**Biorefrigerator Security System**

Biomedical Engineering Senior Design

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Progress Report 4

Spring 2024

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# Client Report

The importance of performing verification and validation tests is to close the loop on the waterfall `

## Instructions for Manufacturing

## Instructions for Assembly [unfinished]

1. Take all circuit components and place them into their respective slots, making sure that the components are in the right orientation as below [insert picture]
2. Attach wires to all components and thread the limit switch wire through the closer

## Instruction for Use (Hold off for now until proper assembly)

1. Attach the limit switch to door of the CLE, in the gap between of the gasket and the top of the door such that the limit switch lever arm is pressed against the body of the CLE
2. Switch the power slider on the battery holder to the “on” position
   1. Ensure that the LCD screen displays “Monitoring”

## Safety Precautions

There are several safety precautions that should be heeded when handling the device.

1. The device should be stable on the CLE and not be at risk of falling, as that can result in risks of exposed wires and other parts that can injure a person.

i. This means that any screws and fasteners should be tightened completely

1. The device, especially the interiors where there are wires, should not be interacted with any liquid substances as there is wiring, and wiring touching water can result in detrimental effects on a user.
2. The alarm flash could potentially, at worst, cause seizures to someone who is epileptic, even though the odds are low for that to happen.

i. As long as entering the pincode results in the ceasing of alarm flashing and sound, then this should not be a problem as it is preventable.

1. Do not try to open the box for no reason besides fixing the interior, as there is a risk of the parts coming off of their positions where they were intended to stay at.
2. Ensure the area is not overheated or else the parts may not function properly due to temperature effects.

Based on a thorough search of the FDA Recognized Consensus Standards website, only one applicable Recognized Consensus Standard was found. This is UL 1642 for lithium batteries, which is meant to “reduce the risk of injury due to fire or explosion” [5].

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, a device that consists of 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:

## Recognized Consensus Standards

Table 1: Standards Table

| **Standard** | **Description of Standard** |
| --- | --- |
| ANSI C18.1M-2021 | This standard refers to portable primary cells and batteries for the purpose of ensuring electrical and physical interchangeability, minimizing proliferation, and defining a standard of performance. |
| ANSI/BHMA A156.4-2019 | This standard pertains to door closers, outlining specifications and requirements for their design, testing, and performance. It ensures the reliability and safety of door closer mechanisms in various applications. Evaluations conducted under this standard include those of door control, durability, appearance, and pivots. |
| IEC 60601-1-8 Ed. 2.2 b:2020 | This standard relates to medical electrical equipment, specifically focusing on the alarms and alarm systems used in medical devices. It provides guidelines for the design, testing, and implementation of alarm systems to ensure their effectiveness and reliability in alerting healthcare professionals to potential issues. |
| Occupational Safety and Health Standard 1910.95 | Occupational Noise Exposure: This standard pertains to the maximum noise level that workers can be exposed to for varying lengths of working hours. |
| IEC 63356-2 Ed. 1.0 b:2022 | This standard focuses on LED light sources. It outlines requirements and testing procedures to ensure these components' reliability, safety, and performance in electrical systems. |

## Verification and Validation Protocol

Validation tests will involve both small and large-scale assessments to confirm functionality, durability, and usability. The small-scale testing will focus on testing during the prototyping phase, while large-scale testing is based on hypothetical plans for testing past the scope of this class’ timeline.

| **Test** | **Metric** | **Test Protocol** | **Target** |
| --- | --- | --- | --- |
| Cost | US Dollars | 1. Sum final costs of components and materials | $200 or less |
| Battery Life | Months | 1. Use a multimeter to measure voltage before usage and then again after 1 hour. 2. Repeat 3 times. 3. Use the average difference in voltage per hour to calculate the theoretical battery life. 4. Repeat for all 4 batteries and perform a T test. | 6 months or more |
| Weight | Pounds | 1. Weigh the final assembly with a digital scale. 2. Perform a one sample T test with the hypothetical target value. | 10 lbs or less |
| Passive Operation | Door Status | 1. Install the final assembly on the intended CLE 2. Open the CLE door    1. The door status should read as open. 3. Let go of the door and let the device close it automatically    1. The door status should read as closed | Status shown is accurate to real life |

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. So far, our design choices have let us prototype a product that is roughly around $150 in value of the parts used in the final design even though we have spent more than that in overhead for research and development. Once we produce our product in bulk, individual part costs will go down and could give us room to gain a profit margin while charging $150 or less.

