**Biorefrigerator Security System**

Biomedical Engineering Senior Design

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Progress Report 3

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# **Problem and Objective**

Figure 1: Introductory Figure for the Design

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Above is our current prototype for a combined lock and sensor system that keeps the door to a biological freezer closed.

## **Problem** Statement

Current methods of ensuring that a frequently accessed controlled laboratory environment (CLE) remains closed are limited by the need for human input, which requires a human to physically close the CLE. Humans typically interact with the CLE by opening or closing the doors manually. Requiring the use of human input introduces the possibility of human error. Some newer models of CLE’s have methods to signal that it is left open such as audible alarms; however, older CLE models may not have a method to signal that it is accidentally left open. The most common error of human input in CLEs is accidentally leaving them open. This error can result in significant risk to the integrity of materials within them, such as DNA or cells.

<https://ieeexplore.ieee.org/document/9083491> (Food Transportation and opening door)

<https://ieeexplore.ieee.org/document/9548219> (Door Opening Effect)

<https://ieeexplore.ieee.org/document/10386421>

<https://ieeexplore.ieee.org/document/7917619>

<https://www.eppendorf.com/us-en/eShop-Products/Cold-Storage-c-WebPMain-H-44537>

(From a company that sells ULT fridges, so probably a highball estimate, but even 50% of their estimate is $200k per fridge in sample value)

## Design **Objective**

The objective of the Biorefrigerator Security System is to develop a device that minimizes the risk of sample deterioration due to prolonged exposure to ambient conditions. We aim for the device to be power efficient, affordable, easy to install, and easy to use. Primary intended use cases are CLEs such as chemical and biological laboratory refrigerators.

## Design Solution

Our design solution is a device that enables automatic closure of CLE doors without the need for laboratory workers to intervene. The main housing of the device will be installed on the door of the CLE, and the arm will be attached to the top of the CLE. A hook-style lock system is attached atop the closer housing in order to resist opening the CLE when in the locked state. The main housing of the device will contain a PIN pad that users will use to lock and unlock the CLE. The door status is considered “closed” when a limit switch that is placed in the door is pressed. Once not pressed, the door status will read as “open”. The LED and speaker alarms are set to trigger when the door status changes to “open” when the locked status is “locked” or when the door is open for over two minutes. The device will be powered by disposable 9V batteries. Figure 1 illustrates the device when fully assembled.

Since the last progress report, we have some possible changes that will be made. Primarily, due to the difficulty of working with aluminum, we have ordered some steel sheets to make the body out of instead. Additionally, we are inserting a display screen into the body so that the PIN code is visible while the user is typing it in. This change also comes with our ordering of a different microprocessor, which will make bluetooth connection possible, which would allow us to make an app that provides a user log of the CLE. Since a method of monitoring the individual users who access the CLE is secondary to the objective of keeping it from opening, we will only implement such a feature if time and resources allow.

-new regulatory rules we learned of, some minor changes to list based on recent discoveries and input, ways to validate the steps maybe (or ways that can make it easier based on the design changes)

# **Verification and Validation**

In order to follow the design practices of medical devices, we must follow the Food and Drug Administration’s (FDA) Quality System Regulation 21 CFR Part 820. 21 CFR Part 820 is designed to help in the design and production of medical devices and is composed of two critical pathways: verification and validation. These pathways are used to help serve as a framework for quality assurance as well as help guide the design process. Verification will focus on ensuring that our device meets the requirements given in our Engineering Design Specifications (EDS) while validation will focus on ensuring that the user needs and intended use is satisfied.

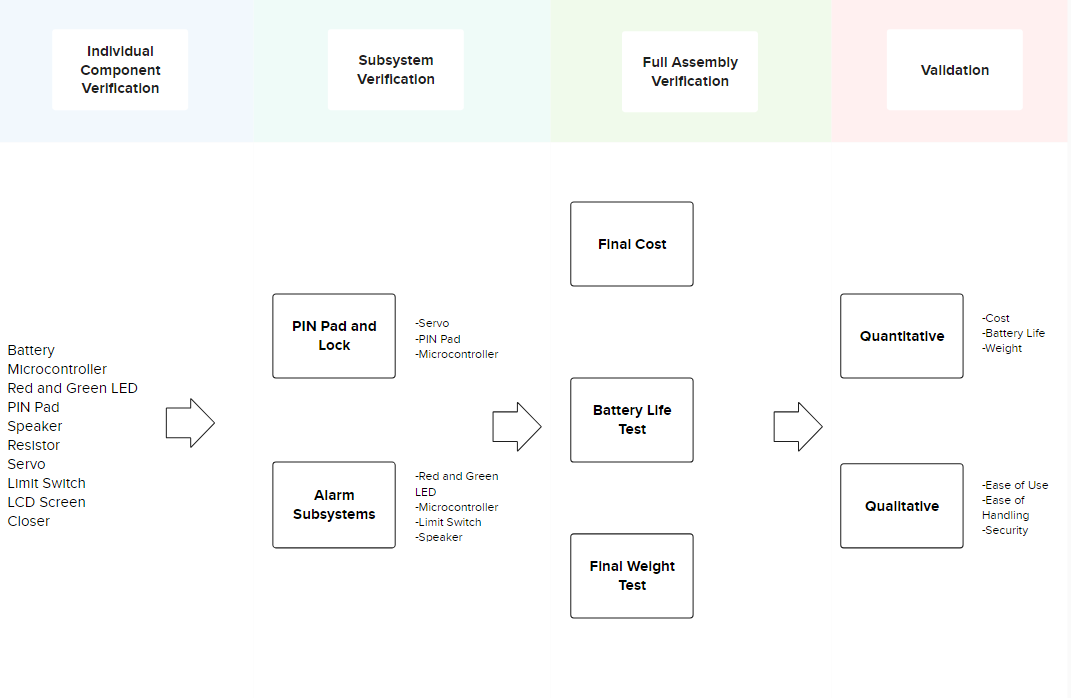
Recognized Consensus Standards must be also given to meet the regulations of the FDA. give more detail on how we found each standard

## Recognized Consensus Standards

Given the emphasis on electrical safety and reliability in devices used in laboratory settings, following the relevant standards is of utmost importance. In this context, such a device (in this case, an alarm and locking device) should meet standards for electrical safety, functionality, and reliability. To ensure that these standards are met, the following section goes over verification processes to ensure that all components and systems function properly along with validation testing to ensure the system works as intended in meeting user needs. Here are the following standards we will be using:

## Verification

### **Verification Process Flow**

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### **Individual Component Verification**

The goal of verification tests is to confirm all used materials are functional prior to assembly. This is to ensure that no other factors can affect future tests. This phase includes an assessment of the battery, microcontroller, and closer. Afterward, we will test components as a subsystem and finally test the entire system overall. This will help us focus on ensuring that our devices meet the requirements given on our EDS.

**Battery**

*Purpose:* To ensure that the circuitry and program are effective when active, we must confirm the batteries are properly working. Testing will involve measuring voltage and battery life.

*Test Protocol:*

1. Turn on the multimeter
2. Turn the dial to the voltage setting 15V
3. Touch the red probe to the positive terminal and the black probe to the negative terminal
4. Note the voltage shown
5. Perform an average and standard dev.
6. After getting voltage, test for maH using the multimeter over 1 minute, then divide by 1000 to get aH
7. After getting maH, test how much energy the microprocessor draws using the multimeter over 1 minute (both idle and when activating the servo)
8. The battery life is now: V\*aH(battery) / wH(microprocessor) to get the hours that the battery will last
9. The acceptable range is 6-12 months
10. Obtain data from other sources and base our results on results from data

**Microcontroller Component Testing**

*Purpose:* By testing each component of the Arduino, we will effectively find any defect that might exist before Validation testing.

