Pressure Based Spirometry:

Mobile Spirometry Using a Pressure Transducer

by

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ABSTRACT

Spirometry is a type of pulmonary function test that measures the amount of air volume and the speed of air flow from a patient's breath in order to assess lung function. The goal of this project is to develop and validate a mobile spirometer technology based on a differential pressure sensor. The findings in this paper are used in a larger project that combines the features of a capnography device and a spirometer into a single mobile health unit known as the capno-spirometer. The following paper discusses the methods, experiments, and prototypes that were developed and tested in order to create a robust and accurate technology for all of the spirometry functions within the capno-spirometer. The differential pressure sensor is set up with one inlet measuring the pressure inside the spirometer tubing and the other inlet measuring the ambient pressure of the environment. The inlet measuring the inside of the tubing is very sensitive to its orientation and position with respect to the path of the air flow. It is found that taking a measurement from the center of the flow is 50% better than from the side wall. The sensor inlet is optimized at 37 mm from the mouthpiece inlet. The unit is calibrated by relating the maximum pressure sensor voltage signal to the peak expiratory flow rate (PEF) taken during a series of spirometry tests. In conclusion, this relationship is best represented as a quadratic function and a calibration equation is computed to provide a flow rate given a voltage change. The flow rates are used to calculate the four main spirometry parameters: PEF, FVC, FEV1, and FER. These methods are then referenced with the results from a commercial spirometer for validation. After validation, the pressure-based spirometry technology is proven to be both robust and accurate.

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INTRODUCTION

In short, spirometry is a pulmonary function test that can evaluate the state of a subject's lungs based on various measurements of the volume and flow rate of his or her expired breath. Similar to how a thermometer can quantify the severity of a fever, a spirometer is able to quantify the state of a person's lung functions. This type of test has many applications with the most prominent being in the field of asthma and COPD diagnosis and treatment. Another common medical test that is performed with patients suffering from respiratory illnesses is a capnography test. As a result, research began in the Center of Bioelectronics and Biosensors during the summer of 2012 to create a mobile health (aka mHealth) device that can perform both capnography and spirometry tests. This single device, named the capno-spirometer, can connect to a Smartphone via Bluetooth in order perform all of the tests.

Before spirometry, Asthma patients would need to first experience an asthma attack before proper treatment. Now, a properly performed spirometry test can detect the signs of an asthma attack, allowing for preventative treatment.

In the past, patients would need to travel to a doctor's office in order to perform a standard spirometry test. This was largely because of the bulky machinery. Today, handheld spirometers are sold commercially and used in the home of the patient or even on-the-go.

There are many challenges to creating a personal mobile health instrument such as the capno-spirometer. First, the device must be user friendly. It is important to ensure that the user can perform the tests on their own without the help of a medical professional. Next, the device must be robust. The unit must be able to withstand all of the mistakes and possible accidents that can occur during its operation and storage. This can be as simple as withstanding a drop on the floor to as complicated as repelling a hacker trying to steal the patients' medical records. Another challenge is to keep the device low cost. Since the device is to be used in the average household, it must be affordable by the average user. And lastly, the device needs to be

accurate. The patients need to be able to trust the results from the tests in order to make important health-related decisions.

The following paper outlines the methods, experiments, and prototypes that were developed and tested in order to create a robust and accurate technology to be used for all of the spirometry functions within the capno-spirometer.

Chapter 2

BACKGROUND

Spirometry has many applications within the fields of asthma, COPD, and oxygen therapy. The list below shows a few reasons to take a spirometry test:

- To evaluate symptoms, signs or abnormal laboratory tests (i.e. dyspnea, chronic cough, chest tightness/cough during exercise, frequent colds)
- To measure the effect of disease on a pulmonary function.
- To assess therapeutic interventions (i.e. bronchodilator or steroid treatment, management of CHF, etc.)
- To assess preoperative risk
- To screen individuals at risk of having pulmonary diseases (i.e. smokers, obesity, occupational exposures)
- To assess the prognosis of a disease
- To assess health status before enrollment in strenuous physical activity programs
- To assess patients as part of a rehabilitation program
- To assess risks as part of an insurance evaluation
- To assess individuals for legal reasons (i.e. Social Security disability, personal injury lawsuits, etc.)

As shown in the list above, (Web Source [2]), there a many reasons to perform a spirometry test. The two most prominent uses are to evaluate the symptoms of patients with pulmonary problems and to assess patients as part of a rehabilitation program. *Figure 1*, on the next page, shows a standard setup for spirometry test.

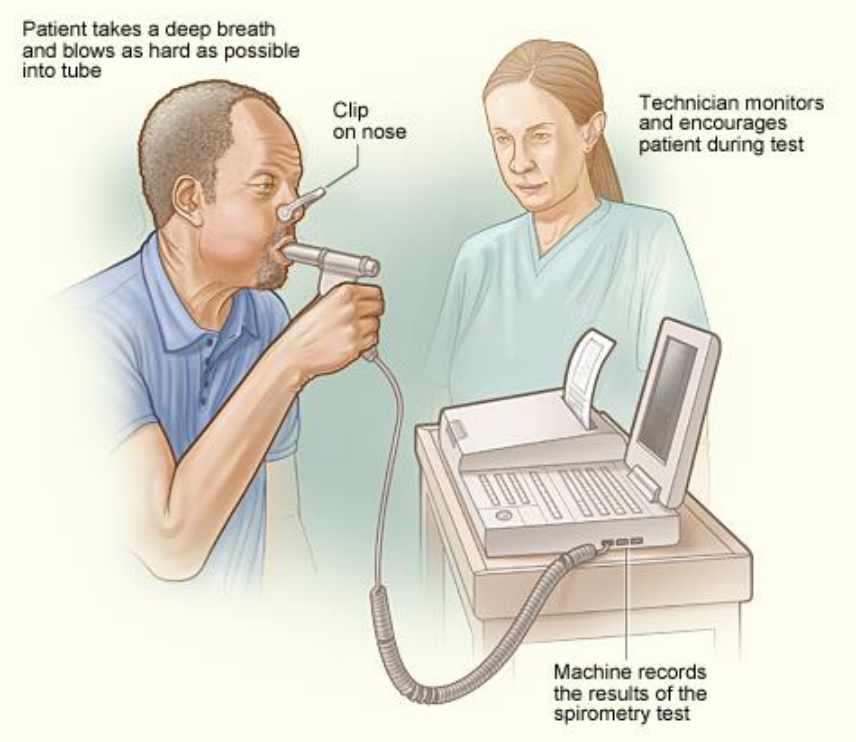

Figure 1. A typical spirometry test equipment (Web Source [1]).

The figure above shows a standard setup for a spirometry test. This test involves a patient taking a deep breath and then proceeding to breathe as hard as possible through a tube. The patient will continue to breathe as hard as possible until his/her lungs are completely empty. This patient will continue to repeat this process until they have achieved their strongest possible breath. This information is then sent to a machine that can record and display the results.

The results of a spirometry test can be interpreted and categorized into over forty different parameters. The majority of this information can be taken from a graph that plots the volume expired vs. the flow rate. A sample spirometry graph is shown in *Figure 2*, below.

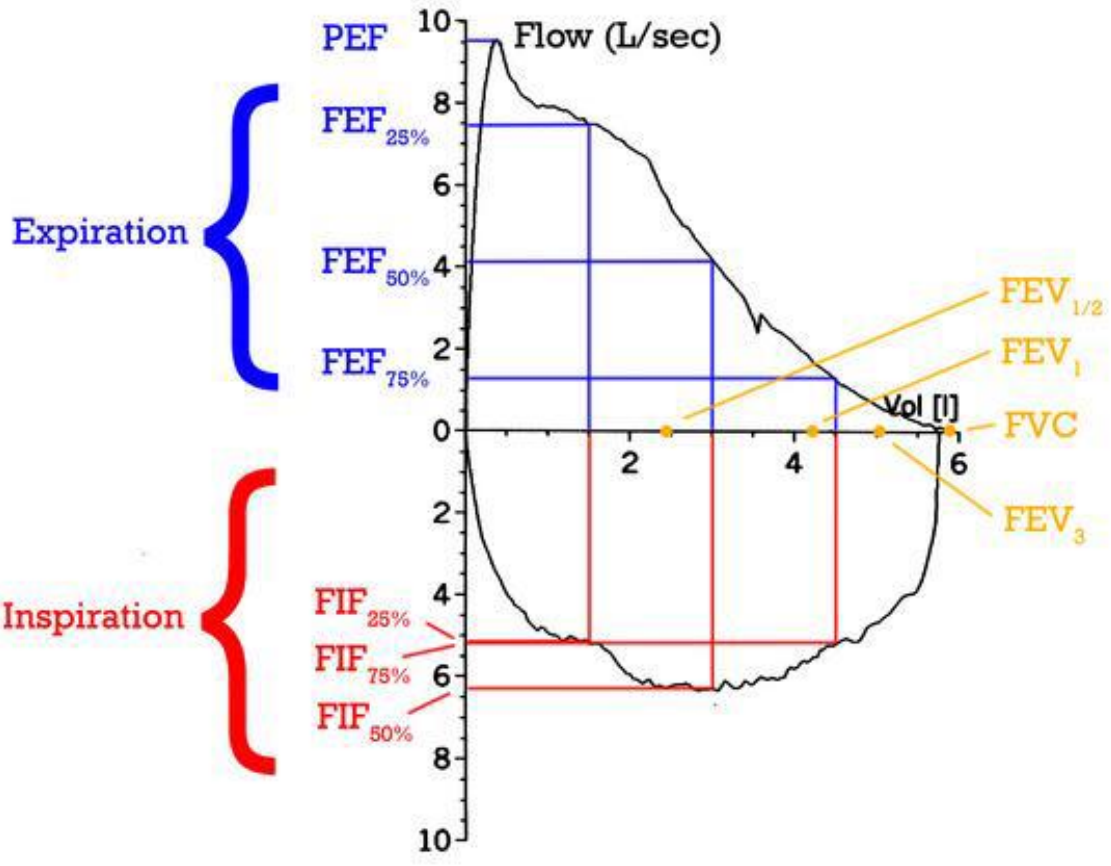

Figure 2. A standard spriometry graph showing flow vs. volume (Web Source [2]).

