Remotely Adjustable Cast
Design Document

ECE 445 Senior Design

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1 Introduction

1.1 Problem

For broken limbs, there are a couple types of casts: plaster, fiberglass, splint, AirCast. And while each type of cast has its own benefits, each one also has drawbacks. The non-AirCast casts are traditional since they are very durable, but they are also heavy, not removable (so they can get mold), and require doctor visits in order to monitor healing progress and to change the cast.

AirCasts are newer on the market since they address the problems of traditional casts. AirCasts are lighter and removable which gives more freedom and mobility to patients, but due to that, they are hard to properly put back on by the patient. They can also be more expensive sometimes. At the moment, patients with AirCasts do not have a way of adjusting the cast back to the doctor set strap tightness as done by the doctor.

We will build a remotely adjustable air cast for patients who wear a cast.

My customer has a problem with improper adjustment of air casts after removable which affects how they heal.

My product solves my customer's problem by returning the cast to the doctor-adjusted settings, so the cast is properly fitted even after removal.

1.2 Solution

We would like to create an AirCast that is auto-adjustable which would address some of the problems with the AirCast and traditional casts. Essentially, the AirCast boot will have automatic strap tightening (and air cell inflation as a stretch goal) which will make the cast removable, allow the patient to wear the AirCast properly for healing, and decrease in-person doctor visits.

After a patient removes the cast, the patient is able to bring the cast back to the position given by their doctors using an app which records the strap tension and air cell pressure set by the doctor. The self-removal of the cast allows the user to wash their broken limb which prevents mold from growing in the cast. Additionally, doctors do not need to see patients each time the patient's cast adjustment is changed/misplaced. There is the opportunity for telehealth visits in order to rehabilitate the patient since the cast can be adjusted remotely and just record new air cell inflation and strap tightness. Additionally, the auto-adjustment capabilities will improve the patient's and doctor's experience by allowing for more accurate treatment through the addition of pressure and force sensors to the cast.

1.3 Visual Aid

Figure 1: Solution Concept (Visualized)

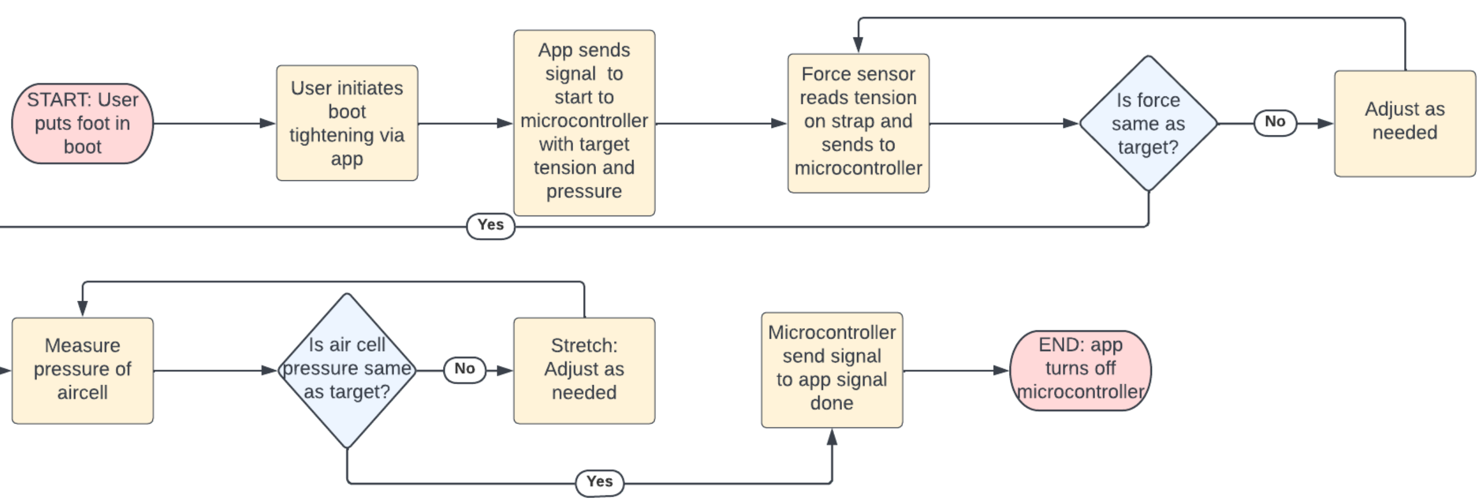

Figure 2: Boot Logic Flowchart

1.4 High Level Requirements

- The cast's straps are adjusted/tightened per doctor's settings without manual adjustment
- The doctor's cast adjustments for pressure and tightness can be stored
- All necessary components for auto-adjustment of the cast fit on the cast without extreme addition to the original weight of the cast (less than double (goal to have additional components (not boot) be less than 1lb))

