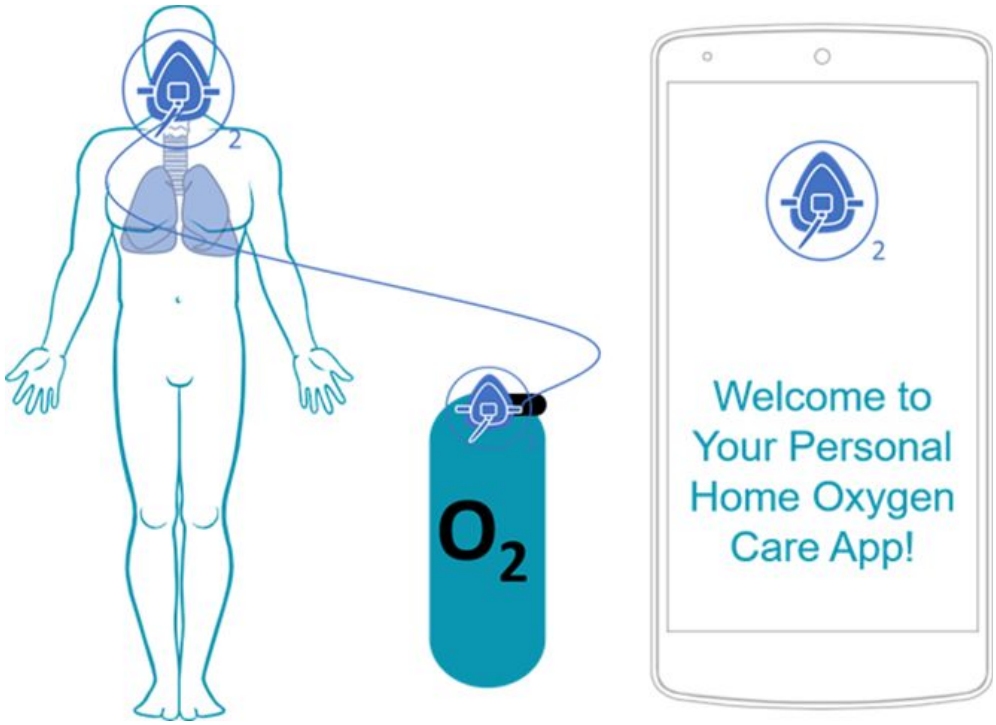
Wireless Control of In-Home Oxygen Liter Flow



Life-Changing Game-Changing Engineering Company (L.G.E.C)

Vanderbilt University

Team Members:

Carla-Jane Pax - Biomedical Engineering Class of 2019

Elliot Grant - Biomedical Engineering Class of 2019

Gabriel Hoppock - Biomedical Engineering Class of 2019

Lamya Jaigirdar - Biomedical Engineering Class of 2019

I. Executive Summary

Over 100,000 patients in the United States are diagnosed with Idiopathic Pulmonary Fibrosis (IPF), a lung disease which requires long term oxygen treatment (LTOT) [1]. These patients require different amounts of oxygen in L/min for everyday activities such as walking, sleeping, chore, sitting, etc. For example, sitting typically requires ~2 L/min whereas walking requires ~6 L/min.

Currently, it is troublesome to control the oxygen liter flow rate knob to meet patients' oxygen requirements because oxygen concentrators are typically stored away. When patients wish to change their activity, they are required to change their physical state to go control the oxygen liter flow. This is where the need for our project's technology stems. Between daily activities patients are unable to adjust their oxygen liter flow which leads to worsened hypoxia, pulmonary vasoconstriction, pulmonary hypertension, breakdown or bleeding of the nasal passages, etc. based on whether the oxygen liter flow is continually too high or too low [1]. Often times, patients even lack knowledge regarding what their oxygen liter flow concentration should be.

