Low-Cost Spirometer

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Abstract

Current spirometers on the market often have retail prices of over $1,000. As a result of this high cost, many physicians practicing in developing countries lack the resources to purchase spirometry equipment. The development of a low-cost, reliable spirometer would allow these physicians to make more quantitative assessments of their patients' pulmonary health. A standardized coaching program that would instruct and motivate patients through spirometric maneuvers would also prove beneficial to the reproducibility of results. To address these issues, three different spirometer designs have been proposed, all of which include a coaching procedure. By assessing the performance of each option in a variety of areas, our team selected a design and will pursue the manufacture and testing of it through the rest of the semester.

Motivation

A spirometer is a tool that can be used to measure respiratory volume and flow rate. A typical spirogram plots the expiratory air flow against the total expiratory volume. Figure 1 shows an example test spirogram, contrasted against the values expected for the test, shown by a dotted line. This information is commonly used to diagnose chronic obstructive pulmonary disease, or COPD. According to the American
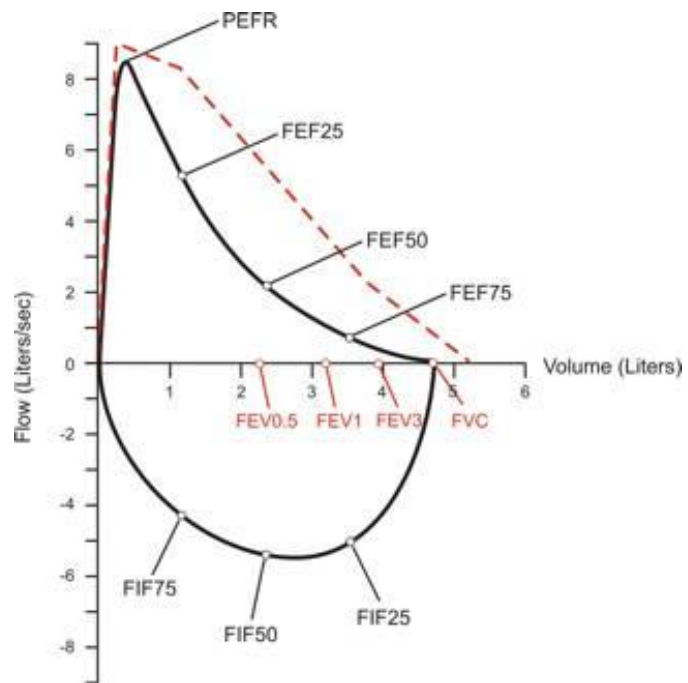
Figure 1 – Typical Spirogram [1]

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Association for Respiratory Care, COPD is currently the fourth greatest cause of death worldwide, and over 600 million have been diagnosed with the disease. [2] Unfortunately, many of those diagnosed reside in developing countries in which health care providers are unable to purchase spirometric equipment that frequently costs over $1000. As a result, millions of COPD sufferers are unable to be effectively monitored and treated for their disease.

Another factor influencing the efficiency of COPD treatment is the high potential for variability between tests. Traditionally, a patient performs the spirometry maneuvers while being monitored and instructed by a trained technician. Unfortunately, the quality of coaching provided by different technicians can lead to significantly different results. These variances have the potential to be even more significant if the patient is monitored at various facilities.

Problem Statement

In attempt to increase global access to spirometric equipment, Dr. David Van Sickle of the University of Wisconsin's department of Population Health Sciences is seeking the design of a low-cost, reliable spirometer. The project includes the physical design of the spirometer, software development, and designing a universal interface. The spirometer should be capable of measuring lung flows and volumes and should be usable by patients without the aid of a trained technician. The device should also be able to connect to a computer via USB to display and store the data. As the procedures are performed, a combination of client and server software will graphically display flow and volume data, monitor and evaluate the quality of the maneuver, and instruct the subject when their performance needs to be corrected. The software should also carry out some

rudimentary analysis and interpretation using algorithms that are freely available from the American Thoracic Society. The entire product should be widely affordable to physicians in developing countries and increase the reproducibility of pulmonary function measurements by delivering the standardized instruction and coaching across test sites.

Background Information – Climate Considerations

Temperature and humidity are factors that can greatly affect the function of electronic devices. The climates of emerging countries vary greatly not only between different countries, but within a specific country as well. Therefore, we need to design the spirometer to be able to function in the many possible weather conditions that it may face. We investigated the climates of the countries that our spirometer is planned to be initially tested in.

