# Stimdia Medical: Patient Diaphragmatic Effort Lung Simulator
## BME 200/300
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**Client:** Stimdia Medical

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## Abstract

Mechanical ventilation (MV) is an extremely common medical procedure both in the U.S. and abroad. Unfortunately, many patients have a difficult time weaning from the ventilator, resulting in prolonged periods of MV. These patients in particular are at high risk for ventilator-induced diaphragm dysfunction (VIDD). Stimdia Medical's pdSTIM phrenic nerve stimulator aims to alleviate VIDD by stimulating the phrenic nerve to contract the diaphragm. Their current system works with patients who cannot produce any effort, but will not accommodate patients who can produce some effort under their own power. They tasked this BME 200/300 group with modifying a Michigan Instruments Test Lung to expand and contract under the power of a motor to simulate full or partial diaphragm contraction. The team designed and fabricated a functioning system to simulate patient effort. Testing showed this system is strong enough to produce the maximum desired pressure in the test lung, but it is inaccurate at doing so. A handful of sources of error were identified and the team feels confident that fixing these errors would result in the creation of a sufficiently accurate testing apparatus.

# Table of Contents

# I.   Introduction

## Motivation

Up to 20 million patients per year require mechanical ventilation (MV) globally [1]. This number has risen in the past decade as worldwide life expectancy has increased, and it is only expected to increase further in the coming decade [2]. While lifesaving, MV can be problematic for the 20% of patients who require a prolonged period of time to wean from the ventilator [3]. One issue patients face is cost. While healthcare costs vary widely both within and outside the United States, it was found that American patients who needed MV faced significantly higher costs than those who did not [4]. Consequently, reducing weaning time would also reduce patient healthcare expenses. Furthermore, patients who take longer to wean also risk diaphragmatic atrophy. A 2008 study showed that the diaphragm atrophies rapidly, in as little as 18 hours, when not used due to proteolysis in diaphragm fibers [5]. For this reason, Stimdia Medical is working on their pdSTIM system, a phrenic nerve stimulator that aims to reduce ventilator-induced diaphragm dysfunction (VIDD). This device operates by delivering an electrical stimulus to the phrenic nerve to contract the diaphragm, which has been proven to prevent or reverse VIDD [6,7]. Currently, the pdSTIM system works with patients who cannot produce any effort, or diaphragm contraction, during MV. To build a more complete product, Stimdia wants to make their product compatible with patients who can produce limited diaphragmatic effort. By modifying their Michigan Instruments Test Lung to expand and contract under the control of a motor, the group will model patient diaphragmatic effort so that Stimdia Medical can make an improved pdSTIM system that will solve the problems many patients face with MV.

## Competing Designs

There are currently no existing devices that both simulate a human lung and model the effort they can produce. However, there are similar devices to the Michigan Instruments Test Lung that the team will be using.



**Figure 1.** An image of the Michigan Instruments Test Lung with its case

This image shows the lung housed in its case. Unlike the InGar Medical Quicklung Breather or their ASL 5000 breathing simulator, the Michigan Instruments lung will be useful for the project because its lung volume and compliance can be manually adjusted [8]. These other test lungs are made for different purposes than engineering medical devices, like medical training or ventilator testing. However, there is an existing patent for a ventilating apparatus that includes mechanisms that could be useful in this project.
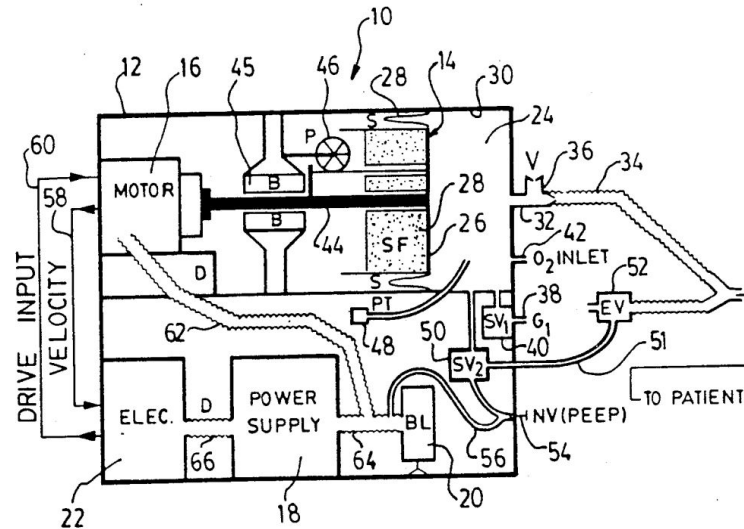


**Figure 2.** A schematic for a lung ventilator device

The above **Fig. 2** shows a diagram for U.S. Patent number 5,044,362 [9]. This lung ventilator device aims to deliver an air-gas mixture by the control of an electric motor actuated piston. Although the design for this project does not involve delivering air, this patent is useful because it shows how an electric motor can be driven by a breath waveform signal to create pressure, as must be done in this project. Also, there are competing phrenic nerve stimulators on the market that are worth noting.



**Figure 3.** An image of the receiver, electrode, and antenna for Avery Biomedical's Mark IV Diaphragm Pacing System

As shown above, Avery Biomedical's Mark IV Diaphragm Pacing System is similar to the pdSTIm system in that they both are used to stimulate the phrenic nerve. However, the pdSTIM system is specifically designed with electrodes that are not implantable and are easily removable so they can be used for MV. On the other hand, Avery's system is implantable and is geared towards assisting patients with spinal cord injury or central sleep apnea [10]. In summary, there are other phrenic nerve stimulators out there, like the Synapse Biomedical NeuRx or Atrotech OY's Atrostim PNS, but they must be implanted and are geared toward treating diseases other than VIDD [11].

## Problem Statement

At this moment, lung simulators cannot model patient effort during MV, which is problematic because some patients can produce limited diaphragmatic effort. Using a phrenic nerve stimulator that does not account for this patient effort could have disastrous consequences. Therefore, the team is tasked with modifying a commercially available lung simulator so that patient effort may be controlled and used to influence future designs of the pdSTIM system.

# II.   Background

## Biology and Physiology

The diaphragm is a dome-shaped muscle that acts under voluntary or involuntary control, and it separates the chest cavity from the abdominal cavity. While intercostal, abdominal, and neck and collarbone muscles aid breathing to an extent, the diaphragm is the primary muscle involved in expanding and contracting one's lungs. During inhalation, the diaphragm contracts and moves downwards so that the lungs can expand and create vacuum pressure to draw in air. During exhalation, the diaphragm relaxes and the lungs constrict, forcing air outwards [12]. In an average, healthy person the diaphragm can create pressures of up to $\pm100$ cmH$_2$O, but the typical resting pressure only reaches about $\pm10$ cmH$_2$O [13,14].

