UNIVERSITY OF SOUTHERN CALIFORNIA

BME 405: SENIOR PROJECTS: MEASUREMENTS AND INSTRUMENTATION

FALL 2024

FINAL PROJECT:

ReFlex Glove for Stroke Recovery

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Section 1. Brief Description of Product or Device

Strokes are one of the leading causes of disability worldwide, with nearly 795,000 individuals suffering from a stroke each year [1]. Strokes can drastically impact an individual's life, causing side effects such as memory loss, difficulty balancing, vision impairment, and paralysis on one side of the body [2]. One particularly significant challenge stroke survivors face is limited hand function, specifically with weakened grip strength [3]. In fact, after a patient has a stroke, they often have limited function of their upper extremities, and 50% of those affected have remaining impairments more than three months after having a stroke [4]. During this time, these individuals experience difficulty completing everyday tasks. Given these current challenges, there is a need for an assistive device to give stroke rehabilitation patients control over their day-to-day lives.

Our device, the ReFlex Glove, is designed to assist patients with weakened grip strength, helping them regain control over everyday activities. For example, as seen in our storyboard above, an individual who recently suffered from a stroke may want to pick up a glass of water. Due to their weakened grip strength, they may struggle to hold and pick the glass up. However, the ReFlex Glove contains sensors on three fingers that will detect when the user will want to grab the glass. Upon detection, it will strengthen the grip of three fingers by promoting flexing, thus enabling the individual to pick up the object. When the individual wants to release the object, they can press a button to restore the glove to its original resting position.

Key Stakeholders

a. Primary Stakeholder: Stroke Patients

The ReFlex Glove primarily benefits stroke survivors who experience weakened grip strength. Restoring grip strength allows them to perform activities of daily living independently. It is shown that most stroke recovery patients regain most of their motor function within the first year, so constant limb training is essential [5].The glove's lightweight design and user-friendly controls ensure that it is comfortable and intuitive, minimizing any learning curve for elderly users.

b. Secondary Stakeholders: Family Members and Caregivers

Family members and caregivers often play a crucial role in assisting stroke patients with everyday tasks. The ReFlex Glove reduces the need for direct physical assistance, allowing caregivers to focus on emotional support rather than solely physical labor. This shift enhances the quality of interaction between the patient and caregiver, reducing caregiver burnout and enabling a more positive, balanced relationship.

c. Tertiary Stakeholders: Healthcare Professionals (Doctors and Physical Therapists)

For healthcare professionals, the ReFlex Glove serves as both an assistive and therapeutic tool. It can be integrated into rehabilitation exercises to promote neuroplasticity and improve motor recovery. Additionally, its potential for tracking usage data could provide insights into patient progress, enabling therapists to tailor their treatment plans and monitor the effectiveness of various rehabilitation strategies.

Main Stakeholder

As previously mentioned, the primary stakeholder for our device is stroke rehabilitation patients who experience a weakened grip strength. The primary needs of the user have been listed below and contributed to the overall design of our device:

1. Device to assist in picking up objects when indicated.
2. Device to assist in putting down objects when indicated.
3. Lightweight, portable device that will not hinder hand function.
4. Customizable device that can be tailored to individual users.

Market for Product

To estimate the market for the ReFlex glove, it is important to consider the specifics of the target user. The ReFlex Glove is made for stroke patients who have limited grip strength. For the purposes of this calculation, the primary focus was kept on the United States. Currently, there are approximately 7 million stroke survivors in the US [7]. Amongst these survivors, about 50- 70% experience upper limb impairments that affect their functional independence [8]. Because "upper limb impairments" was not explicitly defined from this article, the conservative estimate of 50% is used to approximate the number of individuals that have impaired grip strength from their stroke. Thus, about 3.5 million people would fall into the category of "target user." From a broader perspective, the number of individuals suffering from strokes continues to increase. In fact, between 2020 and 2022, there was an 8% rise in the number of stroke patients [9]. This trend highlights the growing need for effective rehabilitation tools such as the ReFlex Glove.

Regulatory Pathway

Stroke is a major societal and economic issue with many in the U.S. alone experiencing the lasting disabilities that limit independence in daily activities. There is a significant gap in accessible and affordable care. Our assistive device aims to help stroke patients regain control of their lives by providing a lightweight, portable, and easy-to-use solution outside of clinical settings.

If we were to conduct human trials, the process would start with IRB approval to ensure safety and ethical standards are met. For regulatory approval, we would consider using a predicate device to demonstrate similarity and speed up the FDA approval process under the 510(k) pathway. In terms of handling volunteers participating in the trial, we would fully inform the participants of how the product works, what is expected of them, potential risks, and that they are able to withdraw at any point. We would record data on user satisfaction, product consistency, and potential improvements. Once consent is gathered then the participants will enter the trial anonymously in order to protect their privacy. If a patient decides to drop out of the trial or there is a case of adverse effect, we will pause the trial and address the concerns. This will likely lead to design improvements which we will do before continuing the trials.

Our product aims to fill the gap in affordable stroke assistive devices by focusing on user-friendly solutions. We believe that this approach can have a real impact on stroke patients struggling with rehabilitation and common day-to-day functions.

Competitive Products Currently on Market

Products similar to the ReFlex Glove exist on the market and have been detailed below, including information on how they differ from the created product.

1. Saebo Glove: The Saebo Glove is a hand rehabilitation glove made to help stroke patients improve their mobility. The Saebo glove focuses on getting the wrist and hand in a functional position to properly grab an object. The device has rubber bands on the back to help hold the hand open. However, this device's primary focus is positioning the hand correctly and extending all fingers. It does not aid in the motion of picking up an object, minimizing the assistance it can offer. Furthermore, the device lacks customization and is manufactured at a fixed size.

2. Ipsihand: Ipsihand works to utilize healthy brain activity to detect when the user wants to complete a particular movement. When the intent is detected, then the glove will open and close in response. This is done in an effort to retrain a new part of the brain to properly control the disabled arm. Though Ipsihand may work to enable grip strength, the product costs $30,000 which is nearly 10x more than products such as the Saebo Glove, which costs $350.

3. RobHand: The RobHand is a device made to improve hand mobility in patients that have had a stroke. Though it aids in restoring hand mobility, it is not fit for everyday use due to its bulkiness and stationary design.

Though each of these devices work to aid stroke patients, they fall short in providing a comprehensive solution that combines affordability, functionality, and ease of use for everyday rehabilitation. This leaves a need for a product such as the ReFlex Glove on the market.

Saebo: https://www.youtube.com/watch?app=desktop&v=OZsZacfw2Xk&t=39s
Ipsihand: https://www.neurolutions.com/ipsihand/
RobHand: https://www.youtube.com/watch?v=kGzmM9gVKs8

Essential Features
Because the device is intended to assist patients in everyday activities to restore some normalcy to their everyday lives, it is important that it has the features listed below.

1. Force Detection for Activation of Grip Controls
    a. The use of force sensors will be essential to detect when the stroke patient wants to grip an object. The force sensor, located on the palm of the glove, may provide input to trigger the servo motor to flex the fingers. Simply put, when they want to grab an object, the glove will tighten their grip and hold an object. If the glove cannot recognize the user's intent to grip an object, it will likely cause the user more frustration than assistance.
2. Release Mechanism for Device Disengagement
    a. To allow the individual to release an object, they can press a red button to return the glove to its initial position, extending the fingers back outward. With this, the user will have more control over their actions. It will ensure that they are able to successfully pick up and release objects. Without this feature, the user will be significantly limited in their capabilities and will be unable to fully complete a task, preventing their independence in day-to-day life.
3. Battery Function for Continued Use

    a. This device is intended to be used throughout the day, likely needing to remain on the individual's arm and hand for long periods of time. Because it is powered by a battery pack, its power source may be easily changed to promote the longevity of the device. This feature is essential as it will affect both the primary and secondary stakeholders. For example, if the device were to have a poor power source, then it may result in more stress for the primary and secondary stakeholders along with the need to purchase an entirely new device.
4. Adjustable, Lightweight Design for Extended Use
    a. As seen through the devices currently existing on the market, many are bulky and add a significant amount of weight to the hand. If many mechanical components are added and hinder the movement of the hand, then it would likely cause more difficulty for the primary stakeholder. Comfort and adaptability are essential because the glove is intended to be worn every day. Along with being durable and lightweight, the materials should not cause user fatigue when performing regular duties or extended rehabilitation sessions [3].

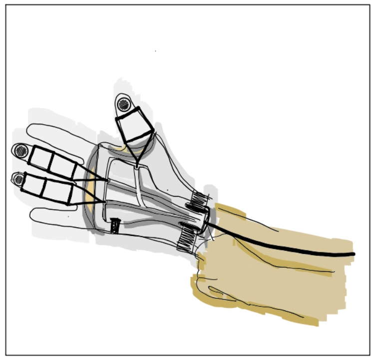
Section 2. Use Cases to MVP Requirements

The ReFlex Glove was designed to address the specific needs of stroke survivors with impaired grip strength, enabling them to gain autonomy in everyday activities and tasks. Translating use case scenarios into technical MVP requirements ensures the device is both functional and achievable within the constraints of time, resources, and technology. Each scenario reflects a critical interaction that informed the glove's design parameters and technical specifications.

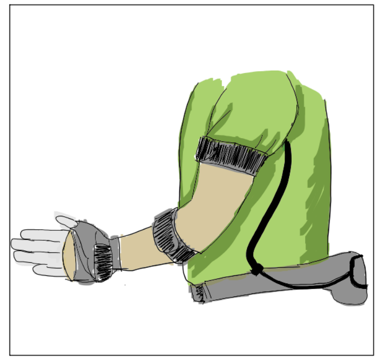
Logical Use Cases

One of the primary use cases involves assisting stroke patients in picking up objects. For instance, a user with limited grip strength may struggle to pick up a glass of water. This scenario necessitates a system capable of detecting the user's intent to grip an object and responding with proportional mechanical assistance. The ReFlex glove archives this through a force sensor integrated into the palm area. The sensor detects subtle pressure changes, signaling the system to engage the servo motors, which in turn flex the glove's fingers. By ensuring this action is seamless and intuitive, the glove enhances the user's confidence in performing daily activities independently. When the user wants to release the object, they can press the red button and put the glass of water back down.

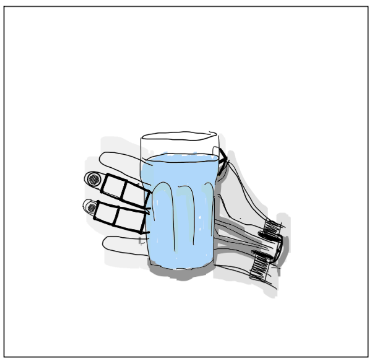
STROKE PATIENT EXPERIENCES TROUBLE HOLDING GLASS DUE TO WEAKENED GRIP STRENGTH



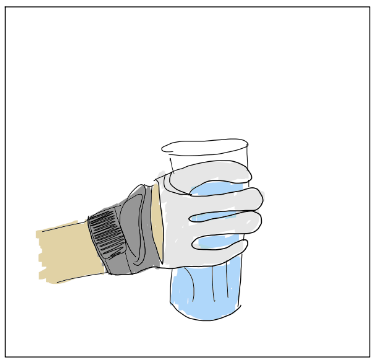
PATIENT PUTS ON REFLEX STROKE GLOVE



ATTACH WAIST BAND HOUSING & VELCRO ARM STRAPS. NOW REFLEX DEVICE IS ON CORRECTL



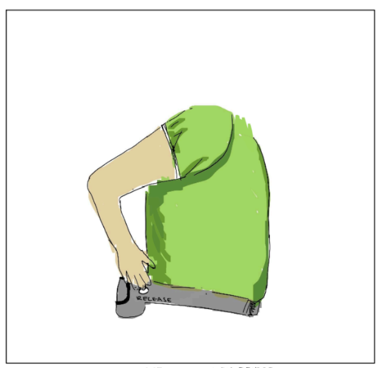
FORCE SENSORS ON FINGERTIPS DETECT PATIENT ATTEMPTS TO GRAB WATER GLASS. TRIGGERS GLOVE CLOSURE.



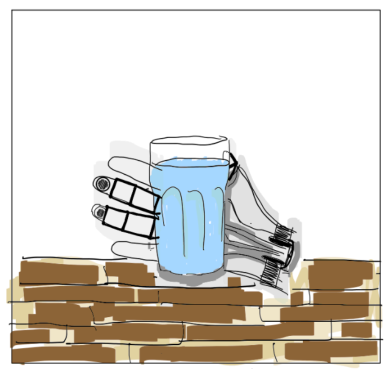
ACTIVATED REFLEX DEVICE ALLOWS PATIENT TO GRAB GLASS.

SUCCESSFUL ACTION! PATIENT W/ AID OF REFLEX IS ABLE TO CONDUCT TASKS

PATIENT IS DONE DRINKING & WANTS TO PUT GLASS DOWN.

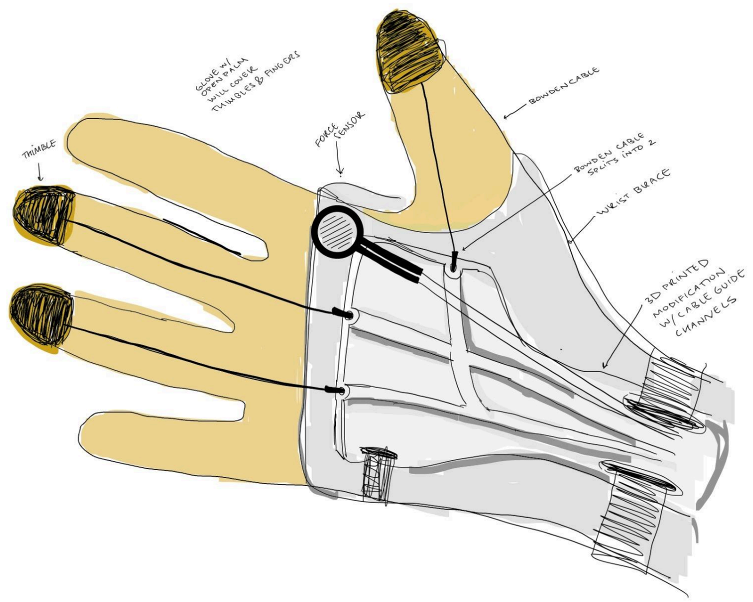


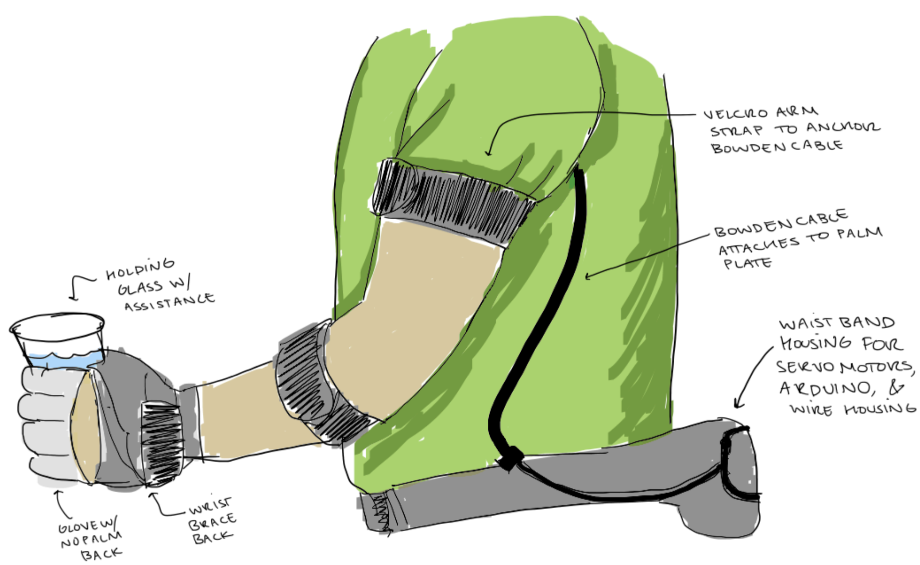
PATIENT PUSHES RELEASE BUTTON ON DEVICE.



REFLEX DEVICE RELEASES & PATIENT SUCCESSFULLY RELEASES GLASS.

Functional Requirements Based on Use Case





Force Detection for Grip Activation

A key component of the ReFlex Glove's operation is its capacity to recognize the user's intention to grip. Force sensors that are carefully positioned in the palm are the main component of this function. These sensors pick up changes in pressure and translate them into electrical signals that the microcontroller can process. To guarantee that the system reacts only to intentional grasping attempts, the force sensors are set up to activate only when the applied pressure exceeds a certain threshold. By doing this, unintentional activations that can irritate users or undermine their trust in the gadget are avoided. Because of their great sensitivity, small size, and resilience to repeated usage, the sensors were chosen. They can precisely record grip-related forces without generating discomfort or restricting hand movement because of their location in the palm, close to the base of the fingers.