India experiences the most extreme temperature conditions, and the weather patterns differ greatly in different regions. During the monsoon season, average relative humidity is measured over 90%. The desert region experiences extremely hot temperatures averaging around 45°C. Paraguay has extreme temperatures in the mid 40°C range and humidity up to about 85%. Mexico experiences climate conditions similar to that of Paraguay. [3]

Electronic circuits are prone to failure in high temperatures and damp conditions. Sensor components are especially sensitive to these conditions. To limit the effect that the climate conditions will have on the accuracy of our circuit, we selected a pressure sensor that is pre-calibrated to be accurate in temperatures ranging from 0 to 85°C. We do need to design the handle to seal off the electronic circuit from the outside environment as

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much as possible to eliminate the possibility of condensation forming on the inside and damaging the circuit.

Design Requirements

Our design constraints need to meet not only our client's needs but also the standards set by the American Thoracic Society for all spirometers. See the document *ATS/ERS Standardisation of Spirometry*, 2005 update for the full description of spirometer requirements [4]. To meet these standards, our device must be able to record air flows of at least 8 liters. It must also be able to produce accurate results in the various climates that exist in emerging nations. As noted above, these nations possess extreme temperature and humidity ranges that our device must be able to perform in. Because the device may be transported to other clinics over rugged terrain via primitive methods, the spirometer must be durable and portable. The device should need only an initial calibration at the time of manufacture to minimize setup time and training required in the field. To reduce the possibility of spreading communicable diseases, the spirometer must be easily and quickly disinfected. The spirometer needs to have a universal interface with any computer via USB connection to display and analyze the results of the pulmonary function tests. Besides analyzing the data, the software on the computer must deliver standardized coaching and instruction to the user during the maneuvers. This standardized coaching will eliminate the need of a specially trained technician to administer the tests in the field. This standardization will also provide consistency in the coaching at multiple sites and increase the reliability of the tests across these sites. Finally, the spirometer must cost less than $50 so that emerging nation clinicians can afford it.

Current Devices

There are many spirometers currently on the market, most of which cost over a thousand dollars. This amount of money is too large for an emerging country clinic to invest in, even if the investment will eventually be paid back.

Some companies that manufacture spirometers include SDI Diagnostic, MicroDirect, and Welch Allyn. SDI Diagnostic manufactures six different spirometers ranging from $995 to $2395 [5,6]. The Spirolab II is a top of the line spirometer that costs $2395 and the Astra 300 is a middle of the line spirometer that costs $1429 (Figure 2). SDI Diagnostic advertises high-tech features like a touch screen, Bluetooth, and a bidirectional turbine with a rotary sensor, and a sturdy carrying case. All of these features drive up the cost of their spirometers.

Figure 2: The SDI Diagnostics Spirolab II (left) and SDI Diagnostics Astra 300 TouchScreen Spirometer (right). [9]

MicroDirect spirometers are somewhat more affordable than SDI Diagnostic spirometers with the SpiroUSB costing $1419.55 and the spiro√Compact portable spirometer costing

$195 [5,8] (Figure 3). However, the compact spirometer only measures FEV1, so it is

not useful in most medical diagnoses. These spirometers are also above the range of $50.

Figure 3: The Microdirect SpiroUSB (left) and spiro√ (right)
spirometers. [7,8]

The Welch Allyn SpiroPerfect spirometer (Figure 4) features single use mouthpieces,

incentive graphics, and automatic interpretation and analysis. This spirometer seems

perfect, except for its cost of $2000 with a calibration syringe and $1660 without one

[5,9].

Figure 4: The Welch Allyn SpiroPerfect[TM] with calibration syringe. [9]

Overall, all spirometers on the market are far too expensive for use in emerging

nations where a high cost of investment is a huge deterrent from buying them. Cheaper

spirometers are simply not accurate or versatile enough to be used in clinical settings, and

with high incidences of COPD in the developing world, a lack of a reliable, affordable

spirometer is unacceptable.

Design Alternatives

Pressure Sensor
Our first design uses a differential pressure sensor measuring the pressure drop across the

flow tube of the device. From the measured

pressure, we can calculate the velocity of the

air moving through the mouthpiece using

the equation $v = k \sqrt{P}$, where v the air

velocity, k is some constant, and P is the

measured pressure. The constant will be

determined by passing air of a known

velocity through the mouthpiece and reading

Figure 5 – Pressure Sensor model

the pressure sensor output. Once the velocity is known, we can calculate the flow rate of

the air, which can be integrated to yield the volume of air exhaled.