The phrenic nerve originates somewhere between vertebrae C3 to C5, depending on the individual. There is a left and a right phrenic nerve. Emerging from the spinal cord, the nerves then travel inferiorly past the lungs and the heart where they terminate at the central tendon of the diaphragm. The nerves provide motor innervation to the entire diaphragm and sensory innervation to the central tendon [15].

Proteolysis, or the enzymatic breakdown of proteins, has been observed to occur in the myofibers of human diaphragms after as little as 18 hours of disuse. Other diaphragm-weakening factors that result from disuse include decreased protein transcription, increased oxidative stress, and mitochondrial dysfunction [16,17]. These events cause the diaphragm to atrophy, resulting in decreased diaphragmatic force output, which can be problematic for those who need to get off of a ventilator [5]. Fortunately, phrenic nerve stimulation has been shown to decrease or eliminate the adverse effects of MV [7]. A 2013 study found suppressed IGF-1 transcription, which is an important hormone for growth and development. After phrenic nerve stimulation, diaphragm function was restored and the study cited restored IGF-1 transcription as a possible reason for this effect [6]. Regardless of the mechanism, phrenic nerve stimulation has been shown multiple times to eliminate VIDD in MV patients.

# Design Research

The task the team needed to accomplish was to raise and lower the bellows of a mechanical lung in a controlled fashion. Under the guidance of Stimdia Medical and U.S. Patent 5,044,362, to use a DC motor, current controller, and Simulink program to achieve this goal.
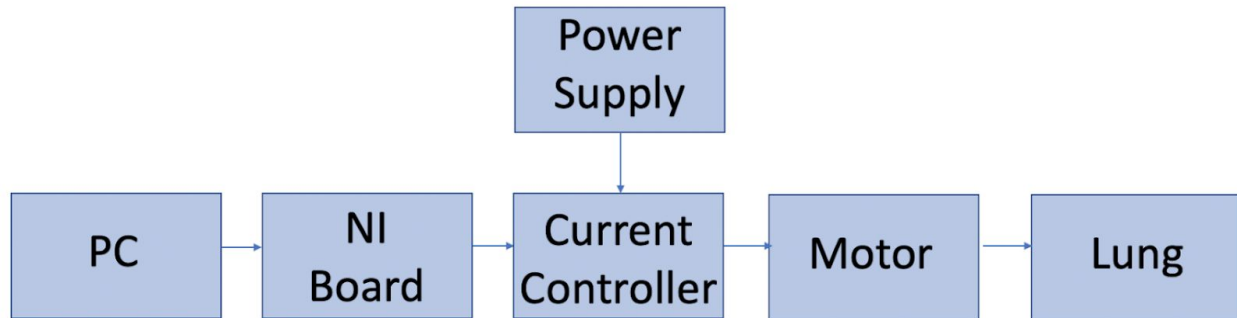


**Figure 4.** A block flow diagram showing the basic setup of the design

As **Fig. 4** shows, the general outline of the design was laid out. Then, the next step was to select the exact components to use in this design. Starting with the lung and working backward, components were chosen.

**Lung**



**Figure 5.** An image showing how the maximum required force was found

Given that part of the design criteria was the ability of the design to be able to generate a vacuum pressure of up to 50 cmH$_2$O, the team first needed to calculate how much force would be required to do this at the lowest compliance, or the most extreme case. **Fig. 5** shows how a force gauge attached to the test lung was used in combination with a manometer (bottom left) to measure the maximum force that was required from the motor.

### Motor

The type of motor the team selected was a high torque, low speed motor DC motor. DC motors use magnetic fields to generate a desired torque [18]. The generated torque is proportional to the current supplied to the motor, and desired breath waveforms can be generated by varying the current supplied [19]. The type of DC motor that the team selected is the Haydon Kerk Brush DC Motor (Product number: ID33005-SP) because, after converting the required force to a torque, it has a torque-to-current ratio ($K_T$) that fits the needs of this project [20]. Also, the motor will need to connect to the lung bellows in some way. As the proposed final design describes, this will be done through a tension cable. The team planned to use a cable that can withstand a tension of 200N because that is greater than the maximum force required to raise the lung by 50N. In the end, the team ended up purchasing rope the cheapest rope from Home Depot that could sustain this load.

### Current Controller

Next, working backward from the motor, is the current controller that converts an analog signal into one that is usable for a motor. Stimdia selected Servo2Go's AZ12A8 controller because it is designed for brushed DC motors, is well protected against over-voltage and over-current, and is relatively easy to integrate into a circuit [21]. Additionally, it only requires a 20V, 10A power supply which is not too extreme.

### Power Supply

To power the current controller, a power supply was required. The team used the Dr. Meter 30V, 10A power supply because it is capable of meeting the power requirements of the current controller [22].
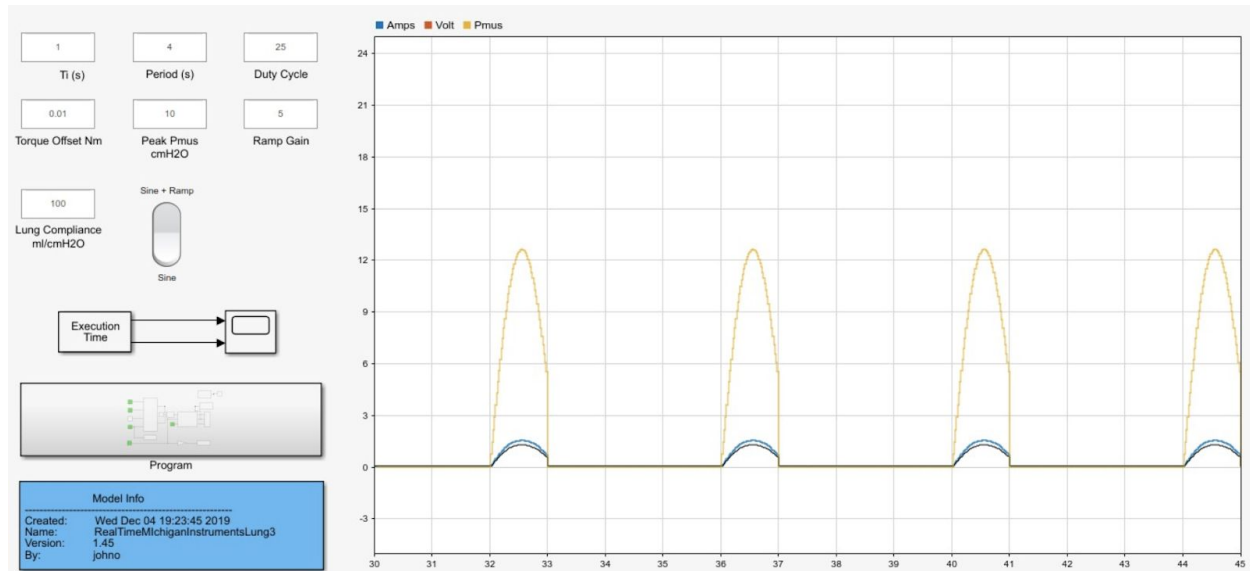
**Simulink Program (PC)**