Although the current solution works well, adding more sensors to each finger in subsequent iterations could increase the sensing capacity. This would increase the glove's versatility by enabling it to detect partial grips or object-specific grip patterns. Additionally, sensitivity and lifespan may be increased by switching from resistive sensors to capacitive or piezoelectric equivalents. More sophisticated software techniques, such machine learning-based pattern recognition, may also improve the glove's comprehension of human intent and provide a more customized response.

Release Mechanism for Object Disengagement

After grasping an object, the release mechanism guarantees that users may put the glove back in its neutral state. The fingers are extended back to their resting position by means of a mechanical button that, when pressed, instructs the microcontroller to reverse the servo motors. Setting down a drink or utensil is made easier by this function, which lets users release objects with ease. The physical limits of the user were carefully taken into account when designing the button. People with limited hand strength or mobility can use it because of its ergonomic positioning and minimal actuation force. The button is connected to the microcontroller via a debounced input circuit to guarantee dependable functioning, avoiding accidental activations brought on by vibrations or quick presses. In order to carry out the release command, the microcontroller prioritizes the interpretation of the button signal and instantly overrides other operations.

While the current design functions well, accessibility might be improved by including alternate release methods. For example, gesture-based commands employing motion sensors could offer a user-friendly solution for those with limited hand mobility, while voice-controlled activation would enable users to operate the glove without physical contact. Users' confidence and happiness with the gadget would increase if the button included haptic feedback, which would provide tactile confirmation of successful activation.

Servo Motor Control for Finger Actuation

The ReFlex Glove uses servo motors coupled to Bowden wires to actuate fingers. The glove can firmly grasp and release things thanks to these motors, which precisely regulate the flexion and extension of the fingers. Because servo motors can maintain a set angle without continuously drawing power—a trait that is essential for firmly retaining objects—they were selected above other motor types. To ensure precise and seamless motion, the microprocessor produces pulse-width modulation (PWM) signals to regulate the servo motors. A Bowden cable, which converts rotational motion into linear motion and draws the fingers into a gripping position, is connected to each motor. By passing through specific grooves in the glove, the Bowden cables minimize friction and guarantee reliable operation. To ensure that the motors could produce enough torque to grasp objects of different weights and sizes, the design underwent extensive testing.

Adding proportional control, in which the force sensed by the sensors is directly proportional to the degree of finger bending, could improve the servo motor system. More adaptable and natural grasping might be possible as a result. Performance and user experience would be enhanced by the adoption of quieter, higher-torque servo motors, especially in social situations when noise is an issue. Using cutting-edge low-friction materials or coatings in place of conventional Bowden cables could further minimize wear and boost effectiveness. Furthermore, the motor control system could identify and fix misalignments or irregularities while in use by including real-time feedback loops.

Portable and Efficient Power Supply

A 6V battery pack made up of four AAA batteries connected in series powers the glove. This setup offers almost two hours of continuous running while striking a compromise between portability, cost, and runtime. By mounting the battery pack on the user's hip, the ergonomics are improved and the hand's weight is decreased. In order to save energy and prolong battery life, the microcontroller is configured to switch to a low-power mode while the glove is not in use. Because AAA batteries are readily available, reasonably priced, and simple to replace, they were chosen. To guarantee safety while in use, the battery pack has a protective case and safe connections. In order to eliminate fluctuations that can affect performance, the power distribution system was meticulously built to supply the microcontroller and servo motors with constant voltage and current.

Using rechargeable lithium-ion batteries might drastically save waste and increase runtime. Users might be able to conveniently recharge their battery pack with a modular charging port, doing away with the need for regular replacements. A battery level indicator that provides visual or app-based feedback on remaining power should be added to enhance usability. Portability and sustainability could be further improved by investigating renewable energy sources, such as kinetic energy harvesting devices or tiny solar panels built into the glove.

Lightweight and Adjustable Physical Design

Comfort and versatility are given top priority in the glove's physical design. Lightweight materials used in its 3D printing reduce wearer fatigue over time. The glove's modular parts and adjustable straps enable it to fit a variety of hand sizes, guaranteeing accessibility for a wide range of users. By placing the motor housing on the user's hip, less strain is placed on the hand, enabling more fluid movement. Bowden cables run via channels built into the glove's construction, guaranteeing seamless and effective performance without sacrificing comfort or style. Features like simple adjustment mechanisms and a snug yet flexible fit are also included in the design to assist users with different levels of dexterity.

Advanced materials like carbon fiber composites could be used in future versions of the glove to further reduce weight without sacrificing durability. Quick-release buckles or magnetic closures could be added to the adjustable features to make it simpler to put the glove on and take it off. Sweat-resistant and antibacterial materials would enhance comfort and cleanliness, especially for consumers receiving prolonged therapy sessions. The glove's versatility might be increased by customizing it to meet certain rehabilitation needs thanks to modular components.

Nonfunctional Requirements

Robust Durability and Replaceable Components

A key component of the ReFlex Glove's design is durability. Every part, including the sensors, servo motors, and Bowden cables, was chosen based on its resistance to mechanical stress and repeated use. Because of its modular architecture, users can swap out individual parts without the need for specific equipment or knowledge, which lowers maintenance costs and guarantees the gadget will continue to work over time. To avoid failures during operation, adhesives and secure fittings were used to reinforce important mechanical connections, such as those holding the Bowden wires.

Using mechanical fasteners instead of glued connections could increase durability by making repairs simpler and ensuring higher dependability. Wear sensors might be incorporated into vital parts to keep an eye on their condition and notify users of possible problems before they arise. The glove's lifespan could be further extended by switching to more sophisticated materials for the 3D-printed components. By adding materials that are waterproof or water-resistant, the glove's use would be extended to more situations and activities.

Cost Effectiveness and Accessibility

The ReFlex Glove was made to be reasonably priced without sacrificing performance. While the modular design reduces long-term costs by enabling customers to replace individual pieces as needed, off-the-shelf components and a simplified assembly procedure keep manufacturing costs low. Patients in underprivileged communities can utilize the glove because of its ease of use and usage of materials that are widely accessible.

Purchasing components in bulk and expanding production through injection molding could improve cost-effectiveness. Partnerships with vendors or charitable groups may help cut expenses and enhance distribution. More flexibility and acceptance in low-resource environments would be possible with the availability of open-source designs and software. Accessibility would be improved without sacrificing functionality with a modular pricing structure that allows users to choose features according to their need and financial constraints.

Section 3. Preliminary Design Documentation

N/A

Section 4. Engineering Design Report

Problem and Need Statement (Restated)

Stroke affects around 800,000 people a year in the US alone, making it one of the top causes of long-term disability globally. Even years after the initial stroke occurrence, almost half of these people continue to have deficits in upper extremity function, especially in hand and grip strength. These disabilities make it extremely difficult to carry out basic activities of daily living (ADLs), such as gripping, lifting, and interacting with items such as cups, cutlery, and personal hygiene products. These disabilities have a detrimental impact on a patient's independence, mental health, and general quality of life in addition to their physical limits.

Regaining motor function, especially in the hands, is frequently given priority from a rehabilitation standpoint since it contributes to the restoration of independence. To encourage neuroplasticity and motor relearning, rehabilitation programs frequently use repetitive, task-specific exercises. Long-term commitment to these therapies is difficult, though, because they are mostly administered in clinical settings under the supervision of physical therapists. The time-consuming, expensive, and physically taxing nature of clinical rehabilitation can pose challenges for stroke survivors who do not have regular access to in-person therapy. Because of this, many patients never fully recover their functional hand strength, which makes them dependent on their caregivers for everyday duties and adds to their burden.

Even while there are assistive devices available to help with hand function or to support rehabilitation, they usually fall short of stroke survivors' practical and economical needs. For at-home use, many of the current solutions are too large, uncustomizable, or too expensive. The effectiveness of the devices that do exist in recovering motor function over time is diminished because they frequently lack the functionality necessary to encourage active involvement in rehabilitation exercises. Therefore, there is an urgent need for an assistive technology that helps patients regain their independence and confidence by bridging the gap between clinical therapy and daily life.

An inexpensive, lightweight, and easy-to-use assistive device that is especially made to help stroke patients regain functional hand and grip strength is desperately needed to address these issues. In order to enable patients to smoothly incorporate therapy into their everyday routines, such a device must prioritize versatility for usage in both clinical and home settings. Over time, users should be able to rebuild neural connections and enhance motor control by using it to assist neuroplasticity through continuous, task-specific training. Crucially, the gadget must serve as a therapeutic tool to support long-term healing in addition to being an assistance tool for daily chores.

The device must be adaptable to different hand sizes, impairment degrees, and rehabilitation objectives in order to satisfy the varied needs of stroke survivors. A lightweight, ergonomic construction that reduces user fatigue with prolonged use, robust materials that can endure repeated use, and user-friendly controls that guarantee accessibility for individuals with cognitive disabilities or limited mobility are important design factors. In order to be widely adopted by patients from a variety of socioeconomic backgrounds, the solution must also provide a balance between pricing and functionality.

Additionally, by empowering patients to carry out fundamental ADLs on their own, the gadget must lessen the strain on caretakers. The gadget can lessen caregiver burnout and enhance the quality of the caregiver-patient interaction by easing the physical strain on caretakers. With the possibility of integrating data monitoring features in the future to remotely monitor patient improvement, the device should also give medical personnel a tool to complement in-person therapy.

In conclusion, an integrated solution is required that supports the rehabilitation process through regular, user-driven workouts and helps stroke patients regain their independence. By meeting these criteria, a gadget like this could help stroke patients recover and improve their general quality of life, bridging the gap between everyday functioning and clinical treatment.

User Identification and Value Derived (Restated)

1. *Principal Users:* Survivors of Strokes. The ReFlex Glove is primarily used by stroke sufferers who have diminished grip strength. The glove provides these people with two essential types of value:

- Functional Assistance: By compensating for reduced hand strength, the glove helps users grasp and control things while performing daily tasks including eating, drinking, and taking care of themselves. The technology lessens reliance on others and provides a sense of autonomy by solving this basic restriction.
-
- Rehabilitation Support: Through regular movement, the glove serves as a therapy tool that aids in motor rehabilitation. Over time, these activities assist users restore motor control and functional independence by promoting neuroplasticity. Because of its portability and ease of use, the glove can be easily incorporated into daily activities at home, which lessens the need for expensive clinic-based treatments.

2. *Secondary Users:* Family members and caregivers. Family members and other caregivers greatly benefit from the ReFlex Glove, in two main ways:

- Decreased Physical Burden: The glove lessens the need for caregivers to provide physical support by empowering stroke survivors to perform simple tasks on their own. This reduces caregiver strain and frees them up to concentrate on psychological and emotional assistance instead of manual labor.

- Better Caregiver-Patient Relationship: By helping the patient become more independent, the glove reduces stress and frustration for caregivers, which enhances their relationship and general quality of life.

3. *Tertiary users:* Healthcare Professionals. The ReFlex Glove is useful as a therapeutic and possible monitoring tool for physical therapists, occupational therapists, and other medical professionals:

- Therapeutic Aid: The glove is a useful supplement to in-clinic therapy sessions because it makes it easier to perform repetitive, task-specific activities that are essential for rehabilitation. Compatibility with a variety of rehabilitation programs is guaranteed by its ergonomic and lightweight design.

- Standardization and Remote Monitoring: Data-tracking capabilities may be included in future versions of the glove to assess patient progress and adherence, allowing therapists to customize treatment regimens and deliver consistent care—even from a distance.
- Patient Compliance: The glove helps guarantee adherence to recommended rehabilitation regimens by enabling patients to continue therapy at home, which eventually improves results.

Functional Requirements and Metrics

1. *Grip Assistance:* The glove must generate a gripping force of at least 15 N to securely hold common objects.
2. *Release Mechanism:* The release mechanism must operate with an actuation force of < 1.5 N, ensuring accessibility for users with limited strength.
3. *Lightweight Design:* The glove's total weight, including motors and electronics, must be ≤ 1.5 lbs (680 g) to prevent user fatigue.
4. *Battery Life:* The glove must provide a runtime of at least 2 hours of continuous operation or 8 hours of intermittent use, ensuring sufficient power for daily activities.
5. *Fit and Adjustability:* The glove must accommodate hand circumferences ranging from 6.5 to 9 inches, ensuring a comfortable and adaptable fit for various users.
6. *Servo Motor Performance:* Servo motors must produce a minimum torque of 0.2 N·m to effectively flex and extend the glove's fingers.
7. *Force Sensor Sensitivity:* The force sensor must detect pressures in the range of 0.2 N to 5 N, ensuring precise and responsive grip detection.
8. *Durability:* The glove must withstand 1,000 grip-and-release cycles, demonstrating reliability under repetitive use.
9. *Noise Level:* The servo motors must operate at ≤ 40 dB, ensuring quiet functionality suitable for social settings.

10. *Portability:* The entire system, including the motor housing and battery pack, must have a volume of ≤ 0.5 cubic feet, ensuring ease of transport.
11. *Safety:* The applied force on the fingers must not exceed 20 N to prevent discomfort or injury to the user.
12. *Usability:* The glove must enable users to perform basic gripping and releasing tasks within 30 minutes of initial training, ensuring accessibility for users with limited dexterity or cognitive impairments.

