Stimdia Medical: Patient Diaphragmatic Effort Lung Simulator

BME 200/300

October 8, 2019

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 with modifying a Michigan Instruments Test Lung to expand and contract under the power of a DC motor to simulate full or partial diaphragm contraction. The team has made CAD designs of a system that will accomplish this task, and plans on testing the lung to determine the appropriate motor to purchase. Once the motor is purchased, the team can commence fabrication.

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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. Also, there are competing phrenic nerve stimulators on the market that are worth noting.

Figure 2. 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 [9]. 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 [10].

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 [11].

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 [12].

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 [13,14]. 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

To accomplish the task of raising and lowering the mechanical lung in a controlled fashion, the team decided, under the guidance of Stimdia Medical, to use a DC motor. The type of motor the team selected will be a DC high torque, low speed motor. DC motors use magnetic fields to generate a desired torque [15]. The torque that is generated is proportional to the current supplied to the motor and desired breath waveforms can be generated from the current supplied [16]. The type of DC motor that the team selected is the DC Permanent Magnet Motor from Grainger due to its high torque capabilities and because it can operate on 12V DC [17]. 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 plans to use a cable that can withstand a tension of 500N. The 500N load was decided upon because that force value is well beyond the maximum loading the lung will require based on previous client research. Grainger's 3/16" diameter galvanized steel cable is capable of supporting more than 2,000 N, so it is viable candidate for this project.

Client Information

Stimdia Medical is a company based in Minneapolis, 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_2O 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 12V 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_2O of the true pressure value, and that the pressure is consistent between breath waves by the same +/- 1 cmH_2O.

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 by car.

Cost

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

III. Preliminary Designs

The Pull Downer

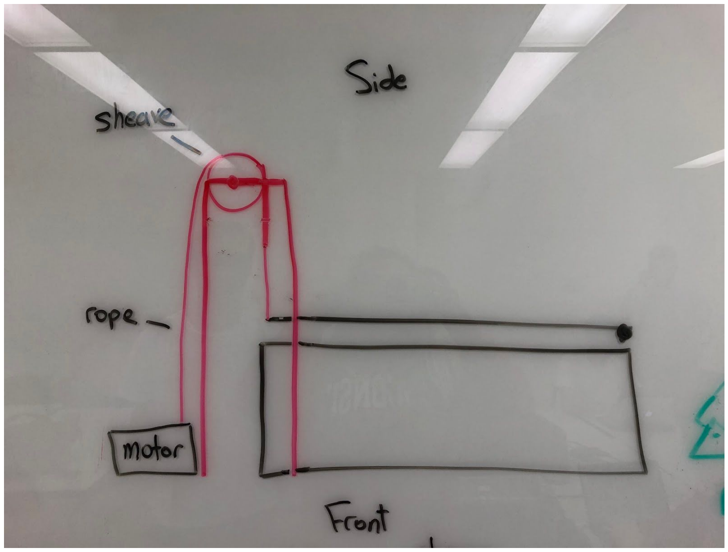


Figure 3. A side-view sketch of the Pull Downer design

This design takes the DC 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 DC 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

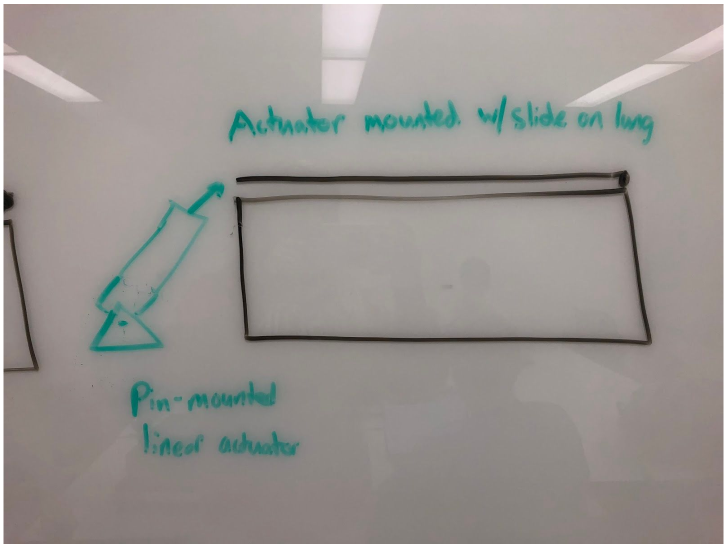


Figure 4. A side-view sketch of the Pump it Up! Design

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

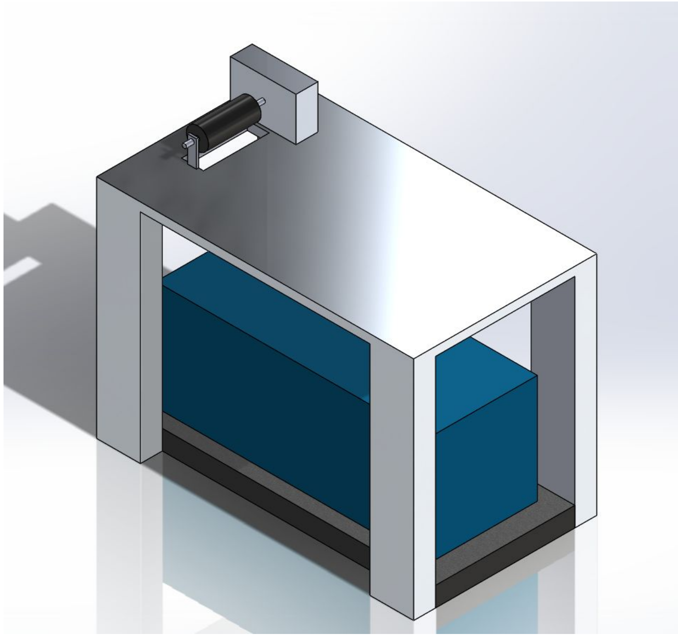


Figure 5. A SolidWorks model of the Ice Fisher design

This design suspends the motor and a spool of rope above the test lung, shown as the blue box. 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.