Though we have focused on the IPF patient population, the need for wireless control of in-home oxygen concentrator liter flow is needed for patients of all respiratory illness that require LTOT and no device currently exists to meet this need on the market. Our project will have a quick and direct impact on patients as we work together with clinicians to develop a mobile application for wireless control of oxygen liter flow through bluetooth connection with a mechanical device that will be designed for a standard oxygen concentrator with hopes of implementing an adjustable one in the future. Furthermore, the smartphone application will rely on a patient's blood oxygen saturation level to change the oxygen liter flow rate based on an individual patients oxygen requirements at the moment. This approach eliminates ambiguity surrounding what a patient's oxygen liter flow rate should be. Finally, our design must be functional, but also easy to use when keeping in mind our likely older-aged end users.

This concept of the device is feasible, but the difficulty of the physical device is having it be able to attach and adjust to different oxygen concentrators. Oxygen concentrators do not all have the same design, and therefore the device will not have just one standard way of attaching itself to the concentrator. Through analysis of different concentrator designs, a general way of attaching our device to these concentrators and stabilizing it should be determined. Since the flow rate on most oxygen concentrators is controlled by the twisting of a know, a general design that can change its size can be created to attach to the knob and then the device can be manually calibrated according to the sensitivity of the oxygen concentrator.

Our device will likely be classified as a Class 2 device as a mobile health application like te oxygen concentrators are as well. Since there is no similar device on the market, it will most likely need

to be classified through de novo with 513(g) approval due to the low risk associated with our device. Communication with the FDA will also be crucial to obtain FDA approval since mobile health technology devices is an emerging field.

Moving on to Medicare and Medicaid coverage; this will be dependant upon FDA approval. If and when FDA approval occurs and claims that the device is safe and effective, Medicare and Medicaid determine if the device is reasonable and necessary. This can be shown by looking at studies of long term effects of having oxygen flow rates that are either too high or too low. Long term damage is inevitable, which shows the need for our device. The device will be able to attach to and alter flow on existing oxygen concentrators, meaning that no new concentrators will need to be made for this device. The user will also have the ability to remove the device if errors occur and the device will be able to be calibrated to the sensitivity of the oxygen concentrator it is being used on. Overall, this should be able to convince the Centers for Medicare and Medicaid Services that our device is reasonable and necessary.

The combined population of the target market is currently 109,853 for the first iteration of the device; his includes both men and women who have idiopathic fibrosis [2]. This population is the primary target because it requires LTOT and has a drastically low life span of 3-5 years after receiving the therapy which creates this critical need for a device that can improve their health outcome while also having a need for an oxygen tank liter flow regulator. While these patients are the end users for the device, the majority of the device and application customers will be medical supply stores. The goal is for this device to be sold alongside an oxygen concentrator so that patients can immediately have the ability to wirelessly control their oxygen flow. The medical supply stores will buy the technology directly from the manufacturer in order to reduce overarching costs of using intermediary companies. This will keep the cost of the final device as sold to the patient reasonably low. When considering the end user, the final price will be around $65. This is a one-time purchase of the device as the application is free to use. Our price takes into account the cost of materials used and the decrease in cost due to increase in production.

In conclusion, the mechanical device to control oxygen liter flow rate on oxygen concentrators and its accompanin app meet a clinical need while presenting an opportunity for future profit.

II. Description of the problem to be solved

Often times patients on LTOT keep their oxygen concentrators set at a constant oxygen flow rate in one location. However, human bodies require different oxygen concentrations for different activity levels. For this reason, an IPF patient can suffer long-term side effects as a result of not adjusting the flow rate on their oxygen concentrators depending on their activity. Fortunately, we also had the opportunity to visit an IPF patient. From this experience, we noticed the patient's lack of knowledge of their oxygen liter flow rate needed, lack of easy communication with doctors, and lack of an easy way to track and store

health information. These factors caused general frustration and confusion for the patient regarding their illness and treatment. There is a need to allow wireless oxygen liter flow control on concentrators to allow patients to obtain adequate oxygen seamlessly in addition to reducing a patient's lack of knowledge surrounding the oxygen liter flow rate he/she requires when adjusting the flow rate.

III. Project objective statement

A smartphone application will be developed in order to change the oxygen liter flow wirelessly based on user input and according to patients' blood oxygen level saturation. A mechanical device will additionally be created to physically move the knob on a concentrator in order to change the oxygen liter flow rate on a standard oxygen in-home oxygen concentrator. The app and the mechanical device will communicate with each other using bluetooth in order to adjust the oxygen liter flow to the patients' needs.