The figure above shows a sample spirometry graph. This plot shows eleven of the over forty different parameters that can be acquired from a single spirometry test. Of the forty, there are four main parameters that every spirometry test should deliver: Peak Expiratory Flow Rate (PEF), Forced Vital Capacity (FVC), Forced Expiratory Volume at One Second (FEV1), and Forced Expiratory Ratio (FER). These parameters can be seen in *Figure 2* above and their descriptions are located in Table 1 on the next page.

Table 1

Spirometry Parameters

	Description
PEF	Peak Expiratory Flow rate. This number is usually displayed in liters per second. It stands as the maximum flow rate achieved by the patient in one breath.
FVC	Forced Vital Capacity. Total volume of air forcefully exhaled between the maximal inspiration and maximal expiration. Simply how much air a person can force out of their lungs in one breath. This number is usually displayed in liters.
FEV1	Forced Expiratory Volume at One Second. Volume of air exhaled in the first full second of the breath. Simply how much air a person can force out of their lungs in the first second. This number is usually shown in liters.
FER	Ratio of the FEV1 to the FVC. Percentage of the total volume exhaled in the first full second (FEV1). Also known as FEV1%. In healthy adults this should be approximately 75–80%.

The table above describes the four main parameters that result from every spirometry test: PEF, FVC, FEV1, and FER. In association with these basic parameters, it is also important to analyze the shape of the curve. The shape alone can provide important information in the diagnosis and treatment of patients with asthma or COPD. Different spirometry curves and their related diagnoses are displayed in *Figure 3* on the next page.

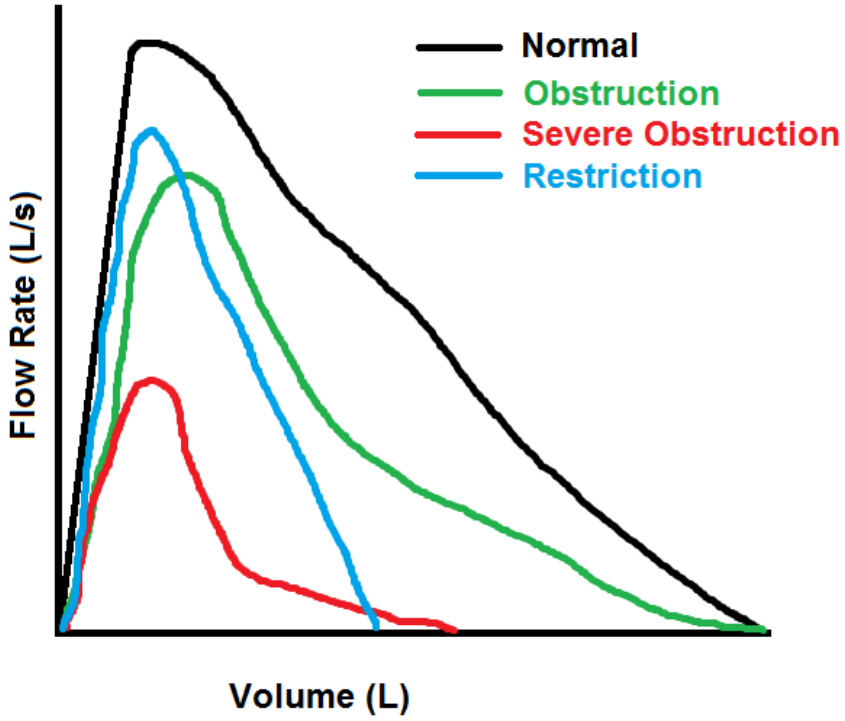

Figure 3. Different spirometry graph shapes.

The figure above shows a couple of the different possible graph shapes and their corresponding diagnoses. These graphs, as well as the parameters, are based on a set of normals. Although every individual is unique, every respiratory system works the same way. Therefore, a system of normal values has been put together in order to compare individual test results. These normal values can be seen in *Figure 4* on the next page.

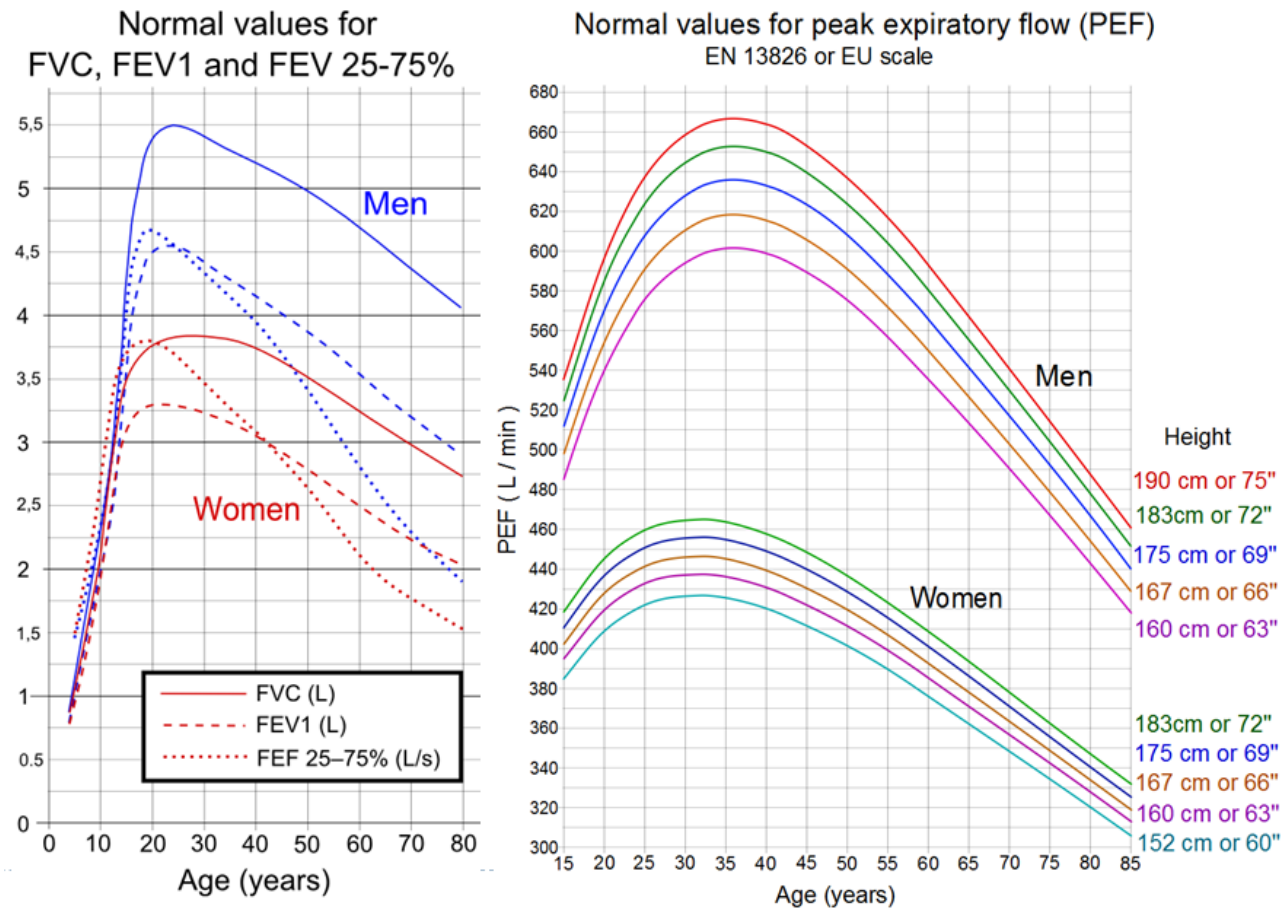

Figure 4. Normal spirometry values (Web Source [2]).

The figure above shows the range for normal PEF, FVC, and FEV1 values for patients of different ages and sizes. It is considered healthy to be within +/- 10% of these normal values.

