 5V active buzzer is utilised that can generate a minimum of 70 dB to a maximum of 105 dB [1][2]. The user may misuse the device by allowing the alarm to run for much longer than intended. According to [40], the consequences of prolonged intervals of listening to sounds of 70 to 105 decibels are communicated in the table below:

85 decibels	Damage to hearing possible after 2 hours of exposure
95 decibels	Damage to hearing possible after about 50 minutes of exposure
100 decibels	Hearing loss possible after 15 minutes
105 decibels	Hearing loss possible in less than 5 minutes

Thus, if the user utilises the alarm incorrectly on the MEDalarm, they may experience possible damage done to their hearing or, in some cases, hearing loss. Lastly, the user may store the MEDalarm incorrectly. To elaborate, medicine can be damaged if it is not properly stored, it is recommended that the user stores the product in an area where there is little heat, moisture, and light [41]. If the user fails to do so, the stored medicine may become damaged, and if ingested, can hinder their health [41].

Environmental: There are several negative consequences on the environment if the MEDalarm is used incorrectly. To begin with, once the MEDalarm reaches the end of its life cycle, it may possibly

contribute to generating electronic waste if incorrectly disposed of. Secondly, it is imperative that the user understands how to properly dispose of medication if it is damaged, expired, or no longer required. This is done as pharmaceuticals are able to easily make their way into soil, water bodies, treatment systems, surface waters, and groundwaters [42]. This can pose several, potential risks to surrounding microorganisms and organisms living in the environment. For example, the presence of steroids that are found in contraceptives in the environment is suspected to affect the development and fertility of some fish, reptiles, and aquatic invertebrates [42]. With such effects, the overall food chain of an ecosystem is put at risk and could potentially cause severe population problems, posing a significant threat to the overall ecosystem. Thus, the patient should be knowledgeable when dealing with the medication that they store within the MEDalarm, and understand how to dispose of medication correctly to avoid such environmental effects illustrated.

Possible negative consequences on safety/environment from intended usage

Safety: As mentioned prior, upon hearing the alarm generated by the 5V active buzzer, it may prove to be irritating, disturbing, or perhaps harmful to the user's hearing depending on their sensitivity to audio. Furthermore, even if the user uses the device as instructed, confusion during the scheduled medication administration could result in the incorrect medication being taken.

Environmental: As mentioned prior, there is a possibility that the user generates potential electronic waste when disposing of the device at the end of its life cycle. Additionally, the user should be wary in the methods they utilise to dispose of damaged or expired medication due to the negative environmental effects associated with it.

Possible negative consequences on safety/environment from misuse of the design

Safety: There are several negative consequences that can result from misusing the design or using it in a manner that was not intended in terms of the safety of the end-user. Firstly, if the user misuses the device, they pose a risk of possibly harming themselves if they use the product in a manner that was not intended or if it becomes damaged. Secondly, the user may misuse the device by setting the schedule administration time to occur more frequently than stated on the label. This particular case can pose

severe health risks to the patient, such as overdosing on medication. Lastly, if the end user misuses the device, it may result in receiving the medication at the incorrect schedule administration time. Similar to the prior consequence, receiving the medication at an incorrect time can pose severe health risks to the end user.

Environmental: There are several negative consequences associated with the environment that result in misusing the design or using it in a manner that was not intended. Once more, if the end user misuses the product or uses it in a manner that was not intended, it may lead to the premature disposal of the device. This poses a possible risk to the environment if the MEDalarm and its components are not properly disposed of, potentially polluting the environment. Furthermore, if the end user misuses the device to the extent where it becomes damaged or begins to malfunction, the user may need to replace the device. This can also lead to possible electronic waste if the design is not properly disposed of, negatively affecting the environment.

Possible ways the design could malfunction

There are several ways in which the design could malfunction. For example, the components that the design is created from could malfunction. The 5V active buzzer incorporated on the MEDalarm could possibly malfunction by not producing an audible reminder during the scheduled medication administration time. The safety concern this poses is that the user may potentially miss their scheduled medication administration time, causing possible health risks. Additionally, the micro-servo motor may possibly malfunction and not lift the lid covering the compartment where the medication is held. The safety concern associated with the micro-sevor is that if the user cannot lift the lid on their own due to possible physical limitations, the user will not have access to their medications. Thus leading to the user not taking their required medication(s) at the required time(s). Also, the buttons on the MEDalarm may malfunction thus restricting the user in scheduling the times of when to take their next medication. This particular malfunction can lead to medication non-adherence, creating the possibility that the user will not take their medication when required leading to health risks. Furthermore, the software created to sound the 5V active buzzer and to take inputs/outputs from buttons could potentially have bugs present in the program(s). Consequently, bugs associated with the program may cause the device to malfunction

and not work properly. For example, the buttons may not take input correctly, the 5V active buzzer may not produce an audio reminder, and the 16x2 LCD may not present the next proper scheduled administration time for the user to observe. Such bugs associated with the software can pose potential safety concerns to the user, as it may prevent them from using the MEDalarm correctly or from retrieving their medication(s) at the scheduled administration time(s).