IV. Final Design Requirements

Application Requirements:

1. The application must be effective
    1.1 Must adjust the oxygen liter flow rate based on the specific patients blood oxygen sat level
    1.2 Should explain how the application works
    1.3 Should allow user to track their oxygen saturation and liter flow requirement
2. The application must be easy to navigate
    2.1 Should have adjustable font sizes for the geriatric population
    2.2 Must provide instructions on how to use the application
3. The application must be secure
    3.1 Must collect user information into separate user accounts
    3.2 Must require authentication to access a user account
4. The application must be easily implementable
    4.1 Must be free for download
    4.3 Must be able for use on all Android devices on all software versions

Device Requirements:

1. The device must be safe

    1.1 Must not decrease patients' respiratory function

    1.2 Must use a direct power source

    1.3 Should have back-up battery capability for emergencies

    1.4 Must adjust oxygen liter flow based on the patients' apparent health conditions and parameters

2. The device must be cost-efficient

    2.1 Should have low manufacturing costs by using inexpensive materials when possible.

3. The device must be easy to implement

    3.1 Must be able to connect to a standard outlet

    3.2 Should be easy to install, remove, and set-up

4. The application must be easily implementable

    4.1 Must be free for download

    4.3 Must be able for use on all Android devices on all software versions

Application and Device Interaction Requirements:

1. The interaction must be accurate

    1.1 Must adjust the oxygen liter flow based on provided protocol

    1.2 Must be capable of calibration

2. The application must be Safety

    2.1 Must be clinically tested on patients

3. The application must be easy to implement

    3.1 Must be intuitive to use

    3.2 Should be easy to connect the device to the application

V. Prototype of the final design

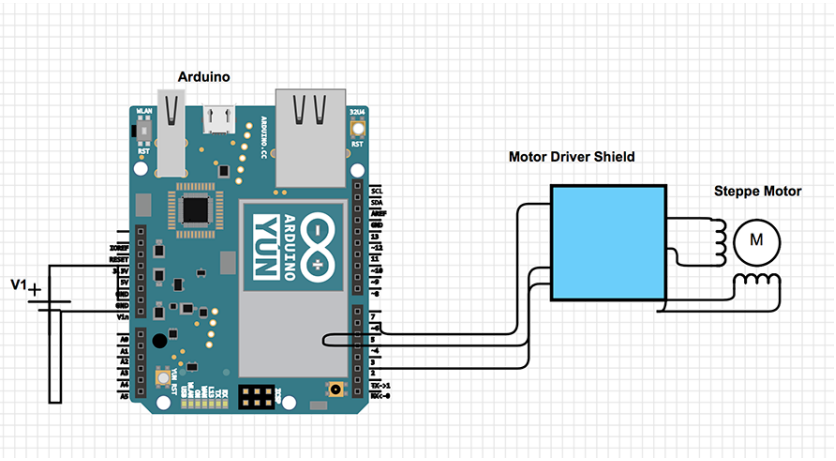


Figure 1: Mechanistic Driver for Device

Figure 1 above shows a general circuit diagram used for the mechanistic driver within the device. This consisted of an Arduino board, breadboard, assorted wires, bluetooth driver, stepper motor driver, and stepper motor.