Chapter 3

PURPOSE AND SCOPE

The purpose of this project stems from the creation a mHealth device combines the performance of capnography and spirometry tests. This capno-spirometer can provide the accuracy of a doctor's visit into the comfort of the patient's home. In order to create this device, the capnography and spirometry sensing technologies are researched and developed.

The science behind a spirometer is based on flow detection. The four main spirometry parameters can be mathematically derived from the flow rate of the patient's breath. PEF is the maximum flow rate during the test. FVC is the integral of the flow rate over the total time of the test. FEV1 is the integral of the flow rate over the first second of the test. And FER is simply the ratio between the FEV1 and FVC. Because every parameter has a relationship with the flow rate, the flow rate is the only thing that needs to be measured.

There are many ways to measure flow rate. The three most common include mechanical turbines, differential pressure transducers, and thermal sensors. In order to get the most accurate test, the spirometer should supply the least amount of resistance as possible, thus increasing the potential for maximum detectable flow rate. Therefore, current spirometers tend to lean towards using the low resistance turbines. However, mechanical turbines have moving parts and these parts would interfere with the capnography portion of the device. As a result, a method using differential pressure to measure the flow rate was pursued.

The scope of this project is to design, fabricate, test, and validate a pressure-based spirometer technology. As a result, this technology must be able to accurately provide the flow vs. volume curve as well as the PEF, FVC, FEV1, and FER values that result from a standard spirometry test. The capnography portion of the device is undergoing research from another student in the lab.

Chapter 4

METHODOLOGY AND PROCEDURES

The methods used to develop the pressure-based spirometer consist of three distinct steps. The first step involves running through a series of proof-of-concept tests in order to determine if this type of technology is possible. Next, the system is optimized and calibrated using leading standards in the field of spirometry. Finally, the technology is put to the test against a reference spirometer in order to validate the findings.

Working with the Center for Bioelectronics and Biosensors, in the Biodesign Institute, gave access to all of the equipment for this project. By using the materials in this a lab, all of the experimental setups are fabricated and tested. At first, a rough version of the capno-spirometer was assembled for proof-of-concpet testing. The first experimental setup is shown in *Figure 5* below.

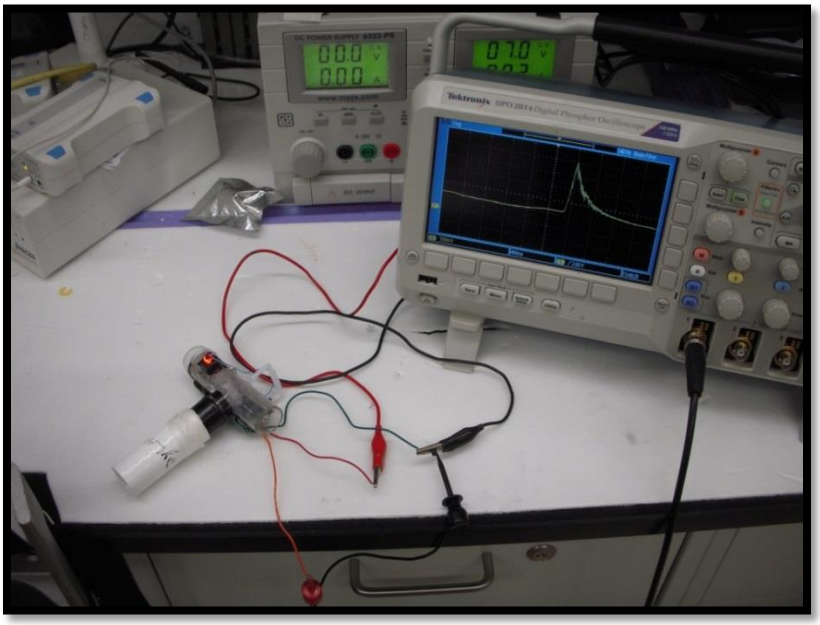

Figure 5. Early capno-spirometer setup used for proof-of-concept testing.

This experimental capno-spirometer, shown on the previous page, was fabricated out of a commercial mouthpiece. Originally designed for the capnography testing, it was altered and equipped to handle spirometry tests later on. The differential pressure sensor was already

mounted on the device's PCB and currently being used for the low flow rates of the capnography tests. This setup has one of the sensor inlets connected to the back of the mouthpiece and the other open to the environment. Therefore, the pressure sensor would output the difference in pressure between inside the tube and outside the tube as a voltage. In order to acquire the voltage data from this pressure sensor, and oscilloscope is directly connected to the output leads of the sensor. Later, the oscilloscope readings from each test are saved onto a flash drive and transferred to a PC for post-processing.

The next step is to develop and optimize a series of post processing methods in order to convert these voltage outputs into meaningful spirometry parameters such as PEF and FVC. In general, most pressure-based flow sensors will use an orifice or similar obstruction in order to create a large difference in pressure. However, with a spirometry test, there should be little-to-no resistance for the patient during the test. Therefore, the pressure difference between inside the tube and outside the tube was quite small. In turn, this resulted in some measurements being near the noise level of the sensor. Because of this, the data acquisition rate and smoothing methods needed to be analyzed and implemented in order to reduce the effect of noise on the system. After applying several combinations of oscilloscope sampling rates and smoothing methods in Origin Pro 8, it is determined that the best results came from a sampling rate 6.25 kS/s and an "Adjacent-Averaging" smoothing method. An example of this method is shown in the figure below.

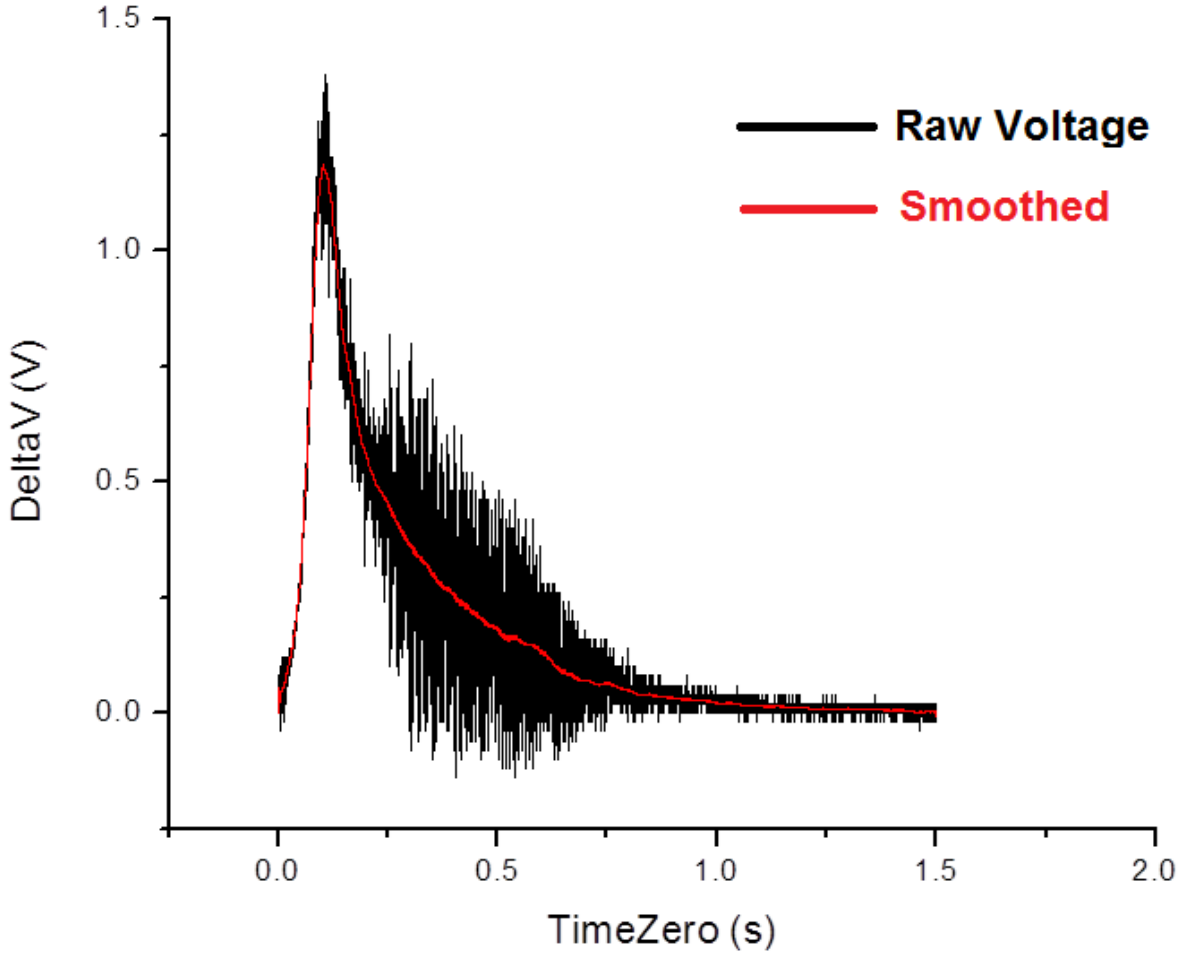

Figure 6. A sample plot showing the data acquired from the oscilloscope.