System Overview: Black Box Model

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               +---------------------------------------------+
               |                  ReFlex Glove               |
               |                                             |
 Inputs        |                                             |       Outputs
 (Classified)  |                                             |       (Classified)
 ============= |                                             |       ===================
               |                                             |
 Force Sensor  --->  Analog signal ---> Microcontroller --->  Servo Motors ---> Mechanical Energy (Finger Flexion)
(Information)  |      (Information)       (Processing)       |  (Energy)
               |                                             |
 Button Press  --->  Binary signal ---> Microcontroller --->  Servo Motors ---> Mechanical Energy (Finger Extension)
(Information)  |       (Information)       (Processing)      |   (Energy)
               |                                             |
 Battery Pack  --->  Electrical Energy ---> System Components ---> Power Distribution ---> Torque for Motors
(Energy)       |             (Energy)                         |     (Energy)
               |                                             |
               +---------------------------------------------+
```

Inputs

1. *Matter:*
   - *None* (The system does not produce physical matter as output.)
2. *Energy:*
   - Analog Force Sensor Data: Continuous pressure readings from the force sensor, digitized at 100 Hz.
   - Digital Button Signal: HIGH/LOW states from the push button, indicating user intent to release.
   - Power Supply: 6V from the battery pack.
3. *Information:*
   - Analog signal from the force sensor, representing the applied pressure.
   - Digital (HIGH/LOW) signal from the Red Push Button, representing the user's intent to release an object.
   - System State: Real-time feedback on whether the system is idle, gripping, or releasing.

Outputs

1. *Matter*:
    - Finger Flexion: Actuation of servo motors resulting in finger flexion via Bowden cables.
    - Finger Extension: Servo motor reversal to release grip and return the fingers to a neutral position.*Energy:*
    - Mechanical energy in the form of servo motor torque, translated into cable-driven motion that flexes or extends the fingers.
2. *Information:*
    - Real-time system state, including:
        - "Idle": No force detected, no motor action.
        - "Grip": Motors activated, fingers flexed.
        - "Release": Motors reversed, fingers extended.

Functional Decomposition of the System

1. Continuous Monitoring

- Function: Continuously monitor the analog signal generated by the force sensor to detect user interaction. The system remains in an idle state unless a valid signal is detected.
- Input: Analog signal from the Alpha MF01A-N-221-A01 force sensor, representing applied pressure.
- Processing: The microcontroller continuously samples the force sensor signal at 100 Hz via its analog-to-digital converter (ADC), generating a digitized signal. This process ensures real-time responsiveness to user input.
- Output: Digitized force data is analyzed to determine the presence of force. If no force is detected, the system loops back to the monitoring state.

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2. Force Detection

- Function: Identify whether any pressure is being applied to the force sensor and differentiate between noise and valid input.
- Input: Digitized force signal from the ADC.
- Processing:
    - A low-pass filter removes high-frequency noise and smooths the signal for analysis.
    - A rolling average is calculated over the last five samples to stabilize fluctuations and ensure accurate force detection.
- Output: Binary decision (Yes/No) indicating the presence of force exceeding the sensor's resting noise level.

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3. Threshold Comparison

- Function: Compare the detected force against the predefined operational threshold to determine user intent to grip.
- Input: Filtered and averaged force data from the detection stage.
- Processing:
    - The microcontroller evaluates whether the force exceeds the preset threshold of 0.2 N, corresponding to a digitized value of 20. This threshold was determined through empirical testing to balance sensitivity and prevent false triggers.
    - If the force meets or exceeds the threshold, it is interpreted as an intentional gripping action.
- Output: Boolean signal (True/False) sent to the next stage, indicating whether to initiate motor activation.

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4. Motor Activation for Grip

- Function: Convert the force detection signal into precise mechanical movement by actuating the servo motors to flex the glove's fingers.
- Input: Boolean signal indicating a valid grip intent.
- Processing:
    - The microcontroller calculates the required angular displacement for each servo motor based on the glove's mechanical design and the predetermined torque requirements to flex the fingers.
    - Pulse-Width Modulation (PWM) signals are generated by the microcontroller to control the servo motors, dictating their rotation angles and speed.
    - The motors translate rotational motion into linear motion through Bowden cables, which transmit force to the glove's fingers.
- Output: Controlled flexion of the fingers, enabling the user to grip objects securely.

---

5. Grip Maintenance

- Function: Maintain the fingers in a flexed position until a release signal is received.
- Input: Feedback from the servo motors holding the Bowden cables in tension.
- Processing:
    - The servo motors maintain a static position by applying a holding torque, referred to as "coast mode."

    - The system monitors the button input continuously during this state.
- Output: Static grip maintained until the release command is issued.

---

6. Release Detection

- Function: Detect if the user has pressed the Red Push Button to signal intent to release the grip.
- Input: Binary signal (HIGH/LOW) from the button.
- Processing:
    - The microcontroller polls the button input continuously within the main program loop.
    - A software debounce algorithm is applied to eliminate transient HIGH/LOW oscillations caused by mechanical bouncing, ensuring only intentional presses are registered.
- Output: Boolean signal (True/False) indicating whether the button has been pressed.

---

7. Release Mechanism

- Function: Reverse the flexion process by commanding the servo motors to return the fingers to their neutral position.
- Input: Boolean signal indicating a valid release command.
- Processing:
    - The microcontroller generates PWM signals to reverse the rotation of the servo motors, unwinding the Bowden cables.
    - The release process is calibrated to ensure smooth and controlled extension of the fingers without abrupt movements.
- Output: Neutral positioning of the fingers, preparing the system for the next gripping cycle.

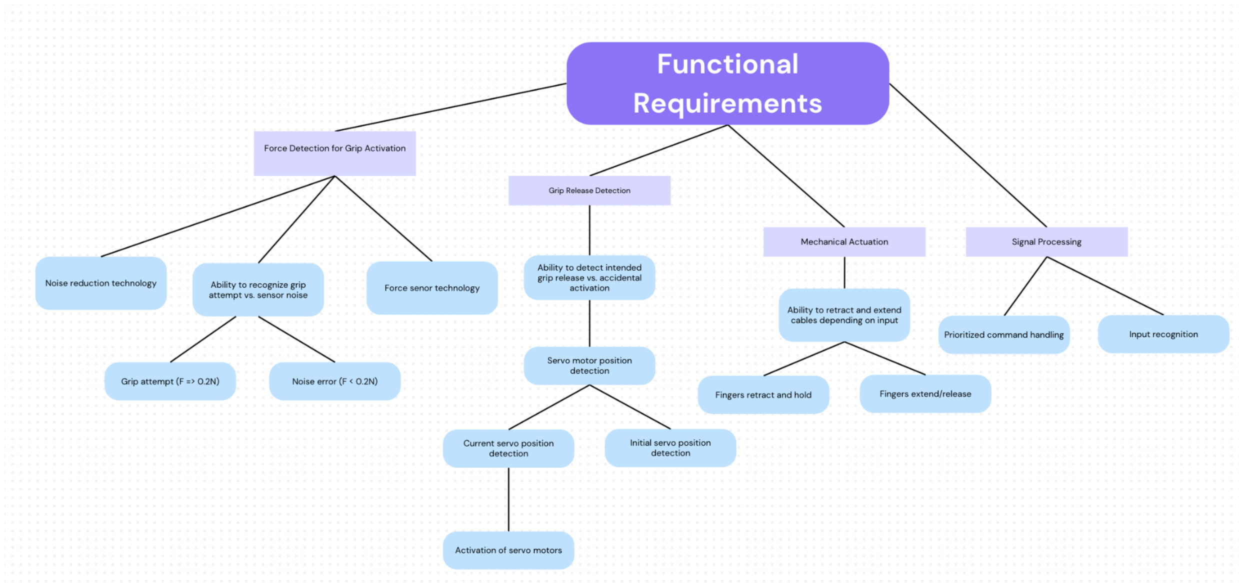
---

8. Power Management

- Function: Provide stable and regulated power to the electronic and mechanical subsystems for continuous operation.
- Input: Power supply from the 6V battery pack, consisting of four AAA batteries connected in series.
- Processing:
    -

    - The microcontroller regulates power distribution to the servo motors, sensors, and internal circuitry, ensuring consistent voltage levels under varying loads.
    - A low-power mode is activated when the system is idle to conserve battery life.
- Output: Reliable power delivery enabling all system components to function seamlessly, with an operational runtime of approximately two hours under continuous use.

Concept Classification Trees for Essential Subfunctions



Concept Combination Table and Screening Matrix for Pulley Method

Concept Screening Matrix for Force Sensors:

Criteria	Resistive Sensor	Capacitive Sensor	Piezoelectric Sensor	Load Cell
Sensitivity (0.2–5 N)	+	+	-	+
Cost	+	-	-	-
Environmental Resilience	+	-	+	+
Compactness	+	+	+	-
Sum of +'s	**4**	**2**	**2**	**2**
Net Score	**4**	**0**	**-1**	**0**
Rank	**1**	2	3	2
Continue	**Yes**	No	No	No

	Concept Screening Matrix For Cable Retraction Method		
	Servo Motors	**Pneumatic Actuation**	**Hydraulic Actuation**
Grip Force (≥ 5N)	+	+	+
Weight	+	-	-
Durability	+	+	+
Cost	+	-	-
Noise Level (≤40 dB)	+	-	-
Ease of Integration	+	-	-
Battery Efficiency	+	-	-
Sum of +'s	**7**	**2**	**2**
Sum of -'s	**0**	**5**	**5**
Rank	**1**	**2**	**2**

Solution Identification and Rationale

The solution for the ReFlex Glove was developed by combining the most effective technologies from the concept classification tree, evaluated through concept screening matrices for each subfunction. For **force detection**, resistive force sensors were selected due to their precision in detecting applied pressures within the required range of 0.2–5 N, compact size, and cost-effectiveness. Alternatives such as capacitive sensors were rejected for their sensitivity to environmental conditions, while piezoelectric sensors and load cells were dismissed due to their unsuitability for static forces and bulky design, respectively. For **mechanical actuation**, servo motors paired with Bowden cables were chosen to ensure precise finger flexion and extension, leveraging their torque capability of 0.2 N·m to generate gripping forces of up to 15 N. Competing concepts, including pneumatic and hydraulic actuators, were rejected due to their excessive weight, noise, and reliance on external power sources, while shape memory alloys were dismissed for their slow response and insufficient force output. For **signal processing**, microcontroller-based systems were selected for their real-time processing capabilities, enabling advanced features like debounce logic and threshold detection. Alternatives such as analog signal conditioning and external processing boards were deemed less flexible or unnecessarily complex. The final solution integrates resistive force sensors, servo motors with Bowden cables, and microcontroller-based signal processing, balancing performance, cost, and usability. This combination ensures the glove meets user needs for reliable grip assistance, lightweight design, and seamless functionality while maintaining affordability and portability.