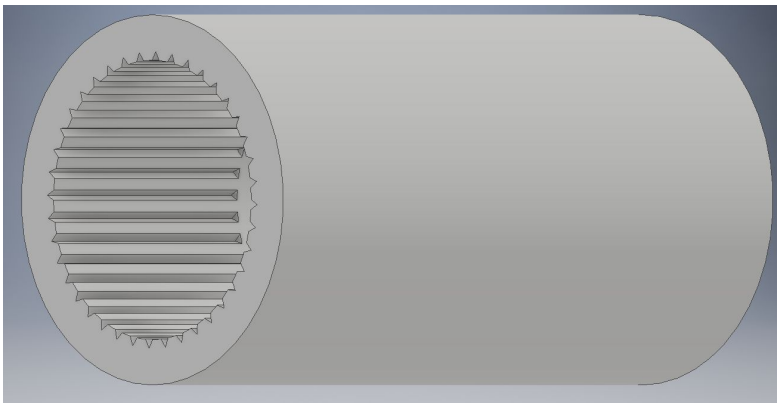
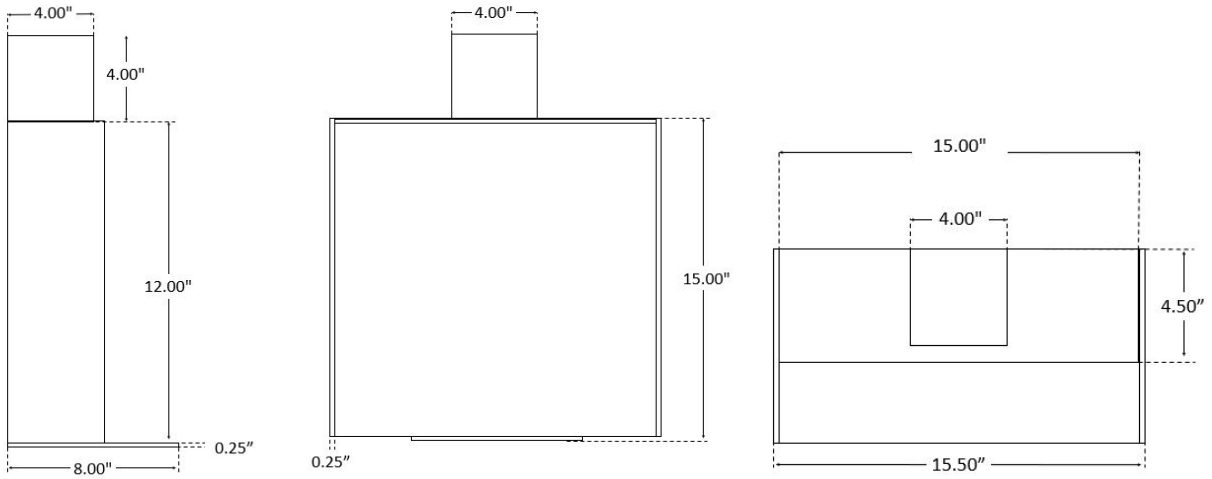


Figure 2: Connection Between Device and Oxygen Tank

Figure 2 above shows the connection created to allow the device to transfer rotation to the oxygen tank. The component is a nylon cylinder with ridges on the interior. The ridges on the component match those on the oxygen concentrator allowing it to fit directly on to the oxygen concentrator knob. The other side of the cylinder connects to the stepper motor thereby transferring the inertia from the stepper motor to the oxygen concentrator knob.



Side View Front View Top View

Figure 3: Container for Device and Oxygen Tank

The mechanistic driver will be contained in an acrylic box atop an acrylic shield that can be placed next to the oxygen tank. The acrylic structure is shown above in Figure 3. The top section of the side and front views shows the box where the mechanistic driver and all of its components will be placed. The rest of the structure will be placed near the oxygen tank and provide support for the mechanistic driver.