**Figure 6.** An image of the GUI for the Simulink program

John O'Mahoney at Stimdia designed a Simulink program that is capable of generating breath waveforms, given all of the inputs necessary for this project like inspiratory time, $P_{mus}$, compliance, etc. These inputs can be seen on the left side of the GUI, and a graph showing the breath waveforms is on the right. While John did most of the coding, the team had to generate a lookup table for this program so it would know how to relate the desired pressure to the signal output. To complete this task, the team used the experimental setup shown in **Fig. 5**, but instead of trying to find the maximum required pressure, the team made a table of the force required to generate different pressures at different compliances. This was done for pressures ranging from -10 to -50 $cmH_2O$ in increments of 10, and for compliances of 10 to 100 $mL/cmH_2O$ in increments of 10.

**NI Board**

Last, the team needed a board to convert the digital signal output from the Simulink program to an analog signal that could be used by the current controller. Stimdia suggested using a National Instruments board because Simulink has many libraries available for interfacing between the two devices. The team used an NI-6009 board because the BME department had it in storage.

# Client Information

Stimdia Medical is a company based in Edina, Minnesota that is working on developing their pdSTIM system as their first product. Trace Jocewicz and John O'Mahony are the engineers who our team works most closely with and who are in charge of developing the pdSTIM system.

# Product Design Specifications

## *Physical and Operational*

The final design must be able to generate a vacuum pressure of 50 cmH$_2$O in a way that is compatible with the Michigan Instruments Test Lung. It must be able to move smooth enough as to effectively model a patient's breath waveform, which is defined by factors like the pressure generated, lung compliance, inspiratory rate, breath rate, and minimum pressure.

## *Safety*

The design must have a DC motor with a set maximum force output so that the test lung is not damaged. Furthermore, it will involve a 30V DC power supply, so it cannot have any exposed wires that could electrocute the operator.

## *Accuracy and Reliability*

The client requested that the final design create a pressure in the lung that is accurate to ±1 cmH$_2$O of the desired pressure value, and that the pressure is consistent between breath waves by the same ±1 cmH$_2$O.

## *Life in Service*

The device must be able to run for 20,000 breaths without the need for recalibration or repair. Repairs, if needed, should be easy to make.

## *Size and Weight*

Once complete, the device will need to be small and light enough to be transported to Stimdia's office in Minneapolis in an SUV.

## *Cost*

The budget for this project is $1000, but Stimdia says the team may be allowed to exceed the budget if it is necessary.

The full Product Design Specifications are available in the appendix.

# III.    Preliminary Designs
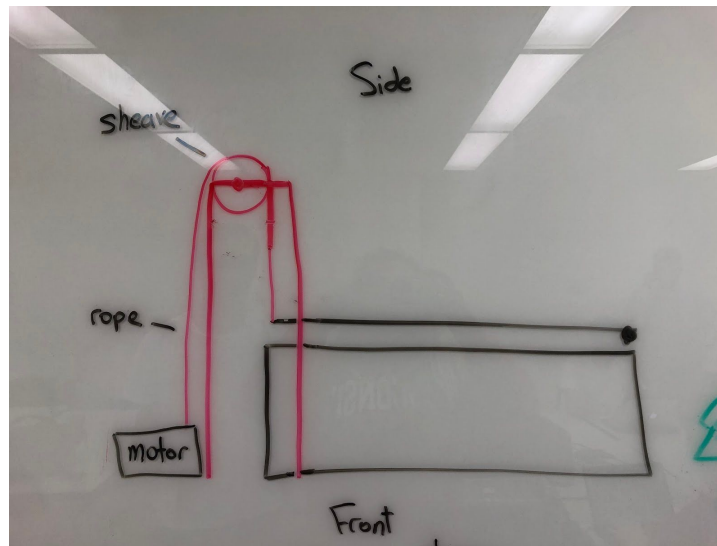
## The Pull Downer



**Figure 3.** A side-view sketch of the Pull Downer design

This design takes the motor and stations it on the ground. A pulley positioned above the peak height of the lung bellows guides a cord from the motor to the radial end of the test lung. This design utilizes a pulley system with a sheave large enough to pull the lung up and down as linearly as possible. The motor's armature shaft is attached to a couple which will wind up the rope of the pulley. The sheave may create friction, affecting the results, and the rope may be pulling at a slight angle which could also lead to inaccuracy.
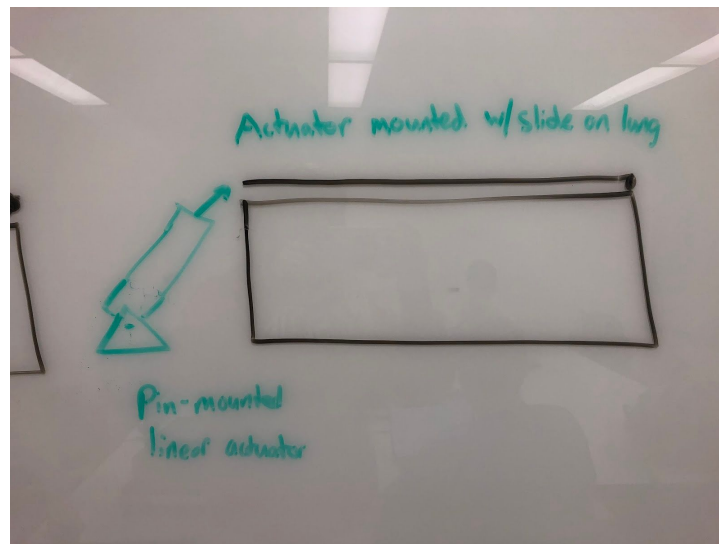
## The Pump it Up