2 Design

2.1 Block Diagram

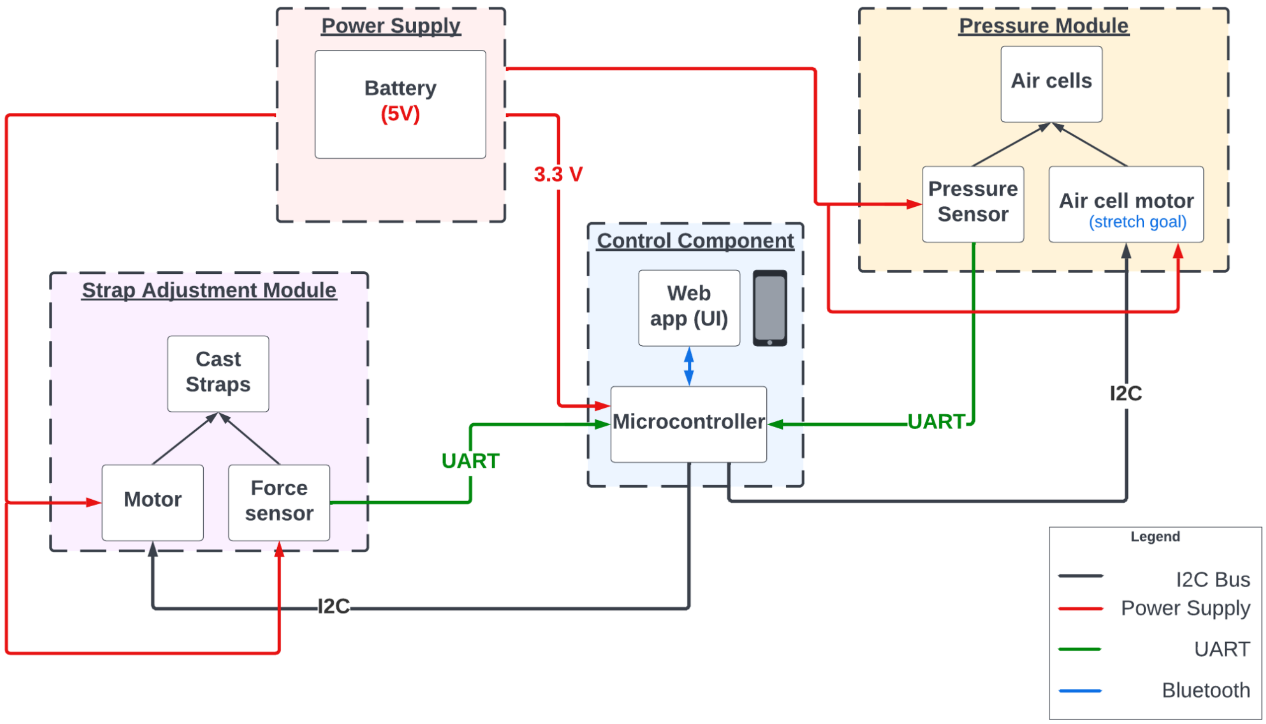

Figure 3: Block Diagram

2.2 Requirements and Verification Tables

A. Control Component

The microcontroller chosen, an ESP32, will communicate with the bluetooth chip, force sensor for the strap adjustment module, and pressure sensor for the pressure module via UART interfaces. Additionally, the microcontroller should send signals to the motor for the strap adjustment module via I2C bus, and receive sensor readings from the force and pressure sensors via UART as well.