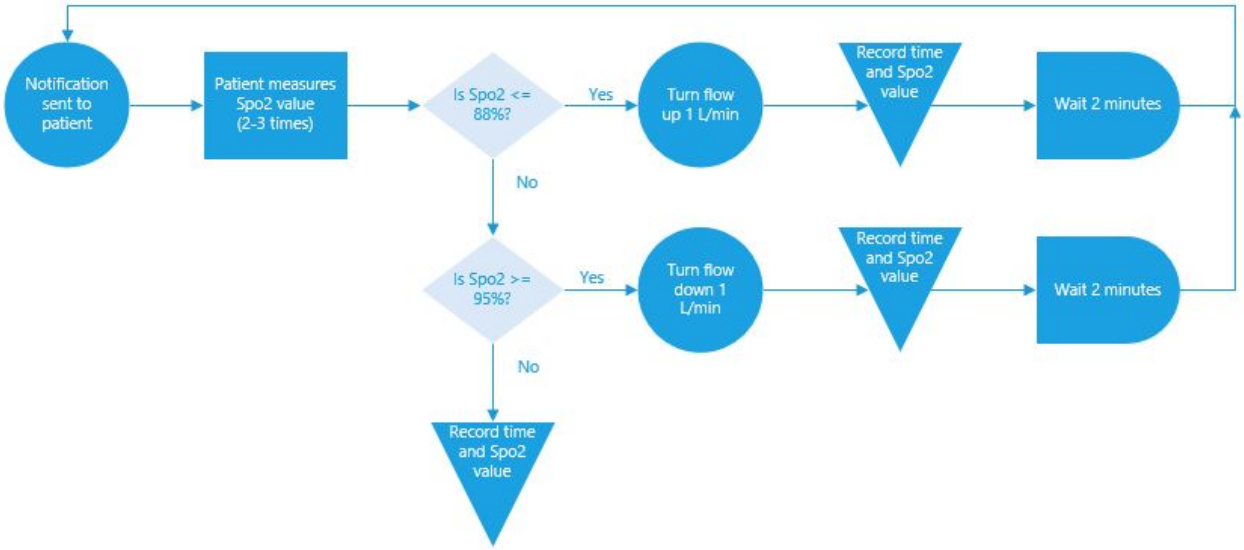


Figure 4: Application Protocol for adjusting Oxygen Liter Flow Based on Oxygen Saturation Levels

The protocol in figure 4 was used to implement the back-end design code for our application. This protocol was developed with the help of Dr.Lisa Lancaster at Vanderbilt's Medical Center.