Organization of the Solution: Mechanical Hardware, Sensors, and Processing Unit

Mechanical Hardware

In order to translate motor torque into linear motion and enable precise finger flexion and extension, the mechanical actuation system makes use of servo motors in conjunction with Bowden cables. After considering other options such shape memory alloy, hydraulic, and pneumatic actuators, which were disregarded because of their inefficiencies, weight, and cost, this design was selected. According to the concept screening matrix, servo motors were chosen because they could produce the necessary torque of ≥0.2 N·m while keeping noise levels below 40 dB.

By housing the servo motors in a small, hip-mounted compartment, the glove's overall weight is decreased and user comfort is increased. Additionally, this enclosure has pulleys and channels specifically designed to reduce friction and guarantee the Bowden cables run smoothly. The glove itself is constructed from PLA Tough, a lightweight and durable material selected for its balance of strength and wear resistance.

Sensors

Because of its accuracy and capacity to identify applied forces between 0.2 and 5 N, the Alpha MF01A-N-221-A01 resistive force sensor is a part of the primary input system and satisfies the functional need for grip detection. Environmental sensitivity and unsuitability for sustained force detection led to the rejection of capacitive and piezoelectric sensors.

To start the release mechanism, a red tactile push button is used as the secondary input. Because of its debounced digital output and low actuation force of less than 1.5 N, this button was chosen to provide dependability and usability even for people with weak hands. The placement of both sensors is intended to provide ergonomic accessibility and smooth communication with the microcontroller.

Electronic Hardware

The Adafruit Feather microcontroller, which powers the electronics of the ReFlex Glove, was selected due to its small size, real-time processing power, and PWM output compatibility. Through efficient signal processing, the microcontroller communicates with the servo motors, push button, and force sensor to control their functioning.

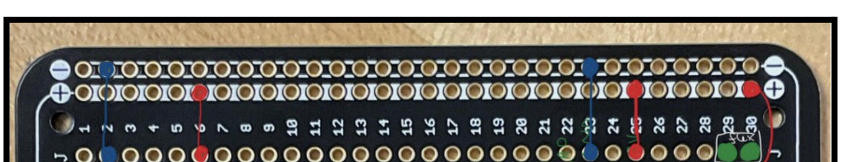
The 6V AAA battery pack that powers the glove was chosen for its mobility and runtime, allowing for at least two hours of continuous use. Stable voltage and current delivery to the microcontroller and servo motors is guaranteed by a regulated power distribution system. Despite having a longer runtime, rechargeable lithium-ion batteries were disqualified for this iteration due to their complexity and cost, as the screening matrix verified.

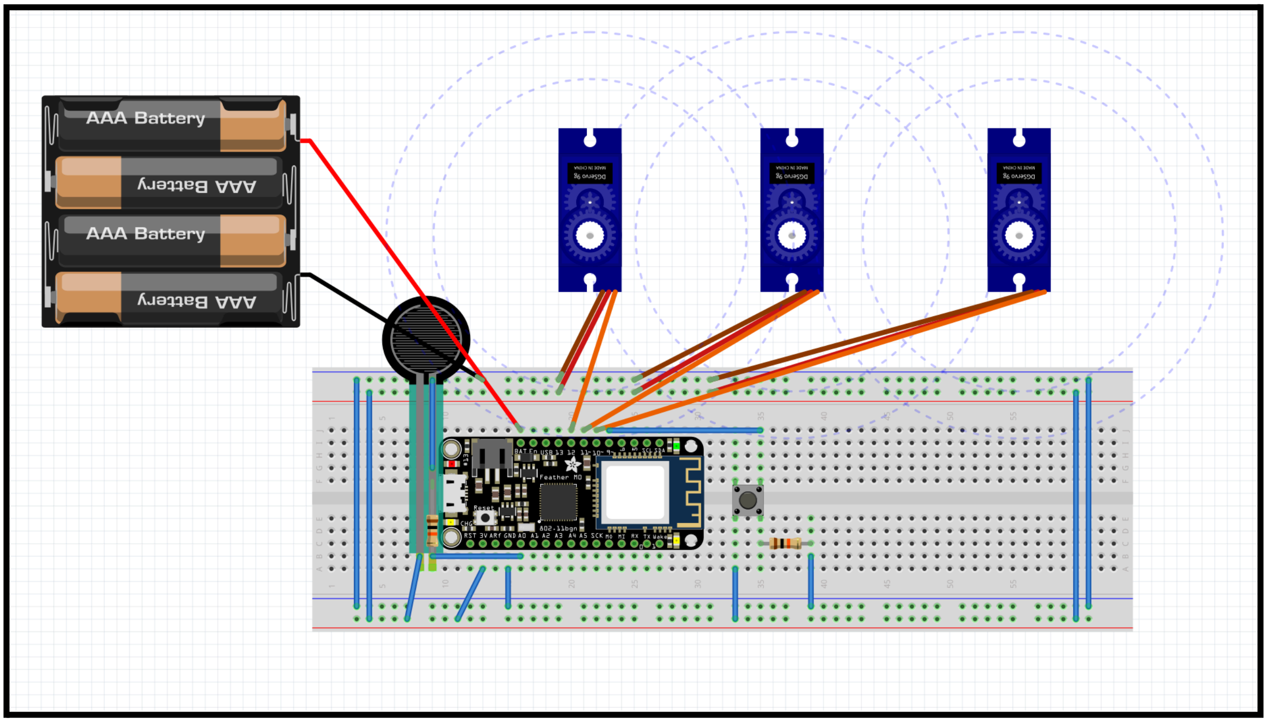
Data Acquisition and Processing Unit

Using its integrated Analog-to-Digital Converter (ADC), the microcontroller digitizes the force sensor's analog signals at a frequency of 100 Hz. Software-based low-pass filtering and rolling averages over five samples are used to reduce noise, making sure that the servo motors are only activated by purposeful grip inputs greater than 0.2 N. In a similar manner, software debounces the push button's signal to stop mechanical bouncing from causing false activations.

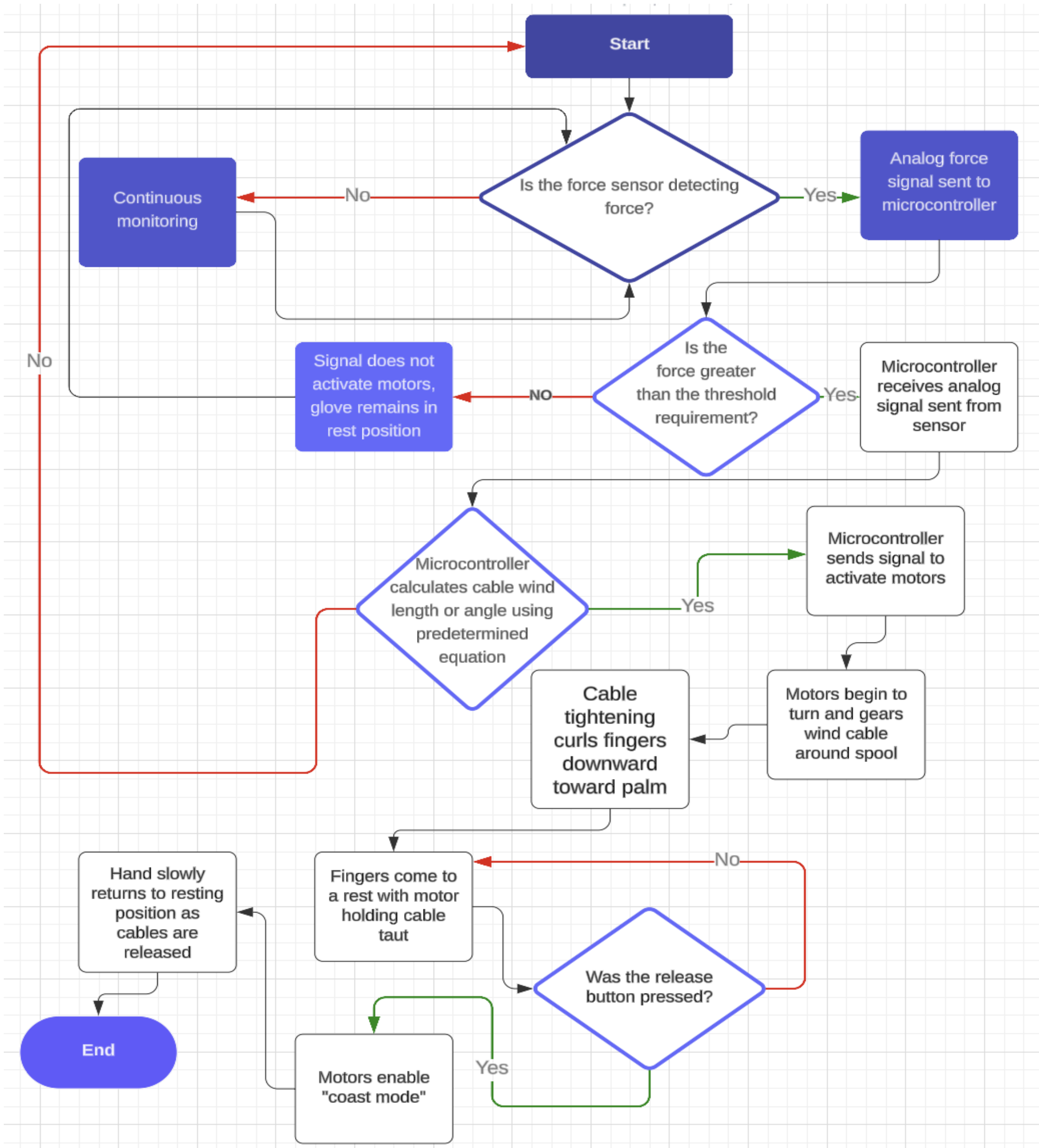
Wiring Diagram

The force sensor, push button, three servo motors, and microcontroller are all integrated into a single circuit by the system wiring. Analog and digital input ports are used to interconnect the sensors, and each servo motor is coupled to a separate PWM output for autonomous control. To preserve signal integrity, all parts share a common ground and the 6V power supply is distributed over a shared power bus. (For comprehensive schematics, consult the wiring diagram that is included in the report.)



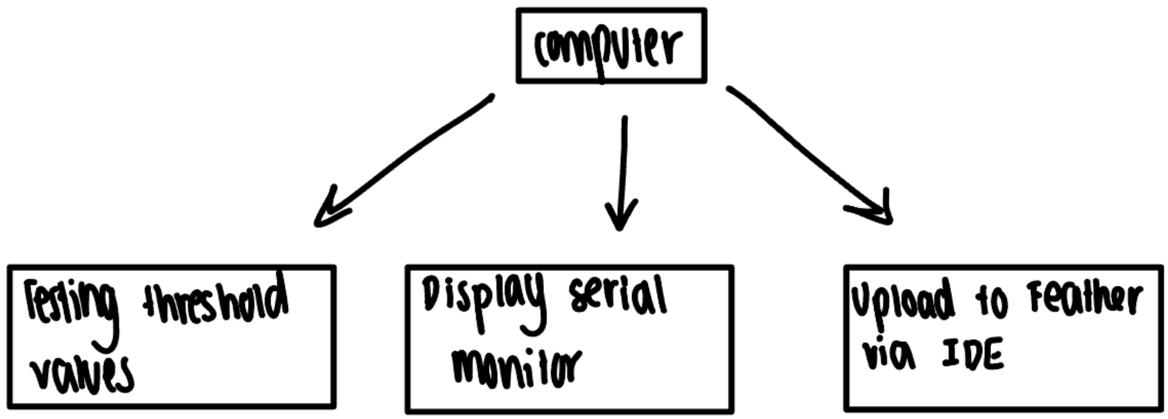


AAA Battery
AAA Battery
AAA Battery
AAA Battery
Feather M0
Reset
802.11bgn

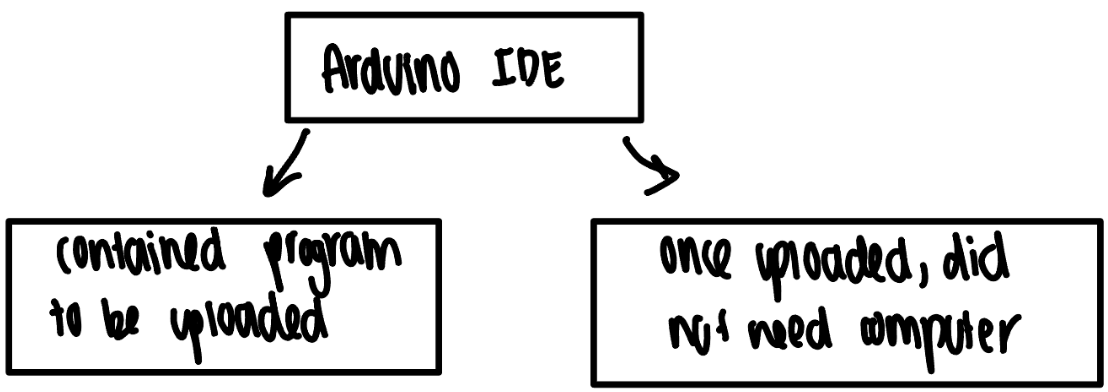

Start
Is the force sensor detecting force?
No
Continuous monitoring
Yes
Analog force signal sent to microcontroller
Is the force greater than the threshold requirement?
NO
Signal does not activate motors, glove remains in rest position
Yes
Microcontroller receives analog signal sent from sensor
No
Microcontroller calculates cable wind length or angle using predetermined equation
Yes
Microcontroller sends signal to activate motors
Motors begin to turn and gears wind cable around spool
Cable tightening curls fingers downward toward palm
Fingers come to a rest with motor holding cable taut
No
Was the release button pressed?
Yes
Motors enable "coast mode"
Hand slowly returns to resting position as cables are released
End

Software Operation: Algorithms and Flowcharts

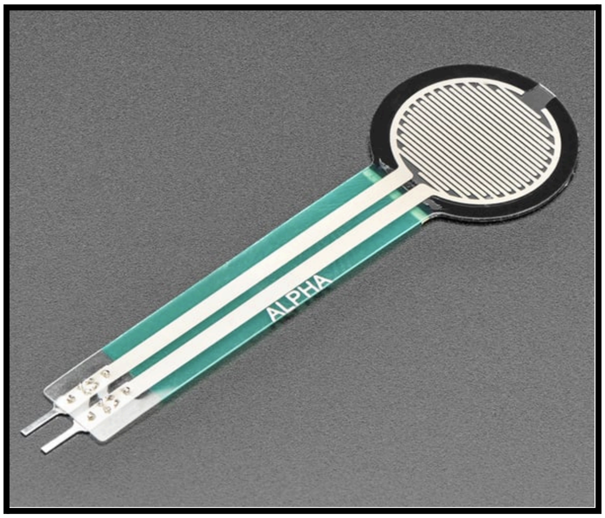
Computer:



Arduino IDE:



Signal Digitization and Processing



Alpha MF01A-N-221-A01 Force Sensor and Red Tactile Push Button

To operate, the ReFlex Glove system needs two important input signals: one from the button and one from the force sensor. To guarantee precise and dependable operation, the microcontroller digitizes and processes these signals.

An Alpha MF01A-N-221-A01 force sensor was chosen for the system due to its excellent sensitivity and accuracy. There were several factors to take into account while determining the threshold value for this sensor in order to optimize sensitivity and guarantee that the servo motors would only be activated in response to an applied force, preventing false activations. Tests using the sensor installed on the brace and connected to the circuit interfaced with the Arduino IDE were carried out in order to determine a dependable threshold. Over the course of five minutes, the sensor was kept at rest and not in contact with any objects, and the output data were observed using a serial monitor. The highest value found under these no-contact circumstances was thought to be the intrinsic noise of the sensor. These readings were averaged, and a threshold of 60 was established to distinguish between noise and actual applied forces. To ensure that the motors would react correctly to applied force and be inactive at rest, this threshold was confirmed by additional testing.

An analog signal proportional to the applied pressure is produced by the sensor when the user applies force. To guarantee real-time responsiveness, this signal is digitalized at a frequency of 100 Hz using the microcontroller's analog-to-digital converter (ADC). To improve accuracy and dependability, the signal is further processed through a number of steps. High-frequency noise is eliminated using a low-pass filter, and fluctuations are stabilized by calculating a rolling average over the previous five samples. To ascertain whether the input is powerful enough to turn on the servo motors, the system applies a threshold equal to 0.2 N, or the predetermined value of 60. When the threshold is exceeded, the microcontroller triggers the motors to flex the glove's fingers, enabling the user to grip objects.

A binary signal (HIGH/LOW) is provided by the button, which functions as a secondary input, indicating the user's intention to release an object. Ensuring precise detection while preventing false triggers brought on by mechanical bounce or accidental inputs were the primary considerations while setting the button's responsiveness. This was accomplished by mounting the button on the bracing at the proper location and connecting it to the circuit that was interfaced with the Arduino IDE. To make sure the button consistently changed states when purposefully pressed and stayed steady when at rest, the digital signal output (HIGH/LOW) was monitored using a serial monitor for five minutes.

A software debounce technique was used to solve mechanical bouncing, which occurs when the button's internal contacts briefly swing between HIGH and LOW states when the button is pressed or released. This technique allowed transient bouncing signals to stabilize before the system recognized the input by adding a brief delay (e.g., 50 ms) to the microcontroller code whenever the button status changed. Following the application of this reasoning, additional testing was done by repeatedly pressing the button in various scenarios, such as mild and firm presses, to mimic actual use. These tests verified that, without recognizing false triggers or missed inputs, the button consistently produced legitimate HIGH signals during deliberate pressing and returned to LOW when released.

The system prioritizes the release action by initiating an interrupt that takes precedence over other processes upon detecting a valid HIGH signal. In order to allow the user to smoothly release the object, this interrupt instructs the servo motors to stretch the glove's fingers to their neutral position.

The ReFlex Glove guarantees smooth transitions between grabbing and releasing things thanks to this meticulously planned digitization and processing processes. Together, the force sensor and button offer great dependability and real-time responsiveness, improving the device's overall usability and performance.