In the figure above, the black curve represents the raw voltage reading from the pressure sensor via the oscilloscope and the red curve represents the smoothed data after some post processing using Origin Pro 8.

A larger voltage change directly corresponds to a larger flow rate. This means that the four main parameters are simply different manipulations of the voltage change within the pressure sensor. PEF is directly related to the maximum voltage change. FVC is directly related to the integral of the voltage change over time. FEV1 is directly related to the integral of the voltage change over the first second.

The final step before calibration is to optimize the orientation and position of the pressure sensor inlet within the tube. There are two orientations to test: sidewall and tube-center, as shown in *Figure 7* below.

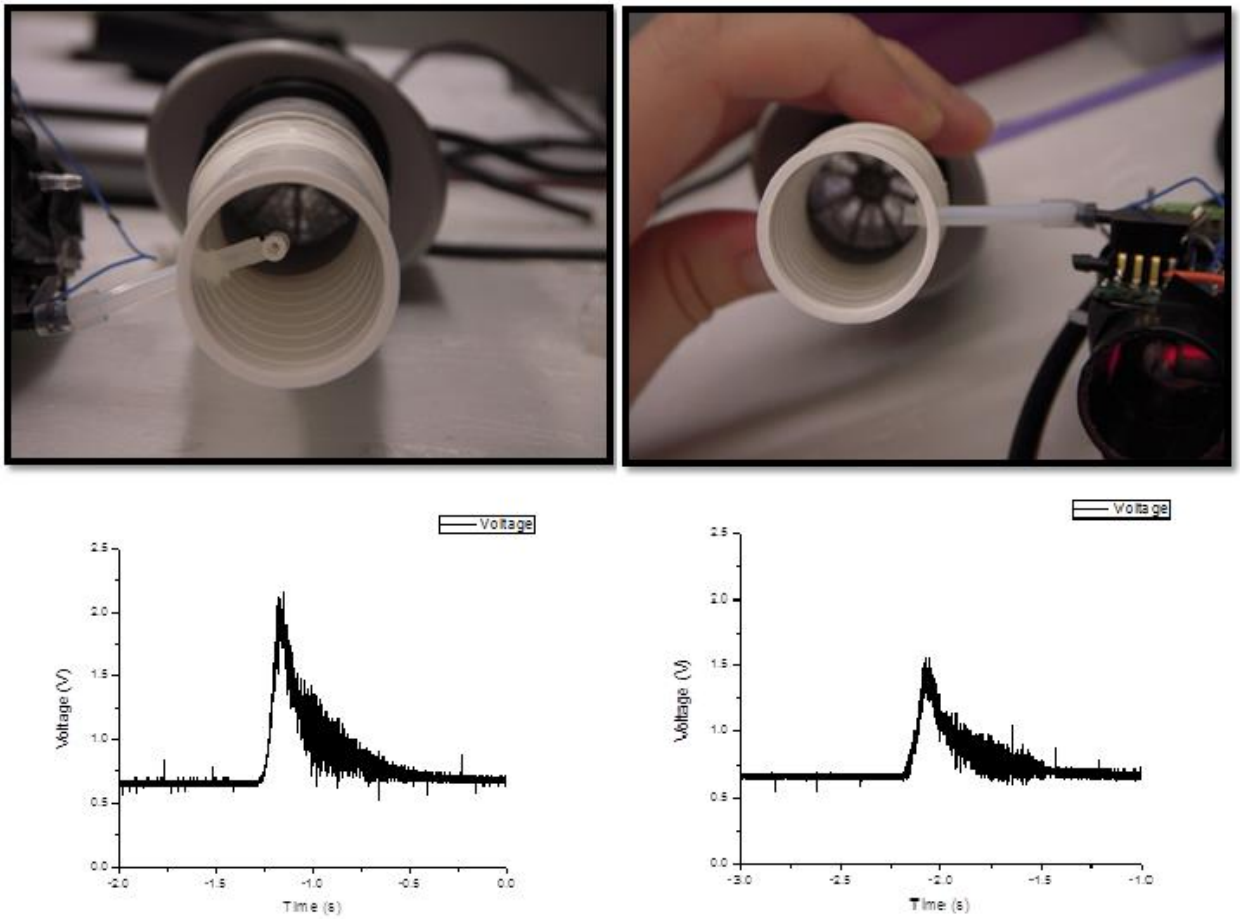

Figure 7. The two experimental orientations for the sensor inlet tubing and their corresponding responses.

The figure on the previous page shows the two different orientations that were tested: sidewall and tube-center. From the graphs, it can be seen that the setup with the tube-centered inlet results in a higher response. These results can be seen more clearly in the tables on the next page.

Table 2

Results for Sidewall Orientation

Test #	Voltage Change (V)	PEF (L/s)	Normalized (V/L/s)
1	1.00	9.22	0.10846
2	0.92	9.39	0.09798
3	0.90	9.31	0.09667

Table 3

Results for Tube-Center Orientation

Test #	Voltage Change (V)	PEF (L/s)	Normalized (V/L/s)
1	1.4	8.74	0.16018
2	1.42	9.26	0.15335
3	1.5	9.42	0.15924

The tables above indicate that the locating the pressure sensor inlet in the center for the flow results in a 50% higher response. This is good because larger voltage changes are easier to measure and calibrate. Upon using this setup for multiple tests, it becomes a concern that the loose state of the tubing has the possibility of supplying a mechanical vibration during testing. In order to avoid this problem, a more permanent solution is designed using SolidWorks. Using computer software like SolidWorks allows for a quick and accurate design process. The figure below shows the final design of the pressure sensor inlet.

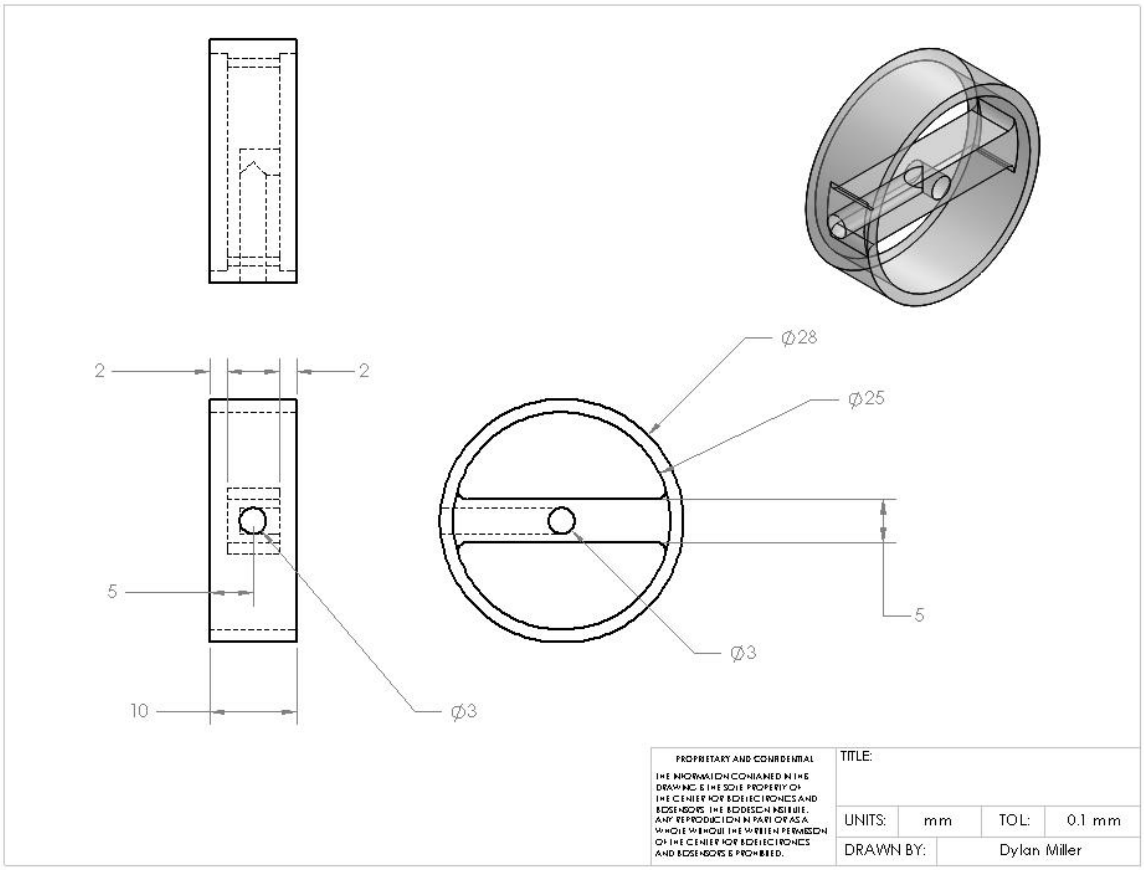

Figure 8. The SolidWorks drawing file of the prototype pressure sensor inlet.