Requirement	Verification
Microcontroller implements control system for the motor of the strap adjustment module by taking inputs from force sensors and outputting motor speed. Microcontroller also translates pressure data to the web interface telling the user if they need to pump the air cell more.	If the bluetooth functionality of the microcontroller is enabled, the proper sensor readings from the pressure sensor and force sensors will be displayed on the web application after being read by the microcontroller. The measured force and pressure readings displayed on the app will match doctor prescription.
Microcontroller must be able to interface with a web application via Bluetooth.	Controls enabled on the developed web application are able to properly change functionality of the microcontroller, and therefore of the strap adjustment and pressure modules as intended.

B. Pressure Module

The pressure module will sense the air pressure inside of the air cells via a SEN-09376 barometric pressure pad sensor between the air cell and the wall of the boot. The force exerted on the pressure pad gives us a sense of how inflated our air cells are. The pressure on the pressure pad will be communicated to the microcontroller. If the stretch goal is hit it will also automatically fill the air cells up until it has reached the prescribed pressure (controlled by microcontroller).

Requirement	Verification
Pressure pad sensor must be able to indicate to the user when they have inflated/deflated the air cells to the intended pressure, while staying within 10-20 mmHg of the local environment pressure value such that the user's blood circulation is not cut off.	When the user views the web application, they should be able to view the correct pressure value of the air cells such that as they inflate/deflate the air cells using the included pump, the reported value in the front-end interface displays the value changing accordingly, and a warning is shown to users if the pressure value reaches 20 mmHg above the local environmental pressure value. The local environmental pressure value will be measured by a separate pressure sensor located directly mounted on pcb.

C. Strap Adjustment Module

The strap adjustment module should be able to utilize a force sensor to find the tension of the straps on the cast, and communicate this tension reading with the microcontroller. The microcontroller should in turn communicate back with the motor in this module to properly adjust the straps based on the force read, and strap tightening necessary based on the stored strap adjustment value.

Requirement	**Verification**
The tension of the straps must be able to be calculated such that the motor runs until the calculated tension value is within the prescribed value ± 3N (estimated maximum value will be ~26N)	When the intended torque is applied to the strap of the boot via the stepper motor at a given angle, the microcontroller receives the tension read by the force sensor and stops the motor when the prescribed tension is reached, while displaying a reading that is accurate to this tension value. The maximum possible value displayed should be no more than 26N according to the maximum torque provided by the motor (~0.8 N*m) at the angle the motor will be pulling the strap at (12°).
Motor must be able to be toggled on/off by receiving a signal from the I2C bus from the microcontroller.	Utilizing the Arduino IDE compatible with the ESP32 microcontroller, the microcontroller is programmed to control the motor, such that a specific command leads to the motor speed changing from 0 to a value > 0.

D. Power Subsystem

The power supply chosen must be able to power the microcontroller as well as the pressure and strap adjustment modules. Additionally, the power supply should be easily rechargeable by the user and be placed in a safe location on the boot where physical damage cannot come easily.

Requirement	**Verification**
Power must not exceed 3.6V ± 0.3V when feeding into the microcontroller	Measure voltage going into the microcontroller at different power supply charges to make sure this is always true
Must be able to power all chips on the board and the adjustment modules	Measure voltage input to all parts that receive power from the power supply & make sure all receive enough power to function based on data sheets

E. Tolerance Analysis

a. Strap Adjustment Module Tolerances

A block that can pose difficulty to our project is the strap adjustment module. One of the main risks of this module is the actual strap tightening via the motor. There are many things that may prevent proper tightening such as the strap becoming detached from the motor but the main thing is that the motor needs to be strong enough to pull the strap to the correct tension. Unfortunately, not much information is available regarding the force required to tighten air casts (or even for shoe laces). We plan to follow a resource found through Instructables [2] for a strap adjustment method using a stepper motor.

We want to use the Nema 14 Stepper Motor (found in our parts list) which has a torque of 0.8 N*m and can utilize our 5V power source, and let's assume that we want to tighten the strap to about 6 lbs of tension on the strap (which is equivalent to ~26.6 N of tension on the strap). Using the force to torque conversion equation $\tau = r * F * sin(\Theta)$ where τ is the torque necessary, r is the radius/distance of the radial arm, F is the force we desire (about 26.6 N), and Θ is our angle between force and radial arm (approximately 12°). We want our radial arm to be the width of the boot since we want the our boot/strap system to look like so:

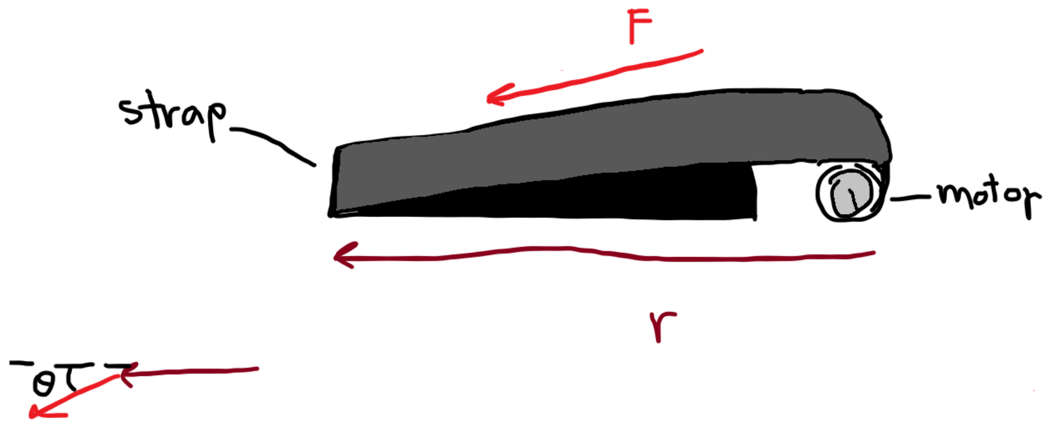

Figure 4: Strap Adjustment Diagram

Therefore, we want our radial arm to be equal to about 5 inches (or 12.7 cm). After plugging everything into the equation, we find that $\tau \geq 0.7\, N * m$. Therefore, assuming we need around 6 lbs to tighten the strap and the length of the strap is around 5 inches, the motor we have chosen will work for tightening the strap. If upon further testing we discover that the strap needs more tension to be properly tightened (which will only be known once we receive the boot), then we will have to reevaluate the motor necessary for this project and find one that can provide more torque. We will use Figures 5 and 6 in order to figure out how to achieve the necessary torque if the radius or angle possible changes based on our boot. This is important as if we cannot adjust the straps using the motor, then our project will not meet our main intended functionality.

b. Pressure Module Tolerances (Stretch)

Instructions for casts are to tighten them until they are taut but not so tight that they cause issues such as restricting blood flow. According to a study by H.V. Nielsen relating external pressure and blood flow, it was found that inflating a compression cuff around a limb to be 10-20 mmHg above the local pressure level restricted blood flow. This means that the pressure module should not allow the air cells to exceed 10 mmHg of the local pressure level. One possible barometric pressure sensor we could use ICP 10100) has operating ranges of 225~825 mmHg. Given that the highest barometric pressure ever recorded is 813.05 mmHG in Agata, Russia on December 31, 1968, the ICP101000 will be capable of operating within tolerance even if it was experiencing the highest ever recorded barometric pressure level ever recorded to this date. For a more realistic example, the highest barometric pressure recorded today (09/15/2022) was around 771 mmHg. This barometric pressure level is well within tolerances showing that our product is capable of handling the most extreme situations and on average days will work well within pressure tolerances, even in the cities with the highest barometric pressure levels.