Integration of Published Algorithms and Code

The ReFlex Glove system was developed with the assistance of external code or published algorithms. Arduino Forums contain helpful starter code on how to properly wire and program the force sensor, button, and servo motor. The parameters within this code, however, could be modified for the purposes of our project. This included integrating loops to activate particular functions of the device.

Engineering Standards for System Development and Testing

The ReFlex Glove was developed using ISO 13485, an international standard for quality management systems in the design and manufacturing of medical equipment, to guarantee a methodical and trustworthy design approach. We implemented risk management, a fundamental tenet of ISO 13485, by anticipating possible failure sources and putting mitigation plans in place. The force sensor, servo motors, and button, for example, were all tested separately on a breadboard before being integrated into the entire system as part of a thorough component validation procedure. The possibility of cascade failures during integration was reduced by this divided strategy. We developed thorough testing procedures and documented the outcomes for every phase of the development cycle. To make sure the force sensor consistently identified pressures above the 0.2 N threshold, for instance, functional tests were recorded. In order to ensure that the servo motors provided the necessary torque without overheating, they were also put through load testing. Additionally, a change management procedure was set up in which any design changes were assessed for how they might affect the overall dependability and performance of the system.

The focus on user safety was another important component of ISO 13485 that was integrated into the design. In order to protect the user from pain or harm, the glove was made to function within safe bounds.

Feedback Integration from Design Review

Important input was given during the design review process to improve the ReFlex Glove's usability and functionality. The usage of Bowden cables to transfer the rotational motion of the servo motor to the fingers was one important suggestion. This method was chosen because it made it possible for a lightweight and effective mechanical connection, which kept the glove flexible and lessened hand strain. Bowden cables ensured smooth and dependable finger movement while preserving the ergonomic shape of the glove by reducing friction and offering a small solution for routing the actuation forces. Attaching the motor housing to the hip instead of integrating it directly onto the wrist was another wise suggestion. This modification improved comfort and made the glove more appropriate for prolonged usage by drastically lowering the weight and bulk on the user's hand. The design also enhanced the glove's overall mobility and balance by shifting the motor assembly to the hip, which made it easier for users to do tasks.

These adjustments, which were motivated by the design review's comments, were essential in improving the ReFlex Glove's usability and making sure it better suited the demands of its target market. Including these components showed how crucial stakeholder involvement and iterative design are to the development process.

Section 5. Functionality Demonstration

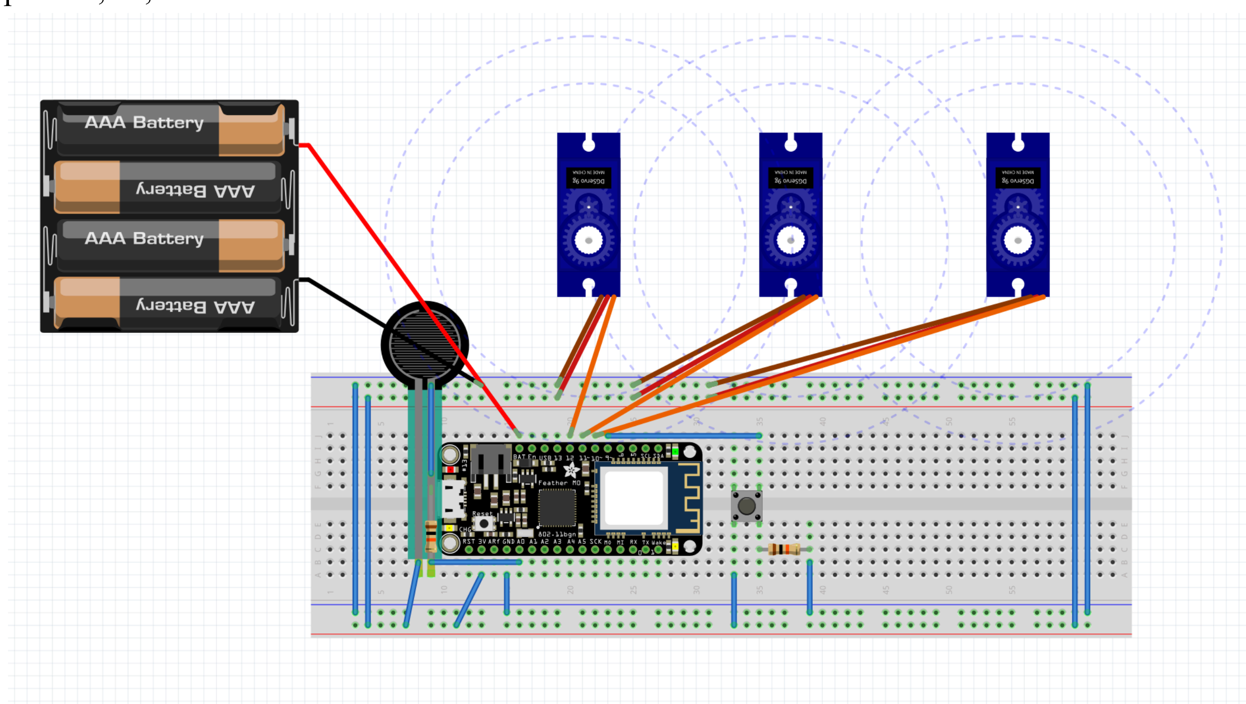
N/A

Section 5. Demonstration Video
N/A

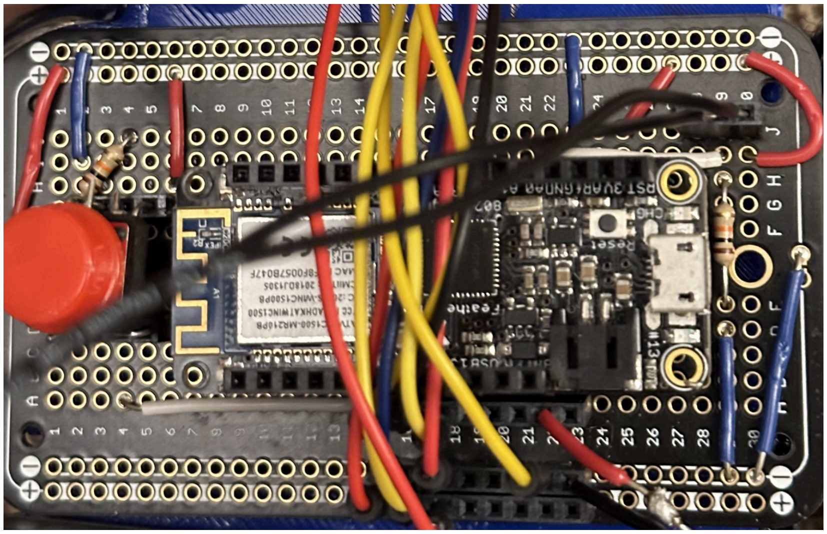
Section 7. Technical Analysis and Code

Electrical Hardware

The primary purpose of the circuit used in the ReFlex Glove was to properly control the servo motors through the integration of a flex sensor and button. The three servo motors, the button, and the flex sensor were connected to pins on the Adafruit Feather microcontroller. This microcontroller was selected so the libraries in Arduino IDE could be utilized and it could easily be connected to a battery for proper function. For the button and flex sensor to function properly, they were connected to 10kOhm resistors as well. This was done as suggested from Arduino documentation online. A 6 Volt battery (supplied by four AAA batteries) was connected to the ground pin and the BAT pin of the Feather. The servo motors of the circuit were connected to ground, power, and their respective pins based on the Arduino code. For our project, we used pins 10, 11, and 12.

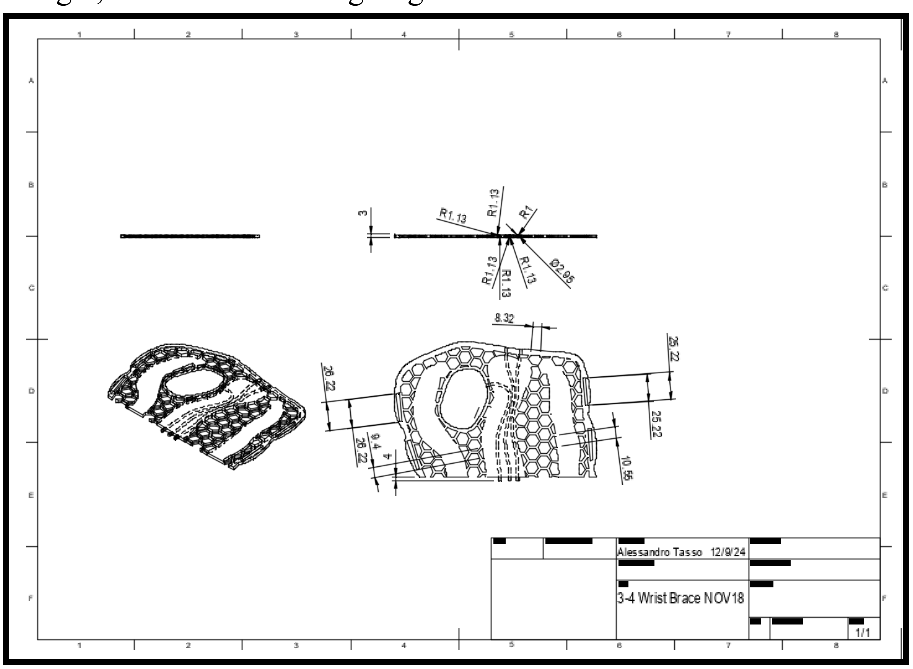


When the components of the circuit were soldered to the PCB board, header pins were used. This caused some difficulty with connections as the flex sensor and button were not directly connected to the PCB board. However, it enabled greater flexibility when components did not operate properly. For example, the flex sensor initially used in this experiment broke while testing, resulting in a need for a new sensor. This was an easy modification due to the header pins. The diagram of the PCB has been shown below, along with the final circuit.



Mechanical Design

There were various mechanical components key to the design. First a glove was created for the palm of the hand. This was designed in Fusion 360 using a pre-existing STL file as a start. A primary purpose of this 3D printed component was to run the wires of the cable from the fingers to the housing unit on the hip. Three channels were added on the glove, one for the thumb, one for the middle finger, and one for the ring finger. Each channel was 2.3mm in diameter.



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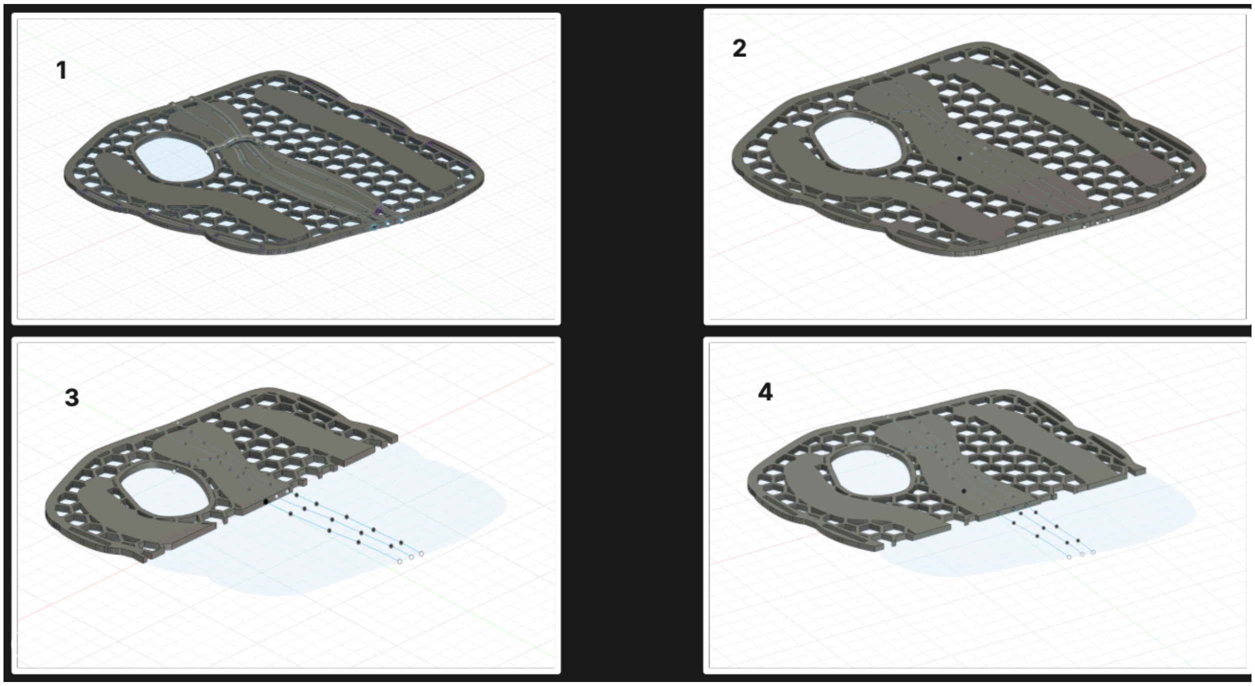
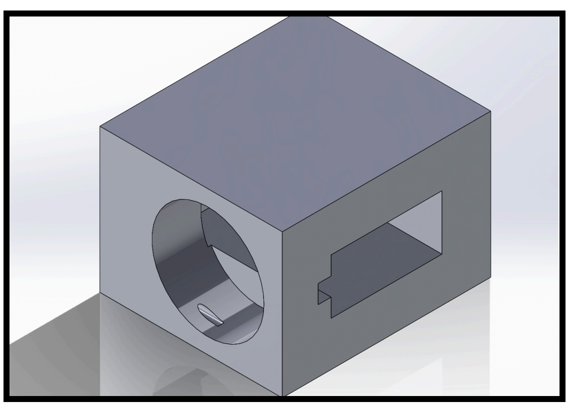
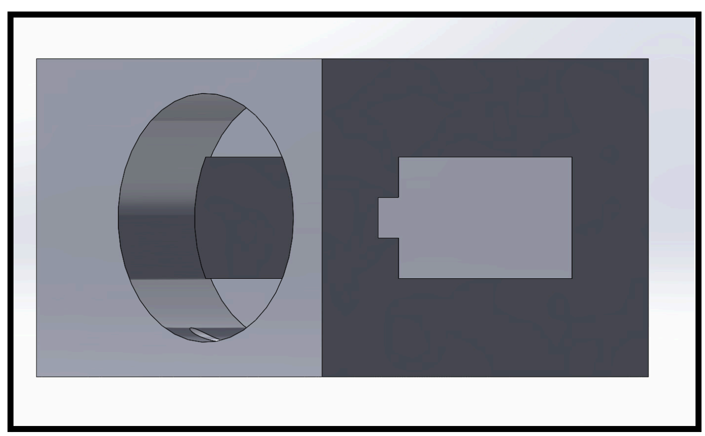
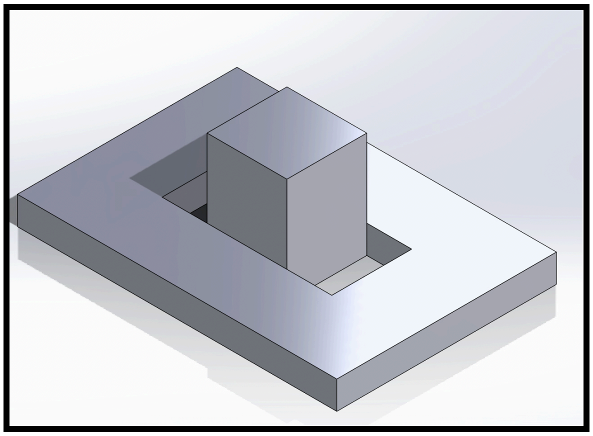
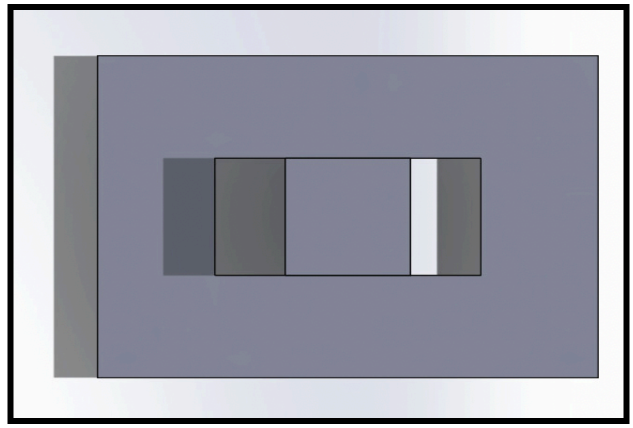


The other mechanical component essential to the design was the housing unit for the pulleys and servo motor. The housing unit was made to attach to the belt of the device, allowing it to be positioned on the hip where it would not restrict movement of the hand. Additionally, the housing unit contained slots for the pulleys, properly aligning the track the wires would run on when flexing and extending the fingers.

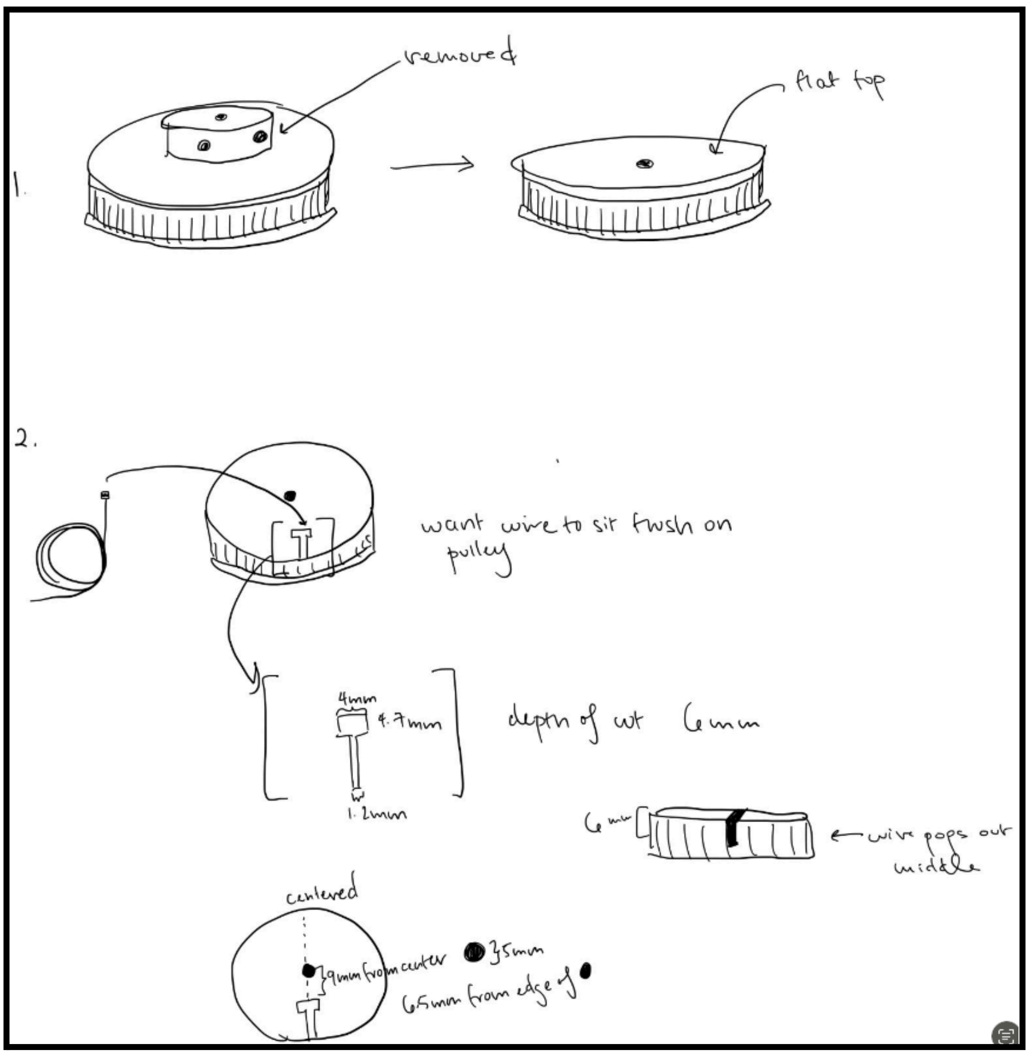








Outside of the housing unit that was used to aid in the functionality of the pulleys, the pulleys themselves had to be modified so that the wire could be secured. To do this, a cavity was created on the top of the pulley with the dimensions that matched the end of the Bowden cable wire. The sketches of this have been shown below.



Material Justification
The pulleys used in the mechanical design were made out of steel. This was done as they should be robust to withstand the constant motion of the servo motors. The housing unit and glove were made with PLA tough. This was done so they could fit the specific models we designed. Furthermore, the 3D printed glove could be heated in the oven so it could be modeled to the user's hand.

Power Budget
Ensuring the proper power was used for the device is essential to ensure proper functionality. To best understand this, an estimate of the device's current draw was taken. The different contributing factors to the current draw have been outlined below:

1. Adafruit Feather (SAMD21)
    a. According to the Adafruit Learning System, the average power draw of the ATSAMD21 + regulator circuitry is 11mA. To simplify calculations, the current draw for this element was reduced to 10mA.
    b. https://learn.adafruit.com/adafruit-feather-m0-adalogger/power-management
2. Servo Motors
    a. Looking at the datasheet for a similar servo motor, the current draw is approximately 170mA.
    b. https://towerpro.com.tw/product/mg995/

These factors were combined to calculate the total current draw:

$$10mA+170(3)mA$$
$$10mA+510mA$$
$$=520mA$$

Here, a battery pack with four AAA batteries connected in series was used. AAA batteries often supply 1.5V each. Because they were connected in series, the voltages could be added as follows:

$$1.5V(4)=6V$$

Alkaline batteries were used for this project, so datasheets were referenced to determine the capacity to determine that standard AAA alkaline batteries have a typical capacity of approximately 1000 mAh. With this information, the runtime could now be calculated.

$$\text{Runtime} = \frac{Battery\ Capacity}{Current\ Draw}$$
$$\text{Runtime} = \frac{1000\ mAh}{520\ mA}$$
$$\text{Runtime} = 1.923 \text{ hours}$$
$$\text{Runtime} = \sim 2 \text{ hours}$$

The battery used in our device was also tested in the idle state. It lasted more than 2 hours, but this is likely due to the fact that it was not in constant operation.

Software

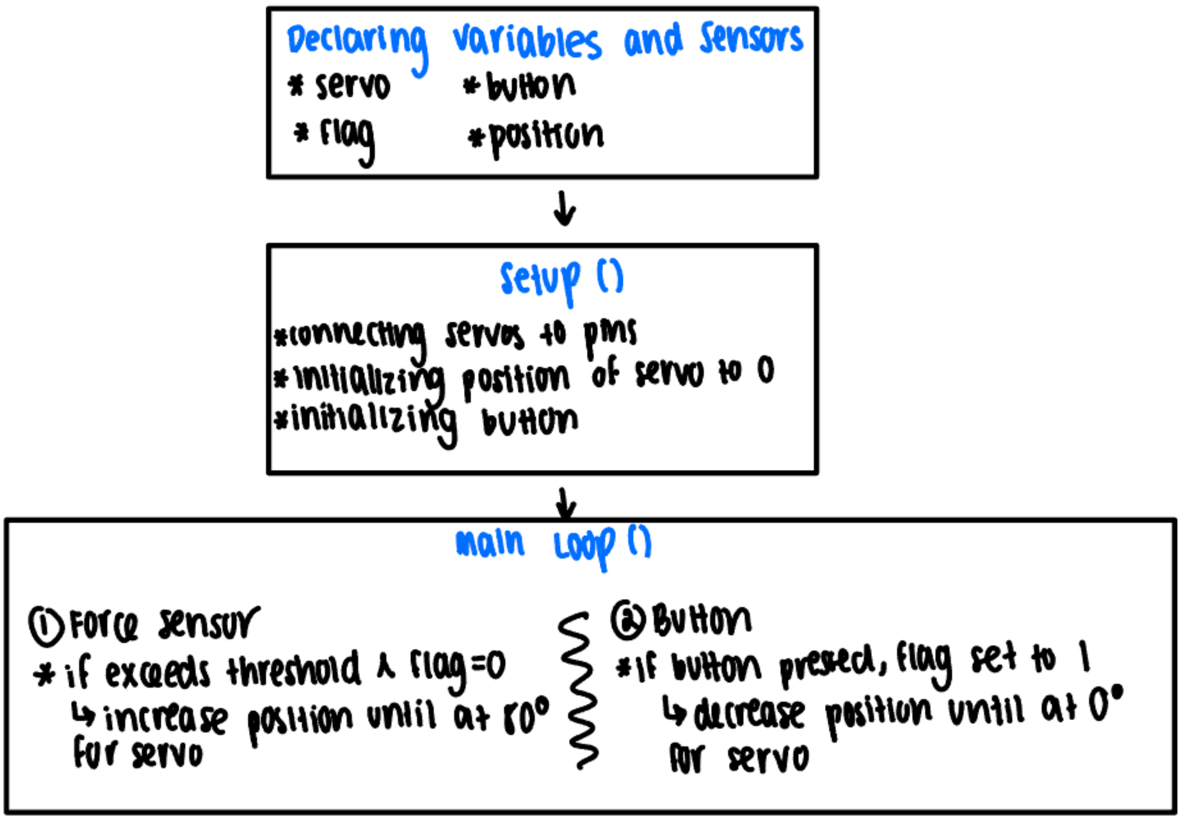
The code required to power this device has been linked below.

https://drive.google.com/drive/folders/1cgZ1taUmojLYRHxWGGLKEdA4UFxvqlFn?usp=sharing

Within this folder, there is the .ino file used in the Arduino IDE. This enables the components of the circuit to function properly. There is also a README.txt file that details the libraries used and how the program may be uploaded to the Feather. Additionally, there is a folder with the video project, demonstrating the use of the device and how it may be properly run.

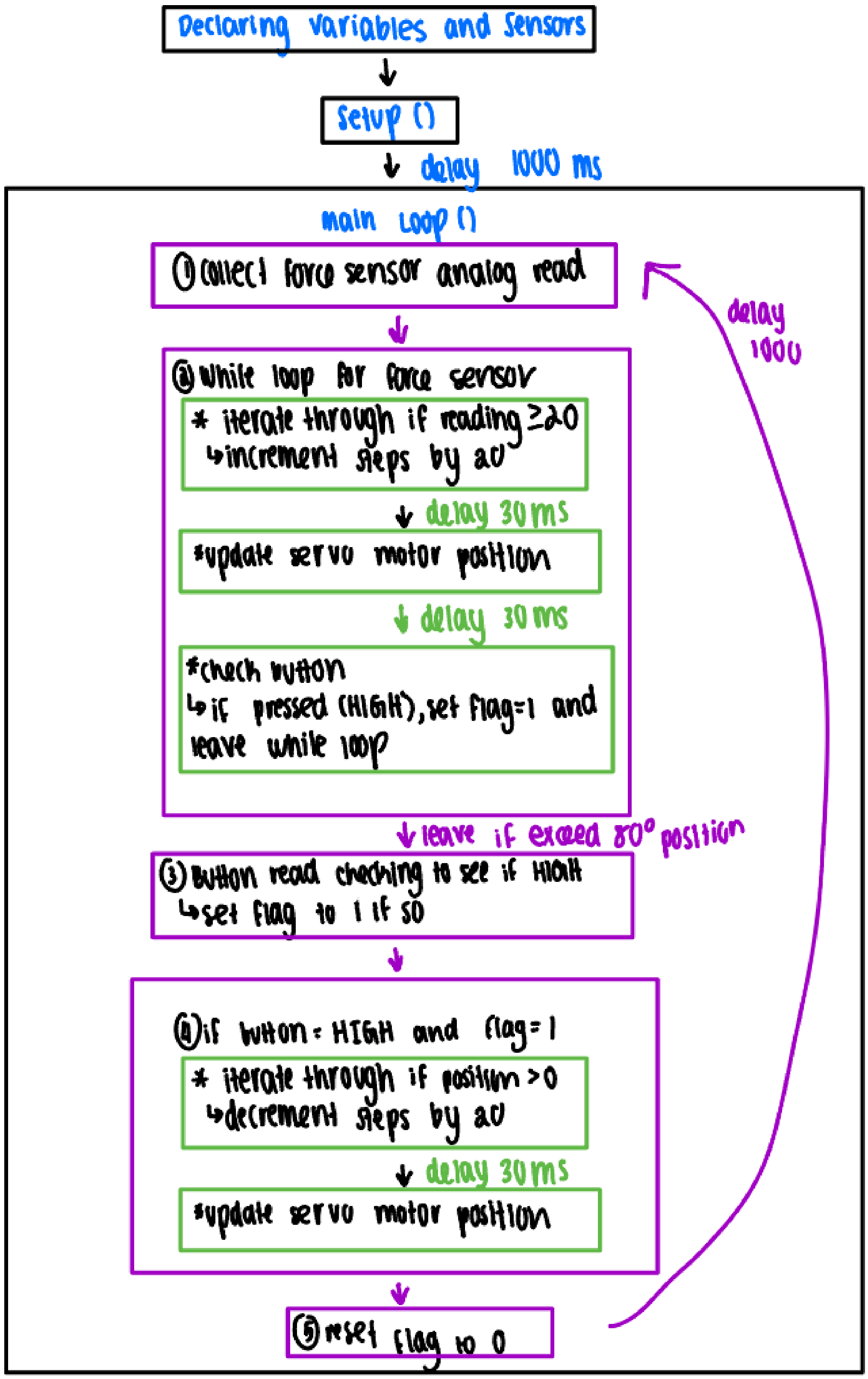
Overall Architecture for Software

The programming for this assignment was completed in Arduino IDE. It was broken into three main components, which can be observed through the block diagram below–initialization, setup, and the main loop.



Description of Subprograms