**Figure 4.** A side-view sketch of the Pump it Up! Design

This design also employs a DC motor, but here it is housed inside of a linear actuator. The linear actuator is pin-mounted to a base on the ground to permit rotation of the actuator about its base, as the lung bellows does not expand in a perfectly linear motion. Additionally, the tip of the actuator needs to be attached to the lung with a roller support because, again, the bellows do not move linearly.
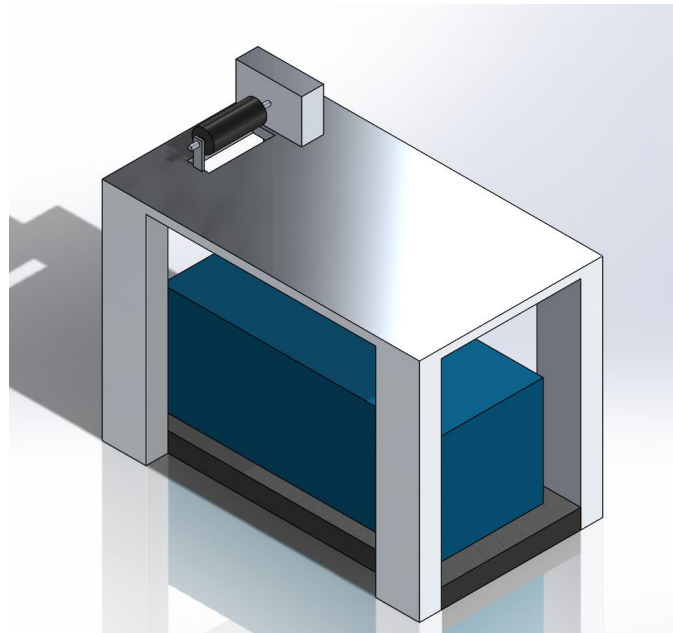
## The Ice Fisher



**Figure 5.** A SolidWorks model of the Ice Fisher design

This design suspends the motor and a spool of rope above the test lung, shown as the blue box. The legs are 2 x 4s measuring 50 cm in height, and the top is a sheet of ¼" pressure treated plywood, measuring 38 x 72 cm. Having the motor directly above the end of the lung bellow allows for a linear approach, leading to the most accurate results. The hole also gives space for the rope to be coiled up, compared to the motor being on the ground. Additionally, the motor is mounted to the top surface, keeping it in place.

# IV.   Preliminary Design Evaluation

## Design Matrix
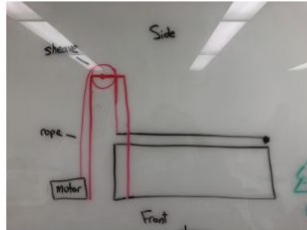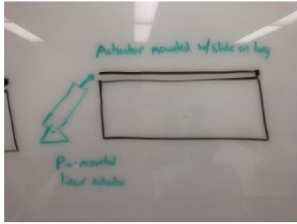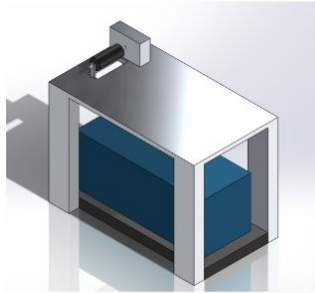
| Design Idea / Criteria | The Pull Downer | | The Pump it Up! | | The Ice Fisher | |
|---|---|---|---|---|---|---|
| |  | |  | |  | |
| Performance (40) | 4/5 | 32 | 2/5 | 16 | 5/5 | 40 |
| Accuracy and precision (30) | 3/5 | 18 | 2/5 | 12 | 5/5 | 30 |
| Simplicity and longevity (15) | 3/5 | 9 | 2/5 | 6 | 4/5 | 12 |
| Cost (10) | 4/5 | 8 | 5/5 | 10 | 5/5 | 10 |
| Ease of Fabrication (5) | 4/5 | 4 | 3/5 | 3 | 4/5 | 4 |
| Total | | 71 | | 47 | | 96 |

**Figure 6.** Design matrix evaluation of patient effort diaphragmatic lung simulators. Each design was graded on a scale of 1 (worst) to 5 (best), and was evaluated with weighted categories. Total points displayed at the bottom are out of 100

*Performance*

Performance is of utmost importance to the client, which is why it received a weight of 40. The device must be able to pull the test lung to a maximum pressure of -50 cmH$_2$O at a compliance of 100 mL/cmH$_2$O. If the device cannot handle this load, the client tests the client runs will not model a human lung to the fullest extent.

*Accuracy and precision*

Accuracy and precision received a weight of 30 because our client needs pressure values to be correct when testing their pdSTIM device. The motor must produce repeatable results within +/- 1 cmH$_2$O and the set pressure must be accurate to the true pressure value within +/- 1 cmH$_2$O. Moreover, the design must allow the motor to to properly simulate breath waveforms.

*Simplicity and longevity*

This category received a weight of 15 because the device will be used by Stimdia Medical for a long time to come, so it must be designed to function for 20,000 breath cycles without need for repair or recalibration. For this reason, a simple design that has few things that can go wrong is desired. If the device is not simple, its users might not use it correctly and cause problems. If the device does not last long, then costly repairs may be necessary.

*Cost*

Cost received a weight of 10 because our results will be used in real life applications and we do not want to cut corners in that area. Furthermore, our budget of $1000 seems to be more than enough to accomplish the task at hand. The device should be designed in a way that minimizes cost while still being able to accomplish the task at hand.