Physically, this design features a T-shaped handle that houses the circuitry for the

device. The shape of the handle helps encourage the user to maintain an upright posture,

which is needed to obtain the best results in a pulmonary function test. Because all the

hardware is enclosed inside the handle of the spirometer, this design is very small and
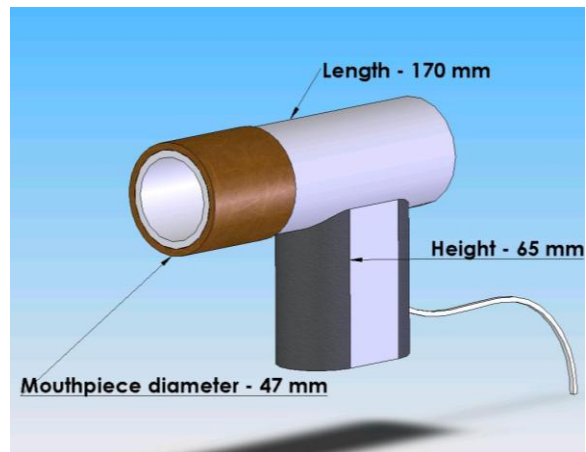
portable. The small size and limited number of parts needed also greatly reduces the price. The most expensive part of the design is the pressure sensor itself, which costs between $6.26 and $8.99 [10]. This sensor has the added advantage that it comes pre-calibrated from the factory. According to manufacturer specifications, the sensor will accurately measure pressure differences over temperatures ranging from 0 to 85°C. The mouthpiece of this design is disposable and made from cardboard. The limited durability of cardboard is beneficial to the design as it will decrease the opportunity for it to be improperly reused between patients. The major disadvantage of this design is the operating cost due to using disposable mouthpieces (~7.5 ¢ per mouthpiece) [11] and maintaining the supply chain in remote areas.

Volume Based Sensor

The second design alternative uses a volume-based sensor. A patient performs the test by exhaling into the elongated tube extending from the device as shown in Figure 6. This tube leads to a bellows-shaped chamber that expands with the volume of exhaled air. The chamber connects to a potentiometer which changes resistance as the bellows expands. This causes the potentiometer to produce an output voltage directly correlated to expiratory volume. The mouthpiece of this design would be held much like a microphone during use and would be a permanent plastic piece that would require disinfecting in between users.

Figure 6 – Volume Sensor example [12]

One advantage to this design is that it would have a low operating cost due to the permanent

mouthpiece, which would not need to be replaced after each use. The permanent mouthpiece also eliminates the need for a reliable supply of mouthpieces to use the device. This design would also be relatively simple to construct, and repairs would be very basic. However, this device would be quite large in comparison to the other designs. The chamber would have to expand to a volume of at least eight liters according to our design constraints, and the elongated tube would also add to the bulk of the device. Reliability is also an issue with this design as the tube contains a significant amount of dead space. This dead space not only weakens the signal, but could also increase the need for calibration.

Anemometer

The third design alternative utilizes an anemometer to detect air flow. The patient would hold the device like a microphone and exhale through the tube shown in Figure 7 and Figure 8. A fan located within the tube, shown in Figure 8, would spin at a rate proportional to the velocity of exhaled air that passes through it. The fan's rotation will cause optical interference of a laser. A pulse counter would detect the rate of interference and generate a signal that can be

Figure 7: Design of Anemometer Device

correlated to air flow. A permanent mouth piece with a disposable rubber coating will be used to maintain sanitation.