*Standards To Meet:* IEC 60601-1-8 Ed. 2.2 b:2020 | Occupational Safety and Health Standard 1910.95 | IEC 63356-2 Ed. 1.0 b:2022

*Test Component Protocols:*

Adafruit METRO M0:

1. Turn on the AdafruitMETRO
2. Install Arduino IDE into METRO
3. “Hello World”
   1. See if it outputs the code
   2. Code in for a simple LED system, with a resistor
      1. Test for AdafruitMETRO, if code works with circuitry, then Adafruit works
      2. Possibly test for multiple pins

Red and Green LED:

1. Add a resistor in series with each cathode
2. Plug into the microcontroller and output 2.1V into the red LED pin
3. See if the red LED lights up
4. Turn off the 2.1 V output
5. Output 2.4 volts into the green LED pin
6. See if the green LED lights up
7. Turn off the 2.4V output

Pin Pad:

1. Activate and program in a certain passcode for the pin pad
2. Type in the passcode
3. If the correct passcode is entered, the lock status will change to “unlocked”

Speaker:

1. Use the METRO to program an alarm sound of frequency 1 Hz and 100% volume level
2. Measure the sound level from 2 feet away
   1. If the sound level is higher than 85 dB, adjust until it is 85 dB or lower
   2. If the sound level is inaudible or softer than the conversational level, the speaker has failed

Resistor:

1. Turn on the multimeter
2. Turn the dial to the resistance setting 20kΩ
3. Touch the red probe to one of the metal wires on the resistor and the black probe to the other wire
4. Note the resistance shown

Servo

1. Program in code with specific angle degrees
2. Note the initial position of the servo, then Note the new position of the servo with the programming, if the difference between the new position and initial position is set similarly to the programmed code, then the servo works.

Limit Switch

1. Turn on the multimeter
2. Turn the dial to the lowest resistance setting
3. Touch the test leads to the terminals of the limit switch
4. Press down the lever arm of the limit switch
5. Note the resistance from the multimeter
6. Release the lever arm
7. Note the resistance
8. Resistance should be low when the lever is pushed down, and high when released

LCD Screen

1. Connect screen to METRO
2. Code METRO to output a 32-character long word to screen
3. See if all cells on the screen can display a character

**Closer:**

*Purpose:* As the main component of the device, testing the closer will be important so that the status of the door can change with the closer component present.

*Standard To Meet:* ANSI/BHMA A156.4-2019

*Test Protocol:*

1. Test the range of motion of the closer arms
   1. The segment of the arm directly connected to the rack and pinion should have a range of motion of approximately 360 degrees
   2. The other segment of the arm should have a range of motion of approximately 180 degrees
2. Install the device onto the intended controlled laboratory environment
3. Test the Air Pressure Release Valve
   1. Open and close the door of the laboratory environment and observe the security and smoothness of closing. The door should close smoothly without slamming

**Attachment System (Epoxy)**

*Purpose:* An epoxy attachment system is how the lock system is attached to the refrigerator. This test is required to ensure the system can be applied properly on the CLE.

*Test Protocol:*

1. An L-shaped aluminum plate with a hole drilled through the exposed arm will be epoxied onto a stainless steel test device
2. Attach a luggage scale to the aluminum plate
3. Pull the luggage scale until the plate comes off
4. Note the scale reading of the maximum force required to pull the plate off

### **Subsystem Device Verification**

We will verify the subsystems of the device first then finally move onto verifying the entire system functions together properly. Subsystems are grouped based on the microprocessor’s two functions: Alarm and PIN Pad/Lock system.

**Microprocessor Subsystems:**

*Purpose:* These tests are final testing before the whole system is tested together. This test will be used to confirm circuit and programming aspects work effectively together before taking into account the physical aspect of the device

*Standards To Meet:* IEC 60601-1-8 Ed. 2.2 b:2020

*Test Protocol:*

1. Alarm
   1. Connect the speaker and LED to the Adafruit Metro in accordance with the circuit schematic
   2. Program the speakers and LED to alarm when the limit switch detects an open door and to turn off when it detects a closed door
      1. Press down on the limit switch and print the current door status to the display
      2. Ensure that the current door status displayed is “closed”
      3. Release the limit switch and print the current door status to the display
      4. Ensure that the current door status displayed is “open”
2. PINpad/Lock system
   1. Connect PIN pad and screen to METRO
   2. Program the lock to activate and deactivate off a default code (1111) then test if it does so
      1. Connect the PIN pad and servo to the Adafruit Metro
      2. Set the door lock status to be “locked”
      3. Print the current door lock status to the display
      4. Input the default code into the PIN pad
      5. Print the current door status to the display, which should now be “unlocked”. The Servo arm should rotate upwards and not block the closer arm
      6. Input the default code into the PIN pad
      7. Print the current door status to the display, which should now be “locked”. The Servo arm should rotate downwards and block the closer arm

**The Whole System Must Be Tested**

*Purpose:* As the final test, this test will be done to ensure the entire system all together is effectively working as it properly should.

*Test Protocol:*

1. The system locks the door when necessary, closes the door in most cases, and sounds an alarm when specified
2. Test system similar to an intended day in the lab
   1. Unlock the system with the pin pan to unlock the servo
   2. Open the door and close it and test if the system detects the door is closed
   3. Test leaving the door open for 3 minutes and test when the speaker and LED go off
      1. Note: the system is supposed to alarm at 2 mins. Testing for 3 minutes will help discover unwanted or unnoticed factors.
   4. Repeat the previous two tests a couple of times
   5. Close the door, final test, if the alarm detects the door, is closed
   6. Lock the system using the pin pad

## Validation

Validation tests will involve both small and large-scale assessments to confirm functionality, durability, and usability. The small-scale testing will focus on general testing, while large-scale testing will help with finalized specifications and detailing.

Small Scale Testing

| **Test** | **Metric** | **Test Protocol** |
| --- | --- | --- |
| Cost | US Dollar | Sum final costs of components and materials |
| Battery Life | Hours | Use a multimeter to measure voltage before usage and then again after 1 hour. Repeat 3 times. Use the average difference in voltage per hour to calculate the theoretical battery life |
| Weight | Pounds | Weigh the final assembly with a digital scale |
| Passive Operation | Door Status | Place the final assembly on a device such as a mini refrigerator and open the door. The door status should read as open.  Let go of the door and let the device close it automatically. The door status should read as closed |

Our gross cost for the whole assembly should be under $150 per unit, since our initial surveys indicated that people would pay $100-$150 for a lock. At a small scale, we do not need to aim for a profit margin since large scale development should decrease per-unit cost because materials will be bought in bulk.

For battery life, we want the end users to be able to use the device without needing to check the battery too much. Since typical uses of 9-volt batteries are usable for 6 months, we will also be aiming for a 6-month lifetime between battery changes.

Our final weight should be light enough to comfortably mount and transport, so under 10 pounds would be ideal.

Finally for actual operation of the device, the bare minimum is that the device successfully closes the door while making it still able to be opened with the application of minimum force along with being able to read the status of the door as open or closed.

## Future Development/Small Scale Development

Due to not having access to mass production or many customers, for the qualitative measures of our product, such as ease of use and handling, we cannot yet test these metrics. However, in the future, our plan is to encourage customers to fill out a survey on their satisfaction with the product.