The code was written to process data for the force sensor and servo motors. The primary function of the code was to initialize all involved sensors and the button, specifying the pins that they would be connected to. Within the main loop, the primary subprograms are the loops for the force sensor and button. The force sensor loop works to get a value from the force sensor in an attempt to detect when the user was attempting to grab an object. When the threshold value was reached, then the servo motor would begin to turn. The second subprogram was the loops for the button. When the button was pressed, the servo motor would rotate the opposite direction. A flag was used in our program as well to assist in operation. In some instances, the servo motor would not turn to its final position by the time the button was pressed. The flag would act as an "override," stopping the motion to the 80 degree position so that it could immediately switch to moving towards 0 degrees.


Declaring variables and sensors
setup ()
delay 1000 ms
main loop ()
① collect force sensor analog read
delay 1000
② while loop for force sensor
* iterate through if reading ≥20
↳ increment steps by 20
delay 30 ms
*update servo motor position
delay 30 ms
*check button
↳ if pressed (HIGH), set flag=1 and leave while loop
leave if exceed 80° position
③ button read checking to see if HIGH
↳ set flag to 1 if so
④ if button = HIGH and flag = 1
* iterate through if position > 0
↳ decrement steps by 20
delay 30 ms
*update servo motor position
⑤ reset flag to 0

Strengths and Weaknesses of Current Design

Given the current design, a primary strength of our device is the housing unit that can be positioned on the hip. This is likely the most unique component of our device as many other gloves or devices for stroke patients attempt to store everything exclusively on the hand. This adds unnecessary weight to the device, making it difficult for patients to use. Another strength of our device is the customization component. The hand can be molded to the individual hand of the patient. It is unrealistic to think that all patients will have a perfect fit to the glove when looking at the generic sizes of small, medium, and large. This device allows for true customization to benefit the target population.

Though there are many strengths to the device, there are areas of weakness as well. In our design, the servo motors attempt to turn to a specific angle when the force sensor gets a reading or when the button is pressed. When testing the device, there were instances in which the pulley mechanism malfunctioned and the servo motors could not reach the desired angle. This would likely cause issues in the hardware over time, breaking the different components of the device. Furthermore, with the program currently used, we determined threshold values to flex the fingers to a particular angle. This was made for the specific case of the glass of water or water bottle. More realistically, not every object would be this size so there should be another way to determine how far the fingers should flex to properly grab the object.

Components to be Improved (Listed in Order of Priority)

If we had more time to continue this project, there are several improvements we would make. First, we would expand the device to include all five fingers, rather than just the thumb, ring, and middle fingers. This would increase the versatility of the device and allow users to perform more complex tasks, such as picking up utensils or pens, rather than being limited to gripping a glass. Broadening the use case would make the device more useful for a wider range of daily activities, further supporting stroke survivors in regaining independence. With the addition of more fingers, we would want to include a way to have the user input whether they want all their fingers to more or just the ones they select.

We would also work on increasing the sensitivity of the device. We would achieve this by adding more force sensors at various parts of the glove. By having various sensor locations, this broadens the systems ability to detect the user's intent to grab different shaped objects. Additionally, we would aim to make the servo motors pull the fingers proportionally to the force sensor readings, enabling a more natural and precise grip taking into account weight and shape of object as well as the patient's strength.

From a design perspective, we would move away from using glue and Velcro which currently limits the device’s modifiability. Instead, we would focus on creating a system that is adjustable. For instance, we would design a brace that is easier to remove and remold to fit different hand sizes. This would make customizing the device a lot easier which is beneficial during clinical trials and rehabilitation centers.

With these future improvements, our goal would be to enhance the device's usability, functionality, and adaptability, ultimately providing a more comprehensive and effective assistive tool for stroke patients.

Environmental Impact

The environmental impact of the ReFlex Glove comes from the materials used, energy consumption, and disposal. The device uses force sensors, servo motors, Bowden cables, microcontroller, plastic for the glove and housing structure and AAA batteries for power. The electronic components are created from mining metals like copper and silicon which can lead to habitat destruction and require a significant amount of energy. Additionally, all the 3D-printed plastic components in our design contribute to plastic waste. The use of non-rechargeable AAA batteries further adds to electronic waste. Batteries require special disposal as they can release chemicals into the environment. A transition to rechargeable lithium-ion batteries could decrease battery waste. The design of the glove helps extend its lifespan by enabling individual components to be replaced without replacing the whole device but certain electronic parts may not be easily recyclable which can contribute to e-waste. Waste from manufacturing, particularly from 3D-printed parts, is another consideration. Changing to more biodegradable or recyclable components would reduce waste. By incorporating more recycling and switching to rechargeable batteries, the ReFlex Glove can align with more eco-friendly manufacturing while maintaining its functionality and accessibility.

Parts and Bill of Materials

Product Name	**Unit Count**	**Price of Each Item**	**Line Price**	**Part #**	**Item Description**
Bowden Cable	3	$9.99	29.97	B08F7SBJB7	Universal Bicycle Transmission Line Bicycle Shift Derailleur Cable and Brake Cable Kit for Bicycle Mountain Road Bike Repair

Hand Model	1	$9.99	9.99	B0783NSNNW	TAPBULL Wood Artist Drawing Manikin Articulated Mannequin with Wooden Flexible Fingers 10" Right Hand (10 inches-Right Hand)
Thimble	2	$1.89	3.78	B07LCLG1T7	4 Pack Sewing Thimble Finger Protector, Adjustable Finger Metal Shield Protector Pin Needles Sewing Quilting Craft Accessories DIY Sewing Tools Needlework(2 Sizes)
Aluminum pulley 6mm shaft	3	$13.99	41.97	B0CBRV9YT6	2PCS Set 2GT Aluminum Timing Pulley 20&60 Teeth 5mm Bore Synchronous Wheel with 2PCS Length 200mm Width 6mm Belt (20-60T-5B-6)
Servo Motor	4	$16.99	67.96	B0C5LWHTQ1	25KG High Torque RC Servo, Miuzei Waterproof Servo Motor Compatible with 1/6, 1/8, 1/10, 1/12 RC Car, Full Metal Gear Steering Servo with 25T Servo Horn（270°）

Glove (S)	1	$22.80	22.8	B0C73 SWD34	
Velcro	1	9.99	9.99	B0CG VPMJB P	0Ft x 1 Inch Hook and Loop Strips with Adhesive, Double Rolls of Heavy Duty Self Adhesive Tape with Backing, Nylon Self Adhesive Tape for Home Office School and Crafting,Black
Super Glue	1	8.51	8.51	B082X GL21J	Gorilla Super Glue Gel XL, 25 Gram, Clear, (Pack of 1)
Force Sensor	1	9.99	9.99	B0D2K 6TVLT	Force Sensor FSR402 for Arduino, ESP32, ESP8266, Raspberry Pi
Push Button	1	8.68	8.68	B01E3 8OS7K	Gikfun 12x12x7.3 mm Tact Tactile Push Button Momentary SMD PCB Switch with Cap for Arduino (Pack of 25pcs) AE1027

Adafruit Feather	1	36.98	36.98	B01F6GJVL6	Adafruit (PID 3010 Feather M0 WiFi - ATSAMD21 + ATWINC1500
Resistor (10kOhm)	1	4.29	4.29	B0BR67DJHM	10K Ohm Carbon Film Single Fixed Resistor 1/2 W (0.5 Watts) 5% Tolerance, (10K R, 10K ohm, 10K Ω) Resistor (40 Pack)
Wires	1	15.19	15.19	B07TX6BX47	22 awg Wire Solid Core Hookup Wires-6 Different Colored Breadboard Wires 30ft or 9m Each, 22 Gauge Electronic Wire PVC (OD: 1.60mm) Arduino Wire

Section 8. Verification

Does the MVP Address Unmet Need?

The Minimum Viable Product (MVP) requirements were successfully met for the ReFlex Glove. The primary function of detecting the user's intent to grip an object and assisting by activating finger flexion through motorized support was achieved. Additionally, the device was able to release the object and be battery pack powered. The ReFlex Glove effectively addresses the unmet need of assisting individuals with weakened grip strength, such as stroke survivors, to regain autonomy in performing everyday tasks. For example, as demonstrated in our storyboard, a user could wear the glove, detect the intent to pick up a glass of water, and receive the necessary support to complete the action. This functionality is critical for enabling users to maintain their independence. The current version of the ReFlex Glove meets the requirements that a user can wear the device portably, activate its functions, and experience an immediate improvement in grip strength. With these functions met, we are able to claim that the ReFlex Glove was successful.ir performance when attached to the Bowden cables threading through the glove. After confirming that all components worked individually and as a system, we transitioned the circuit from a breadboard to a protoboard. We waited until after we ensured a functioning circuit as soldering each component to the protoboard made it more permanent. Furthermore as we had to rely on super glue for connections, we emphasized testing at every stage critical, as glued components could not be modified easily.