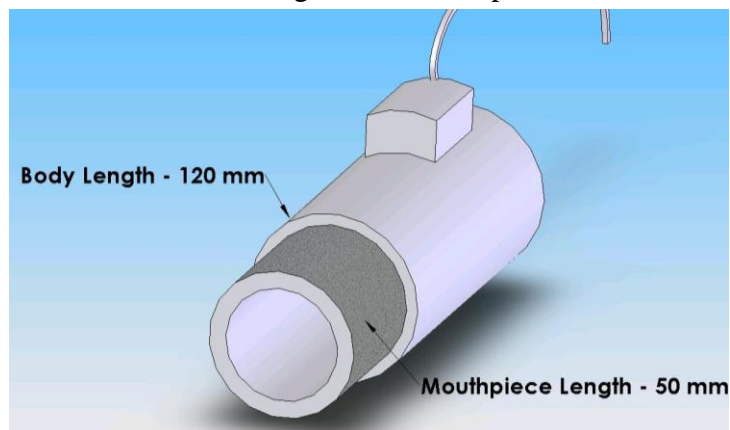This design is very compact and hand-held, allowing it to be quite portable. It also produces a direct measurement of flow instead of calculating it from pressure or volume. However, this design would not be very durable. The small moving parts of the fan could be easily broken and would require more regular maintenance to ensure proper rotation. This frequent maintenance would lead to a high cost operating cost and a lower reliability. Additionally, it is not certain whether the output of the device would be accurate at the end of the maneuver. After the patient has stopped exhaling, momentum could cause the fan to continue rotating despite no air being forced through the tube, producing an inaccurate signal.

Aspects Common to All Designs

Some aspects of the final design will be the same regardless of which spirometer design is ultimately built. Each design outputs an analog voltage which needs to be converted to a digital signal for a computer to analyze. Additionally, regardless of how the spirometer is designed and works, the results of the tests must be processed and evaluated to achieve the necessary flow vs. volume graph. Finally, the standardized coaching procedure will be implemented through audio/visual software installed on the computer the spirometer is connected to.

Design matrix

Category definitions and weightings

In order to assess our three designs, we set up a design matrix (Figure 9) that allowed us to measure how well each of our designs met various criteria. The most important feature of our spirometer design that will set it apart from all other spirometers currently on the market is its cost, and as such it was weighted very highly in our matrix.

Cost was divided into manufacturing and operational subcategories which when combined composed 30% of our matrix. **Manufacturing cost** refers to the cost of mass-producing our design and encompasses material and labor expenses. The **operating cos**t refers to costs associated with maintenance and upkeep.

The other highly weighted category is the **functionality** of the spirometer. The spirometer needs to be both accurate and precise, meeting the standards of the American Thoracic Society. Reliability falls under the **calibration** category. The

Figure 8: Fan located within tube for anemometer design.

spirometer will be properly calibrated before its initial use, and we expect the calibration to be valid for the lifetime of the spirometer. Thus, the reliability of the spirometer is a measure of the stability of the calibration. Together, functionality and calibration make up 30% of our matrix because medical centers in developing countries need to take accurate measurements from patients for years. If the spirometer we design is only accurate for a few months, it is not worth the cost of investment. Furthermore, because repair is inconvenient at best and likely expensive or impossible, these categories are as important as cost.

The **safety** category primarily deals with whether the spirometer has good safeguards against transmission of communicable diseases. A safe spirometer will have quick, intuitive procedures that allow each user a test with very minimal risk of
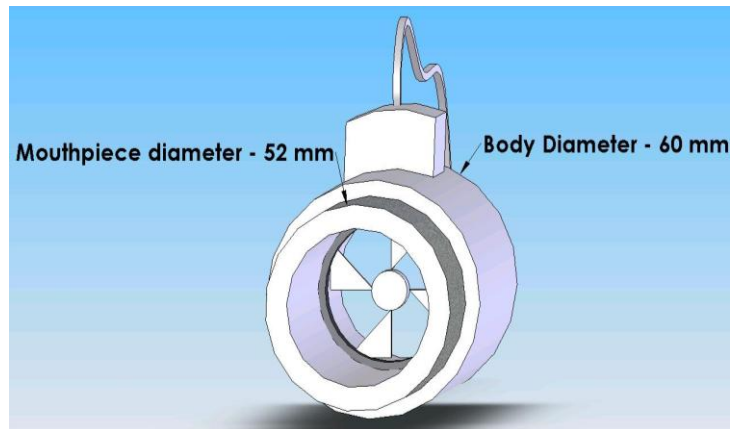
contracting a disease from the previous user. Design **ergonomics** entails the spirometer

being comfortable and easy to use with no detriment to productivity and performance.

We will also add to this category the capability of the design to encourage proper posture,

allowing for maximal lung performance and test accuracy. **Durability** refers to the

ability for the spirometer to still be functional many years in the future with normal usage

plus occasional mishandling or misuse. Finally, **portability** means that the spirometer

should be easy to move between sites and that it should be easily stored in a small space.

Each of these last four categories was only weighted 10% of our matrix because they are

not unique features to our spirometer – spirometers on the market have all of these

features. Also, these features, while relevant, are not as important to our client's

requirements as cost and functionality.