## Large Scale Validation

Large Scale Testing

| **Test** | **Metric** | **Test Protocol** |
| --- | --- | --- |
| Average Cost | Dollar | Sum final costs of components and materials along with manufacturing, then divide per unit |
| Average Battery Life | Hours | Use [small scale test] on a randomly selected 10% of batteries and perform a T test to make sure that all batteries fall within the acceptable value to test for average battery life |
| Average Weight | Pounds | Weigh 1 in 10 random units and average their weights to make sure that it is close to the small scale weight value |
| Passive Operation | Ease of Use | Installation of multiple units should be swift and passcodes should be easily set up. Then, set one alarm to go off and make sure that the source of the sound is easily discerned |

On a large

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# **Preliminary Hazards Analysis**

## Failure Modes and Effects Analysis (FMEA)

**Introduction**

To be aware of any hazards on our device we will construct a *Failure Mode Effects Analysis (FMEA)* following the guidelines given by the American Society of Quality (ASQ). Below are two tables.

Table 1 determines the scale of FMEA Events. They will be broken up into Occurrence (OC), Severity (SV), and Detectability (DT) each having a scale from 1-10 for the purpose of having more specificity. Risk Priority Number (RPN), which is the multiplication of SV, OC, and DT, has been given appropriate scaling from the team as shown on the table. Having Unacceptable Risk is deemed extremely dangerous and additional safety measures must be included to address this risk. Scores given for Acceptable Risk and Unacceptable Risk were chosen based on the expected scoring below 3 for all points of OC, SV, and DT for Acceptable Risk and the expected scoring of 4 for all points of OC, SV, and DT for Unacceptable Risk

Table 2 is a summary of the FMEA chart for our device. We will firstly select the item that must be considered for FMEA guidelines. There will be a Potential Failure Mode or a situation in which damage or error may occur. A scale value for Occurance will be given. Then there will be Potential Effects regarding the situation. A scale value for Severity will be given. Current Control will be stated on the chart to explain how the situation will be noticed. A scale value for Detectability will be given. Finally, an RPN value will be displayed with a Mitigation Strategy to try to prevent the situation from happening in the first place.

Table 1: FMEA Scoring Table

| Occurrence (OC) | 2 = Almost never  4 = Rare/Possible  6 = Occasionally  8 = Often  10 = Extremely Often/all the time |
| --- | --- |
| Severity (SV) | 2 = No safety concerns, but minor effect on functionality of device  4 = Minor injuries and/or minor effect on functionality of device  6 = Minor injuries and/or major effects on functionality of device  8 = Moderate injuries and/or major effect on functionality of device, user needs are not met  10 = Extreme injuries and/or major effect on functionality of device, user needs are worsened |
| Detection (DT) | 2 = Easily detectable (User can see problem immediately)  4 = Detectable (User can make an educated guess on where the problem has occurred)  6 = Moderately Detectable (User can unreliably guess where the problem might be)  8 = Undetectable (User cannot find issue unless they already know that there is an issue)  10 = Impossible |
| RPN Value  SV\*OC\*DT | <27 = Acceptable Risk  27-64 = Moderate Risk  >64 = Unacceptable Risk |

Table 2: Figure Failure Modes and Effects Analysis (Abridged Version)

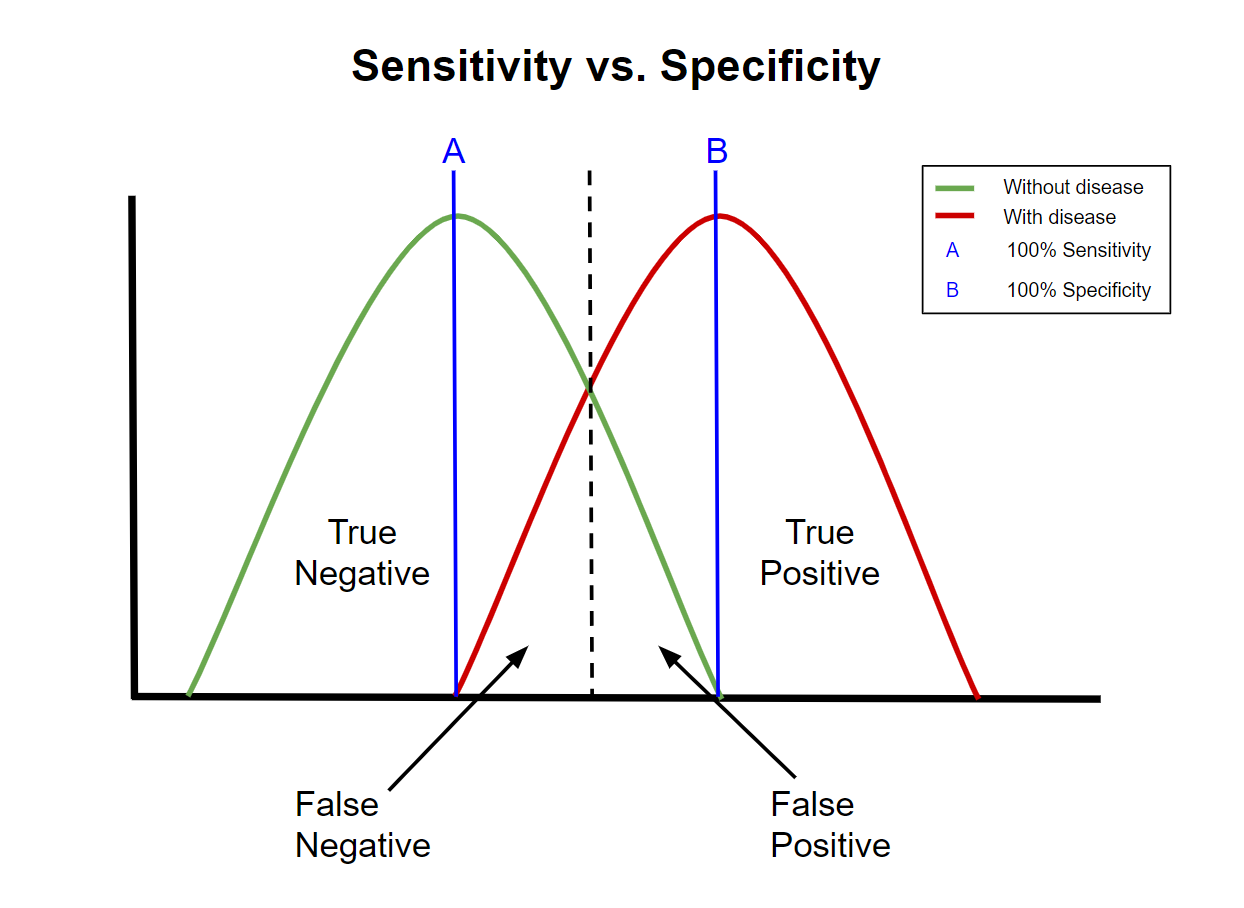
| Item | Potential Failure Mode | Potential Causes | O | Potential Effect | S | Current Controls | D | RPN (S x O x D) | Migration Strategy/ Actions Recommended |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alarm | False Negative  on speaker | (i) The speaker itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The audio alarm will not sound making it difficult to know if the lab door is left open. | 8 | When the device is being assembled, check functionality of the speaker, limit switch, and wire connections. | 6 | 60 | Establish monthly routine check-ups. Ensure verification of the completed system (ex: A door open for too long causes Speaker and LED alarm to activate) |
|  | False Negative on LED | (i) The LED itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The LED alarm will not light, making it difficult to know if the CLE door is left open | 8 | When the device is being assembled, check functionality of the LED, limit switch, and wire connections. | 6 | 60 | See above |
|  | False Positive on speaker | (i) The limit switch may be stuck  (ii) crossed wires | 4 | The sound will be audible and the user thinks the door is open when it is still closed. | 3 | Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 12 | See above |
| Security | Rejects correct PIN code | See above | 1 | The CLE could be not unlockable. | 3 | Thoroughly test the PIN pad circuit during verification. Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 3 | See above |
| Closer | Door does not close all the way | (i)Insufficient closing pressure  (ii) physical obstruction of the CLE door | 1 | The door could be left open, which can negatively impact samples in the CLE. | 1 | The closer is equipped with values to change closer pressure. The alarms are coded to sound after the doors are open for a specified length of time in case of physical obstruction | 4 | 40 | See above |
| Epoxy | Failure to stick to the intended CLE | (i) manufacturing defect  (ii) Not allowing for the full curing time  (iii) insufficient adhesive coverage  (iv) unclean application surface | 3 | The lock could fall off, meaning that the lock cannot be used properly. | 8 | Device adhesion surfaces are designed with large surface areas | 1 | 24 | Ensure that when applying export, appropriate time and amount must be given to the epoxy before use |
|  | Inhalation of epoxy fumes | (i) poor ventilation during assembly | 5 | Skin, eyes, nose, and throat irritation. Possible trigger for skin allergies and asthma | 5 | None | 2 | 50 | Ensure that when applying epoxy, application is done where it is well ventilated or provide masks as needed. |
| Electrical | Short Circuit | (i) Water damage  (ii) Faulty wiring  (iii) Loose connections  (iv) Overheating | 3 | The circuitry for the whole device would not function, resulting in possible lock failure. | 8 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 144 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
| Structural | Rust | (i) Exposure to moisture  (ii) Exposure to acids  (iii) Contact with dissimilar metals | 2 | The lock could potentially degrade over time due to rust, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 2 | 12 | Proper controls are deemed sufficient |
|  | Material Wear | (i) friction | 3 | Degradation over time due to friction, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Device was built with tough materials to withstand many use cycles, and will be smooth to reduce friction | 2 | 18 | Proper controls are deemed sufficient |
| Battery | Exposure to moisture | (i) condensation from the CLE  (ii) Liquid spills | 4 | A battery with moisture would have its function impaired due to reduced resistance | 7 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 4 | 112 | Remind the user that the device must be placed away from moisture and in a clean and dry area before applying |
|  | Overheating | (i) heating from the electrical components  (ii) heating from the CLE  (iii) Faulty wiring | 2 | A battery that is too hot will not function properly | 6 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 72 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
|  | Battery dies | (i) Extended use | 2 | The lock will not work because there is no battery power. | 8 | None | 1 | 16 | Keep a stock of 9V batteries. Replace at appropriate/said times on the battery box |
| User | Door is forced open when locked | (i) User ignores resistance of the hook mechanism  (ii) hook mechanism malfunction | 2 | If the door is opened when locked, then damage to the servo, hook, and arms is possible. | 6 | Alarms are in place to prevent this, and the servo and hook assembly provides resistance to opening when the device status is “locked” | 2 | 24 | If there’s resistance to opening, check if the LED is green |
| Manufacturing | Loose device structural connections | (i) Loose screws  (ii) Improper tolerances | 4 | The lock structure could be unstable, which could prompt anywhere from the lock not functioning to the lock structure to break. | 5 | Manufacturing within standard tolerances, and ensuring properly tightened screws and connections during verification and assembly | 4 | 80 | Tighten loose connections with a screwdriver if applicable |