c. Plots

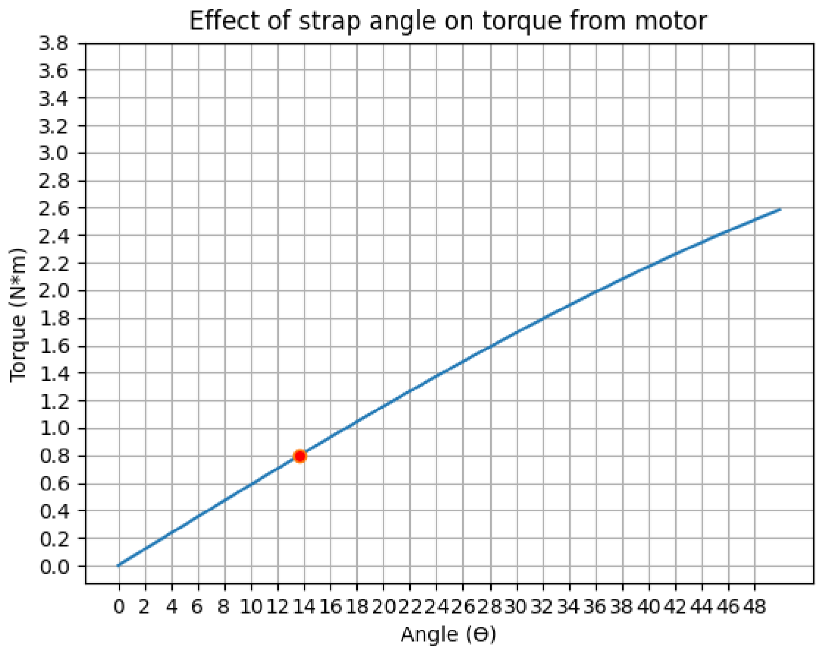

Figure 5: Plot of Angle Θ vs *Tension* τ *and maximum torque provided by motor 0.8 N*m at 13.7 degrees*

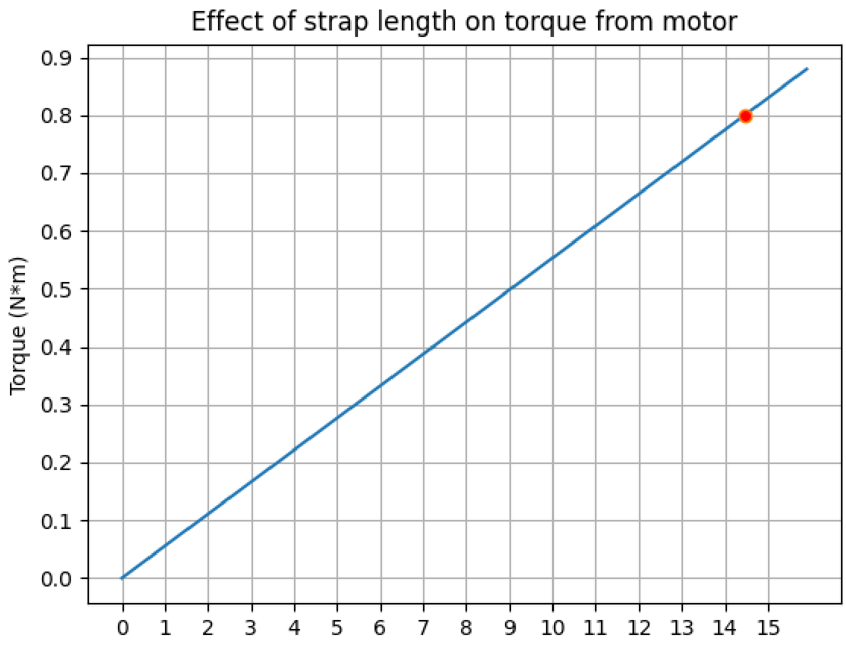

Figure 6: Plot of Radius r vs *Tension τ and maximum torque provided by motor 0.8 N*m at 14.46 cm*

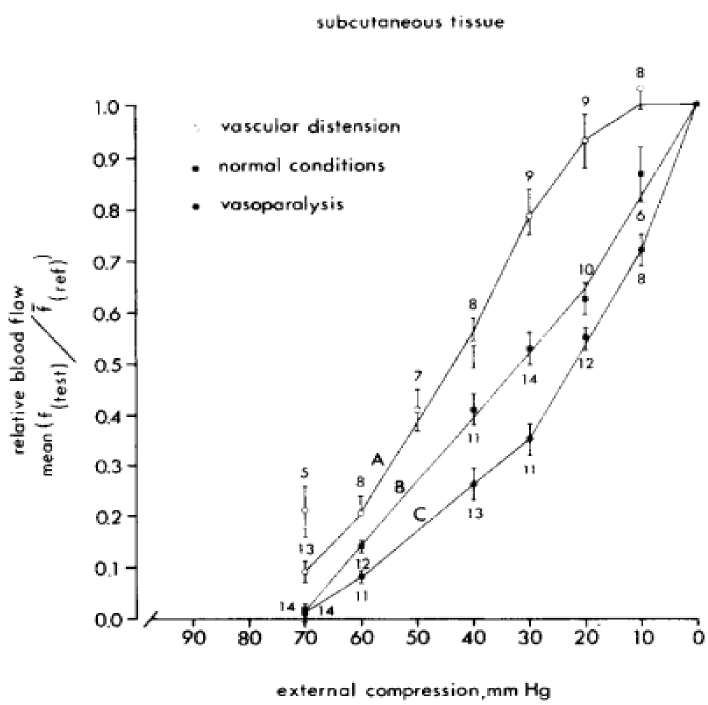

Figure 7: Plot of relative blood flow vs pressure of compression [4]