Ideally for battery life, the ideal user experience would be one in which the user does not have to be concerned about the battery running out. Since typical uses of 9-volt batteries have 6-month lifetimes, we will also be aiming for a minimum 6-month lifetime between battery changes with the battery life tested as according to our verification plans above.The final weight of the assembled device should be light enough to comfortably carry and mount on a CLE, so under 10 pounds would be ideal. This number is arbitrary, since the National Institute for Occupational Safety and Health (NIOSH) sets an upper limit for lifting a load with 2 hands as 51 lbs [6]. While this isn’t a regulation by OSHA, but instead just a guideline, our device is already far lighter than this guideline. Therefore, our self-imposed 10 pound limit is the maximum weight we have set for both lifting and mounting a device comfortably for an able-bodied person.

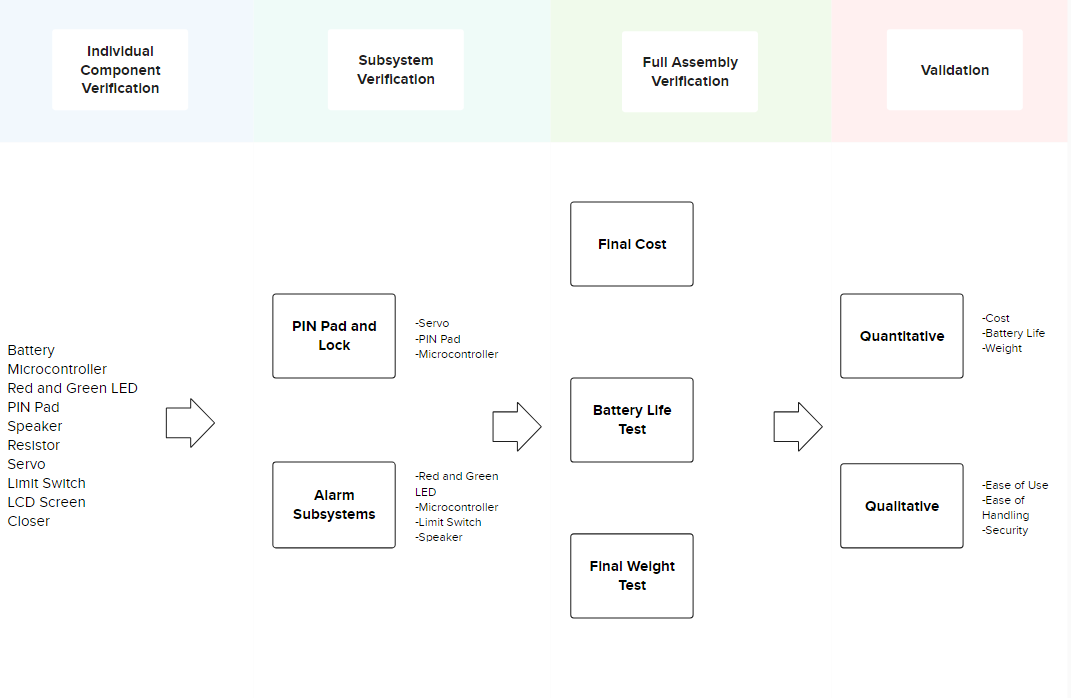
Finally for the operation of the device, the minimum is that the device successfully closes the door while making it still able to be opened while not exerting too much force, which is no more than 5 lbs according to the ADA [7]. Along with this, it should also be able to read the status of the door as open or closed.