*Ease of fabrication*

Ease of fabrication was given a weight of 5 because the team must be able to fabricate a device with the resources available at the College of Engineering.
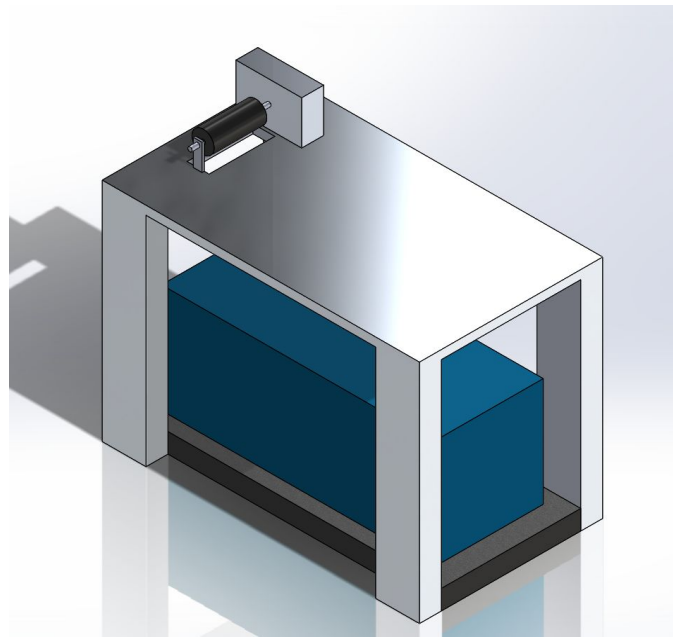
## Proposed Final Design



**Figure 6.** A SolidWorks model of the Ice Fisher design

The team selected "The Ice Fisher" design over the "The Pull Downer" and "The Pump it Up!" for a variety of reasons, starting with performance. This design received the highest performance score because it allows for direct interaction between the motor and the lung. In comparison, the Pull Downer uses a pulley system, which is problematic because the pulley could slip and not end up generating the pressure it was calibrated to do. The Pump It Up also has a performance issue in that the previously mentioned roller support that connects the piston to the lung would be difficult, if not impossible, to design because the lung has limited surface area where a feature like this could be added. This support would require constant lubrication which could complicate the design and interfere with the pressure created in the lung.

Next, the Ice Fisher received the highest accuracy and precision score because it, again, allows for a direct, linear interaction between the motor with the lung. This would make testing the force exerted very easy for us. The team figured that as the lung expands or contracts in the Pull Downer design, the angle of contact between the rope and the pulley would change. This effect would change the tension acting on the lung, and it would be difficult to account for this effect when programming an accurate design. Additionally, the sheave may have friction affecting our results. The Pump It Up received a lower score because the angle of contact between the actuator and the lung would change with the angle of the lung, which would complicate the force-pressure relationship and make it challenging to program an accurate device.

The Ice Fisher was also judged to be the most simple design because it does not require a pulley system or roller support. It tied the Pump It Up for being the least expensive because the cost estimates made by the team were about the same for a linear actuator and a DC motor. Therefore, the Pull Downer received a lower cost score because its pulley would raise the cost, although only by about 20 dollars.

Lastly, the Pull Downer and the Ice Fisher tied for ease of fabrication because the team felt confident the TEAM lab resources would be sufficient to construct these designs, while the team did not feel the same way for the Pump It Up due to its complicated roller support.

# V.    Fabrication/Development Process

## Materials

A complete list of materials used and their costs is available in the appendix. A brief summary of the materials includes the NI-6009 board, current controller, power supply, motor, and test lung. The materials the team used for the stand were 6' of 2 x 4s and ¼" pressure treated plywood, as well as ¼" aluminum sheet metal for the motor mount. In total, eight screws and eight bolts were used.

## Methods

### Stand

The plywood sheet will be cut to size. Four 2x4s will be cut to a height of 50 cm. Two screws per leg will secure the plywood sheet to the legs, and two screws per leg will secure the legs to the lung's case.

### Motor Mount

The motor mount was made of two pieces of aluminum sheet metal bolted together into an L-shape. Features complementary to the motor were milled out of one piece so it would fit snug. Four holes were drilled into the other piece so it could be bolted to the stand. These two pieces were bolted together.

### Wiring and Soldering

Pinout diagrams for the various electrical components were used to connect the components. Wires were soldered onto headers, which were connected to the current controller. For other connections, alligator clips and jumper cables were used.
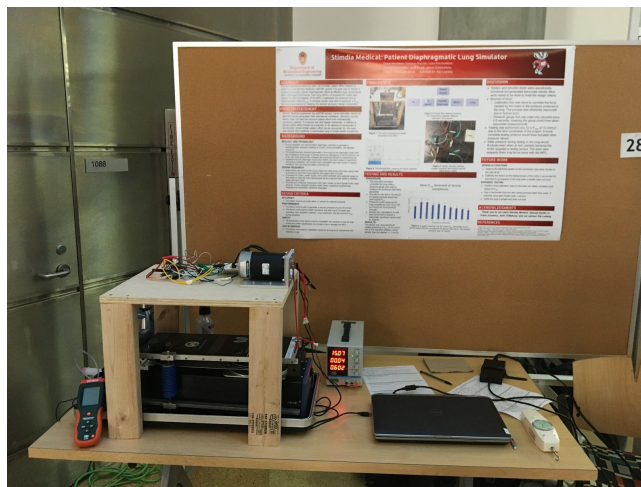
## Final Prototype



**Figure 7.** An image of the final prototype

The final prototype differed from the proposed final design because the position of the motor was moved. Instead of having to cut a hole in the stand like in the proposed final design, the motor was placed on the edge of the stand. This allowed for better positioning of the stand over the test lung and prevented any problems with transmission of force that could arise from having friction between the rope and the stand.

## Testing

One of the design constraints of this project was to create a device that could generate a vacuum pressure of at least 50 $cmH_2O$ in the test lung. Preliminary tests showed the device is more than capable of reaching this pressure. Since this constraint is a test of the motor's output torque rather than a test of the design, the team decided to test the device's accuracy.

A z-test was used to show whether or not the hypothesis that the mean pressure generated equals a given target pressure was used. In order to use a z-test, standard deviation is required. For this reason, the team measured the pressure at 30 breaths for a given compliance, which by the central limit theorem is sufficient for calculating standard deviation. 30 measurements were taken for each compliance, ranging from 10 to 100 $mL/cmH_2O$ in intervals of ten. It total, 300 measurements were taken. Although the client wanted to test for the accuracy of pressures ranging from -10 to -50 $cmH_2O$, the group decided to only test for a pressure of -10 $cmH_2O$ because it is the most commonly found resting lung pressure and because the scope of this project did not allow enough time for gathering and testing 1,500 data points.

Another requirement for using a z-test is that the data must be normally distributed, so a QQ plot was used to verify normality for each compliance. Furthermore, the group wanted to gather data with a power of at least .8, so the sample size required to reach this power was also calculated. Once power

calculations for all compliances showed the team had taken enough measurements, the z-tests were performed. If the p-value of the test is less than .05, the team rejects the null hypothesis that mean $P_{mus} = -10$ cmH$_2$O, and the device is inaccurate. Also, if the standard deviation is greater than one the device will be considered inaccurate.