\*A false positive means that the device reports the CLE as open when it is closed. \*A false negative means that the device reports the CLE as closed when it is open

## FMEA Analysis/Discussion

The Failure Mode Effects Analysis (FMEA) conducted for our device provides valuable insights into potential hazards and their associated risks. Using scales for Occurrence (OC), Severity (SV), and Detectability (DT) ranging from 1 to 10, the Risk Priority Number (RPN) is calculated as the multiplication of SV, OC, and DT. An RPN value below 27 (based on a 3^3 score) indicates an Acceptable Risk, 27 to 64 (based on a 4^3 score) represents a Moderate Risk, while an RPN exceeding 64 signifies an Unacceptable Risk.

Several high-risk scenarios have been identified through this analysis, warranting immediate attention and mitigation strategies. These include instances such as False Negative and False Positive alarms, where the occurrence of these events is relatively rare (OC = 4) but could lead to severe consequences such as compromised security or safety (SV = 8 to 10). Detection of these issues may not always be straightforward (DT = 4 to 8), contributing to elevated RPN values well above the threshold for Unacceptable Risk.



Furthermore, failure modes related to structural integrity, electrical malfunctions, and battery issues also pose significant risks. Instances such as Rust formation, Short Circuits, and Battery Exposure to Moisture exhibit varying degrees of severity and detectability, but their occurrence rates and potential impacts necessitate thorough preventive measures. These measures may include regular inspections, enhanced quality control during assembly, and design modifications to improve resilience against environmental factors.

In addressing these high-risk scenarios, it is imperative to implement robust mitigation strategies. This could involve rigorous testing protocols during production, comprehensive user training to enhance the detectability of issues, and proactive maintenance schedules to mitigate potential failures before they escalate. Additionally, clear documentation outlining troubleshooting procedures and emergency protocols can empower users to respond effectively to unforeseen circumstances, reducing the likelihood of catastrophic outcomes.

By prioritizing risk mitigation efforts for high RPN value items identified in the FMEA, we can enhance the safety, reliability, and functionality of our device, ensuring optimal performance and user satisfaction while minimizing potential liabilities and hazards.

## Risk Mitigation Strategies (Optional)

# **Societal Impact**

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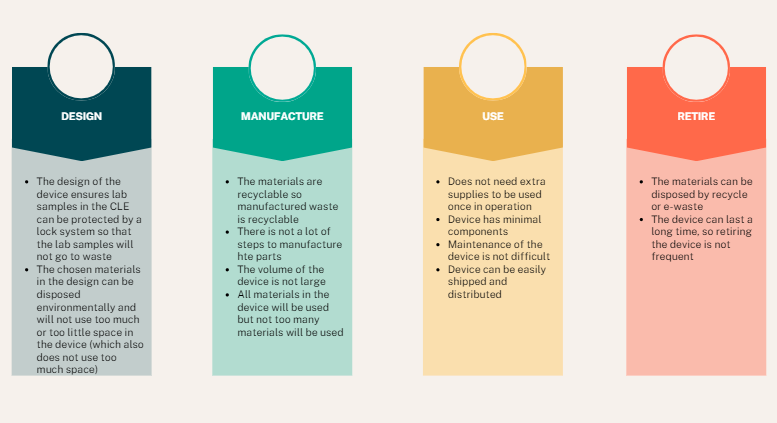
## Value Properties

The design is innovative and novel since it combines an alarm and a pin pad system on a CLE. There is not a widespread solution for a CLE locking system that is reasonably priced and easily accessible. This device will help reduce the risk of CLE’s opening spontaneously or being left open by the user, which can impact the laboratory samples inside the CLE, by ensuring that the CLE door is closed to protect the laboratory samples from decaying. There are existing solutions for CLE locks, but they are not widespread and they are expensive. The customer can benefit from having a secure system to protect their CLE in the lab while also not being too pricey. The combination of an alarm, pin pad, and lock system means that the device will have advantages with different security features all in one device. The device will have a way to notify the user about an open CLE using an alarm, a way to unlock the refrigerator and to shut off the alarm using a pin pad, and a way to keep the CLE closed using a lock system with a closer. The combination of both an alarm and a pin pad system can benefit laboratory users since there is a way to secure the CLE as a preventative measure to ensure the CLE stays shut while ensuring that when the foolproof measure fails, laboratory users can be easily notified by a visible and audible alarm, which in turn will prevent disasters such as losing cells and data. The amount of time saved from having an audible and visual alarm is immense as an alarm system can quickly notify nearby people a CLE is not closed all the way, rather than someone finding out eventually without realizing that the CLE is open when it should not be.