The figure above displays the computer aided design of the pressure sensor inlet. This design followed two main requirements. First, the inlet tubing needed to be at the center of the flow in order to abide by the findings in the previous experiment. Second, the design must be robust and eliminate any mechanical noise during testing. As a result, the inlet is designed with a robust cross-bar through the center of the tube with the inlet to the pressure sensor in the center of the bar. With these two requirements met, the design was pushed to fabrication. A g-code was created using this design and executed on a 3-axis CNC machine in order to accurately manufacture a prototype unit. A picture of this pressure sensor inlet can be seen in the figure below.

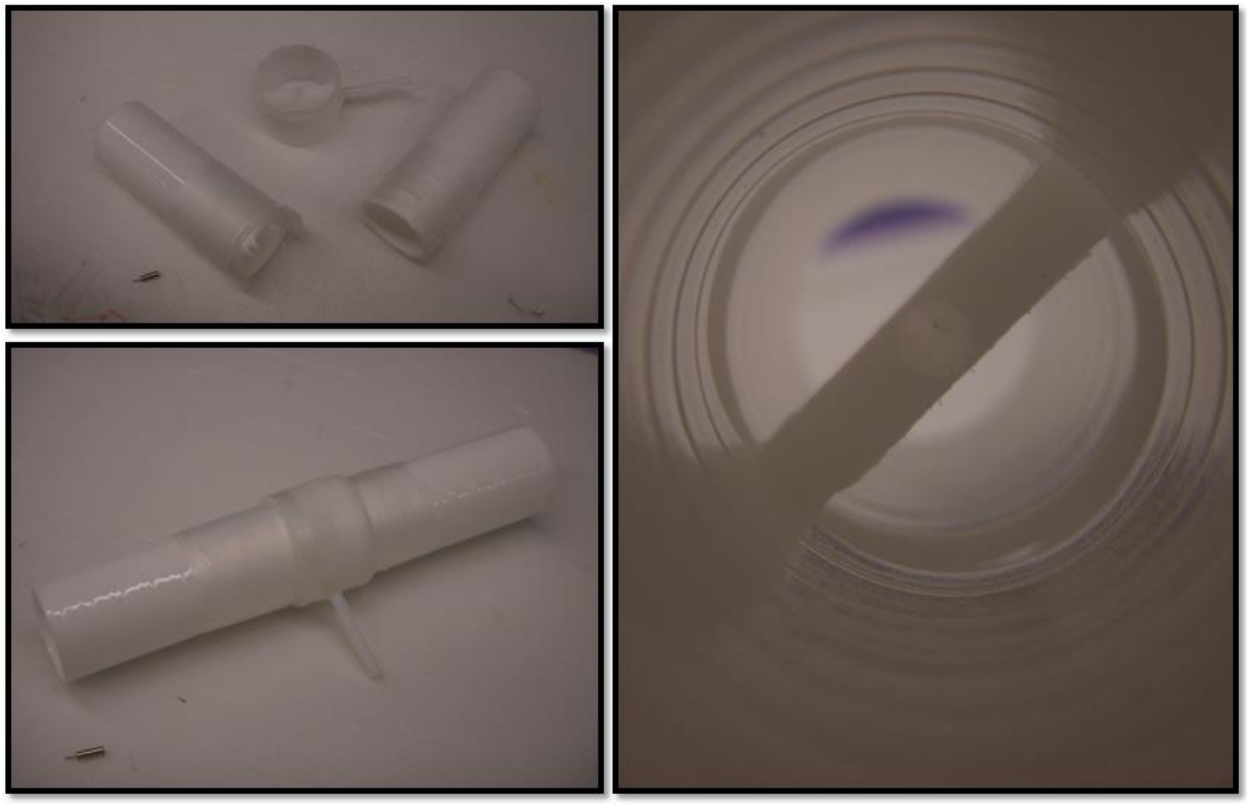

Figure 9. The fabricated pressure sensor inlet and prototype setup.

The figure above shows the completed prototype spirometer consisting of the pressure sensor inlet and two plastic mouthpieces. A new experiment is held in order to determine the optimum length of tube and location of pressure sensor inlet. For this experiment, four different configurations are tested and analyzed. The best configuration is determined by the best (or largest) voltage change from the pressure sensor. The four configurations are shown in *Figure 10*, on the next page.

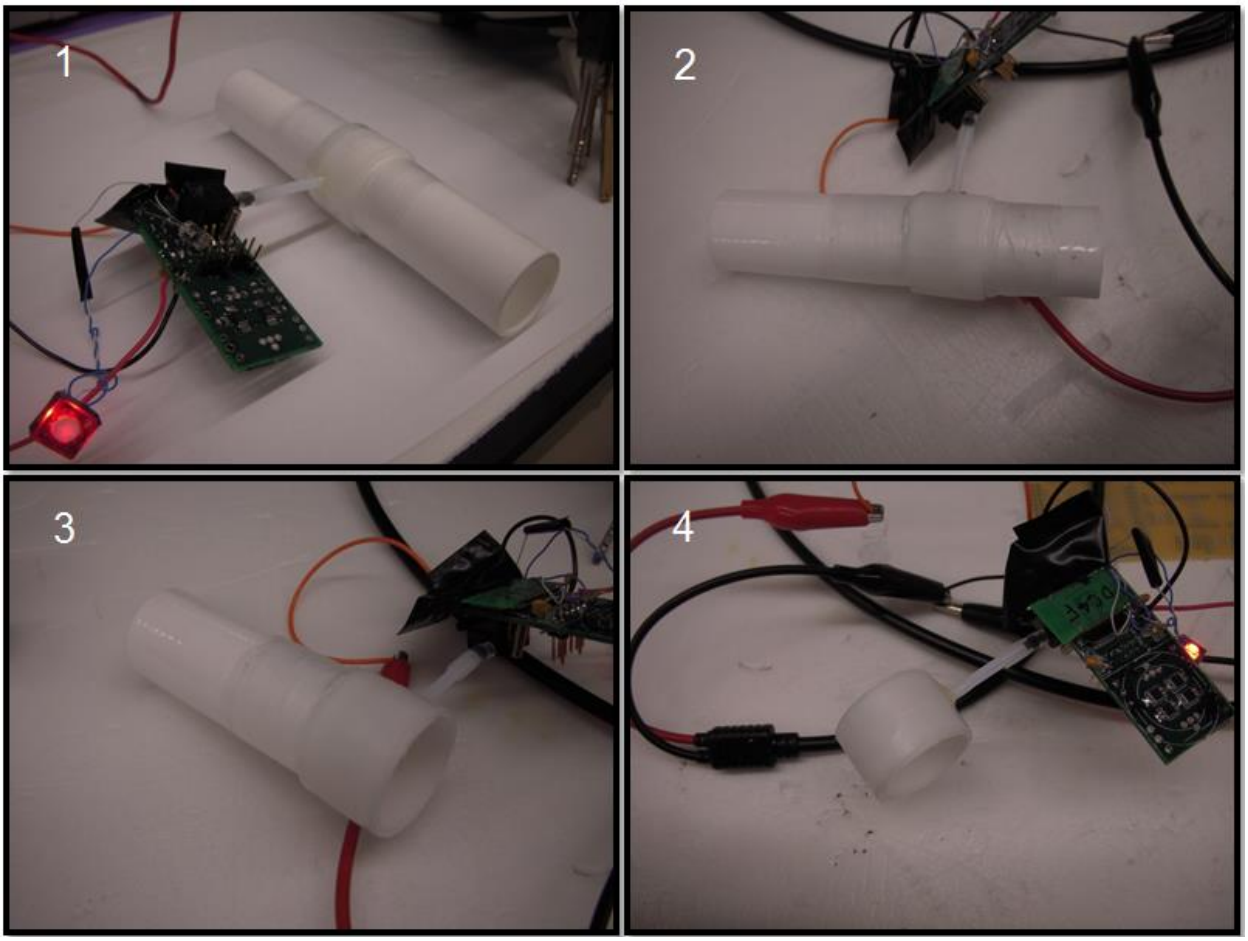

Figure 10. The four pressure sensor positions used for optimization testing.

The figure above shows the four different configurations that test the tube length and pressure sensor position for the prototype. Setup #1 has the sensor in-between two full length tubes. The sensor inlet is 63 mm from the mouthpiece inlet. Setup #2 cuts the inlet tube leaving the sensor at 37 mm. Setup #3 removes the inlet tube. Setup #4 removes the inlet and outlet tubes. Each setup is tested three times at low flow rates to determine which is most sensitive. The results are shown in the figure on the next page.