Preliminary Design Evaluation

Design Matrix

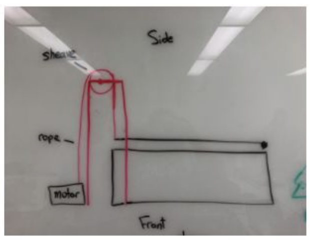
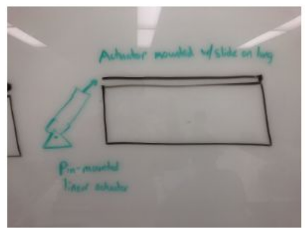
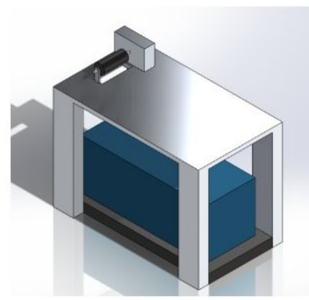
Design Idea / Criteria	The Pull Downer		The Pump it Up!		The Ice Fisher	
						
Performance (40)	4/5	32	2/5	16	5/5	40
Accuracy and precision (30)	3/5	18	2/5	12	5/5	30
Simplicity and longevity (15)	3/5	9	2/5	6	4/5	12
Cost (10)	4/5	8	5/5	10	5/5	10
Ease of Fabrication (5)	4/5	4	3/5	3	4/5	4
Total	71		47		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_2O at a compliance of 100

mL/cmH_2O. 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_2O and the set pressure must be accurate to the true pressure value within +/- 1 cmH_2O. 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

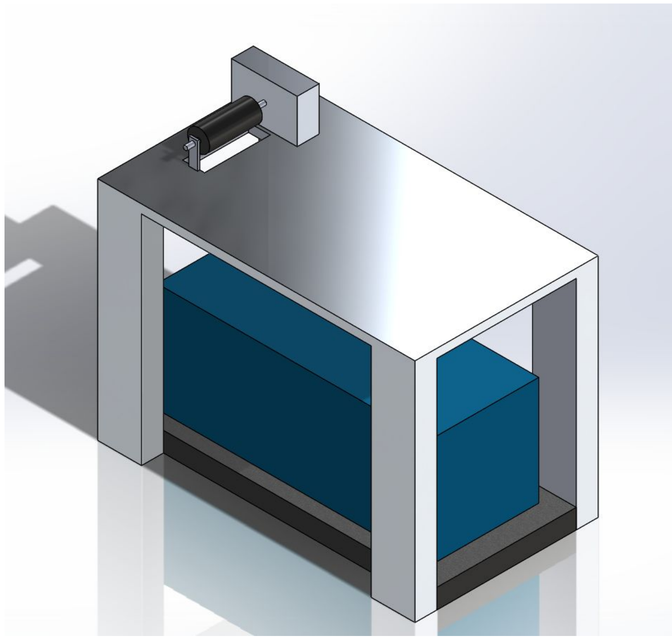


Figure 6. A SolidWorks model of the Ice Fisher design

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 direct interaction of the motor with the lung. 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. The Pump It Up received a lower score because the angle of contact between the rope 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 to 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. Last, 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.

IV. Fabrication/Development Process

Materials

The team will first make the design shown in **Fig. 6** using 2x4s for the legs and ¼" plywood for the top sheet. These components will be secured to each other and to the lung's case by using 12 screws. As of now, motor selection depends on the testing phase.

Methods

The plywood sheet will be cut size (L: 72 cm, W: 38 cm). Four 2x4s will be cut to a height of 49.5 cm. One screw per leg will secure the plywood sheet to the legs, and two screws per leg will secure the legs to the lung's case.

Testing

Before testing of the completed device, the group must test the force required to generate a given lung pressure for a given compliance. The group will have to collect force data for compliance ranging from 10 to 100 ml/cmH_2O across a pressure range of -10 to -50 cmH_2O. These results will be used to decide how much torque the motor will need to produce.

V. Conclusion

The team's clients Trace Jocewicz III and John O'Mahony have challenged us to design and fabricate a patient diaphragmatic effort simulator that is compatible with the Michigan Instruments Lung and can generate a pressure in the lung of -50 cmH_2O. There is currently no simulator on the market that generates patient diaphragmatic effort in a mechanical lung. We will need to design a system controlled by a Simulink Driver that takes inputs of breath rate, inspiratory rate, lung compliance, and minimum exhalation pressure.

The design we developed to supplement the test lung is called the Ice Fischer, and it will include a DC motor that is propped above the lung and a taut cable will be used to create the simulated diaphragmatic effort. The design will be able to vary the applied forces necessary to generate the target pressure in the mechanical lung. This design will be able to accurately generate the target pressure in the lung.

In the upcoming weeks, we will be purchasing parts the following parts: (1) a DC motor, (2) a cable, (3) a force gauge, and (4) a manometer to conduct testing for our future prototype and to fabricate the Ice Fisher, which we will fabricate from wood. Once the team has the force gauge and manometer, we will conduct testing to determine how much force is required from the motor. Potential issues that may arise over the next couple of weeks might include programming a feedback loop to better control force output if this is deemed necessary, and possibly securing the frame to the lung's box.

VI. References

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VII. 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_2O. 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_2O.
- 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:

<u>Physical and Operational Characteristics:</u>

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_2O
    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_2O
    d. It is desired that the motor produce a P_{mus} within +/- 1 cmH_2O 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.