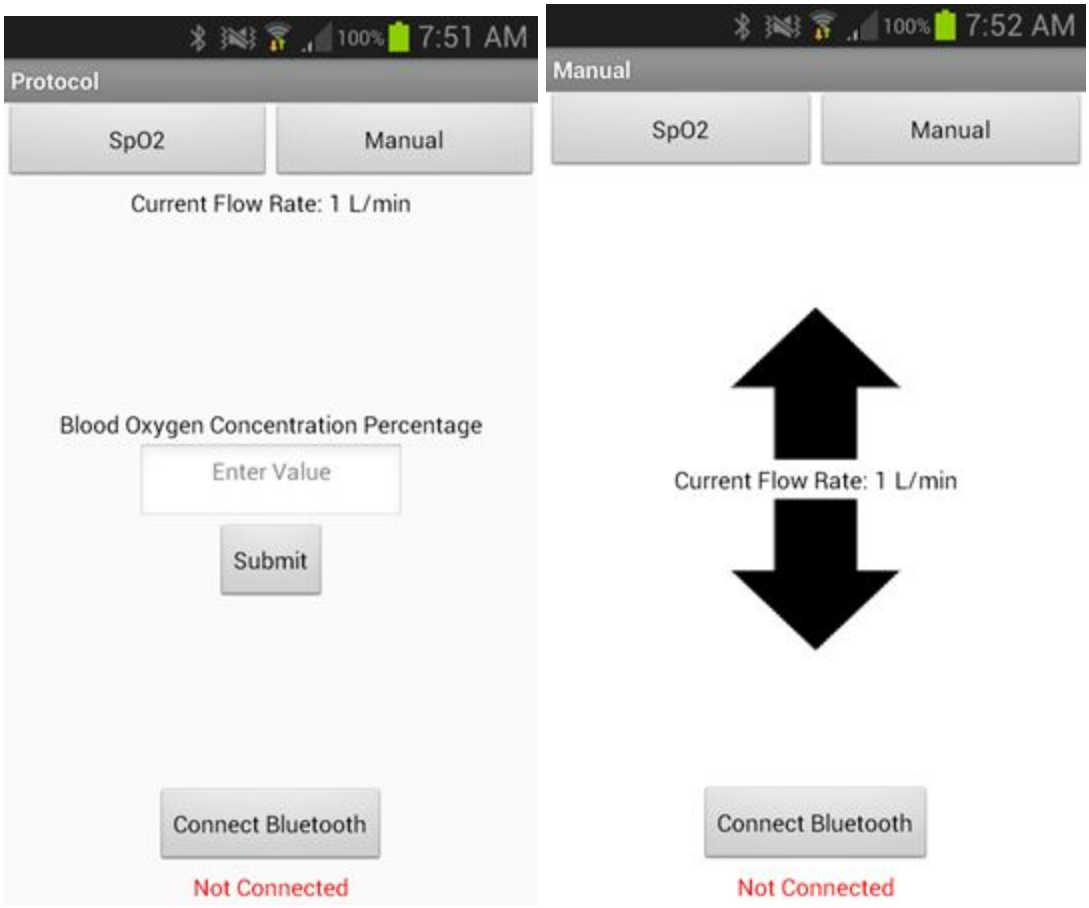


Figure 5: Current Application Interface

In figure 5 you can see the front-end design we have implemented with our back-end for our application. Currently two pages exist for the user to input their blood oxygen saturation level in addition to manually inputting the oxygen liter flow rate the user desires. Our application was build using an open source Android App builder in Java. For further developing our front-end design we have come up with the following sequence.

Step 1:

Option 1: Log-In

Enter: email and/or phone # and password

Option 2: Create a New Account

Enter: name, email, phone, age, birthday, gender, baseline oxygen liter flow rate, password, re enter password

Step 2:

Option 1: Adjust Your Device

Option 1a: Input blood oxygen saturation level

Option 2a: Manually input desired oxygen liter flow rate

Option 2: Access Your Account

Option 2a: View oxygen saturation values overtime classified by activity level and oxygen liter flow rate

Option 3b: Edit your account information

Option 3: Settings

Option 3a: Choose your oxygen concentrator

Option 3b: Adjust font size

Option 3c: Log out

Option 4: Help

Option 4a: How to Use this Application?

Option 4b: How this Application Works?

VI. Proof that the design is functional and will solve the problem (one page). Include test data, market research or pre-clinical/clinical trials

To prove the functionality, feasibility, and efficacy of our design and the subsequent device, we will perform validation and verification testing. To begin validation, L. G. E. C. travelled to the home of a patient experiencing Idiopathic Pulmonary Fibrosis. The patient was observed and interviewed about their experience with IPF and their oxygen tank. The design had been created before this occurred, so the visit confirmed that the design would be applicable to a patient's lifestyle. The next validation step includes making sure that the system created fit the oxygen tank used. Since the system was created using the measurements of the oxygen tank, this step will be validated by making sure that each piece was built with the proper constraints. This will be tested by fitting the device and shield to the oxygen tank and making sure they have a comfortable and operable fit.

To perform verification tests, the oxygen tank will be plugged into an outlet, turned on, and the device and application will be used to adjust the tank liter flow and checked for an adequate adjustment.

After implementation quality of life assessments will also be conducted to obtain an understanding of how our device has made LTOT more comfortable for patients and where areas for potential improvement lie.

VII. Patents/Prior Art

That patent search has yielded systems that are more concerned about the oxygen flow itself and how it is being directly delivered to the patient. One such patent is JP2006325984A, with implanted oxygen sensors for wireless adjustment are based on how well oxygen is flowing inside a patient's oxygen tubes, rather than the patient's blood oxygen saturation level in our design. Another patent,

EP20160167328 aims to curtail hypercapnia, a problem that our technology will indirectly address. This patent detects the oxygen content of the patient and using that in order to address the oxygen needs of the patient. However, this patent states that this is not based upon a closed loop system. While it can sense the change in oxygen, it cannot yet act upon that change to correct the oxygen flow on its own; human knowledge and input is required in order to accurately regulate the flow of oxygen. These patents provide a good base for how to construct a total system using a rotating knob and ta pulse oximeter. Our technology will create a closed loop system that will adjust the oxygen flow rate based on the oxygen of the patient.

Our technology has the potential to be patentable. The application working in conjunction with a motor and knob could be unique to warrant a patent .