In the future after more devices are created and sold, our plan is to encourage customers to fill out a survey on their satisfaction with the product. This survey will gather information on metrics such as how easy our devices were to set up and operate. Along with the survey, we will be testing random units in line with the validation, verification, and failure modes tables laid out in this report. If we find that any of our metrics are measured to be outside of our desired range, we will implement plans to improve the design and issue recalls if an outstanding issue is discovered. For example, if we find that the speaker we decided to use has a chance of being too loud for OSHA requirements, we will issue recalls and replace the speaker with a different one. An example of an issue that does not warrant a recall would be if our suppliers for materials increased prices, causing the cost of manufacturing to be too high. In a situation like this, we would find new suppliers and organize our manufacturing to account for it.

## Verification and Validation Results

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.

Figure 3: Verification Flow Chart

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This subsection will list out each individual component’s purposes and test protocols in order to explain how each component will have their individual verification tests for function. Small-scale test protocols and large-scale test protocols have also been included. We will use small-scale test protocols for our prototyping. Large-scale test protocols are the steps given when mass manufacturing of the device occurs. Large-scale test protocols are similar to small-scale protocols with added details and steps.

*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.

*Standards To Meet*: ANSI C18.1M-2021

*Small-Scale 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

*Large-Scale Test Protocol:*

1. Randomly select 10% of batteries
2. Perform the small-scale test
3. Perform a T test against the target value of 6 months
4. Ensure that the null hypothesis is accepted

**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

*Small-Scale Component Test 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
5. Perform a one sample T test against the rated resistance

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

*Large-Scale Test Protocol:*

1. Randomly select 10% of each component
2. Test using the small-scale test procedures
3. Mark each sample with pass or fail based on the results of the previous step
4. Ensure that at least 90% of the components pass
5. Discard any failed components

**Pressurized Door 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

*Small-Scale 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

*Large-Scale Test Protocol:*

1. Randomly select 10% of pressurized door closers
2. Test using the small-scale test procedures
3. Mark each sample with pass or fail based on the results of the previous step
4. Ensure that at least 90% of the door closers pass
5. Discard any failed components

**Attachment System (Epoxy)**

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

While there was no relevant standard for the use of epoxy resin as an adhesive, the team has deemed it necessary to verify the ability of the adhesive to adhere the device to the CLE. This is to ensure that the adhesion will be able to withstand certain forces such as gravity and the force exerted by the pressurized door closer.

*Small-Scale Test Protocol:*

1. An L-shaped stainless steel 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 stainless steel 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

*Large-Scale Test Protocol:*

1. Randomly select 10% of samples.
2. An L-shaped stainless steel plate with a hole drilled through the exposed arm will be epoxied onto a stainless steel test device
3. Attach a luggage scale to the stainless steel plate
4. Pull the luggage scale until the plate comes off
5. Note the scale reading of the maximum force required to pull the plate off.
6. Ensure that 90% of each sample works and discard the ones that do not work.

### **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. For more information on the entire microprocessor circuit system, refer to the Appendix for the Circuitry Diagram.

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

*Small-Scale 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

*Large-Scale Test Protocol:*

* 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. Randomly select 10% of samples.
     2. Connect the PIN pad and servo to the Adafruit Metro.
     3. Set the door lock status to be “locked”.
     4. Print the current door lock status to the display.
     5. Input the default code into the PIN pad.
     6. 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.
     7. Input the default code into the PIN pad.
     8. Print the current door status to the display, which should now be “locked”. The Servo arm should rotate downwards and block the closer arm
     9. Repeat this test 10 times. Ensure that 90% of the tests work.
     10. Discard any samples that do not work.