# VI.  Results
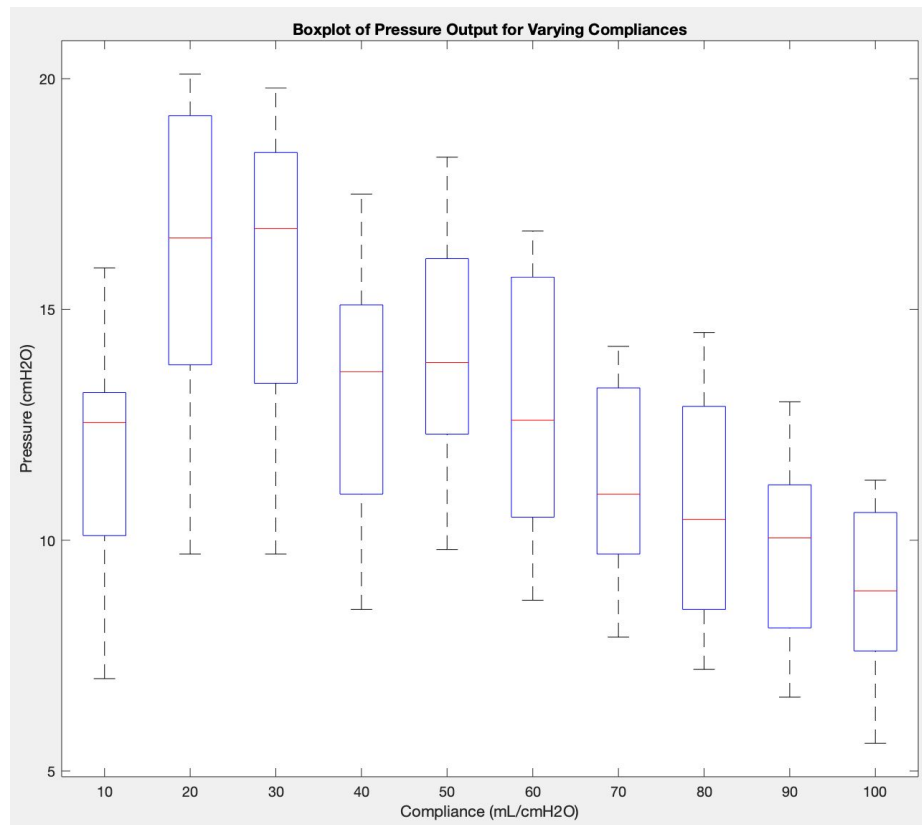


**Figure 8.** A box and whisker plot showing the data for varying compliances, when the target pressure was 10 cmH$_2$O

Unfortunately, p-values for all ten compliances were less than .05. Therefore, the team rejects the null hypothesis and the device is considered inaccurate. The group noticed a general trend shown in **Fig. 8**, that higher compliances generated mean pressures closer to -10 cmH$_2$O, and mean pressures tended to drift upward as compliance decreased. Even though the mean pressure for the higher compliances is closer to 10 cmH$_2$O, their standard deviations are greater than one, so the device is inaccurate.

# VII.  Discussion

Even though the team created a functioning device, it was found to be inaccurate. The device is similar to that found in U.S. Patent 5,044,362, but the team could not find any record of that patent ever

being constructed so the designs cannot be compared. The device was successful in generating vacuum pressures greater than 50 cmH$_2$O, which meets the design constraints.

In terms of ethical considerations, the device was constructed out of non-toxic and recyclable materials. In a broader context, Stimdia wanted this device so they could modify their pdSTIM phrenic nerve stimulator. Clearly, it would not be ethical to use an inaccurate device to calibrate the pdSTIM product because an improperly calibrated nerve stimulation device could harm patients.

The team identified many sources of error that, if fixed, could make the device more accurate. First, turning on the power supply moved the motor to its resting torque, which created a small pressure in the lung. This could be accounted for by playing with the "Torque Offset" setting on the Simulink program. Next, the manometer that was used takes pressure readings at 2 Hz, but the peak pressure of a breath occurs only about every four seconds, depending on the settings. Peak breath only occurs for a split second as well. If the manometer is not perfectly synced with the breath, it will more often than not miss the peak breath reading. This could be fixed by using a manometer with a continuous reading. Moreover, the calibration testing that was used to generate the lookup table was inherently flawed because of human error in making an exact measurement. The tester needed to pull the lung at a constant velocity to keep pressure readings the same, which is near impossible. This could be fixed by using the existing final design to make an automated test setup to make an improved lookup table. Additionally, if the rope between the rotor and the lung is more or less slack between trials, it made the testing less consistent. This could be fixed by 3D printing a custom tethering system to keep the rope at a constant distance. Last, the team suspects there were one or more leaks in the lung, because pressure values varied when the lung should have been sealed. This is tough to fix because the leaks are tough to hear. Helium leak detection could be used, or a new lung could be purchased.

# VIII.   Conclusion

The team's client Stimdia Medical challenged the team to design and fabricate a diaphragmatic effort lung simulator that is compatible with a Michigan Instruments Lung and can generate a pressure in the lung of -50 cmH$_2$O. There is currently no simulator on the market that simulates diaphragmatic effort in a mechanical lung.  The team successfully designed a system controlled by a Simulink driver that takes various inputs like breath rate and compliance and uses it to modulate a test lung.

In the end, the device was successful and came in well under-budget, but it was less accurate than the design criteria dictated. The team suspects fixing a variety of sources of error, like the calibration procedure, could make the device more accurate. Future work would include fixing these deficiencies, then moving on to calibrating the pdSTIM product.

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# X.   Appendix

## Product Design Specifications

Patient Diaphragmatic Effort Lung Simulator, Team Breath, BME 200/300
Client: Mr. Trace Jocewicz III and John O'Mahony
Advisor: Dr. Kip Ludwig
Team:  Seth Roge (Leader)
        Jared Zunenshine (Communicator)
        Parker Callender (BWIG)
        Rehaan Machhi (BSAC)
        Cole Knickelbine (BPAG)

**Function:**
        Mechanical ventilation (MV) is often needed in hospitals. Unfortunately, when a patient is intubated they are likely to develop ventilator-induced diaphragm dysfunction (VIDD), a condition characterized by diaphragm atrophy and dysfunction. Stimdia Medical has developed a system that aims to alleviate this effect via paced stimulation of the phrenic nerve (pdSTIM system). Currently, lung simulators cannot model any patient effort during MV, which is problematic because some patients can produce limited diaphragmatic effort, and also because the pdSTIM systems induces patient effort. Consequently, the team is tasked with modifying a commercially available lung simulator so that patient effort may be incorporated and used to influence future designs of the pdSTIM system.