## Ethical Considerations

There are some ethical considerations for a CLE lock system design. An ethical consideration that is involved is that the alarm signal is only if the CLE is actually open, as if the alarm signals indicating the CLE is open and the CLE is closed, that means that the person wasted time responding to an unnecessary signal and the alarm gave out a false signal as well. Another ethical consideration that will be considered in the design is that the pin pad for the unlocking of the CLE and turning off the alarm can only accept the password set by the users of the CLE so that a random person does not have access to a CLE that they should not have. The pin pad should not just accept any random password, but rather only the password set by the user. Furthermore, the lock should not impede on a user’s ability to open and close the CLE door if the pin pad is activated. The user should be able to open and close the door without issue if the pin pad of the refrigerator is unlocked. An IRB test is not needed since there is no direct human or animal testing involved, but any test that involves another person’s CLE’s would have to have their informed consent by informing them of a potential test of the lock in their CLE’s before conducting the test. There are three main principles in IACUC: replacement, reduction, and refinement. While animal testing is not used for this project, the principles of the IACUC can still be applied. There will not be a lot of replacing for locks as locks tend to last for a long time, so there can be fewer locks manufactured since they are meant for long term usage, hence meeting the reduction principles for IACUC. This project meets the replacement principles for IACUC since the project avoids using animals as animals are not necessary to test on for locks. The refinement processes are applied to the project as the CLE’s and locks will be treated with great care during the testing and the usage of the locks. The data that will be collected, particularly involving the saving of the passwords so that the user can input in a password to unlock and lock the pin pad for the lock, will be protected to ensure that the design meets HIPAA standards regarding protecting user data by ensuring that the password, once entered, will be difficult to be hacked, so random people cannot access the refrigerator without knowing the password.

## Green Engineering



**Design** - The design of the lock involves green engineering principles to manufacture the design. The design has an objective to maximize efficiency and productivity. By ensuring that the lock can lock adequately without any additional parts, the amount of parts needed to ensure that the lock will be locked will be reduced and the laboratory samples inside the CLE will be protected so that there will be less waste of samples. Ensuring protection of the samples in the CLE results in the samples not being impacted by the open door, which can cause the samples to degrade off or die, resulting in the lab workers having to use additional replacement and having to dispose of waste that would have not been waste. Furthermore, the lock is not huge, so the lock would not waste up space that would be used for other items. Additionally, the materials chosen will only be used for their specific purposes and the amount of each material is not too much in the device in order to ensure that we are only using the amount of materials needed for the device so we do not have useless, wasted materials in the lock for no reason.

**Manufacture** - The metal involved, aluminum, is highly recyclable, meaning that any form of waste involved in the manufacturing can be recycled. The manufacturing process will ensure that the parts will be close to each other reasonably so that there is not a waste of space with the device. The design will also not have too many intensive manufacturing steps as all that is needed is the construction of the lock and the wiring, which is not intensive and does not require additional manufacturing materials. The volume of the aluminum material being manufactured is of reasonable size for the lock product, as it is not too large to the point where the material will be wasted. The aluminum will ensure that the device is protected, but to the point where not too much aluminum is used or else it would be a waste of aluminum used. The manufactured product will not be too big or heavy in order to ensure the product is easy to distribute. The product will have additive manufacturing either through 3D printing or through the combination of building multiple parts to adjoin to be one device to ensure that there is no extra waste that will have to be disposed of due to subtractive manufacturing processes, which involve the presence of metal scraps after parts have been subtractively manufactured such as being drilled and CNC milled.

**Use** - The lock is designed to be used for a long period of time, as locks do not get replaced often, so disposing and replacing locks do not happen often, resulting in less waste. The only use of the lock is to use the pin pad for unlocking the alarm when the alarm is heard or seen, so there is no part of the lock that is wasteful or unnecessary to have since there is only one function the human can control over. Furthermore, the device has minimal components besides a pin pad to unlock that the human can directly interface with, so the device is not complicated. The device can be used anywhere without issues with transport, so there is no need to waste anything to help move the device when it can be moved with just hands. Additionally, maintenance of the device is not difficult as the most that needs to be done is simply unscrewing the outer part of the device to check on problems rather than using up emissions to go to a specialized mechanic to fix the device. The lock will be distributed easily as it can be easily shipped to anyone since the size is small and there are no special steps for it to be distributed, especially since the lock is not large and it can be attached on any type of CLE. Moreover, the batteries that will be used in the device are meant to be long lasting so that the amount of times the batteries need to be disposed of is minimal, and the device can also support environmentally friendly batteries being placed in it.

**Retire** - The metal involved, aluminum, is highly recyclable, meaning that any form of waste involved in the manufacturing can be recycled. Besides aluminum, there is not much other waste for the device besides recycling that needs to be specifically checked besides wiring and batteries in the e-waste. The device can also be used for a long time before retiring, so there is no need to retire the device frequently since a lock can last a long time.

## Regulatory Pathway

The device that we have decided upon is an FDA class 1 device. Class 1 medical devices are non-life sustaining or life-supporting, and pose minimal risk of harm to their user. The automatic closer design that we have selected fulfills these requirements, and thus is subject to General Controls. The requirements of the General Controls are the prohibition of adulteration and misbranding, required registration and listing, restricted sale and distribution or use, adherence to Good Manufacturing Practices, and notification of risks, repairs, replacement or refund. The design of the Biorefrigerator Security System will prevent use of the device to perform a function besides closing and locking doors. The device will be registered and listed as the final device is prototyped. The sale and distribution of the device will be restricted similarly to CLEs as the two devices are meant to go together. Good Manufacturing Practices(GMP) refer to the regulation and upkeep of standards in products, people, processes, procedures, and premises[3]. Table [], the FMEA table, is meant to notify users of the risks associated with the device.

The regulatory route that is appropriate for the Biorefrigerator Security System is the exempt regulatory path. The Biorefrigerator Security System falls under the category of “General hospital and personal use devices'' from 21 CFR Part 880. The FDA has exempted most class 1 devices, and in the event that a device falls under a generic category listed in 21 CFR Parts 862-892, that device is exempt from a premarket notification application[1]. In addition, the regulation description of “general purpose laboratory equipment labeled or promoted for a specific medical use” is listed as a product classification that is 510(k) exempt[2]. The device that we have created falls under this regulation description, similar to how freezers are as well.

# **References**

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[1]

“Medical Device Exemptions 510(k) and GMP Requirements.” Accessed: Feb. 29, 2024. [Online]. Available:<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=610#start>

[2]

“Product Classification.” Accessed: Feb. 29, 2024. [Online]. Available:<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=JRM>

[3]

“What are the 5 Key Components of Good Manufacturing Practice (GMP)?,” PharmOut. Accessed: Mar. 02, 2024. [Online]. Available:<https://www.pharmout.net/the-5-ps-of-gmps/>

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# **Appendix**

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## House of Quality

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## Standards to Meet

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## Verification Test Protocols

The goal of Verification tests is to confirm all materials in use are not malfunctioned or dead on arrival. This is to ensure that no other factors can affect future tests. This phase includes an assessment of the battery, microcontroller, and closer. Afterward, we will test components as a subsystem and finally test the entire system overall.

**Battery**

*Purpose:* To ensure that the circuitry and program are effective when active, we must confirm the batteries are properly working. Testing will involve measuring voltage and battery life.

*Test Protocol:*

1. Turn on the multimeter
2. Turn the dial to the voltage setting 15V
3. Touch the red probe to the positive terminal and the black probe to the negative terminal
4. Note the voltage shown
5. Perform an average and standard dev.
6. After getting voltage, test for maH using the multimeter over 1 minute, then divide by 1000 to get aH
7. After getting maH, test how much energy the microprocessor draws using the multimeter over 1 minute (both idle and when activating the servo)
8. The battery life is now: V\*aH(battery) / wH(microprocessor) to get the hours that the battery will last
9. The acceptable range is 6-12 months
10. Obtain data from other sources and base our results on results from data

**Microcontroller Component Testing**

*Purpose:* By testing each component of the Arduino, we will effectively find any defect that might exist before Validation testing.