	Weight	Pressure	Volume	Anemometer
Manufacturing cost	15	10	7	6
Operating cost	15	7	12	8
Functionality	20	15	8	10
Calibration	10	9	7	9
Safety	10	8	6	8
Ergonomics	10	8	6	6
Durability	10	7	5	3
Portability	10	7	2	9
Total	100	71	53	59

Figure 9: Design matrix that allowed assessment of the three design options.

Our three designs fared differently in each of the categories. In the category of

manufacturing cost, we had to take into account the cost of the sensor and the cost of the

materials necessary to build the body of the spirometer. The largest cost component of

the pressure sensor design is the sensor itself whose cost ranges from $6.27-$8.99 per unit depending on quantity. The anemometer design sensor would cost substantially more because a high-quality laser is necessary, and these are expensive instruments. The "sensor" in the volume-based design would be extremely cheap because potentiometers only cost a few cents. This design, however, must be large because it is required to measure 8 liters of air, so material costs would run high. The pressure and anemometer designs have much smaller bodies, so materials would cost a fraction of what the volume-based spirometer's materials would. Because of a moderately priced sensor and a small body, the pressure design received the highest score in the manufacturing cost category.

The primary factors affecting operating cost are disposable mouthpieces and disinfectant. We do not know at the time of writing what disinfectant is required or what quantity, but we will assume that the cost of using disinfectant is less than using disposable cardboard mouthpieces or disposable rubber sleeves. The pressure design uses cardboard mouthpieces, which will cost approximately $0.07 per mouthpiece. The volume design will use a permanent mouthpiece and will need to be disinfected after every use. The anemometer design will use disposable rubber sleeves, which will cost slightly less than each disposable cardboard mouthpiece. However, the expected high repair cost associated with the moving parts in the anemometer affects the rating for the operating cost, resulting in a poor score. The volume design scored the highest in this category because it does not use disposable mouthpieces and it is not prone to breaking.

The pressure and anemometer designs scored higher than the volume design in functionality because they are smaller and have less dead space to affect readings. Dead space has the potential to significantly affect readings, causing the significantly lower

score for the volume sensor. Additionally, the fan in the anemometer design may continue to spin even after the user finishes the trial, affecting the accuracy of the end of the measurement. The pressure and anemometer designs also scored higher than the volume design in calibration because the pressure sensor comes pre-calibrated while the volume would have to be calibrated with a standardized syringe every time the spirometer is used to maintain accuracy. The anemometer will not have to be calibrated every session, although we expect the moving parts will make it necessary to be recalibrated occasionally.

All devices are physically safe – they do not contain any sharp ends or any components that could physically injure the user. The major safety risk associated with our device is the spread of communicable diseases, and it was determined via client and emerging nation physician input that one-use disposable mouthpieces were safer than permanent mouthpieces. This is because some sites in emerging nations may not an appropriate disinfectant readily available. While there is some risk of procedures not being followed properly and a disposable mouthpiece being used more than once, the spirometer will be designed primarily for use in a clinical setting where there are trained personnel who follow protocol.

It was determined that a T-shaped spirometer would encourage the user to hold him/herself more upright when using the spirometer, which gives a more accurate and repeatable result. Users may be tempted to hunch over when breathing into a microphone-shaped mouthpiece, resulting in sub-maximal performance. Repeatability is directly related to user comfort because a bad reading must be thrown out and the user must repeat the exercise until three acceptable readings are obtained. Blowing forcefully

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into a spirometer is strenuous, and it benefits the user to perform minimal number of exhalations to receive acceptable results. The T-shaped spirometer would best facilitate this. The pressure design was the only one that had a T-shaped design, so it fared best in this category.

The pressure design was determined to be the most durable because it contains no moving parts and is thus least likely to break. The volume design could potentially be ruptured, giving it a lower durability score, and the anemometer depends completely on moving parts and a laser that is properly aligned. If either of these anemometer components breaks, the spirometer would be nonfunctional.

The anemometer design was the most portable because it is a microphone-shaped six inch tube. The pressure design is the same length and diameter, but it is T-shaped and thus slightly less portable. The volume design is required to physically store up to 8 L of air, and is thus enormous in comparison, resulting in the lowest score in the portability category.