Constraints

This design was created within 16 weeks, the semester duration of the course. While working under this design constraint, additional constraints limited the device from full functionality. Our device was designed under the assumption that a caregiver or family member could aid the stroke patient putting on the device.

Section 9. Technical Difficulty

Because to its intricate integration of mechanical, electrical, and software components, the ReFlex Glove project exhibits a high degree of complexity and deserves an 8 out of 10. Careful thought had to go into the hardware design, especially to make sure the servo motors with Bowden cables worked effectively and smoothly without experiencing too much friction or misalignment. Additional difficulties arose during the calibration of the resistive force sensor to detect forces between 0.2 N and 5 N since accurate tuning was required to distinguish between noise and purposeful grip inputs. Iterative testing and troubleshooting were necessary to achieve dependable performance under various scenarios. The project was made more challenging by the requirement for accurate calibration, smooth integration, and dependable performance for a medical device application, even if the use of commercially accessible components made procurement easier. The project's technical, practical, and transdisciplinary requirements put it squarely in the upper range of complexity, but the lack of more sophisticated approaches like machine learning or adaptive algorithms prevented the difficulty from rising to the highest levels.

Section 10. Legacy/Lessons Learned-Engineering Standards

Risk Management

For future students, we recommend understanding the principles of ISO 13485 and using them as a guideline during the initial stages of planning. As a guideline, it will help create a systematic approach to the project. What worked for us was creating a written plan that included detailed checklists and internal deadlines. For each stage of the project we included testing of component functionality and we tested system integration in order to address potential issues early on. We found that documenting the process, while time consuming in the moment, allowed us to save time when we had to troubleshoot or if we were unsure how to continue.

Vendors and Sensor Manufacturing Advice

The main obstacle we had during the project was time. Our advice when trying to deal with a time constraint is to order components early. Use Amazon whenever possible, as it offers fast delivery and has a wide range of items readily available. With that being said, conduct research and be sure of what you are getting before you order. We started to draft our order list by talking through the whole project and asking questions like how will this integrate with the rest of our components? What source of power are we using? What is necessary to complete our design requirements? All these specific questions can be answered once you have a deep understanding of your project. Moreover, we talked to a lot of people that were more knowledgeable than us. For example, we consulted Sam and Ray in the DRB basement to help identify the right motors and if our circuit design made sense for our project goals. Understanding your design requirements is critical for efficient decision-making. In our case, servo motors were chosen over DC motors because they allowed us to hold a specific angle, which was necessary because we wanted the servo to return to its original position after there was a release input.

Helpful Knowledge from Previous Classes

In terms of groups being the most prepared to take BME405, there are a couple classes that will put students at an advantage. For most if not all projects will require 3D printing and coding. To obtain these skills, students should take ITP 308 which teaches how to use solidworks to create a 3D design that can be then 3D printed. What is also useful about taking this class is that it will give the skills needed to see an object and understand how it should be broken down into various components to then be modeled in 3D. 3D printing skills will allow groups to build custom components. Other ITP classes will be extremely useful in teaching how to code which may be needed when using microcontrollers or if the route that your group wants to take involves python. Other classes that are helpful are EE 202 and BME 302 which provide information on circuits. BME 404 can also be helpful and was for our project as it covers biomechanics. Everything can be learned, however, so asking questions is really important. Collaborating and seeking advice from peers or mentors is another critical factor. Discuss your design with others to ensure it is coherent and well-thought-out, and if someone is unsure about a component or design decision, find someone who has expertise in that area.

Additional Advice for Future Students

Another valuable piece of advice would be to design the project with replaceability in mind, as components will inevitably fail. For example, when soldering circuits onto a protoboard, use headers to make connections easily swappable. This approach ensures that faulty parts can be replaced without significant work. Prototyping in small increments is also vital. For 3D-printed parts, test individual components before committing to a full design to avoid costly redesigns. A simple design will often be the most reliable, especially when under tight time constraints. Focus on creating a functional minimum viable product first and refine it only if time permits.

Ultimately, combining the structure provided by ISO 13485 with strategies such as segmented testing, ordering early on amazon, and making your design as replaceable as you can will enable future BME405 groups to succeed. By prioritizing simplicity, incrementally testing subsystems, and planning, future teams will be at the best position to deliver functional and innovative designs within the time constraints of one semester.

Section 11. Legacy/Lessons Learned-Lab Notebook

Teamwork Assessment

Team members:	Saci-Elodie Marty	Lauren Tomita	Alessandro Tasso
	Mechanical/Electrical Design	Electrical	Mechanical Design
Contributions:	• Housing/Lid Design in Solidworks • Circuit Assembly • Debugging code in Arduino IDE • PDR/CDR/Demo video	• Programming in Arduino IDE • Circuit Design & Troubleshooting • PDR/CDR/Demo video	• Brace Design in Fusion 360 • Cable & Sheath Integration • General Machine Work • PDR/CDR/Demo video

Human Trial Structure
The parties that would likely be involved in a human trial are as follows:

1. IRB
2. FDA
3. 501(k)
4. Customer Feedback
5. Clinical Trial
6. Analysis of Adverse Effects

The ReFlex Glove would most likely be classified as a Class II Medical Device because it is for rehabilitation and assistive purposes without supporting or sustaining life or presenting a high risk of injury. Class II devices can have a 510(k) where a predicate device can expedite the approval process. For FDA clearance, there is a preclinical stage that is around half a year where safety is ensured. This includes mechanical testing, software validation, and biocompatibility testing for materials that come into contact with the skin. Stage 2 would be clinical trials which take a year or two. The clinical trials would be split into pilot study and pivotal study. The pilot study would be 10 to 20 participants and then the pivotal study would be closer to 100 participants. After receiving clearance, post-market surveillance will be required to monitor long-term safety and efficacy. Overall, the entire process, from preclinical testing to market entry, could take approximately 2-4 years.

Materials and Sensors Justification

The servo motors used in this project were selected as they had previously been used by the group. Servo motors can be programmed to a specific position as opposed to other motors which would require a controller to go to a set position. For example, in our program, we could say Servo.write(position) and it would go to the desired position. The force sensor was selected for this project as it could easily detect when an object came in contact with it. The force sensor also is commonly used in circuitry, so we could modify starter code online for our purpose. Similarly, the pushbutton is often used so starter code could easily be found online to modify for our device.

Ethical Considerations

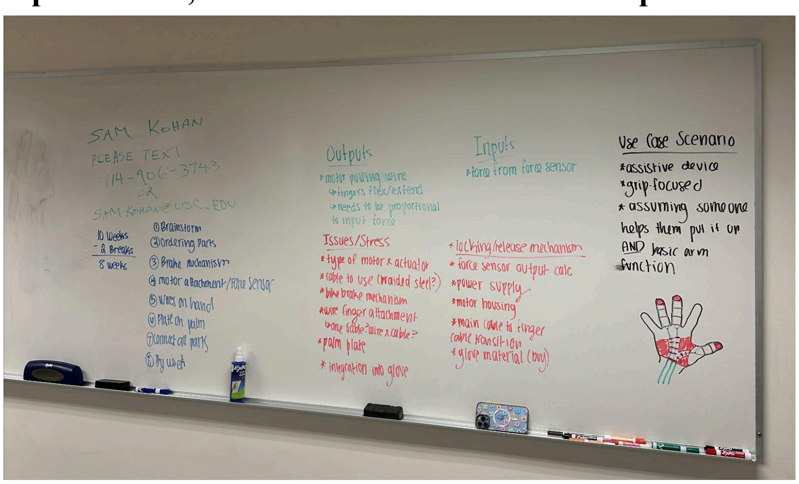
As previously mentioned, this project would likely include the use of human trials to get user feedback and ensure the proper use. While conducting these trials, it is important to prioritize the patient and to meet the safety and efficacy requirements that are needed within such experimentation.

The primary constraint our team operated under was time. With only a semester to build the ReFlex Glove, we had to prioritize MVP features and find rapid solutions to meet project deadlines. Money was less of a limitation, as we had sufficient funds to pay for all the materials and components. As we 3D printed we were able to make custom parts and this helped us stay on schedule. We were unable to find a hand model that would work as none we found were close enough to a human hand. Our team had varying levels of expertise in a wide range of areas from CAD to circuity to coding. Our knowledge was supplemented by advice we seeked for robotics-related challenges, such as servo motor integration and Bowden cable mechanics and for some hardware portions. This collaboration allowed us to overcome technical barriers and ensure the device's functionality within the constraints of the project timeline.

Appendix

Electronic Lab Notebook
BME405: Group 6 (ReFlex Sensor)