This modification to the lung simulator, the Michigan Instruments Test Lung, must generate a pressure of -50 cmH$_2$O. The way in which this is accomplished is still to be determined, but the final design will need to be controlled via a Simulink interface that allows the user to input breath rate, Ti, waveform selection, lung compliance, and the minimum P$_{mus}$ force.

## Client Requirements:

- Design a system that modifies a Michigan Instruments Test Lung to incorporate patient effort so that work of breathing may be simulated
- Choose and justify a motor and motor controller that would be able to simulate patient effort (if this option is chosen). The motor should generate a maximum force, P$_{mus}$ of -50 cmH$_2$O.
- Choose and justify a DC power supply to power the motor (if this option is chosen)
- Build a mount to hold the motor and motor controller
- The modification must be controlled via a Simulink driver, where the user can input breath rate, Ti, waveform selection, lung compliance, and the minimum P$_{mus}$ force.
- Develop a general theory of operation document.

## Design Requirements:

Physical and Operational Characteristics:

1. Performance Requirements:
   a. Must be able to provide a pressure of -50 cmH20
   b. Must be able to vary the force to simulate the different magnitudes of patient effort
   c. Must be compatible with the Michigan Instruments Lung
   d. Must be able to input breath rate, the desired P$_{mus}$ waveform, lung compliance, and a minimum P$_{mus}$
2. Safety:
   a. Must be able to safely simulate patient effort without damaging the Michigan Instruments Lung
   b. Must be able to safely operate while a ventilator is attached to the Michigan Instrument Lung
   c. The device will use a DC power source, so care must be taken to prevent electrocution and fire hazards. There can be no exposed wires.

3. Accuracy and Reliability:
   a. Must be able to simulate a maximum P$_{mus}$ of -50 cmH$_2$O
   b. The motor must be able to deliver sufficient torque to provide a force range of 15 to 60 N.
   c. It is desired that the motor produce a repeatable P$_{mus}$ every time, within +/- 1 cmH$_2$O
   d. It is desired that the motor produce a P$_{mus}$ within +/- 1 cmH$_2$O of the value the Michigan Instruments Test lung reads

4. Life in Service:

      a. The simulator must be able to be shipped cross-country and be easily assembled.

      b. The device must function for as long as Stimdia Medical needs it to test their products. An estimate of this time period is three years of being used five days a week for one hours a day.

5. Shelf Life:
      a. Although there are no plans to keep the device in storage, this could change. Since the device will have a motor, current controller, and batteries, it should be kept in a dry place at room temperature to give it the longest shelf life.

6. Operating Environment:
      a. The device will be used at room temperature, normal pressure, normal humidity, and free from any extreme conditions (shock loading, dirt or dust, insects, etc.). Using the device in any of these conditions could compromise its function. It should only be operated by someone trained to do so.

7. Size:
      a. The device, when taken apart, should be small enough to fit in a box that can be sent in the mail.
      b. The device should be relatively easy to set up and take apart for transport purposes.

8. Weight:
      a. The weight of the device should not exceed what an average person can carry.

9. Materials:
      a. All materials used will not be toxic.

10. Aesthetics, Appearance, and Finish:
      a. The device should be relatively easy to set up and take apart for transport purposes. The end product should be cleaned up (ex: no sharp edges, extra rope, etc.)

Product Characteristics:

1. Quantity:
      a. One patient effort simulator must be produced.

2. Target Product Cost:
      a. The target cost of the simulator is under $1000. As there should be few manufacturing costs, the team will try to keep costs low as possible by purchasing parts with a good balance between cost and effectiveness.

Miscellaneous:

1. Customer:
    a. The customer, Stimdia Medical, is a company that creates biomedical devices. This solution, if effective, will help them modify their phrenic nerve stimulator.
2. Competition:
    a. While there are test lungs out there, there are no existing patient lung effort simulators. The competing method of producing patient effort is to manually raise the test lung bellows to simulate a given pressure. This method will be useful for calibration.