Final design

The final design features a pressure sensor built into a T-shaped plastic body with a disposable cardboard mouthpiece (Figure 10). The spirometer connects to a computer via universal serial bus (USB) which
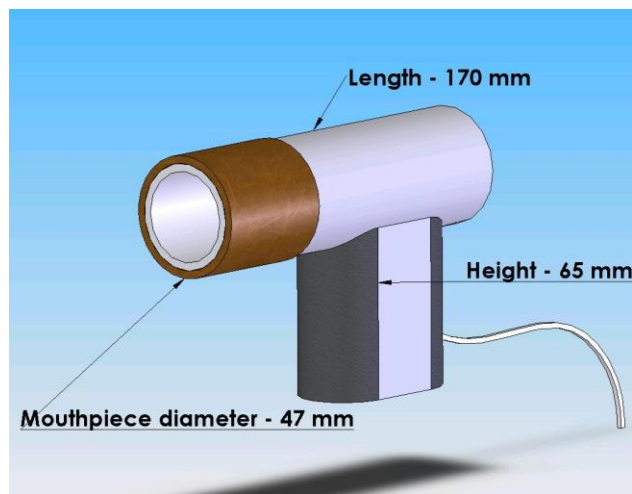
Figure 10: Final spirometer

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will perform analog to digital conversion and data processing. If desired, data can then be displayed on a screen which will also display specific numeric characteristics of the spirogram.

Ergonomics

We made an effort to design the spirometer so that is usable by people with a wide range of abilities while still being practical. We incorporated as many principles of universal design as we could, including equivalent means of use for all users and accommodation of the user's preferences and abilities. Coaching software will be developed that will make spirometer use simple and intuitive, giving the user audio and visual feedback to make the measurement easier and more accurate. Some principles could not be taken into account without sacrificing accuracy of the spirometer. These principles include a tolerance for error and low physical effort by the user. However, the T-shaped spirometer that was selected should partially accommodate both of these principles. Because the T-shape would force the user upright, a more accurate measurement will be obtained, potentially allowing fewer repetitions because of discarded bad measurements. Fewer measurements would result in a low physical effort by the user. Additionally, safety, comfort, ease of use, productivity, and aesthetics were all considered in our design and are reflected in the design matrix.

Potential problems and future work

We have already encountered the problem of a low voltage output from our pressure sensor, and we expect to encounter similar problems with our sensors as we continue testing. When we are finally able to trigger a large enough voltage response from our pressure sensor, we may find that it varies widely and does not give a repeatable enough

voltage for a given air flow. To accommodate these potential difficulties, we will allow

at least two weeks for testing our pressure sensor extensively.   The key parts of our

spirometer design are one-time calibration and repeatable measurements. It is impossible

to measure how far calibration deviates over the course of more than a few weeks, but we

plan on testing extensively for repeatability of measurement. Finally, if time permits, we

will develop coaching videos that would aid new users in performing spirometry

maneuvers and also help universalize how users are motivated across sites.

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APPENDIX: Product Design Specifications

Low-cost, Open-source Spirometer
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Client: David Van Sickle, PhD
Advisor: Professor Mitch Tyler
Last Updated: 3/9/09

Background and Problem Statement: Spirometers are used to diagnose many pulmonary diseases including chronic respiratory diseases that affect approximately 300 million people. Many of these people do not have access to a spirometer because current models are expensive and operation requires a trained technician to administer the procedure. The purpose of this project is to develop a low-cost spirometer usable without the aid of a trained technician. The project includes the physical design of the spirometer, software development to display and analyze results, and designing a universal tool to provide audiovisual coaching on the tests.

Client requirements

- Interface spirometer with a computer via USB cable
- Affordable for use in emerging countries
- Handheld and durable
- Standardized audio/visual respiration coaching for patient
- Easy to maintain sterility
- Minimize calibration
- Simple and universal instructions for operation
- Graphically display results of FVC maneuver, including FEV1 measurements
- Monitor and evaluate the quality of the maneuver
- Provide feedback to the subject about their performance after each test
- Carry out some rudimentary analysis and interpretation of results