*Standards To Meet:* IEC 60601-1-8 Ed. 2.2 b:2020 | Occupational Safety and Health Standard 1910.95 | IEC 63356-2 Ed. 1.0 b:2022

*Test Component Protocols:*

Adafruit METRO M0:

1. Turn on the AdafruitMETRO
2. Install Arduino IDE into METRO
3. “Hello World”
   1. See if it outputs the code
   2. Code in for a simple LED system, with a resistor
      1. Test for AdafruitMETRO, if code works with circuitry, then Adafruit works
      2. Possibly test for multiple pins

Red and Green LED:

1. Add a resistor in series with each cathode
2. Plug into the microcontroller and output 2.1V into the red LED pin
3. See if the red LED lights up
4. Turn off the 2.1 V output
5. Output 2.4 volts into the green LED pin
6. See if the green LED lights up
7. Turn off the 2.4V output

Pin Pad:

1. Activate and program in a certain passcode for the pin pad
2. Type in the passcode
3. If the correct passcode is entered, the lock status will change to “unlocked”

Speaker:

1. Use the METRO to program an alarm sound of frequency 1 Hz and 100% volume level
2. Measure the sound level from 2 feet away
   1. If the sound level is higher than 85 dB, adjust until it is 85 dB or lower
   2. If the sound level is inaudible or softer than the conversational level, the speaker has failed

Resistor:

1. Turn on the multimeter
2. Turn the dial to the resistance setting 20kΩ
3. Touch the red probe to one of the metal wires on the resistor and the black probe to the other wire
4. Note the resistance shown

Servo

1. Program in code with specific angle degrees
2. Note the initial position of the servo, then Note the new position of the servo with the programming, if the difference between the new position and initial position is set similarly to the programmed code, then the servo works.

Limit Switch

1. Turn on the multimeter
2. Turn the dial to the lowest resistance setting
3. Touch the test leads to the terminals of the limit switch
4. Press down the lever arm of the limit switch
5. Note the resistance from the multimeter
6. Release the lever arm
7. Note the resistance
8. Resistance should be low when the lever is pushed down, and high when released

LCD Screen

1. Connect screen to METRO
2. Code METRO to output a 32-character long word to screen
3. See if all cells on the screen can display a character

**Closer:**

*Purpose:* As the main component of the device, testing the closer will be important so that the status of the door can change with the closer component present.

*Standard To Meet:* ANSI/BHMA A156.4-2019

*Test Protocol:*

1. Test the range of motion of the closer arms
   1. The segment of the arm directly connected to the rack and pinion should have a range of motion of approximately 360 degrees
   2. The other segment of the arm should have a range of motion of approximately 180 degrees
2. Install the device onto the intended controlled laboratory environment
3. Test the Air Pressure Release Valve
   1. Open and close the door of the laboratory environment and observe the security and smoothness of closing. The door should close smoothly without slamming

**Attachment System (epoxy)**

*Purpose:* An epoxy attachment system is how the lock system is attached to the refrigerator. This test is required to ensure the system can be applied properly on the CLE.

*Test Protocol:*

1. An L-shaped aluminum plate with a hole drilled through the exposed arm will be epoxied onto a stainless steel test device
2. Attach a luggage scale to the aluminum plate
3. Pull the luggage scale until the plate comes off
4. Note the scale reading of the maximum force required to pull the plate off

**Microprocessor Subsystems:**

*Purpose:* These tests are final testing before the whole system is tested together. This test will be used to confirm circuit and programming aspects work effectively together before taking into account the physical aspect of the device

*Standards To Meet:* IEC 60601-1-8 Ed. 2.2 b:2020

*Test Protocol:*

1. Alarm
   1. Connect the speaker and LED to the Adafruit Metro in accordance with the circuit schematic
   2. Program the speakers and LED to alarm when the limit switch detects an open door and to turn off when it detects a closed door
      1. Press down on the limit switch and print the current door status to the display
      2. Ensure that the current door status displayed is “closed”
      3. Release the limit switch and print the current door status to the display
      4. Ensure that the current door status displayed is “open”
2. PINpad/Lock system
   1. Connect PIN pad and screen to METRO
   2. Program the lock to activate and deactivate off a default code (1111) then test if it does so
      1. Connect the PIN pad and servo to the Adafruit Metro
      2. Set the door lock status to be “locked”
      3. Print the current door lock status to the display
      4. Input the default code into the PIN pad
      5. Print the current door status to the display, which should now be “unlocked”. The Servo arm should rotate upwards and not block the closer arm
      6. Input the default code into the PIN pad
      7. Print the current door status to the display, which should now be “locked”. The Servo arm should rotate downwards and block the closer arm

**The Whole System Must Be Tested**

*Purpose:* As the final test, this test will be done to ensure the entire system all together is effectively working as it properly should.

*Test Protocol:*

1. The system locks the door when necessary, closes the door in most cases, and sounds an alarm when specified
2. Test system similar to an intended day in the lab
   1. Unlock the system with the pin pan to unlock the servo
   2. Open the door and close it and test if the system detects the door is closed
   3. Test leaving the door open for 3 minutes and test when the speaker and LED go off
      1. Note: the system is supposed to alarm at 2 mins. Testing for 3 minutes will help discover unwanted or unnoticed factors.
   4. Repeat the previous two tests a couple of times
   5. Close the door, final test, if the alarm detects the door, is closed
   6. Lock the system using the pin pad

## Validation Test Protocols

Small Scale Testing

| **Test** | **Metric** | **Test Protocol** |
| --- | --- | --- |
| Cost | Dollar | Sum final costs of components and materials |
| Battery Life | Hours | Use a multimeter to measure voltage before usage and then again after 1 hour. Repeat 3 times. Use the average difference in voltage per hour to calculate the theoretical battery life |
| Weight | Pounds | Weigh the final assembly with a digital scale |
| Passive Operation | Door Status | Place the final assembly on a device such as a mini refrigerator and open the door. The door status should read as open.  Let go of the door and let the device close it automatically. The door status should read as closed |

Large Scale Testing

| **Test** | **Metric** | **Test Protocol** |
| --- | --- | --- |
| Average Cost | Dollar | Sum final costs of components and materials along with manufacturing, then divide per unit |
| Average Battery Life | Hours | Use [small scale test] on a randomly selected 10% of batteries and perform a T test to make sure that all batteries fall within the acceptable value to test for average battery life |
| Average Weight | Pounds | Weigh 1 in 10 random units and average their weights to make sure that it is close to the small scale weight value |
| Passive Operation | Ease of Use | Installation of multiple units should be swift and passcodes should be easily set up. Then, set one alarm to go off and make sure that the source of the sound is easily discerned |