Saci-Elodie Marty, Alessandro Tasso, Lauren Tomita

September 17, 2024: Brainstormed different aspects and requirements of the project



September 24, 2024: Worked on PDR and BOM

- Had meetings with Sam, Arjun, and Ray about what motor will be needed and specific details for the BOM
- PDR was completed and submitted on Friday

October 1, 2024

- Sandro: worked on CAD of palm plate
- Saci: updated BOM, estimations of power needed to move finger (average torque)
- Lauren: played around with the sensors and arduino to see how signals will be integrated

October 4, 2024

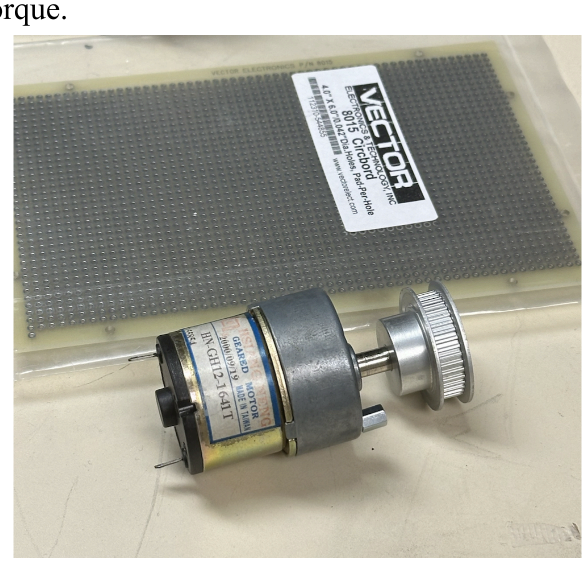
Notes from conversation with Sam:

- arduino
- small breadboard (soldering one)
  - 8015 circbord
- solder the pins of IC to small breadboard
- mount bracket to holes of motor and then u can mount it wherever

- forward and reverse is high low. general purpose IO
- digital pin

- battery also goes to board and is connected to IC chip
- board ground to arduino ground
- diff power for arduino
- IC. MP6513 motor driver
- motor shaft 6mm

-> Conversation with Sam, landed on using a DC motor because it is really strong and will have high torque.

- 

- Decided to use a pulley to attach wire to the DC motor.

October 8, 2024

- Milled hole into pulley and fit wire into pulley securely
- Sam helped with this.
- 

- Connection was strong and successful

October 9, 2024

- Sandro: printed first model of glove
- 
- Attempted to mold palm plate to hand

Thermal properties		
	Test Method	*Typical value*
Melt mass-flow rate (MFR)	ISO 1133 (210 °C, 2.16 kg)	6 – 7 g / 10 min
Heat deflection (HDT) at 0.455 MPa	ISO 75-2 / B	58.3 ± 0.7 °C
Vicat softening temperature	ISO 306 / A120	63.7 ± 0.3 °C
Glass transition	ISO 11357 (DSC, 10 °C / min)	59 °C
Melting temperature	ISO 11357 (DSC, 10 °C / min)	152 °C

- Finding the temperature for when glove put in the oven

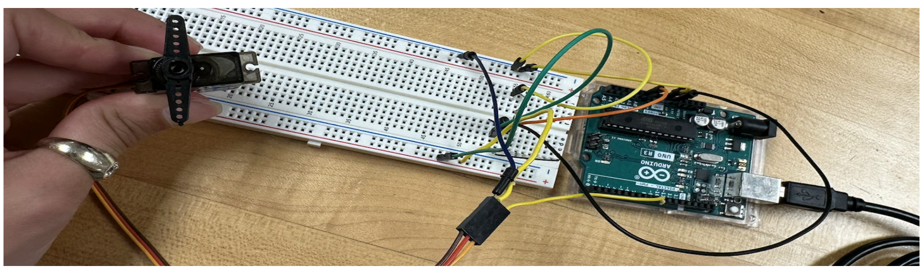
- Landed at 100 degrees for 5 mins. Over melted first time so reducing to 1 min in oven
- 
- Molded palm plate. First iteration. As a trial run we printed half the palm so the print would go faster. Must print the whole thing now

October 14, 2024
- Got the DC motor and the chip but wrong chip so must order another chip
- Chip ordered
- Printed the whole palm plate. Print was good but the thumb wire wasn't hitting the right spot. Won't bend the thumb how we want so another print was designed.

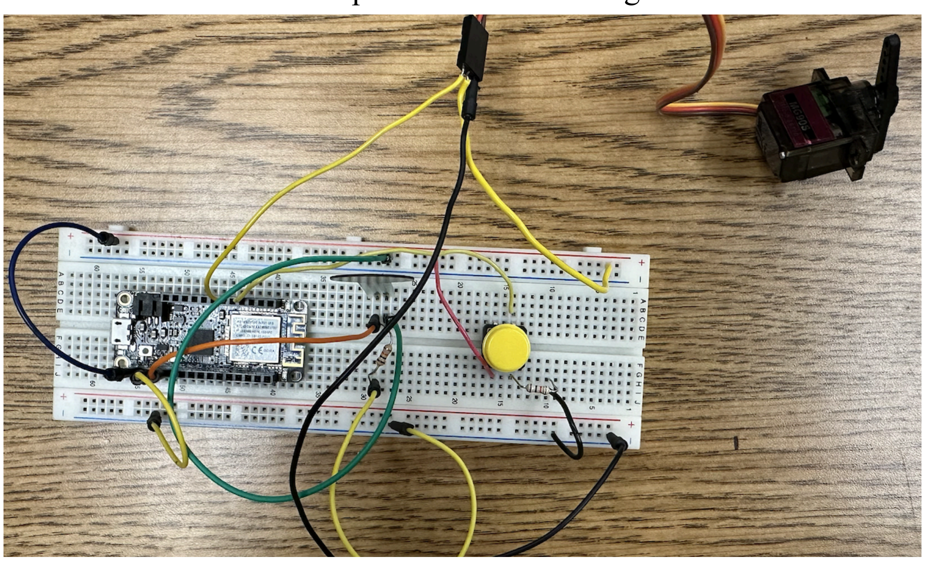
October 18, 2024
- 

- New print. Angle for the thumb wire is too sharp so can't thread through the wire. The mechanics of how it will bend the thumb was good. Will print again with different wire path and less long because not necessary
- After conversation with Sam and Trent, we realized that we need to use a servo, not a DC motor because the DC motor can't track the angle so it won't return to the same spot -> Pivoting to servo

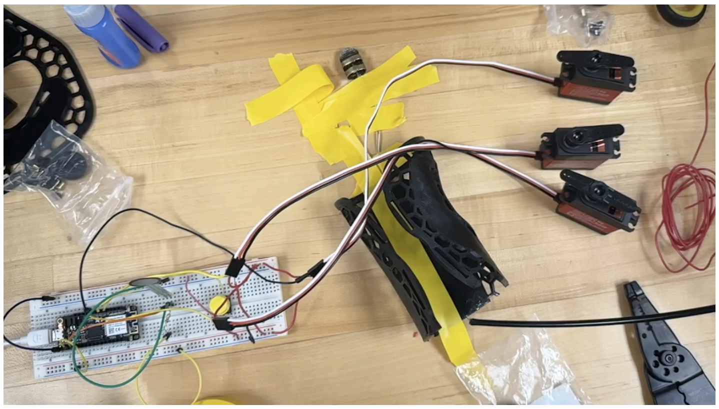
October 21, 2024

- Clarified what we need to buy new and put it in order.
- Then started to work on using servo with a small one that was found in the lab.
- Code written, just move servo 180 to the right and then back. Force sensor not incorporated yet
- Used arduino for this
- Realized servo was shaking when coming back from max rotation -> Fixed code
- Image of circuit with servo and arduino attached below
- 

October 22, 2024

- Goal: have circuit work with feather and incorporate button and force sensor
- Circuit attached below completed and functioning
- 

October 26, 2024

- Goals:
    - 1. Attach pulley to servo motor attachment
    - 2. Test servo strong enough to pull the wire to curl the fingers (test new servo)
    - 3. Attach 3 servo motors to the circuit
    - 4. Thimble to wire connection
- Saci expanded Lauren's one gear code to three. (Goal 3)
- Video of it working included in the drive. Image attached below. This is the new servo which works with the circuit. Computer was used as the battery. Unable to test because waiting for glue to dry
- 
- Attached thimble to wire with glue. Connection worked. (Goal 4)
- Attached pulley to servo motor attachment with glue. Connection worked and was strong enough. (Goal 1)

October 29, 2024

- Saci: Sketched out the board
- Lauren: Attempted to start soldering but ran out of time

November 2, 2024

- Saci/Lauren: Soldered board but did not work. trouble shoot on Nov 2/resolder everything

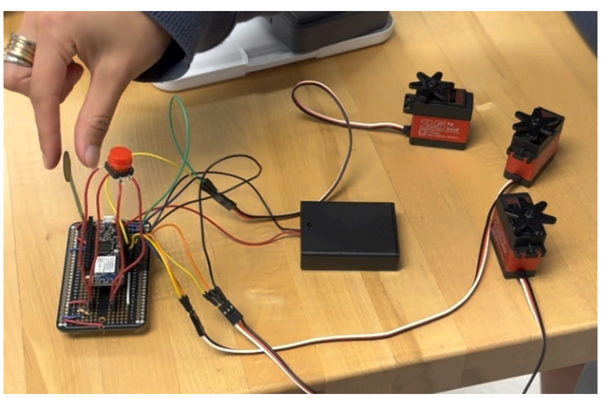
- Sandro: working on housing compartment

November 4, 2024
Checklist of what is left to do:

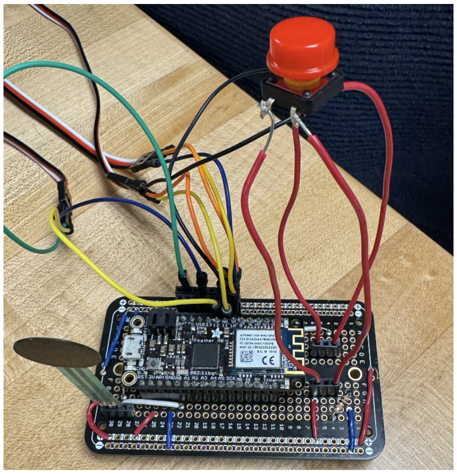
- [x] ~~Solder board correctly: how to attach the button? I think solder directly and have board be along housing box with button sticking out~~
- [x] ~~Give board to Sandro to finish the housing~~
- [ ] Figure out wire lengths
- [ ] Print housing
- [ ] Put everything into housing: do we need to buy a hip pouch or is velcro fine? Or Laurens pouch
- [ ] Reprint brace with small ports to glue wire sheath
- [ ] Mold brace
- [ ] Cut gears, attach wire to gear
- [ ] Cut wire
- [ ] Thread wire through brace, glue wire sheath
- [ ] Glue wire to thimble
- [ ] Glue attachment to gears
- [ ] Can a wooden hand be used as a model? If not, need alternative
- [ ] trace wire along body with velcro

What was completed?

- [x] ~~Solder board correctly: how to attach the button? I think solder directly and have board be along housing box with button sticking out~~
- [x] ~~Give board to Sandro to finish the housing~~

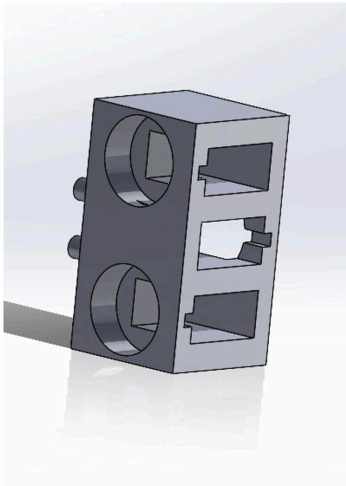


- Issue was that we needed to connect the ground to the other side ground. Easy fix!

- 
- Final circuit image
- Discussed how the housing should be done and modeled it with cardboard
-  
- Decided to print housing in two parts. Shelf part aim to be completed by tomorrow to be able to print

November 5, 2024

- [ ] Start housing print
- [ ] Start glove print
- [ ] Finish milling sketch to give to Jake tomorrow



November 6, 2024

- Meet with Jake to figure out milling of pulley
- Pick up prints

November 8, 2024

- Print of housing had wrong measurement so need to print again
- The hole for wires also closed up. Print ran again
- Give Jake pulleys so fix in the Baum Maker space

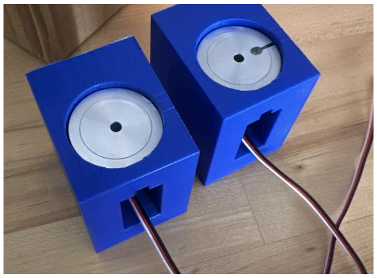
- Veteran's Day -

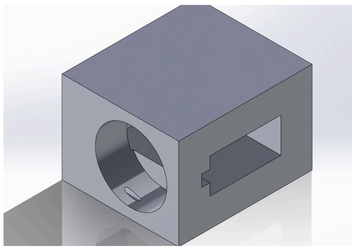
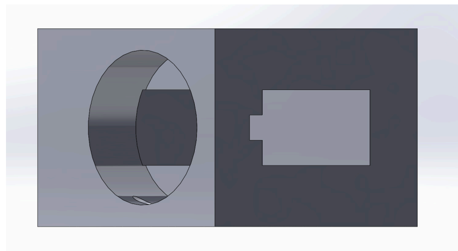
November 12, 2024

- Print of housing doesn't work again
- Decided to split up the housing print so each motor gets own housing so that the print will go faster and more efficient
- Printed housing for 1 servo
- Picked up pulley from Baum maker space
- 

November 13, 2024

- Housing print was successful
- Printed 2 more



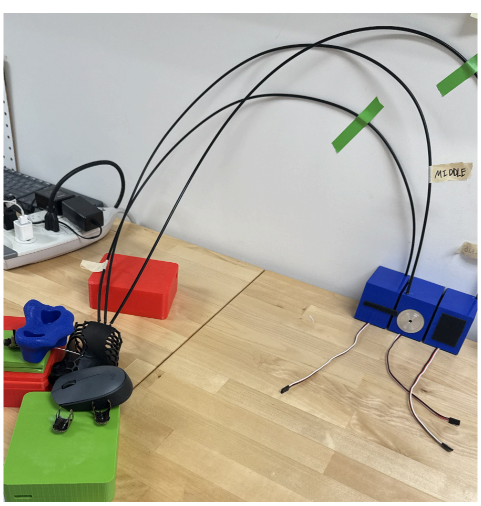
Final Week Timeline:
November 17, 2024 (Sunday)

- Glue wire into pulley
- Glue propeller to pulley
- Solder wires for battery
- Velcro housing together

November 18, 2024 (Monday)

- Glove print

November 19, 2024 (Tuesday)

- Mold glove to Saci hand/wooden
- Thread wire through brace, glue wire sheath
- Cut wire
- Measure out wire for force sensor
- Glue thimbles
- Glue sheath to brace
- 

November 20, 2024 (Wednesday)

- Test!!
- Debug anything, change angles that servos pulls
- finish the gluing

November 22, 2024 (Friday)

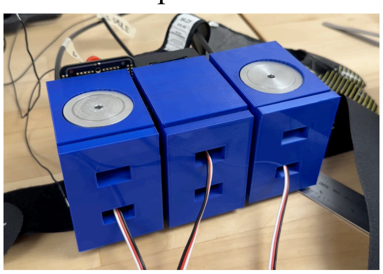
- Test and Film final video demo
- Velcro wires to wrap around arm

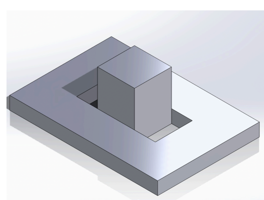
November 23, 2024 (Saturday)

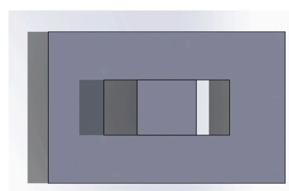
- Edit video and submit before deadline

November 25/26 (Monday and Tuesday before break)

- Housing lid printed x3
- Components attached by velcro and velcro belt made



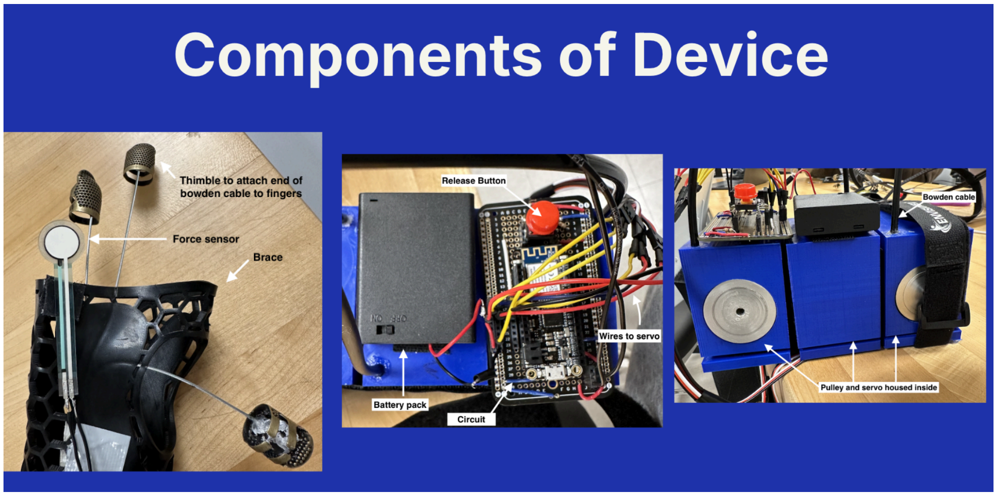




- Thanksgiving Break -

December 2, 2024

- Final test before presentation
- Make and finish presentation slides
- Last minute touches to make it more aesthetically pleasing (group wires together, cut wires, etc)



December 2, 2024

- Present ReFlex Glove in the lab!

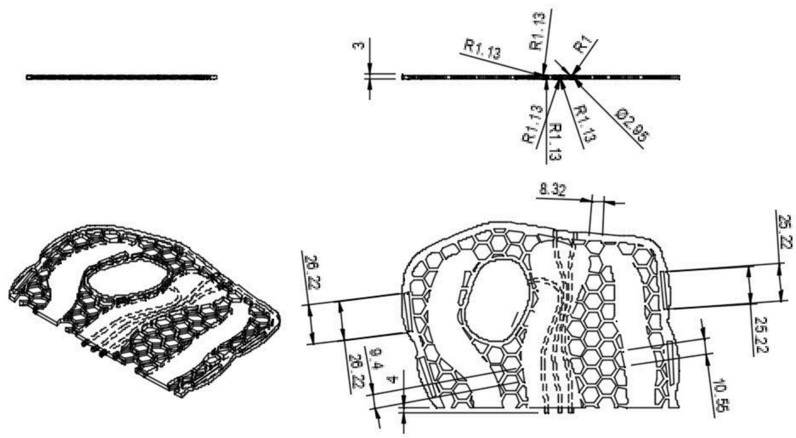
Rest of the week:

- Finish CDR and submit by Sunday
- Meet on Sunday to group edit

Data sheets of components used:
Adafruit microcontroller SAM D21 M0:
https://ww1.microchip.com/downloads/en/devicedoc/40001884a.pdf
Battery: https://data.energizer.com/pdfs/l92.pdf
Servo motor:
https://urgenexrc.com/products/25kg-high-torque-rc-servo-waterproof-servo-compatible-with-1-6-1-8-1-10-1-12-rc-car-full-metal-gear-steering-servo-with-25t-servo-horn-270
Force sensor:
https://cdn.sparkfun.com/assets/8/a/1/2/0/2010-10-26-DataSheet-FSR402-Layout2.pdf

Starter Code:
https://arduinogetstarted.com/tutorials/arduino-force-sensor
https://docs.arduino.cc/built-in-examples/digital/Button/

Drawing Files:



[redacted] [redacted]

[redacted]
Alessandro Tasso 12/9/24

[redacted]

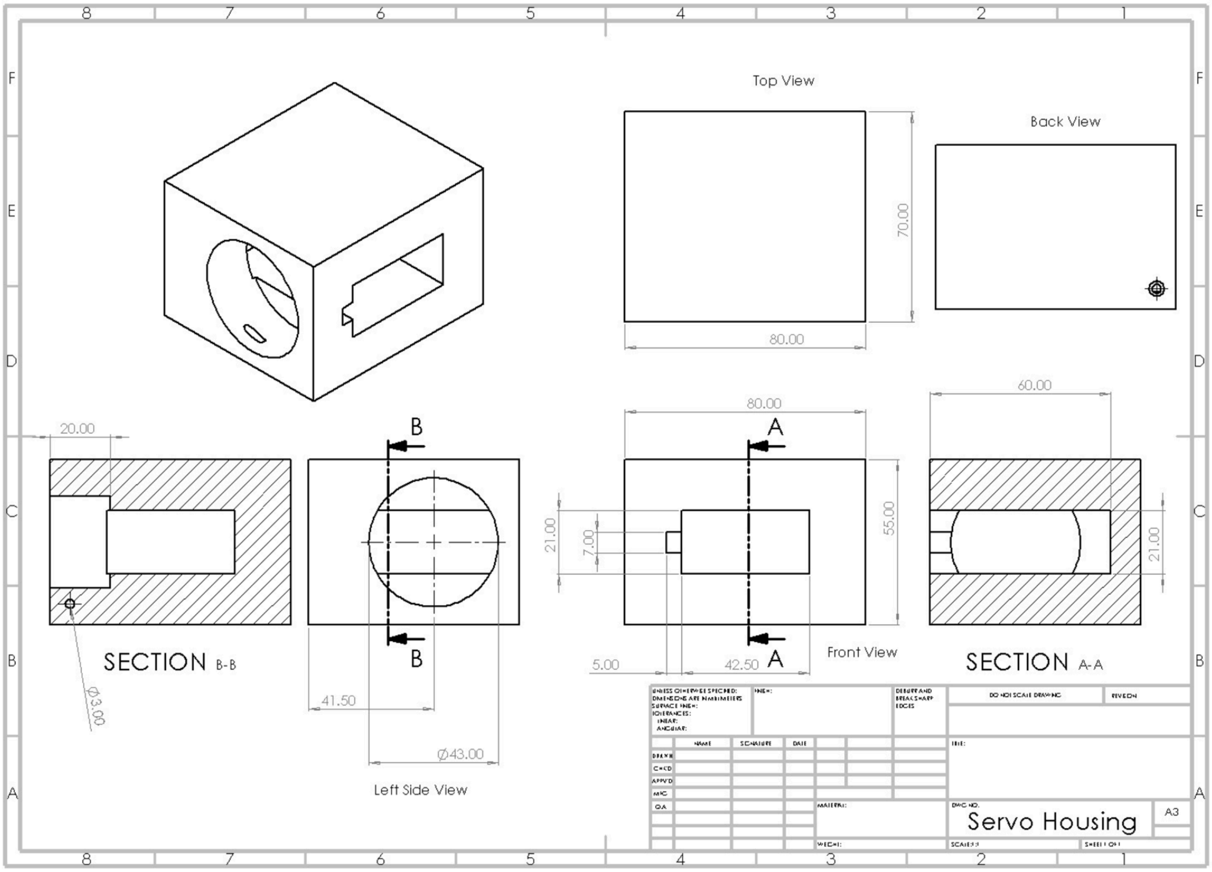
[redacted]

[redacted]

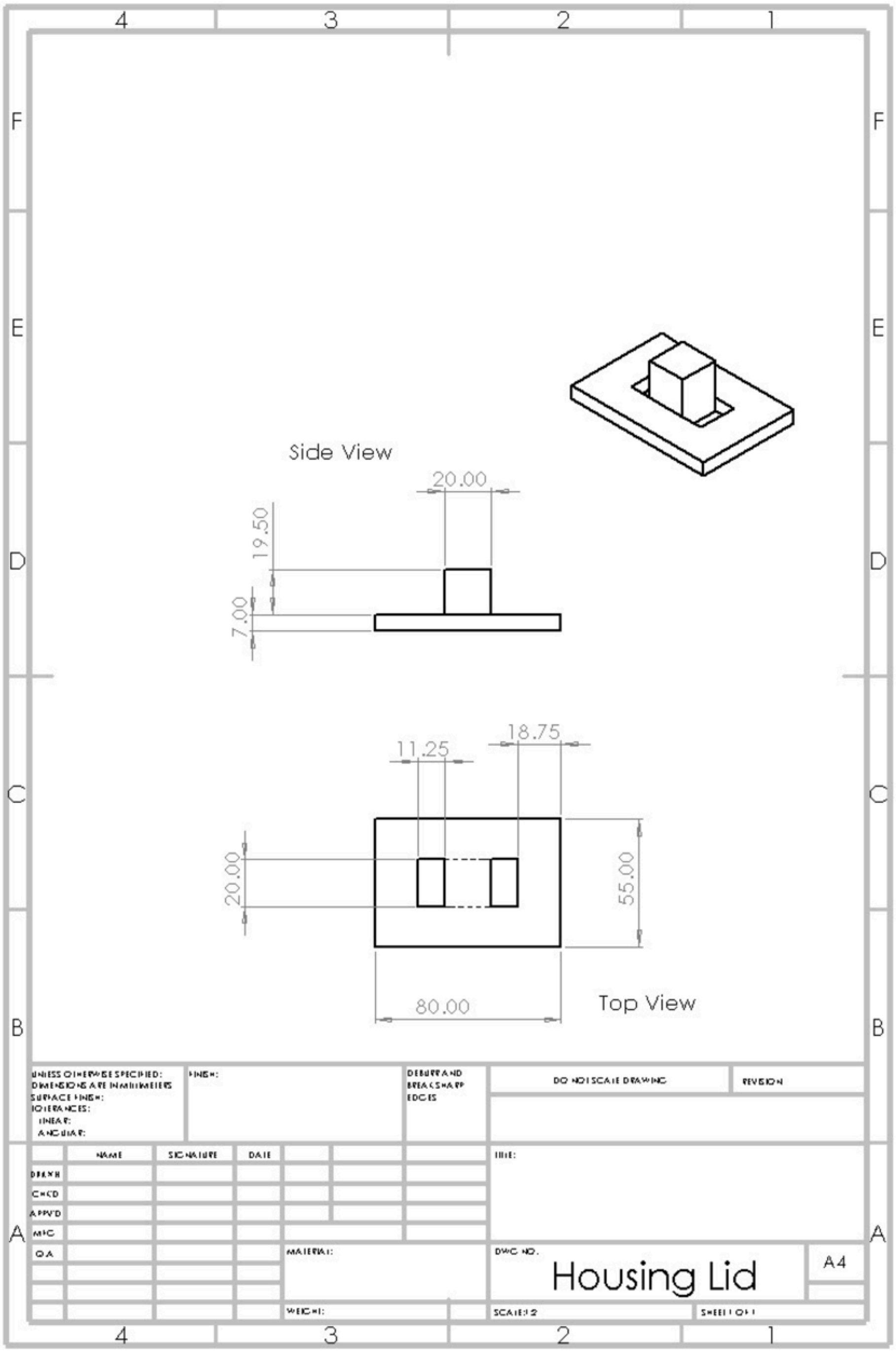
[redacted]
3-4 Wrist Brace NOV18

[redacted]

[redacted] [redacted] [redacted]
1/1



Top View
Back View
70.00
80.00
60.00
80.00
A
B
20.00
21.00
7.00
55.00
21.00
SECTION B-B
SECTION A-A
Front View
5.00
42.50
41.50
Ø3.00
Ø43.00
Left Side View
Servo Housing
A3



References:
[1] https://www.cdc.gov/stroke/data-research/facts-stats/index.html
[2] https://www.stroke.org/en/about-stroke/effects-of-stroke
[3] My grandmother (Christine Yoon) who underwent the stroke recovery process
[4] https://bmcneurol.biomedcentral.com/articles/10.1186/s12883-016-0733-x
[5] https://www.medicaljournals.se/jrm/content/html/10.2340/16501977-2530

[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9860207/
[7]
https://www.utmbhealth.com/services/neurology/procedures-conditions/stroke/stroke-facts#:~:text=Stroke%20is%20the%205th,stroke%20survivors%20in%20the%20U.S.
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