Design requirements:
    1. Physical and Operational Characteristics
        a. *Performance requirements*: Capable of continually measuring air flows between 0 and 14 L/sec for at least 15 seconds and recording air volumes of at least 8 L. With a flow of 14 L/s, the total resistance of the spirometer should be less than 0.15 kPa/L·sec. Should display plots of flow vs. volume and volume vs. time on the laptop screen preferably in real time, as well as display data numerically. Device will need to withstand these pressures and air flows multiple times daily and still be able to function accurately. Software should be open source and capable of running on Linux-based platforms. The patient's name, age, gender, smoking status, height and weight must be stored by the computer. In addition, environmental data such as temperature, humidity, date, testing site and other information found in Table 8 of the American Thoracic Society (ATS) standards for accuracy and

repeatability as per ATS*/ERS Standardisation of Spirometry*, 2005 update. Data from the measurements should be recorded in the standard format described in the standards for accuracy and repeatability section of *Standardisation of Spirometry*, 2005 update. If data is input in a measure other than the spirometry standard, the computer should convert the data to the appropriate units. The computer should monitor and evaluate the quality of the maneuver and instruct the patient when changes in the maneuver are necessary. Rudimentary analysis and interpretation should also be performed.

b. *Safety*: The spirometer should not pose a choking hazard and should contain no components that could physically injure the user. Standardized and automated audiovisual instruction and coaching- in appropriate language and at appropriate literacy level - should ensure that the patient is able to safely perform the test, and if so, safely guide and assist the patient and provider through the test with a maximum of eight repetitions as per *ATS/ERS Standardisation of Spirometry*, 2005 update. The spirometer should use an affordable disposable mouthpiece with a minimal lifespan (to minimize the likelihood of reuse) so that communicable diseases are not spread between users.

c. *Accuracy and Reliability*: Patient data obtained independently should meet ATS standards for accuracy and repeatability as per *ATS/ERS Standardisation of Spirometry*, 2005 update. Accuracy and reliability should be maintained with only initial factory-set calibration in varied temperature and humidity conditions. Standardized respiration coaching should ensure repeatable pulmonary measurements. Mouthpiece should be designed such that there is no variability in their attachment to the spirometer, which potentially yields inconsistencies in the length of the spirometer.

d. *Life in Service*: The unit will be used multiple times per day for a period of 10 years. Also, software should be capable of being easily updated to fix bugs and provide additional features.

e. *Shelf Life*: Unit should be able to withstand various modes of international transportation

f. *Operating Environment*: The unit should maintain accurate function in varying climates and high humidity from exhalation. Exhaled air is assumed to be at body temperature (37oC) and saturated with water vapor (100% humidity). The unit may be operated by a patient without technical training or supervision.

g. *Ergonomics*: The spirometer should be comfortable to use with either hand while sitting or standing. The mouthpiece should be comfortable to use for the duration of a full set of tests, at least 10 minutes. Audiovisual coaching tool should accommodate a range of languages and literacy.

h. *Size*: The unit should be handheld and easily portable, no more than 30 cm (1 foot) in length and 8 cm (3 in) in diameter. Protrusions up to 15 cm (6 in) are acceptable. The cord connecting the spirometer to a PC should be between 2 and 3 meters (6 to 10 feet) in length.

i. *Weight*: The maximum weight for the unit is 500 grams (1.1 lb)

j. *Materials*: Materials should be inexpensive yet durable. The chosen materials should be abuse-tolerant, easily manufactured on a mass scale, and water and heat resistant to deformity or breaking. k. *Aesthetics*, *Appearance, and Finish*: The material should look sleek yet not slip when held in the hands. The user

interface should be professional and intuitive. There should be an option for entering information in metric or English units.

2. Production Characteristics

a. *Quantity*: One prototype whose design can be mass-produced and a version of software required to run the spirometer and display and interpret test results.

b. *Target Product Cost*: Less than $50, preferably around $20

3. Miscellaneous

a. *Standards and Specifications*: Unit should meet international standards for safety, specifically those of the World Health Organization (WHO) as per *Medical Device Regulations: Global overview and guiding principles* and should be compatible with a personal computer. Also, all operation information, such as that printed in manuals, the coaching software, and on the spirometer itself, must be conveyed in a universal fashion for multi-lingual understanding.

b. *Customer*: Emerging nation healthcare practitioner

c. *Patient-related concerns*: Device mouthpiece should be replaced between uses

d. *Competition*: Most devices on the market are expensive:
- SDI Diagnostics Spriolab II: $2395
- SDI Diagnostics Astra 300 Touchscreen Spirometer: $1429
- Microdirect spiro√ Spirometer: $195
- MicroDirect Micro Spirometer: $351.55
- MicroDirect SpiroUSB (with Spida5 software): $1419.55
- The lowest cost spirometer was developed at the Indian Institute of Technology - Bombay and costs around $80.