F. Circuit Schematics

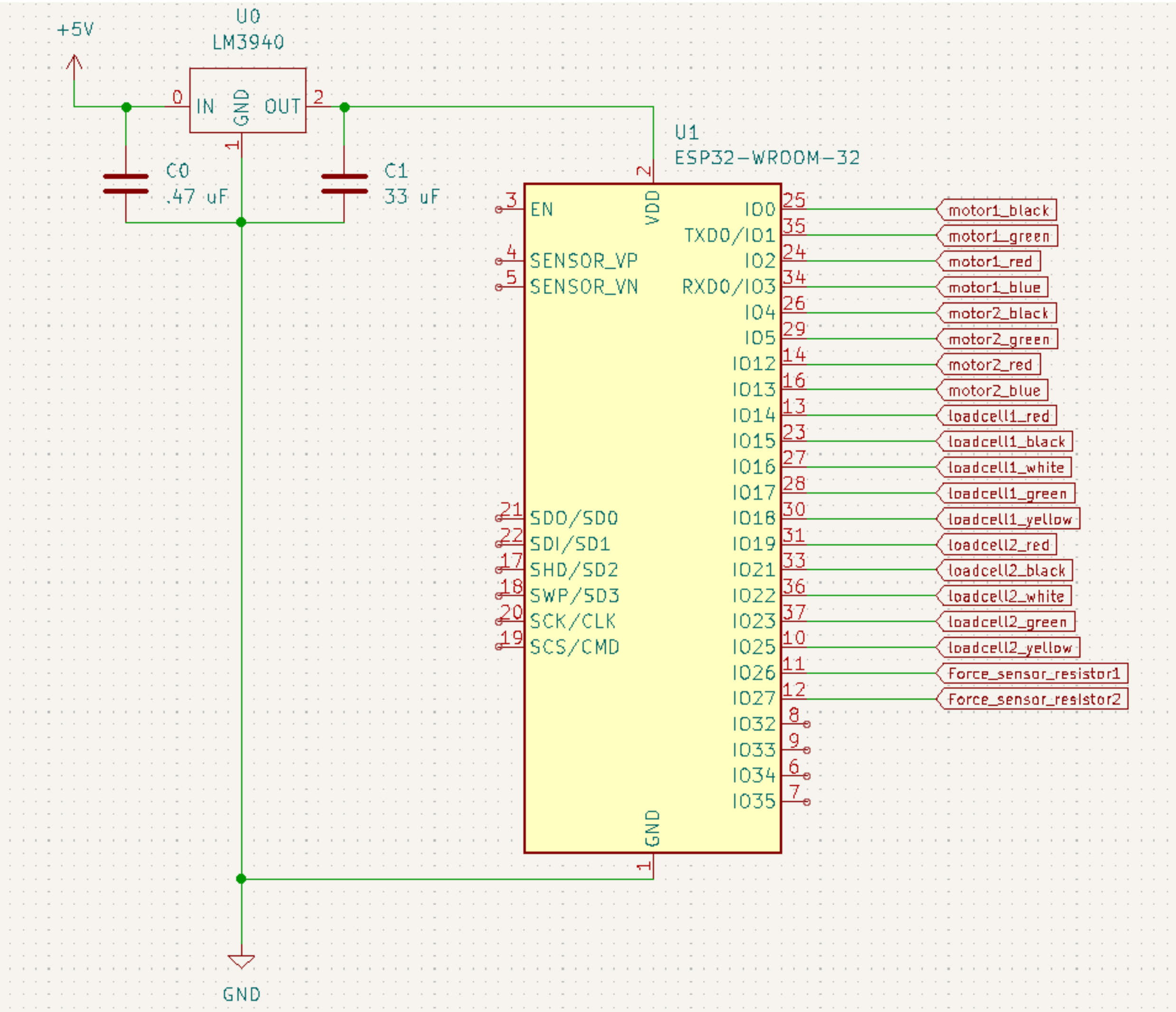

Figure 8: An esp32 is hooked up to 3.3 volt output of voltage regulator. The io ports of the esp32 are controlling 2 stepper motors, taking inputs from two load cells and two force sensing resistors.