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## Circuitry Details

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## Failure Modes and Effects Analysis

| Occurrence (OC) | 2 = Almost never  4 = Rare/Possible  6 = Occasionally  8 = Often  10 = Extremely Often/all the time |
| --- | --- |
| Severity (SV) | 2 = No safety concerns, but minor effect on functionality of device  4 = Minor injuries and/or minor effect on functionality of device  6 = Minor injuries and/or major effects on functionality of device  8 = Moderate injuries and/or major effect on functionality of device, user needs are not met  10 = Extreme injuries and/or major effect on functionality of device, user needs are worsened |
| Detection (DT) | 2 = Easily detectable (User can see problem immediately)  4 = Detectable (User can make an educated guess on where the problem has occurred)  6 = Moderately Detectable (User can unreliably guess where the problem might be)  8 = Undetectable (User cannot find issue unless they already know that there is an issue)  10 = Impossible |
| RPN Value  SV\*OC\*DT | <27 = Acceptable Risk  27-64 = Moderate Risk  >64 = Unacceptable Risk |

| Item | Potential Failure Mode | Potential Causes | O | Potential Effect | S | Current Controls | D | RPN (S x O x D) | Migration Strategy/ Actions Recommended |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Alarm | False Negative  on speaker | (i) The speaker itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The audio alarm will not sound making it difficult to know if the lab door is left open. | 8 | When the device is being assembled, check functionality of the speaker, limit switch, and wire connections. | 6 | 60 | Establish monthly routine check-ups. Ensure verification of the completed system (ex: A door open for too long causes Speaker and LED alarm to activate) |
|  | False Negative on LED | (i) The LED itself may be damaged  (ii) The limit switch is damaged  (iii) Loose connections  (iv) wiring damage | 1 | The LED alarm will not light, making it difficult to know if the CLE door is left open | 8 | When the device is being assembled, check functionality of the LED, limit switch, and wire connections. | 6 | 60 | See above |
|  | False Positive on speaker | (i) The limit switch may be stuck  (ii) crossed wires | 4 | The sound will be audible and the user thinks the door is open when it is still closed. | 3 | Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 12 | See above |
|  | False Positive on LED | (i) The limit switch may be stuck  (ii) crossed wires | 4 | The light will turn on making nearby users believe the door is open when it is not | 3 | Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 12 | See above |
| Security | Accepts incorrect PIN code | (i)Software malfunction (ii)crossed wires may change the received passcode from the one input | 1 | The CLE could be unlocked when not supposed to. | 5 | Thoroughly test the PIN pad circuit during verification. Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 6 | 30 | Provide circuit diagram and review and fix as needed.  Wipe previous passcode data, Reinput new passcode |
|  | Rejects correct PIN code | See above | 1 | The CLE could be not unlockable. | 3 | Thoroughly test the PIN pad circuit during verification. Check wire connections during assembly. Design the case with ample wiring space and include cable routing brackets. | 1 | 3 | See above |
|  | Servo does not rotate all the way | (i)Buildup of debris may limit the range of motion of the servo  (ii) Manufacturing error | 4 | The lock will not properly open or close at the specific angle it should, resulting in difficulty in opening the CLE doors and/or damage to the servo and hook assembly | 6 | Test the servo during validation. Design the servo mount with enough space to clean the servo if needed | 2 | 48 | Replace or provide instructions for maintenance of the component. Pressurized air or a cloth may be used to clear debris in the gaps |
| Closer | Door does not close all the way | (i)Insufficient closing pressure  (ii) physical obstruction of the CLE door | 1 | The door could be left open, which can negatively impact samples in the CLE. | 1 | The closer is equipped with values to change closer pressure. The alarms are coded to sound after the doors are open for a specified length of time in case of physical obstruction | 4 | 40 | See above |
|  | Excessive closing pressure | (i) improperly tuned sweep speed  (ii) improperly tuned latch speed | 2 | The CLE door could be slammed shut, jostling the contents inside. | 4 | The closer is equipped with values to change closer pressure | 2 | 16 | See above |
| Epoxy | Failure to stick to the intended CLE | (i) manufacturing defect  (ii) Not allowing for the full curing time  (iii) insufficient adhesive coverage  (iv) unclean application surface | 3 | The lock could fall off, meaning that the lock cannot be used properly. | 8 | Device adhesion surfaces are designed with large surface areas | 1 | 24 | Ensure that when applying export, appropriate time and amount must be given to the epoxy before use |
|  | Sticks to user during assembly | (i) touching the epoxy resin during installation | 5 | The sticking could be hard for the user to remove from themselves. | 4 | None | 1 | 20 | Ensure that when applying epoxy, appropriate protection is used to prevent the epoxy from sticking on the user. |
|  | Inhalation of epoxy fumes | (i) poor ventilation during assembly | 5 | Skin, eyes, nose, and throat irritation. Possible trigger for skin allergies and asthma | 5 | None | 2 | 50 | Ensure that when applying epoxy, application is done where it is well ventilated or provide masks as needed. |
| Electrical | Short Circuit | (i) Water damage  (ii) Faulty wiring  (iii) Loose connections  (iv) Overheating | 3 | The circuitry for the whole device would not function, resulting in possible lock failure. | 8 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 144 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
| Structural | Rust | (i) Exposure to moisture  (ii) Exposure to acids  (iii) Contact with dissimilar metals | 2 | The lock could potentially degrade over time due to rust, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 2 | 12 | Proper controls are deemed sufficient |
|  | Material Wear | (i) friction | 3 | Degradation over time due to friction, potentially with a small risk of loss of the function of moving parts such as the servo, arms, or rack and pinion system. | 3 | Device was built with tough materials to withstand many use cycles, and will be smooth to reduce friction | 2 | 18 | Proper controls are deemed sufficient |
|  | Epoxy Buildup/residue | (i)excessive adhesive usage  (ii)drip during installation | 4 | Uncured epoxy resin may cause skin irritation, respiratory issues and may be flammable. Cured epoxy resin will only pose aesthetic issues | 2 | None | 2 | 16 | Ensure that instructions provided to the user tell them to use an appropriate amount of epoxy. Otherwise, give instructions to use epoxy remover |
|  | Moisture Damage | (i) condensation from the CLE  (ii) Liquid spills | 4 | Rust and damage to electrical components | 6 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 6 | 144 | If there is any moisture, check the immediate area and also if there are any gaps in the device as well as check inside the CLE and fix the problem immediately. |
|  | Thermal Expansion | (i) heating from the electrical components  (ii) heating from the CLE | 2 | Expansion of materials and components may reduce the available space and lead to crowding. | 2 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 24 | Check the temperatures in the electrical components and CLE and if it's not cold enough, adjust the temperature. |
| Battery | Exposure to moisture | (i) condensation from the CLE  (ii) Liquid spills | 4 | A battery with moisture would have its function impaired due to reduced resistance | 7 | Check the assembled device for any gaps. Device was designed to be positioned away from any possible spills | 4 | 112 | Remind the user that the device must be placed away from moisture and in a clean and dry area before applying |
|  | Overheating | (i) heating from the electrical components  (ii) heating from the CLE  (iii) Faulty wiring | 2 | A battery that is too hot will not function properly | 6 | Check wiring during verification and assembly. Designed with space between components to improve air flow | 6 | 72 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of damaged components may be necessary based on the severity of the damage. |
|  | Battery dies | (i) Extended use | 2 | The lock will not work because there is no battery power. | 8 | None | 1 | 16 | Keep a stock of 9V batteries. Replace at appropriate/said times on the battery box |
|  | Acid Leak | (i) Physical damage to the battery  (ii) Extreme temperatures  (iii) Age | 2 | Corrosion of components and structural materials may occur. Users may also experience skin burns, inhalation irritation, and possible blindness if the acid come in contact with the eyes | 6 | None | 4 | 48 | Ensure that the batteries can be easily replaced every so often to ensure that there is no acid leak because of old and damaged batteries. Make the battery replacement user friendly and not complicated. |
| User | PIN Code is forgotten | (i) User forgets PIN code | 5 | The lock cannot be opened by this user | 2 | Master passcode will be provided to administrator, and will be included on documentation | 1 | 10 | Full system reset of the device. |
|  | Door is forced open when locked | (i) User ignores resistance of the hook mechanism  (ii) hook mechanism malfunction | 2 | If the door is opened when locked, then damage to the servo, hook, and arms is possible. | 6 | Alarms are in place to prevent this, and the servo and hook assembly provides resistance to opening when the device status is “locked” | 2 | 24 | If there’s resistance to opening, check if the LED is green |
| Manufacturing | Loose device structural connections | (i) Loose screws  (ii) Improper tolerances | 4 | The lock structure could be unstable, which could prompt anywhere from the lock not functioning to the lock structure to break. | 5 | Manufacturing within standard tolerances, and ensuring properly tightened screws and connections during verification and assembly | 4 | 80 | Tighten loose connections with a screwdriver if applicable |
|  | Power does not transfer from the microcontroller | (i)Faulty wires  (ii)Damage to the microcontroller  (iii)Loose connections  (iv)Battery issues listed above | 2 | The lock will simply not function at all as it does not have the power needed. | 8 | Test battery and microcontroller during verification, check wiring during assembly | 3 | 48 | Disassemble the PIN Pad casing and assess the current state of the internal components. Ensure complete connections. Replacement of components may be necessary based on the cause. |