## MATLAB Code

```
close all;
clear all;

data10 = [13.1, 13.1, 10.8, 7.00, 10.0, 13.2, 12.5, 10.2, 7.80, 12.7, 12.6, 13.4, 10.4, 10.1, 13.1, 12.6, 13.5,
14.6, 11.0, 10.1, 13.6, 14.9, 11.9, 8.90, 10.9, 15.9, 15.0, 9.50, 9.80, 13.1];
data20 = [19.5, 19.8, 18.7, 13.8, 10.8, 19.1, 19.6, 16.6, 10.8, 15.0, 19.3, 18.0, 14.0, 9.70, 16.5, 19.6, 16.6,
9.80, 15.5, 19.5, 14.1, 10.1, 14.8, 19.2, 11.1, 14.2, 18.7, 20.1, 17.1, 13.7];
data30 = [15.1, 18.2, 16.1, 13.0, 10.7, 14.7, 17.7, 19.8, 16.7, 13.6, 9.70, 17.0, 19.7, 16.8, 12.8, 18.4, 19.8,
12.6, 15.3, 19.6, 18.7, 13.1, 10.8, 13.4, 17.2, 19.1, 17.5, 13.4, 19.8, 17.2];
data40 = [17.5, 15.0, 13.3, 14.0, 14.7, 14.0, 12.0, 11.5, 10.5, 8.50, 8.60, 8.70, 9.40, 10.5, 11.5, 12.0, 12.7,
14.0, 14.7, 16.1, 16.4, 9.80, 11.0, 12.6, 15.0, 16.1, 16.0, 16.3, 16.0, 15.1];
data50 = [18.1, 16.3, 13.9, 12.3, 11.0, 12.2, 13.3, 18.0, 16.0, 14.0, 13.1, 10.5, 11.0, 12.8, 13.8, 16.7, 16.7,
16.7, 15.6, 13.8, 12.5, 9.80, 10.7, 12.0, 13.6, 16.1, 18.3, 15.9, 15.8, 15.7];
data60 = [12.7, 9.80, 8.70, 9.30, 15.7, 16.5, 15.1, 11.7, 16.3, 16.6, 14.3, 12.5, 12.4, 10.0, 10.5, 16.6, 16.4,
14.0, 11.3, 9.50, 12.7, 15.4, 16.7, 14.7, 12.3, 10.6, 9.70, 9.80, 12.0, 16.4];
data70 = [9.70, 14.1, 12.0, 9.60, 8.60, 10.6, 13.7, 14.0, 11.3, 12.2, 13.3, 10.3, 7.90, 10.4, 12.1, 14.2, 12.6,
10.7, 8.80, 9.10, 14.2, 11.5, 8.60, 10.8, 14.0, 13.8, 11.2, 10.6, 8.30, 10.8];
data80 = [14.5, 8.00, 9.70, 7.20, 8.50, 8.30, 7.70, 9.00, 10.8, 11.6, 12.7, 8.80, 8.30, 7.60, 8.00, 9.10, 11.0,
11.9, 13.5, 13.8, 12.1, 10.0, 9.00, 10.1, 10.9, 13.1, 13.4, 13.5, 13.5, 12.9];
data90 = [8.00, 7.70, 6.60, 9.00, 8.90, 10.0, 8.40, 10.2, 13.0, 10.2, 12.0, 12.7, 11.0, 7.00, 9.00, 10.3, 12.8,
11.6, 8.30, 7.80, 11.2, 13.0, 6.70, 10.8, 12.9, 10.1, 8.10, 6.80, 8.90, 10.8];
data100 = [10.2, 5.80, 8.80, 7.60, 7.10, 7.40, 8.60, 10.9, 10.7, 8.50, 6.60, 8.10, 10.6, 10.9, 8.90, 5.90, 8.30,
10.2, 11.3, 5.60, 9.00, 9.70, 11.2, 8.40, 6.60, 8.90, 10.3, 11.1, 9.20, 11.3];
matrix = transpose([data10; data20; data30; data40; data50; data60; data70; data80; data90; data100]);

m10 = mean(data10);
m20 = mean(data20);
m30 = mean(data30);
m40 = mean(data40);
m50 = mean(data50);
m60 = mean(data60);
m70 = mean(data70);
m80 = mean(data80);
```

```matlab
m90 = mean(data90);
m100 = mean(data100);

s10 = std(data10);
s20 = std(data20);
s30 = std(data30);
s40 = std(data40);
s50 = std(data50);
s60 = std(data60);
s70 = std(data70);
s80 = std(data80);
s90 = std(data90);
s100 = std(data100);

n10 = sampsizepwr('t', [50, s10], m10, .8);
n20 = sampsizepwr('t', [50, s20], m20, .8);
n30 = sampsizepwr('t', [50, s30], m30, .8);
n40 = sampsizepwr('t', [50, s40], m40, .8);
n50 = sampsizepwr('t', [50, s50], m50, .8);
n60 = sampsizepwr('t', [50, s60], m60, .8);
n70 = sampsizepwr('t', [50, s70], m70, .8);
n80 = sampsizepwr('t', [50, s80], m80, .8);
n90 = sampsizepwr('t', [50, s90], m90, .8);
n100 = sampsizepwr('t', [50, s100], m100, .8);

figure;
qqplot(data10);
qqplot(data20);
qqplot(data30);
qqplot(data40);
qqplot(data50);
qqplot(data60);
qqplot(data70);
qqplot(data80);
qqplot(data90);
qqplot(data100);

z10 = ztest(data10, 10, 1)
[h,p] = ztest(data10, 10, 1)
z20 = ztest(data20, 10, 1)
[h,p] = ztest(data20, 10, 1)
z30 = ztest(data30, 10, 1)
[h,p] = ztest(data30, 10, 1)
```

```
z40 = ztest(data40, 10, 1)
[h,p] = ztest(data40, 10, 1)
z50 = ztest(data50, 10, 1)
[h,p] = ztest(data50, 10, 1)
z60 = ztest(data60, 10, 1)
[h,p] = ztest(data60, 10, 1)
z70 = ztest(data70, 10, 1)
[h,p] = ztest(data70, 10, 1)
z80 = ztest(data80, 10, 1)
[h,p] = ztest(data80, 10, 1)
z90 = ztest(data90, 10, 1)
[h,p] = ztest(data90, 10, 1)
z100 = ztest(data100, 10, 1)
[h,p] = ztest(data100, 10, 1)

namingVector = [10, 20, 30, 40, 50, 60, 70, 80, 90, 100];
boxplot(matrix, namingVector);
```

## Expenses

| Item | Description | Manufacturer | Part Number | Date | QTY | Cost Each | Total | Link |
|---|---|---|---|---|---|---|---|---|
| Whitewood Stud 2x4 | 6' | Home Depot | 750298153253 | 10/3 | 1 | 2.61 | 2.61 | N/A |
| Birch Plywood | 2'x4' | Home Depot | 099167465418 | 10/3 | 1 | 24.07 | 24.07 | N/A |
| Rope | 5', .125" diameter | Home Depot | 257-932 | 11/7 | 2 | 1.25 | 2.50 | N/A |
| Rope Fastener | .125" diameter | Home Depot | N/A | 11/7 | 1 | 6.25 | 6.25 | N/A |
| ⅜" Aluminum sheet | 6"x12" | UW-Madison TEAM Lab | N/A | 11/1 | 1 | 41.56 | 41.56 | N/A |
| Poster | Poster for presentation | UW-Madison Library Printing Services | N/A | 11/8 | 1 | 43.00 | 43.00 | N/A |
| TEAM Lab | Includes price for | UW-Madis | N/A | 10/1 | 1 | 50 | 50 | N/A |

| Materials Fee | using machinery, wires (approx. 4'), zip ties, solder, screws, nuts, and bolts | on TEAM Lab | | 5 | | | | |
|---|---|---|---|---|---|---|---|---|
| NI-6009 Board | DAC data acquisition device - free from BME closet | National Instruments | 6009 | 10/1 | 1 | 245 | 245 | https://www.ni.com/en-us/support/model.usb-6009.html |
| Current controller | Current controller, output to DC motor - paid for by Stimdia Medical | Servo2Go | AZ12A8 | 10/3 | 1 | 185 | 185 | https://servo2go.com/az12a8/ |
| Power supply | 30V, 10A - paid for by Stimdia Medical | Dr. Meter | PS-3010DF | 10/3 | 1 | 98.99 | 98.99 | https://www.amazon.com/gp/product/B07S1NPF5G/ref=ppx_yo_dt_b_asin_title_o01_s00?ie=UTF8&psc=1 |
| Motor | Brushed DC motor - paid for by Stimdia Medical | Haydon Kerk | ID3005-SP | 10/3 | 1 | 330.77 | 330.77 | https://prototypes.haydonkerk.com/ecatalog/brush-dc-motors/en/brush-dc-motors-ID33005-SP |
| **TOTAL:** | | | | | | | | **$1,029.75** |