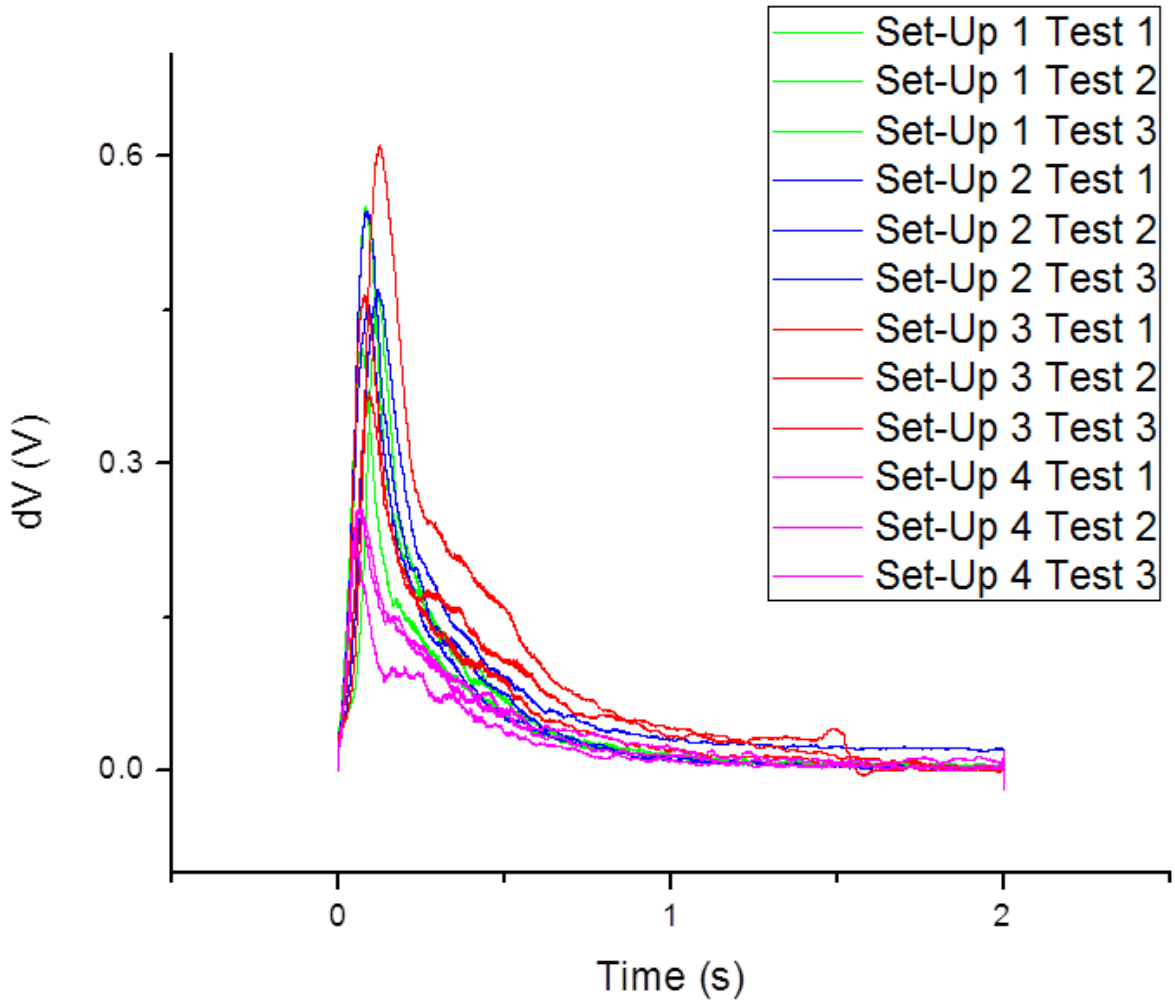

Figure 11. A plot of the results from the four pressure sensor positions.

The figure above shows the results of the four configurations at low flow rates. For each setup, the average maximum value from each test is taken in order to determine the best location for the sensor inlet. The results are shown in the table on the next page.

Table 4

Results for Pressure Sensor Position

Setup	Distance (mm)	Average Max (V)
1	63	0.47603
2	37	0.49006
3	0	0.50181
4	0	0.24344

From the table above, setup #3 has the highest average maximum voltage change. Based on these results, setup #3 is determined to be the optimum configuration. Next, the device is calibrated and validated.

Chapter 5

DATA ANALYSIS AND RESULTS

In order to calibrate the differential pressure sensor, setup #3 is hooked up in series to an Oxycon Mobile device. Oxycon Mobile is a portable cardiopulmonary stress testing device from CareFusion that can measure breathing flow rates with an accuracy of 0.05 L/min. Various flow rates are passed through setup #3 and Oxycon Mobile in order to record pressure sensor voltage changes and their corresponding PEF values. These values are then plotted against eachother in order to calibrate the pressure sensor. This calibration is shown in the figure below.

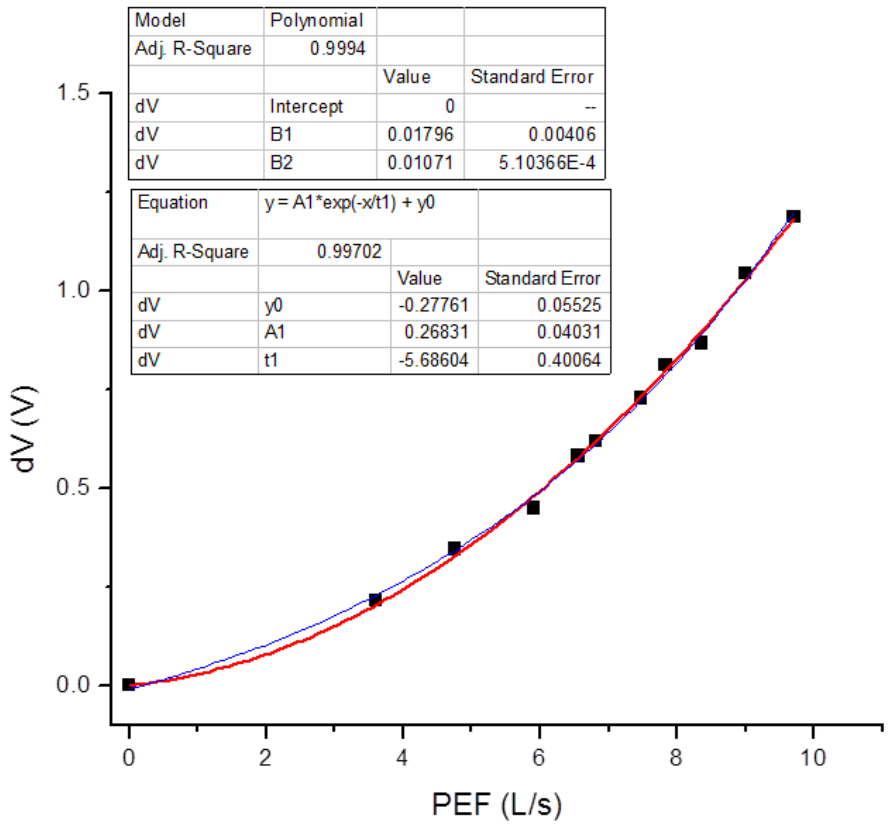

Figure 12. A plot of the two calibration curves.

Figure 12 shows the voltage change (dV) of the pressure sensor vs. the peak expiratory flow rate (PEF) reading from the oxycon device. The data points seemed to follow one of two different calibration curves: a quadratic or an exponential. Both formulas are applied and it can

be seen that the quadratic is more accurate. Therefore the quadratic calibration curve is used to calculate flow-rate based on the voltage change of the pressure sensor. The equation below shows the relationship between the flow rate (f) and voltage change (dV).

$$f = 9.66285(\sqrt{dV + 0.007529} - 0.086722) \quad (1)$$

Equation (1), above, calculates the flow rate for a given voltage change. By implementing this equation on the voltage data from the pressure sensor, one can produce a flow rate vs. time graph for each spirometry test. With this information, the four parameters PEF, FVC, FEV1, and FER can be calculated.

In order to validate this calibration, the methods are put up against a commercial device. The commercial device referenced in this project is the MicroLoop Spirometer. This professional device is designed for use by doctors and physicians in their practice. A picture of the MicroLoop Spirometer is shown in *Figure 13* on the next page.

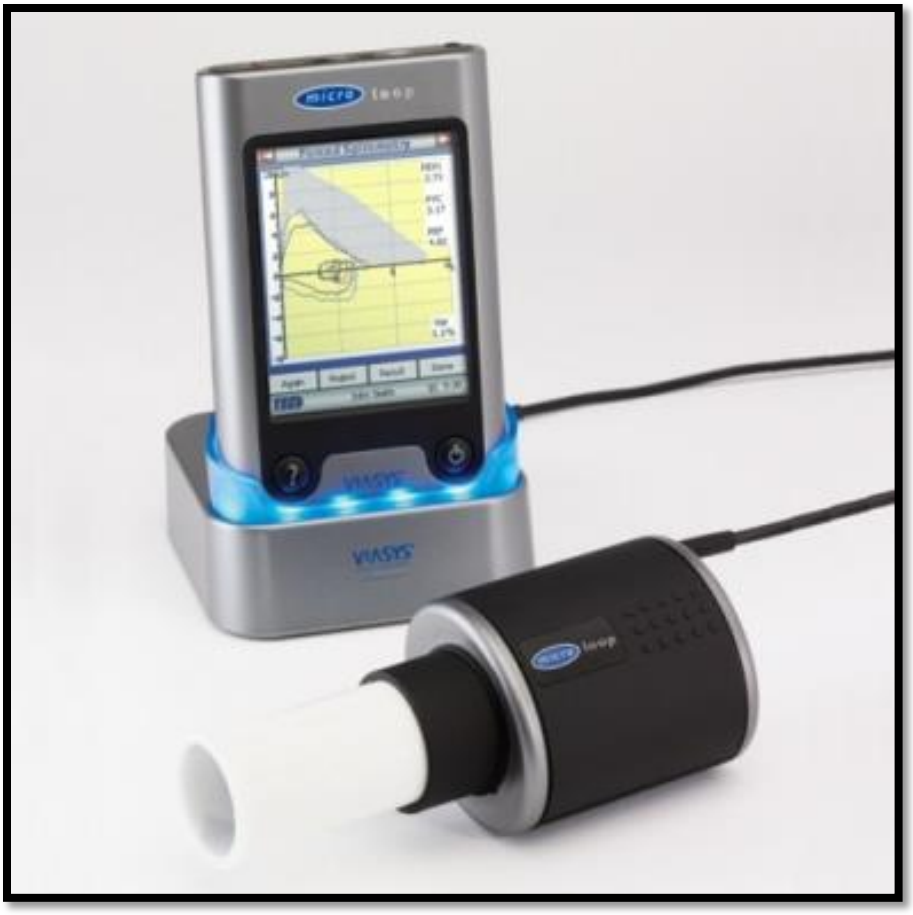

Figure 13. The MicroLoop Spirometer used as a commercial reference device (Web Source [3]).