VIII. Anticipated regulatory pathway.

Both our mobile application and mechanical device will likely be a combined Class 2 medical device because it is non-invasive and is not life sustaining, but rather an addition to the oxygen concentrator to improve the current system for increased efficacy and ease of use for patients. The oxygen concentrators we will be building our mechanical device and mobile application for are Class 2 devices as well. There is not a high risk associated with our product apart from malfunction which may leave the patient unaware of what the oxygen liter flow is when they rely on the equipment and do not physically adjust the flow on their own. The application will be similar to other FDA approved mobile applications. Though there are wireless remote control oxygen concentrators, no one has created a wireless control of standard in home oxygen concentrators that has a knob to adjust oxygen liter flow using a mobile application while also obtaining oxygen saturation information as a parameter for adjustments. For this reason, even though our device is a Class 2 device, a 510(k) won't be applicable. A 513(g) will have to be filed to go down the de novo route rather than a PMA due to the low risk associated with the device. There is a lot of uncertainty regarding FDA approval for mobile medical apps. The FDA encourages manufacturers of mobile medical apps that perform patient-specific analysis to contact FDA to discuss what, if any, regulatory requirements may apply to their mobile. Based on the FDA's guidance for mobile health applications since our mobile medical apps will control the oxygen liter flow, it is considered an accessory to the connected device (oxygen concentration) and is required to comply with the controls applicable to that connected device.in order to address any associated risks. As of right now general controls will be followed as well as special controls of the oxygen concentrations themselves in conjunction with our device and whatever else the FDA deems appropriate.

IX. Reimbursement

For our device to receive Medicare and Medicaid reimbursement, it must first be approved by the FDA. The device can be found as reasonable and necessary for oxygen treatment by showing the long term results of having oxygen flow rates either too high or too low for the individual receiving the treatment. The device will also be able to integrate with existing oxygen concentrators. For these reasons, the device should be covered by Medicare and Medicaid.

X. Estimated manufacturing costs

To determine the initial profit margin and revenue from the device, a bill of materials was created and can be seen below in Table 1.

Item	Quantity	Price Per Item ($)	Total Price ($)
Arduino Uno Board [3]	1	17.60	17.60
Stepper Motor [4]	1	12.99	12.99
Stepper Motor Driver [5]	1	5.95	5.95
Bluetooth Driver [6]	1	10.99	10.99
100 ft of Electrical Wire [7]	1/20	8.85	0.4425
12*24 Sheets of Acrylic [8]	4	11.06	44.24
Total			92.21

Table 1: Bill of Materials for Wireless Oxygen Liter Flow Device

The above Bill of Materials shows that the cost for the components of the wireless oxygen device is around $92. Once this product is scaled-up in order to reach mass production, the price of the materials will decrease due to bulk purchases and agreements between the manufacturer and component supplier. Costs will also decrease as the volume of product made increases and manufacturers become experts at creating the L.G.E.C technology. L.G.E.C. can actively reduce cost by finding less-expensive materials to use to create the container and mechanistic driver associated with the device. Because of the reasons listed above, it can be estimated that the device will have a manufacturing cost of around $50.

XII. Potential market

Optimally, the ideal market for the oxygen tank liter flow device represents the best fit between our technology, and the critical need of the target populations. As a device used in medical, yet non-clinical situations our main consumers would be patients who need to receive LTOT. Other stakeholders who may purchase the device include individual family members or caretakers of oxygen therapy patients, doctors and clinicians suggesting the device for patients, oxygen tank companies buying the device for each tank they produce, and large corporations focused on chronic illness / elderly care. This market requires an efficient, reliable, and easy-to-use device and user interface that is compatible with most oxygen tanks, and has simple installation steps and little to no maintenance required. Another requirement would be for the device to be low cost, yet this is not prioritized by the market since the future device may be covered by insurance.

After fully identifying the potential market, the next step is to determine the size of the market and whether or not it is large enough to justify device manufacturing and testing. The global market for oxygen therapies was estimated to be $7.1 billion in 2015 and is only expected to increase as more patients are diagnosed with chronic lung diseases. Initially, we would focus on targeting the North American oxygen therapy market share which was estimated at $3 billion in 2015 [9]. This decision was made as this is the largest regional section of the oxygen therapy market and also represents one of the most stringent in terms of medical devices and their regulation. Beginning in this region will be difficult but force early innovations to the device as it undergoes regulation testing. This iterative process will lead to a better solution for patients in need of oxygen therapy. The device will initially be tested on patients that have IPF as this is the patient population that we have available through our sponsors. This market is small with around 13.2 per 100,000 women and 20.2 per 100,000 men having the condition in the United States [2]. This corresponds to 43,415 women and 66,438 men based on the current U.S. population [10]. The combined population of the target market is currently 109,853 for the first iteration of the device.