\*A false positive means that the device reports the CLE as open when it is closed

\*A false negative means that the device reports the CLE as closed when it is open

## Engineering Design Specifications

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| Metrics | Units | Corresponding User Needs | Range | Target Value | Direction of Improvement |
| --- | --- | --- | --- | --- | --- |
| Price | US Dollar | Affordability | $14-$984 | $300 | To be minimized |
| Battery Life | Weeks | Power Delivery | 1- | 8 | To be maximized |
| Passive Operation | Binary | Ease of Handling | Fully Active to Fully Passive | Mostly Passive | To be maximized |
| Number of Components | Numerical | Ease of Manufacturing | 10-100 | 20 | To be minimized |
| Established Technology | Binary | Practicality | Yes or No | Yes | N/A |
| Weight | Pounds | User Friendliness | 1 to 8 | 7 | To be minimized |

## 

## Bill of Materials

| **Component** | **Material** | **Purchasing Location** | **Part Number** | **Quantity** | **Weight** | **Price Per Unit** | **Total Price** | **Notes** | **Link** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **6061 Aluminum** | 6061 Aluminum | Amazon | N/A | 2 | 1.755 lbs per sheet | $18.99 | $37.98 | The body for the PIN pad | [6061 Aluminum](https://www.amazon.com/Aluminium-Aluminum-Finely-Polished-Deburred/dp/B08M63VD66/ref=asc_df_B08M63VD66/?tag=hyprod-20&linkCode=df0&hvadid=507685853899&hvpos=&hvnetw=g&hvrand=13803444464249626083&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=1013763&hvtargid=pla-1244865546405&psc=1&mcid=73ecb0c2c16c363090a3ab1a556c41a9&gclid=CjwKCAiAqY6tBhAtEiwAHeRopVNa8dwxIhKlyLCnpZvd1lSsjFA1dELC7lDzbDw5YA9n06tZS93lMhoC3QAQAvD_BwE) |
| **Screws** | 18-8 Stainless Steel | McMaster-Carr | 97613A529 | 1 | ~0 | $17.36 | $17.36 | For the Body attachment. 10 Pack | [Screws](https://www.mcmaster.com/97613A529/) |
| **Adafruit METRO M0** | Microcontroller | Adafruit | 2488 | 1 | 0.042 lbs | $17.50 | $17.50 | Coding component for alarms, PIN pad, potentiometer | [Adafruit METRO](https://www.adafruit.com/product/3505) |
| **Red and Green Indicator LED** | LED | Adafruit | 4042 | 1 | Not Available | $1.75 | 1.75$ | Light Alarm | [RED/GREEN LED](https://www.adafruit.com/product/4042) |
| **PIN Pad** | N/A | Adafruit | 3845 | 1 | ~0 | $6.50 | $6.50 | The PIN pad itself | [PIN Pad](https://www.adafruit.com/product/3845) |
| **Wires** | PVC Coated Copper | Amazon | B08BBXTBL7 | 1 | 0.79 lbs total | $14.94 | $14.94 | Wiring for the device | [Wires](https://www.amazon.com/Gauge-Wire-Solid-Core-Hookup/dp/B08BBXTBL7/ref=sr_1_4?crid=2YFKFOA4RD63X&dib=eyJ2IjoiMSJ9.UIo5E3q7NzPjkxQwKGNfdQ3FuhAzLC-mAshupgLoSkDXkWJc1I1QggnkW8dAvnQAoPGPPllbJenMA18wVx0t9j-gmsoh0NwyJyPDq3IPxBP2T55pKQpW10vA9NtuKP_kZATr4Ul6AlKtvMASqldw9Q.xbG82dSqDf78ub71xgXVEjiEBb7RhIcGF8l26PJFpKs&dib_tag=se&keywords=wires&qid=1705265164&s=hi&sprefix=wire%2Ctools%2C199&sr=1-4) |
| **Potentiometer** | Potentiometer | Adafruit | 562 | 1 | Not Available | $0.95 | $0.95 | 10k kiloohms | [Potentiometer](https://www.adafruit.com/product/562) |
| **Adhesive (Epoxy)** | Epoxy Resin | Amazon | N/A | 1 | 0.125 lbs total | $12.45 | $12.45 | 2 pack, Metal Adhesive | [Epoxy Resin](https://www.amazon.com/J-B-Weld-Original-Reinforced-Strength/dp/B0B5VNG2YT/ref=asc_df_B0B5VNG2YT/?tag=hyprod-20&linkCode=df0&hvadid=598238944920&hvpos=&hvnetw=g&hvrand=16027891236110708106&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=1013763&hvtargid=pla-1695224676408&mcid=13a156f4cdf13c26a20bfeb5266c44ce&gclid=CjwKCAiAqY6tBhAtEiwAHeRopf2Vh7qsXWIDqrsuZjqCuv6-VXtDVUysLzUv1R-RMKNJFESZMiPzWBoCWzAQAvD_BwE&th=1) |
| **Speaker** | N/A | Adafruit | 1891 | 1 | 0.01 lbs | $1.75 | $1.75 | Speaker for the alarm | [Speaker](https://www.adafruit.com/product/1891) |
| **Closer** | Aluminum | Amazon | ‎SOULONGg850ya231w | 1 | 2.31 lbs | $20.81 | $20.81 | Will use for hydraulic components | [Closer](https://www.amazon.com/Aluminum-Commercial-Automatic-Closing-Independent/dp/B08GPD3W6V/ref=asc_df_B08GPD3W6V/?tag=hyprod-20&linkCode=df0&hvadid=680463214693&hvpos=&hvnetw=g&hvrand=18051584580321407561&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=1013721&hvtargid=pla-2260095885309&psc=1&mcid=624b2ed7d3513a4e9b84fd5e8e249870) |
| **Internal Brackets and other small parts** | PLA | UC Davis | N/A | As needed | ~0 | Variable | Variable |  |  |
| **Resistor** | 10kΩ 5% | Adafruit | 2784 | 1 pack | ~0 | $0.75 | $0.75 | For voltage divider | [10kΩ resistor](https://www.adafruit.com/product/2784) |
| **Battery Holder** |  | Adafruit | 67 | 1 | 0.05lbs | $3.95 | $3.95 |  | [Battery Holder](https://www.adafruit.com/product/67) |
| **Servo** | Micro Servo | Adafruit | 2307 | 1 | 0.03lbs | $11.95 | $11.95 |  | [Servo](https://www.adafruit.com/product/2307) |
| **Battery** | 9V battery | Amazon | N/A | 1 pack of 4 | 0.05lbs | $9.55 | $9.55 | Power source for device | [9V battery](https://www.amazon.com/Amazon-Basics-Performance-All-Purpose-Batteries/dp/B0774D64LT?th=1) |
| **Sum of Prices/Weights** |  |  |  |  | ~7 lbs |  | $158.19 |  |  |

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