The figure above shows the professional spirometer used in the validation of the methods developed in this paper. This MicroLoop spirometer uses a mechanical turbine that is considered to be a "Gold Standard Transducer." By putting the testing set-up in series with this "gold standard" device, the methods outlined in this paper can be validated. These validation plots are shown in the following figures.

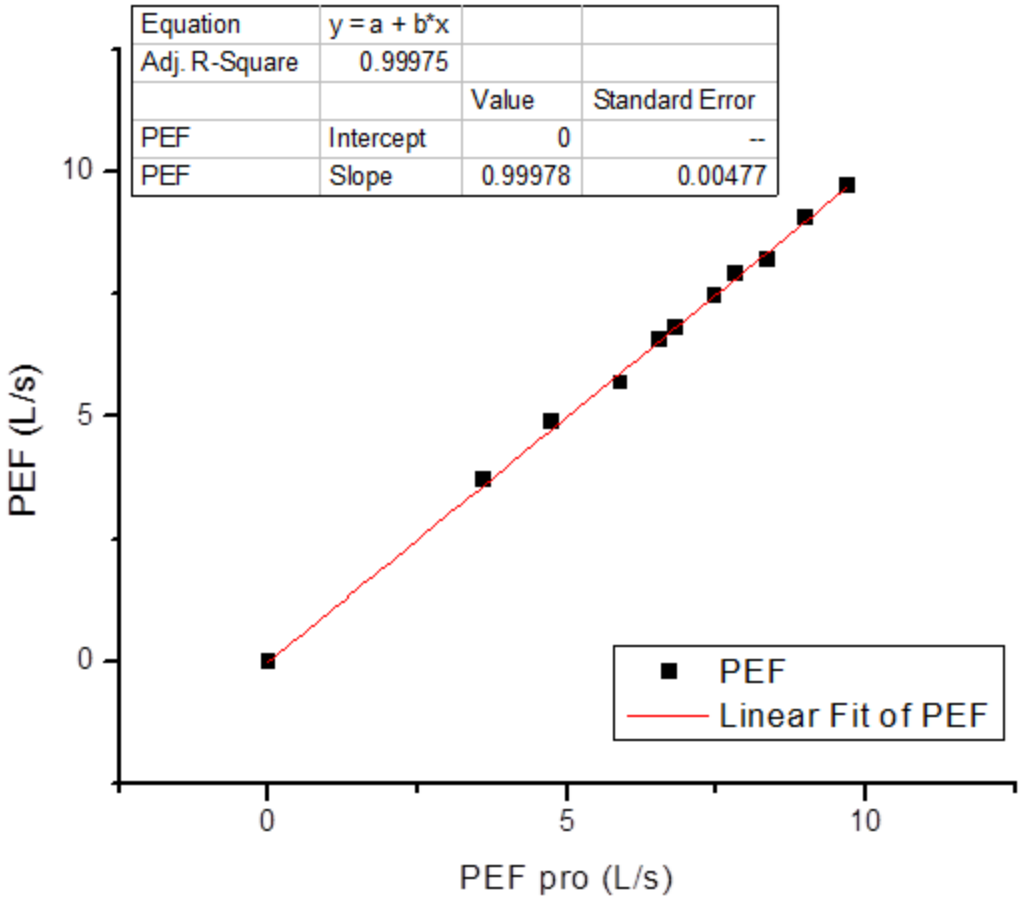

Figure 14. The validation plot for PEF.

The figure above shows the PEF reading from the test setup (PEF) vs. the PEF reading from the professional spirometer (PEF pro). A linear fit is used to determine the correlation between the developed methods and the professional device. A slope value close to 1.00 shows a strong relationship. This linear fit shows that the researched methods match the professional read-out for PEF at nearly one-to-one.

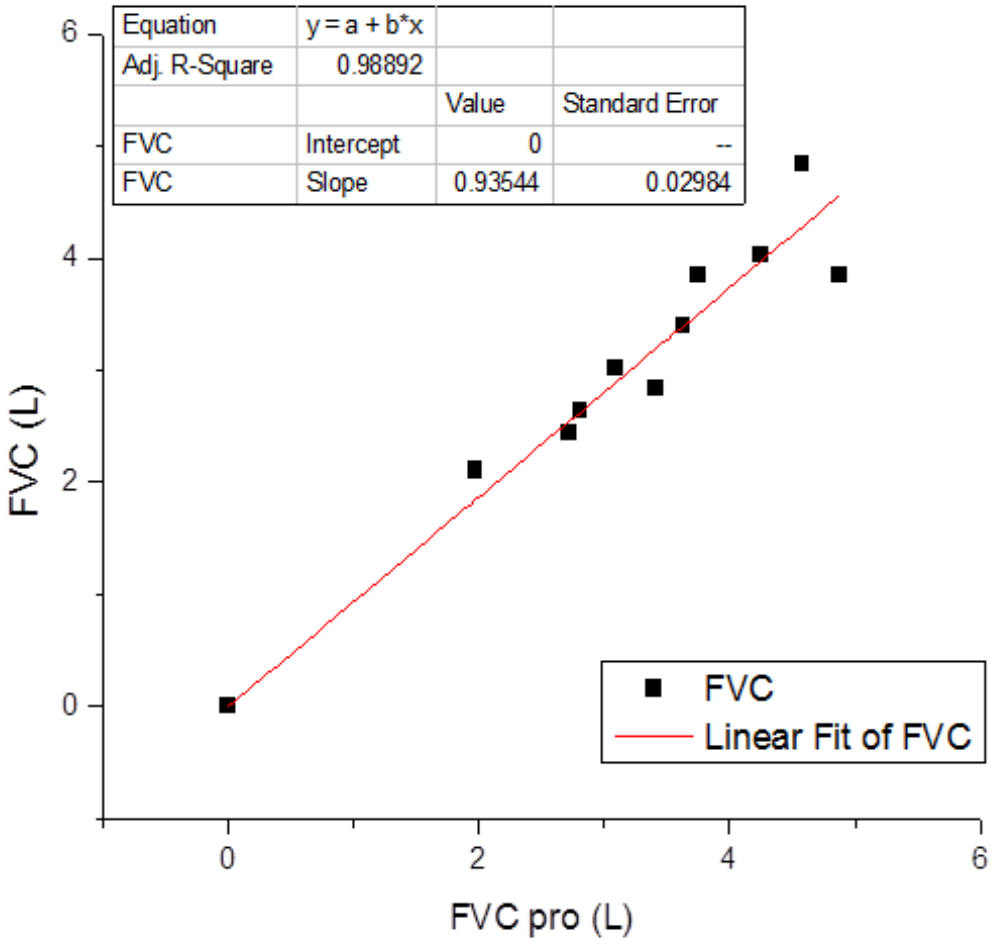

Figure 15. The validation plot for FVC.

The figure above shows the FVC reading from the test setup (FVC) vs. the FVC reading from the professional spirometer (FVC pro). A linear fit is used to determine the correlation between the experimental setup and the professional device. A slope value close to 1.00 shows a strong relationship. This linear fit shows a slope of 0.94, indicating that the researched methods match the professional read-out for FVC very well.