As previously stated, the device will likely cost around $50 to manufacture, making a selling price of $65 reasonable. For a one-time purchase of a device, L.G.E.C. believes this is a low cost for the benefits obtained from wireless control of an oxygen concentrator.

XIII. References

1. Reference, G. H. (n.d.). Idiopathic pulmonary fibrosis. Retrieved April 10, 2019, from Genetics Home Reference website: https://ghr.nlm.nih.gov/condition/idiopathic-pulmonary-fibrosis
2. LEY, B. AND COLLARD, H., 2013. Epidemiology of idiopathic pulmonary fibrosis. Dove Medical Press, 5, 483-492.

3. MOUSER ELECTRONICS. 2019. Arduino A000052. https://www.mouser.com/ProductDetail/Arduino/A000052?qs=JYLCs0CWXI0EuuE9AXNMFg%3D%3D&gclid=CjwKCAjwqLblBRBYEiwAV3pCJum7O-ut1KLLuIHE2kDe38q14D4lUkoUg5MBRNnGwAl5AD7NjMfb0RoCejAQAvD_BwE
4. AMAZON. 2019. Stepperonline stepper motor nema 17 bipolar 40mm 64oz.in(45Ncm) 2A 4 lead 3D printer hobby CNC. https://www.amazon.com/Stepper-Motor-Bipolar-64oz-Printer/dp/B00PNEQI7W/ref=asc_df_B00PNEQI7W/?tag=hyprod-20&linkCode=df0&hvadid=309777532761&hvpos=1o1&hvnetw=g&hvrand=13202131286732922917&hvpone=&hvptwo=&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9013193&hvtargid=pla-458488325758&psc=1&tag=&ref=&adgrpid=63226431993&hvpone=&hvptwo=&hvadid=309777532761&hvpos=1o1&hvnetw=g&hvrand=13202131286732922917&hvqmt=&hvdev=c&hvdvcmdl=&hvlocint=&hvlocphy=9013193&hvtargid=pla-458488325758
5. POLOLU. 2019. Stepper motor driver. https://www.pololu/category/120/stepper-motor-drivers
6. AMAZON. 2019. HiLetgo ESP-WROOM-32 ESP32 ESP-32S development board 2.4GHz dual-mode WiFi + bluetooth dual cores microcontroller processor integrated with antenna RF AMP filter AP STA for arduino IDE**.** https://www.amazon.com/gp/product/B0718T232Z/ref=ppx_yo_dt_b_asin_title_o00_s00?ie=UTF8&psc=1
7. DEL CITY. 2019. 18 Gauge Primary Wire - 100 Feet. https://www.delcity.net/store/18-Gauge-Wire/p_181398.h_181558.r_IF1003?mkwid=s&crid=38094426869&mp_kw=&mp_mt=&gclid=CjwKCAjwqLblBRBYEiwAV3pCJrlrm1AyC6Kis_Bhq7JNCHMIFde0sCiHVQEta0DWUiV4vNJ4ComDfxoChJMQAvD_BwE
8. BLICK. 2019. Clear acrylic sheets. https://www.dickblick.com/products/clear-acrylic-sheets/?clickTracking=true&wmcp=pla&wmcid=items&wmckw=28945-1006&gclid=CjwKCAjwqLblBRBYEiwAV3pCJr7SE4eQ1a-ZtVA2mXrNQCMMwhCC3pMAWwEF0E73ahwYbefNpG1szRoCcu0QAvD_BwE
9. GRAND VIEW RESEARCH. 2018. Oxygen therapy market size, share & trends analysis report by product (oxygen source equipment, oxygen delivery devices, static, dynamic), by application, by and-use, and segment forecasts, 2018 – 2024. Grand View Research. 978-1-680838-829-9. https://www.grandviewresearch.com/industry-analysis/oxygen-therapy-market
10. UNITED STATES CENSUS. 2019. U.S. and world population clock. https://www.census.gov/popclock/