Test Plan

Test 1: 5V Active Buzzer

The 5V active buzzer incorporated in the design must produce an audio reminder ranging from a minimum of 70 dB to a maximum of 105 dB in order to alert the end user. Thus, this particular requirement will be tested in order to ensure that the 5V active buzzer produces an audio level within this range. As the MEDalarm can be implemented in a variety of environments, such as a home or nursing home, several cases must be tested. The following test plan will consider the following test cases:

- Test Case #1: The end user is in the same room as the MEDalarm.
- Test Case #2: The end user is in the adjacent or consecutive room that the MEDalarm is located in.

Although there are a multitude of other potential test cases, it is rather difficult to conduct all possible other cases due to their complexity. Thus, the two above test cases are considered to promote clarity and avoid complexity.

Test Setup:

Although two test cases must be tested, the setup for both test cases is rather simple in order to sufficiently test the requirement specified. For Test Case #1, the test will utilise one singular lab room that satisfies the identified environmental parameters. The MEDalarm will be placed inside of the lab room with the hand-held sound level metre utilised to detect the audio produced by the 5V active

buzzer. The MEDalarm will have multiple consecutive timers set in order to record the amount of decibels produced by each audio reminder. Note that multiple trials will be conducted in order to ensure accuracy and precision of the recorded results. For Test Case #2, the test will utilise two adjacent/consecutive lab rooms which satisfy the identified environmental parameters. Similar to Test Case #1, the MEDalarm will be placed inside of the first lab room. The hand-held sound level metre will then be placed in the adjacent/consecutive lab room. Once set up, the MEDalarm will have multiple consecutive timers set in order to record the amount of decibels produced by each audio reminder. Note that multiple trials will be conducted in order to ensure accuracy and precision of the recorded results.

Environmental Parameters:

The test will be conducted utilising two environments, with their corresponding parameters as expressed below:

- Test Case #1
    - The first test case will be conducted within a lab room. Note that the lab room must be well insulated from any sound that is external and internal to the lab. This parameter allows for the hand-held sound level metre utilised to detect audio produced only by the 5V active buzzer. Ensuring that the external and internal parts of the lab room are quiet allows the hand-held sound level metre to precisely and accurately detect the audio produced by the 5V active buzzer.

- Test Case #2
    - The second test case will be conducted utilising two adjacent/consecutive lab rooms.. Similar to Test Case #1, the lab rooms must be well insulated from any incoming sound that is external and internal to the lab. This parameter is put in place to ensure that the hand-held sound level metre accuracy and precisely detects the audio produced only by the 5V active buzzer.

Test Inputs:

A sound level detector mobile app ($\pm\ 0.05\ dB$) [46] will be utilised in order to detect the audio produced by the 5V active buzzer.

Quantifiable Measurement Standard:

Multiple trials will be conducted and recorded to ensure that the recordings of the sound levels produced by 5V active buzzer fit within the 70 dB - 105 dB range identified. Additionally, multiple trials are conducted to ensure that the accuracy and precision of the recordings of the sound levels are sufficient/accurate.

Pass Criteria

The 5V active buzzer must produce an audio reminder within the 70 dB - 105 dB range identified in both test cases.

Test 2: NUCLEO F401RE Timer

The NUCLEO F401RE timer incorporated in the design must be tested to ensure that it is accurate and precise. This requirement must be tested to ensure that the input time provided by the end user alarms the user at the correct time. Additionally, as the LCD conveys the time at which the end user's next scheduled medication administration time is, the timer must be accurate and precise and alarm the user at the expressed time. Note that the MEDalarm timer will be set multiple different times during the requirement test. Multiple trials will be conducted in order to ensure accuracy and precision of the recorded results.

Test Setup:

The test setup for this particular requirement test is simple and straightforward. The MEDalarm and electronic device (used to access TAI) will be placed next to each other within the lab room.

Environmental Parameters:

The requirement test will take place within a standard lab room. For this particular requirement test, there is one significant environmental parameter required. The key component related to the test is accessing the TAI. As this will be done on a device, some form of strong connection to the internet must be supplied. Thus, the lab room in which the test will take place must have access to a strong internet connection.

Test Inputs:

To conduct the test, International Atomic Time (TAI) will be utilised to determine the accuracy and preciseness of the timer incorporated in the MEDalarm. International Atomic Time is utilised as it is accurate to one three hundred millionths of a second per year [48]. To access TAI, the following website is utilised [49]. Upon the completion of each trial, the time the TAI shows when the audio reminder plays is recorded, as well as the time expressed on the LCD of when the timer should sound. The accuracy and precision of the clock will then be calculated from the recorded results.

Quantifiable Measurement Standard:

Multiple trials of the requirement test are conducted to ensure a sufficient level of accuracy and precision is present in the recorded results and final accuracy. To remain accurate, the accuracy of the clock should be no more than $\pm\ 5\ \frac{seconds}{day}$ [51].