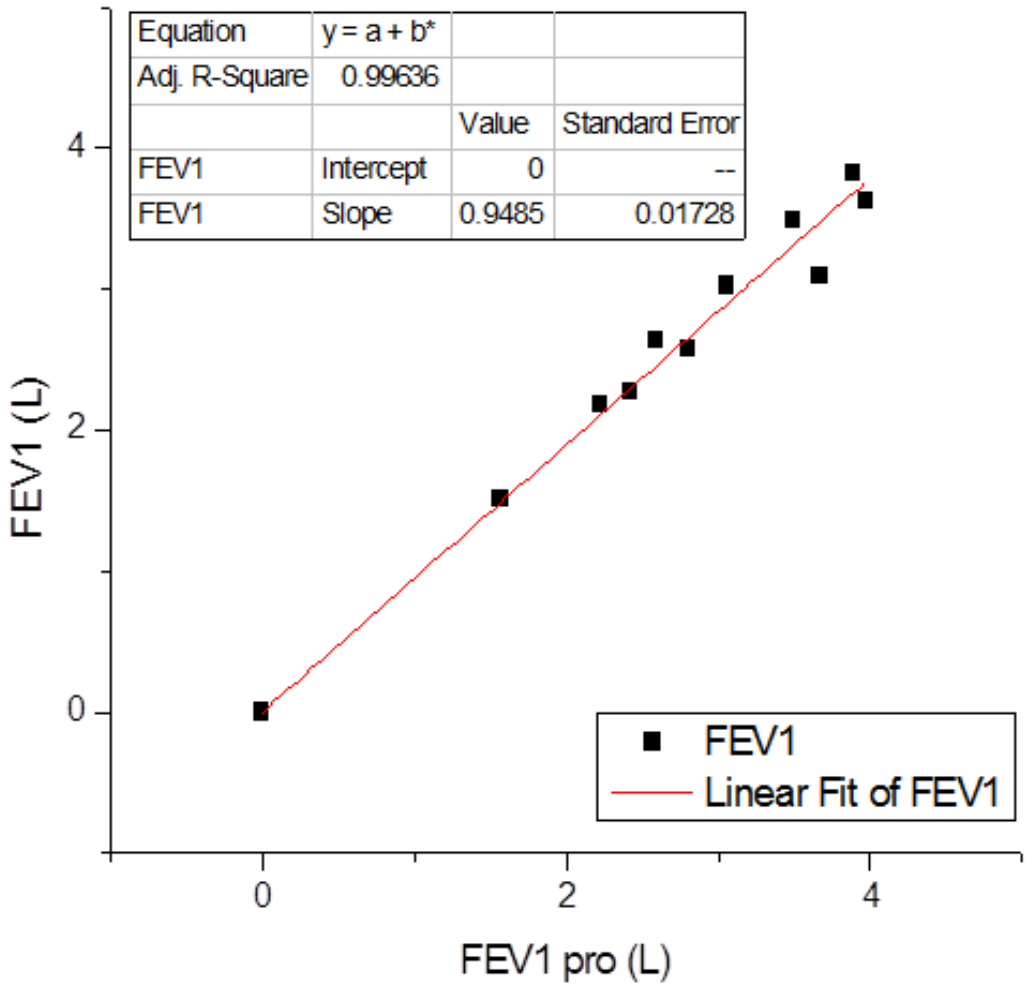

Figure 16. The validation plot for FEV1.

The figure above shows the FEV1 reading from the test setup (FEV1) vs. the FEV1 reading from the professional spirometer (FEV1 pro). A linear fit is used to determine the correlation between the researched methods and the professional device. A slope value close to 1.00 shows a strong relationship. This linear fit shows a slope of 0.95, indicating that the researched methods match the professional read-out for FVC very well.

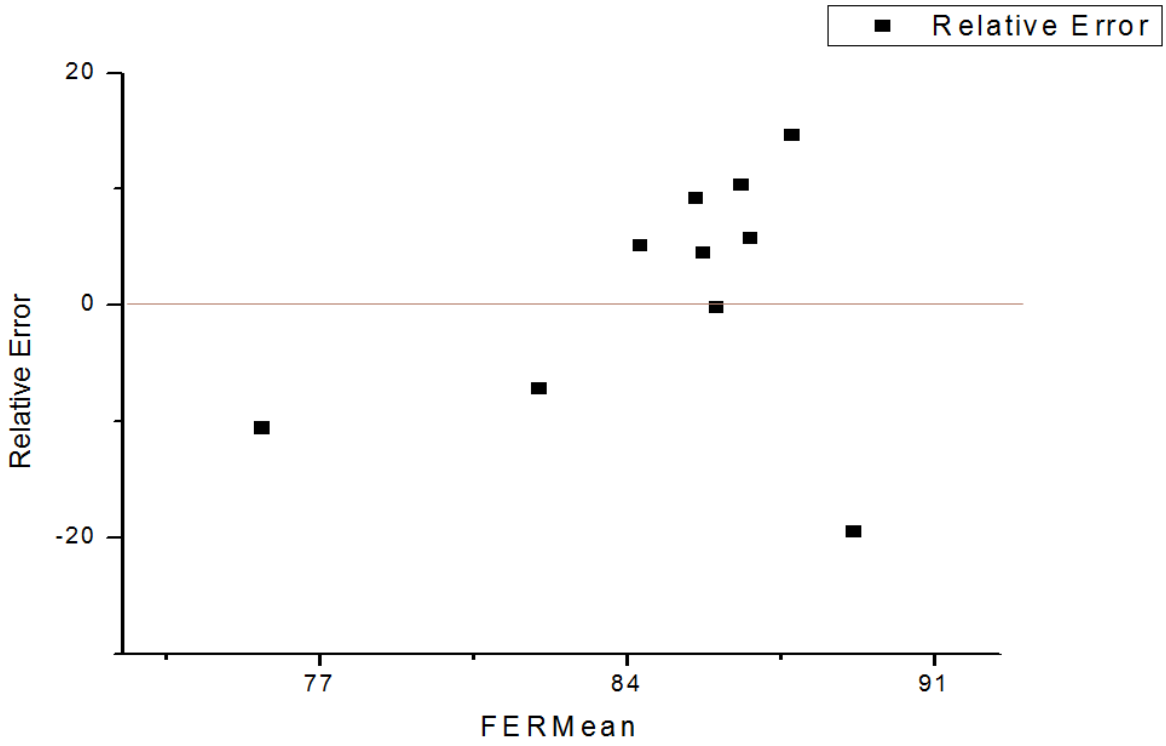

Figure 17. The validation plot for FER showing the relative error.

The figure above shows the relative error between the FER readings from the test setup the FER readings from the professional spirometer. This is calculated by finding the percent ratio of their difference to their mean. By plotting this relative error vs. the mean value, it is clear to see that values are within +/- 20% from each other. The magnitude of this error is acceptable, showing that the researched methods match the professional read-out for FER quite well.

Chapter 6

DISCUSSION

The results show that the pressure-based spirometry is viable. When compared to the commercial spirometer, the results from each test match very well. This project is considered to be a success. The technology developed in this project is tested and validated and all of the goals laid out in the scope of the project have been met.

As for the future of this project, the technology is to be implemented in the capno-spirometer. The capno-spirometer is a single portable unit that can perform spirometry and capnography tests side-by-side and send the results to a Smartphone via Bluetooth. The methods outlined in this paper will serve as the backbone for all of the spirometry tests, measurements, and calculations within this device. As of April 2013, the full working prototype of the capno-spirometer is under development. An early 3D design of this device is shown in the figure below.

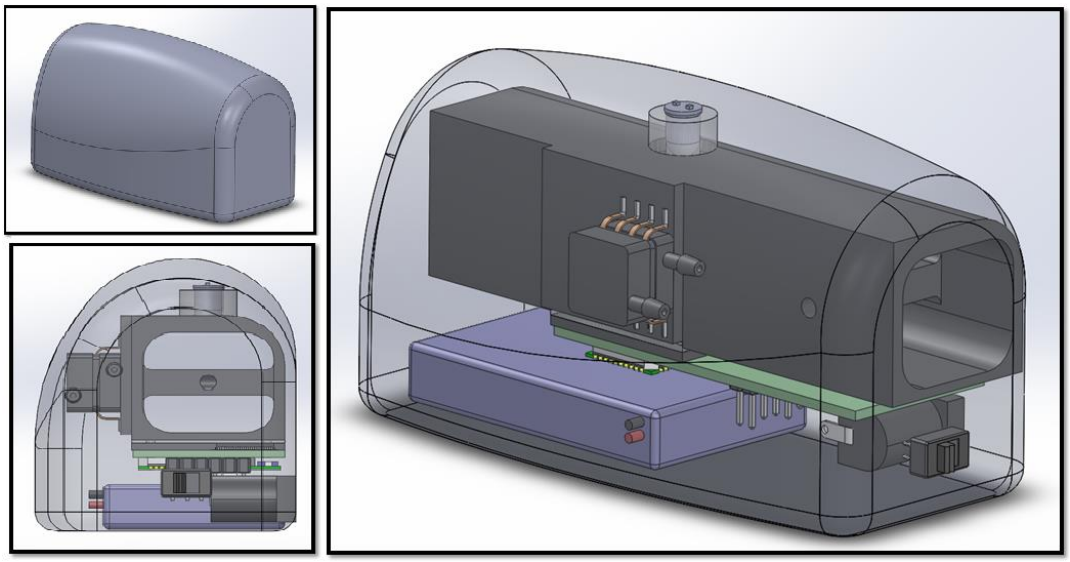

Figure 18. The early design for a fully functional capno-spirometer prototype.

Figure 18 shows the early design of the capno-spirometer. The Center for Bioelectronics and Biosensors plans to have a full working prototype by Summer 2013.

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