3 Cost & Schedule

3.1 Cost Analysis

Description	**Manufacturer**	**Price**	**Link**
AirCast	DJO Global	$13.37 - shipping, already owned	Link
ESP32 MCU Module	Adafruit	$8.95	Link
Nema 14 Stepper Motor (may try to find alternatives already owned by ECE 445 lab)	STEPPERONLINE	$16.57	Link
SEN-09376 ROHS Pressure Pad Sensor	Sparkfun	$12.50 (x2)	Link
USB Battery Pack	Adafruit	$39.95	Link
Motor Mount (may try to find alternatives already owned by ECE 445 lab)	Adafruit	$8.95	Link
Force Sensor - SEN-10245 (however might decide to use torque on motor in order to calculate tension on strap instead)	Digi-Key	$4.50	Link
Linear Voltage Regulator - LM3940IT-3.3	Digi-Key	$2.63	Link
WH-10 Hinged NEMA Enclosure	PolyCase	$16.12	Link
ISDCB812 - Ribbon Wires	Digi-Key	$13.33 (x4)	Link

The total part cost for this project is $189.36. Assuming a wage of $40/hour for each of our team members, the total salary for each team member will be = $40/hour * 2.5 * 80 hours = $8,000. So the total labor cost for this project will be $8,000/team member * 3 team members = $24,000 total labor cost. The total cost of this project comes out to $24,189.36.

3.2 Team Schedule

Week	Task	Person
September 25 - 30	Talk with ECE Machine Shop about motors for strap adjustment and placement	Everyone
	Begin PCB design (list of components needed on board)	Alice + Saloni
	Sensor data ↔ microcontroller transmission design	Jack
	Complete Design Document	Everyone
October 3 - 7	Continue PCB design (& PCB Board Review)	Alice + Saloni
	Design Review with Instructor & TAs	Everyone
	Start designing strap adjustment module with motors and sensor data readings	Jack
	Soldering Assignment	Individual - Everyone
October 10 - 14	Place PCBway Orders (Need to pass audit by 10/11)	Everyone
	Teamwork Evaluation I	Everyone
	Visit Machine Shop (Revisions)	Everyone
October 17 - 28	Keep track of PCB order	Everyone
	Continue strap adjustment module with motors + Sensor data testing	Alice + Saloni
	Begin pressure sensor module sensor testing	Jack
October 31 - November 4	2nd Round PCBway order (Need to pass audit by 11/1)	Everyone
	Work on PCB and other modules	Everyone
	Individual Progress Reports	Individual - Everyone

November 7 - 11	Work on PCB board	Alice + Saloni
	Finalize strap adjustment and pressure subsystems	Jack
November 14 - 18	Finalize PCB board and all subsystems	Everyone
	Mock Demo to TA	Everyone
November 21 - 25	FALL BREAK	N/A
November 28 - December 2	Final Demo to Instructor and TAs	Everyone
December 5 - 9	Final Presentation	Everyone
	Complete Final Papers	Everyone
	Complete Lab checkout + Lab Notebook	Everyone
	Final teamwork evaluation	Everyone

4 Ethics & Safety

4.1 Ethics

In section I and II of the IEEE Code of Ethics [5], it says we must hold paramount the health and safety of the public and disclose any factors that might endanger the public as well as not cause harm to others. Given that our product is a health care product, it is imperative that it works as intended and will not cause any harm to the users of the product. One potential ethical concern related to the product malfunctioning, is the product being improperly adjusted and causing more harm than good to the user, and potentially extending the recovery time necessary. To mitigate this issue, it is very important to disclose any parts of the product that could, if they malfunction, cause any harm. In addition, this will be addressed by ensuring the strap adjustment and pressure modules function as intended prior to release for patient use of the product.

Section I also mentions that it is important to consider all of the societal implications that a new innovation may have on the public. While ideally our product only has positive societal impact where it provides the public with a better cast experience getting better care than with any other type of cast, it is unrealistic to expect that will be the case. One factor to consider is price and how adding more technology to a cast like this will raise the cost of the cast and patients that are prescribed the use of this cast will have to pay more to get the treatment they need. It also must be shown that recovery with this cast will be better than recovery with other casts (measured by some metrics for example, timeline or strength of injured area). If this is not the case then adding this extra technology is only adding extra unnecessary costs to patients.