**Full Assembly Verification**

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

*Small-Scale 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 pad 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

*Large-Scale 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. Randomly select 10% of samples.
   2. Unlock the system with the PIN pad to unlock the servo
   3. Open the door and close it and test if the system detects the door is closed
   4. 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.
   5. Repeat the previous two tests a couple of times
   6. Close the door, final test, if the alarm detects the door, is closed
   7. Lock the system using the PIN pad
   8. Repeat the above steps on ten separate refrigerators
   9. Ensure 90% of the components pass
   10. Discard any failed components

## 

## Final Bill of Materials

| **Component** | **Material** | **Purchasing Location** | **Part Number** | **Quantity** | **Weight** | **Price Per Purchase** | **Total Price** | **Notes** | **Link** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Case | PLA | UC Davis | N/A | Per kg | ~1/2 kg | $30 per kg | $15 |  |  |
| 18 Gauge Steel Sheet | Mild Steel | Amazon | B08GFXMXNG | 1 | 1.42 lbs per sheet | $29.90 | $29.90 | Attachment Block | [Stainless Steel](https://a.co/d/a3CqhTq) |
| Screws | 18-8 Stainless Steel | McMaster-Carr | 92010A216 | 1 pack | ~0 | $7.01 | $7.01 | For the Body attachment. 100 Pack | [Screws](https://www.mcmaster.com/92010A216/) |
| 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) |
| 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) |
| Closer | Aluminum | Amazon | ‎SOULONGg850ya231w | 1 | 2.31 lbs | $20.81 | $20.81 | Will use for hydraulic components | [Closer Link](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) |
| Limit Switch | Aluminum and plastic | Amazon | V-156-1C25 | 1 | Not Available | $1.00 | $1.00 |  | [Limit Switch](https://a.co/d/gz5lPw8) |
| 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) |
| Red and Green Indicator LED | LED | Adafruit | 4042 | 1 | Not Available | $1.75 | $1.75 | Light Alarm | [RED/GREEN LED Link](https://www.adafruit.com/product/4042) |
| Pin Pad | N/A | Adafruit | 3845 | 1 | ~0 | $6.50 | $6.50 | The pin pad itself | [Pin Pad Link](https://www.adafruit.com/product/3845) |
| Speaker | N/A | Adafruit | 1891 | 1 | 0.01 lbs | $1.75 | $1.75 | Speaker for the alarm | [Speaker](https://www.adafruit.com/product/1891) |
| Resistor | 10kΩ 5% | Adafruit | 2784 | 1 | ~0 | $0.75 | $0.75 | For LEDs | [10kΩ resistor](https://www.adafruit.com/product/2784) |
| Battery Holder |  | Adafruit | 67 | 1 | 0.05 lbs | $3.95 | $3.95 |  | <https://www.adafruit.com/product/67> |
| Servo | Micro Servo | Adafruit | 2307 | 1 | 0.03 lbs | $11.95 | $11.95 |  | [Servo](https://www.adafruit.com/product/2307) |
| ELEGOO MEGA 2560 R3 | Microcontroller | Elegoo | B01H4ZLZLQ | 1 | 0.14lbs | $19.99 | $19.99 |  | [ELEGOO MEGA 2560 R3](https://www.elegoo.com/products/elegoo-mega-2560-r3-board) |
| LCD Backlight | LCD Display | Adafruit | 181 | 1 | Negligible | $9.95 | $9.95 | Possible HUD | <https://www.adafruit.com/product/181> |
| Female/Male Jumper Wire | Silicone Covered | Adafruit | 1953 | 1 | ~0.03lbs | $1.95 | $1.95 | F/M Extension - 20 x 6" (150mm) | <https://www.adafruit.com/product/1954> |
| Male/Male Jumper Wire | Silicone Covered | Adafruit | 4482 | 1 | 0.03lbs | $1.95 | $1.95 | M/M Extension - 20 x 6" (150mm) | <https://adafruit.com/product/1957> |
| Mini Breadboard | Plastic | Amazon | EK2137 | 1 | 0.01 lbs |  |  |  |  |
| Sum |  |  |  |  | ~6 lbs |  | $171.15 |  |  |

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## Final Engineering Drawings

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