Pass Criteria

The NUCLEO F401RE timer will pass the requirement test if the accuracy of the clock is measured to be no more than $\pm$ 5 $\frac{seconds}{day}$ [51].

Test 3: Size of Medication Storage Compartment

The medication storage compartment incorporated in the design must be tested to ensure that users are able to access and retrieve the stored medications. As expressed in the requirement specifications, it was stated that the average width of a finger is approximately 2 cm and the average width of a thumb is 2.5 cm [17]. Also, the smallest average length that a finger is able to have is approximately 65 mm [53]. Utilising these quantities, a requirement test can be conducted on the medication storage compartment (rectangle) of dimensions 7 cm × 5 cm × 5 cm. Thus, this requirement test aims to confirm that the compartment comfortably accommodates the finger, and thumb allowing the user to access and retrieve medications with ease.

Test Setup:

The test setup for this particular requirement test is simple and straightforward. The medication storage compartment that is incorporated in the MEDalarm design is required. The test inputs of: pieces of plastic (with largest dimensions possible), the simulated finger and the simulated thumb are placed within the compartment.

Environmental Parameters:

For this particular requirement test, there are no significant environmental parameters required. Thus, the test will take place within a standard lab room.

Test Inputs:

There are several inputs required to test the size of the medication storage compartment to be adequate. In order to simulate a finger and thumb the test requires that the medication storage compartment will be measured by a ruler and the volume will be calculated. After, the volumes of the average finger and thumb will be calculated. Once completed, the three volumes will be compared. Also, another test input required would be the medication storage compartment with dimensions of of dimensions 7 cm × 5 cm × 5 cm. Volume of finger: 20.42 cm^3. Volume of thumb: 31.91 cm^3.

Quantifiable Measurement Standard:

If the medication storage compartment successfully has enough room for the simulated finger and simulated thumb, the 7 cm × 5 cm × 5 cm dimensions of the box are then sufficient.

Pass Criteria

The medication storage compartment is able to fit the pieces of plastic, simulated finger and thumb with ease while also providing further volume.

Test 4: Material of MEDalarm (polycarbonate)

The material, polycarbonate, that the MEDalarm is created from must be tested. This requirement specification must be tested as the end user may potentially inflict damage to the MEDalarm causing it to break or become damaged. Thus, the impact resistance, the measure of how well a material or product can endure impacts without fracturing. of the material of polycarbonate must be tested. As there are a variety of ways that the user is able to damage or break the MEDalarm, we will focus primarily on one test case, dropping the MEDalarm, to measure/estimate the impact resistance of polycarbonate from varying heights.

Test Setup:

The test setup for the particular requirement test is simple and straightforward. It requires utilising the test inputs of the various small boxes composed of polycarbonate. Multiple trials of dropping the small boxes of polycarbonate will be conducted in order to observe varying values of impact resistance. With each trial, the height and mass of each box is calculated in order to calculate energy and later, impact resistance.

Environmental Parameters:

There are no significant environmental parameters that need to be considered when undergoing this particular requirement test. Thus, the test is conducted within a standard lab room.

Test Inputs:

To conduct the requirement test, as we cannot utilise the MEDalarm when fully constructed to avoid any potential damages done to the overall product. Thus, the test inputs that we require to conduct the requirement test would be several boxes composed of polycarbonate that will participate in the drop test.

Quantifiable Measurement Standard:

The impact resistance of polycarbonate is 320 J/M [55].

Pass Criteria

If the impact resistance of the small boxes is smaller than the quantifiable measurement standard, the MEDalarm is unlikely to suffer damage.

Test 5: Mechanical Mechanisms

The entire MEDalarm storage system depends on the functionality and longevity of its mechanical systems. This would consist of the opening of the medicine compartment and the general body of the system. Since the servo provides access to the user’s medicine, it is imperative that it is not

subject to wear and tear (i.e. breaking after a few uses) and should consistently move the lid up the same amount for accuracy and accessibility.

Test Setup:

In order to test the MEDalarm's durability, it will simply be placed on a table in the lab room.

Environmental Parameters

This test requires no particular environmental parameters other than access to a consistent power output as the servo will be repeatedly tested.

Test Inputs:

In order to effectively determine the durability of the servo mechanism in a timely manner, a short timer of one minute will be set. In order to determine the consistency, a ruler will be used to determine the lift distance of the lid and recorded after each trial. The state of the mechanism will also be determined qualitatively.

Quantifiable Measurement Standard:

Multiple trials will be conducted on the servo mechanism directly after one another to evaluate evidence of any possible deterioration. In order for the servo to be consistent, the position of the servo should not stray further than 0.2cm from its initial position.

Pass Criteria

After the trials are complete, no more than 0.2cm variation should have occurred in any of the tests with no change in the quality of the mechanism to be considered durable and accurate.

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