In section I of the IEEE Code of Ethics [5], it is stated that in order to commit ourselves to uphold the highest ethical and professional conduct, we must ensure that we are protecting others' privacy. In this case, we must ensure to protect the data privacy of the users of the adjustable cast, as data regarding users' adjustments and pressure level will need to be stored in the frontend portion of the project. In order to combat this, we will need to instill a process of acquiring permission from the physician/doctor of the patient to release this data to the patient, as well as permission from the patient for their data to be stored within the application. This way, we are doing our best to uphold the highest ethical conduct according to the IEEE Code of Ethics by protecting the privacy of the users.

When it comes to testing out our product it will be necessary to test on humans since that is going to be the user of the product. In order to be able to test on humans you must get approval from an IRB (Institutional Review Board). We would need to get premarket approval of medical devices, via a premarket approval application

4.2 Safety

In terms of safety, there are 2 main points of concern: battery usage and wrong boot adjustment. Since our boot is intended to be worn by the user throughout the day, we require a portable battery pack so that the user doesn't have to plug their boot into a power source each time they want to put on the boot again. This also means that the portable battery source should be placed in an area of the boot so that physical damage cannot come to it from user movement and possibly external obstacles, as much as possible. Also, we have to consider using a power source powered by commercially available replaceable batteries (such as AA or AAA) or using a rechargeable battery pack (like a phone power bank). We have decided to use the rechargeable battery pack (see parts list for model) since that allows us to embed the battery pack and gets rid of any need to remove the battery pack or do anything that could potentially bring misuse and danger to the user outside of charging with a traditional micro-USB. This is also intended to avoid constructing our own power circuits which can introduce more error than using a commercially available rechargeable battery pack and also to prevent lab dangers which can arise when constructing power limiting or recharging circuits, as per the General Battery Safety document.

Our other safety concern is to the user in which the boot sensors could potentially malfunction and improperly adjust the boot. For example, there is the chance that the boot could tighten too much and hurt the user or it could adjust too loosely which could create an improper fitting boot which could cause the user to further injure their foot. Thankfully, this seems like more of a software problem since we are going to be using sensors (pressure and force) to decide whether or not to further inflate the air cell or tighten the straps. If we were to use quantities rather than using sensors (for example, if we decided to adjust the strap by X amount of inches after an initial sensor reading versus needing to adjust to Y force applied by the strap), that could cause improper adjustment. Additionally, our motors will not be able to provide enough tension on the straps to injure the foot, so that risk is mitigated. We plan to continuously measure the tension on the strap while adjusting until we reach the intended tension. The same goes for the air cell pressure. This is intended to mitigate the risk of improper tightening and to have the most accurate adjustment.

There aren't mechanical safety concerns to the users, but for our group, we plan to mitigate those by following Lab Safety Guidelines and not being alone in the lab.

5 Citations

[1] "Air Cast Vs. Plaster". *Healthfully*. [Online]. Available: https://healthfully.com/air-cast-vs-plaster-6618746.html (August 24, 2022).

[2] "AutoStrap - a Self Tightening Strap". *Instructables*. [Online]. Available: https://www.instructables.com/AutoStrap-a-Self-Tightening-Strap/ (September 6, 2022).

[3] "Cities with the Highest Barometric Pressure Today". *Barometric Pressure App*. [Online]. Available: https://barometricpressure.app/leaderboards/highest-barometric-pressure (September 15, 2022).

[4] H.V. Nielsen. "External pressure – blood flow relations during limb compression in man." *National Library of Medicine*. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/6659990/ (September 15, 2022).

[5] "IEEE Code of Ethics." *IEEE*. [Online]. Available: https://www.ieee.org/about/corporate/governance/p7-8.html (September 7, 2022).

[6] "PART 814 - PREMARKET APPROVAL OF MEDICAL DEVICES". *Code of Federal Regulations*. [Online]. Available: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-814 (September 7, 2022).

[7] "Plaster or Fiberglass? A Guide to Casts". *Healthline*. [Online]. Available: https://www.healthline.com/health/types-of-casts (August 24, 2022).