Low-cost, Open-source 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. Through testing and redesign of prototypes from Spring 2009 and Summer 2009, we have developed a low-cost prototype that facilitates laminar air flow evidenced by a linear flow-pressure curve (R^2>0.996). We measured and corrected volumes based on plunges from a 3 L syringe, and volumes from 28 of 30 plunges were within American Thoracic Society standards. The prototype outputs real-time graphs of flow vs. time and volume vs. time in a Java program. In the future, the accuracy of the measurements will be improved by using more advanced calibration techniques and audiovisual coaching tools will be integrated into the software to improve reproducibility among patient trials. In addition, extensive testing to validate the design will also be conducted with the intention to progress the design to large-scale production.

Background and Motivation

A spirometer is a tool that can be used to measure respiratory volume and flow rate. This information is commonly used to diagnose chronic obstructive pulmonary disease, or COPD. According to the American Thoracic Society's Standardisation of Spirometry, the readings given by spirometers play an essential role in monitoring and assessing general pulmonary function in the same way that blood pressure is used to monitor cardiac health.[1] According to the American 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, health care providers in developing countries are unable to purchase spirometers because they frequently costs over $1000. As a result, millions of people with COPD are not effectively monitored or treated.

Spirometry is also essential in the diagnosis and treatment of asthma, a chronic respiratory disease that, according to the World Health Organization, affects an estimated 300 million people worldwide. The severity of asthma is especially prominent in low and lower-middle income countries, where approximately 80% of asthma fatalities occur.[3] This disproportionate amount of deaths in these countries is in no small part due to the lack of essential diagnostic and monitoring equipment available in these countries. The provision of spirometric equipment at a price affordable to physicians practicing in low and lower-middle income countries will help address problems of under-diagnosis and under-treatment and raise the quality of care for millions of people with chronic respiratory disease. A team from IIT-Bombay has attempted to provide a low-cost spirometer to address this problem.[4] However, this device uses expensive technology, such as Bluetooth capability, that unnecessarily increases the cost of the device. The combination of a high and increasing prevalence of chronic respiratory diseases and the current absence of competing alternatives creates a massive demand for low-cost spirometry equipment.

Spirometric Maneuver and Interpretation

To perform a forced expiratory spirometric maneuver, the user must first inhale as much as possible, then exhale as much and as forcefully as possible into the spirometer for at least six

seconds with no hesitation, coughs, sub-maximal effort, or leakage[2,5]. Three acceptable maneuvers must be obtained, with the user resting between maneuvers, to produce valid results.

The results of the maneuver are displayed graphically as a Volume-Time or Flow-Volume curve called a *spirogram*. Air volume should be corrected to account for ambient temperature and pressure, and for patient sex, age, height, and weight[5]. Corrections based on race are also standard[6]. Using the flow data and spirogram, the following values can be calculated for each patient:

- Peak expiratory flow (PEF) – the maximum air flow in liters per second the user is able to attain in a maneuver
- Forced vital capacity (FVC) – the total air volume in liters the user is able to exhale in a maneuver
- Forced expiratory volume *t* (FEV_t) – the air volume expired at time *t*
- FEV_1/FVC - A useful ratio in assessing pulmonary function.

These values can be used to make preliminary diagnosis of lung obstructions or restrictions and further tests can be recommended. Example of diagnoses based on spirometry values are shown in Table 1.

LUNG DISEASES AND SPIROMETRY RESULTS

Interpretation	FEV1/FVC	FVC	FEV
Normal person	normal	normal	normal
Airway obstruction	low	normal or low	low
Lung Restriction	normal	low	low
Combination of Obstruction/Restriction	low	low	low

Table 1: Diagnosis of airway obstruction or restriction based on spirometry parameters[5].

Other formats of the spirogram are also used clinically. The shape of the flow-volume curve, for instance, can help a clinician in lung function diagnoses.

Current Commercial Spirometers

Most diagnostic spirometers on the market cost over a thousand US 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 manufacturers of commercial spirometers include SDI Diagnostic, MicroDirect, and Welch Allyn. SDI Diagnostic manufactures six different spirometers ranging from $995 to $2395 [7,8]. 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.

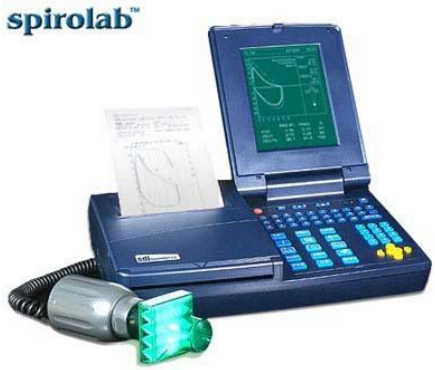

Figure 1: The SDI Diagnostics Spirolab II (left) and SDI Diagnostics Astra 300 TouchScreen Spirometer (right).[8]

MicroDirect spirometers are somewhat more affordable than SDI Diagnostic spirometers with the SpiroUSB costing $1419.55 and the spiro√Compact portable spirometer costing $195 (Figure 3).[9,10] 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 2: The Microdirect SpiroUSB (left) and spiro√Compact (right) spirometers.[9,10]

The Welch Allyn SpiroPerfect spirometer (Figure 3) 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.[7,11]

Figure 3: The Welch Allyn SpiroPerfectTM.[10]

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, the lack of a reliable, affordable spirometer is unacceptable.

Recently, so-called "pocket spirometers" have emerged that can measure FEV1 in addition to peak flow. These spirometers are safe to use and have some mathematical checks to verify data quality. However, even though these spirometers are inexpensive, they lack capabilities to display graphical information such as volume-time and flow-volume graphs. As such, they should not be used for diagnostic purposes, but rather as a primary screening.[12]

Design Requirements

In attempt to increase global access to spirometric equipment, we sought to design a low-cost, reliable spirometer. This project includes the physical design of the spirometer, software development, and designing a universal interface. There are several design criteria that the design must meet. 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. All users aged 8 and up should be able to use the device, so it should be ergonomically acceptable for users of varying heights and hand sizes. A table of hand measurements taken of 8-year old children is found in Table A1 in Appendix A. As the procedures are performed, a combination of client and server software should graphically display flow and volume data, ideally in real-time. It should 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. Full Product Design Specifications (PDS) can be found in Appendix B.

Regulations and Standards

ISO 26782:2009

In July, 2009, the International Organization for Standardization released a document, ISO 26782:2009, containing a variety of requirements specific to spirometers. Many of these requirements were identical to those mandated by the ATS. This document did provide additional information about physical markings that should be displayed on our spirometer, as well as methods for validating the performance of our spirometer. In Annex B of ISO 26782, it is recommended that validation of the spirometer's accuracy be tested with a computer controlled airflow source into which 13 different test patterns would be administered. The 13 patterns, as well as the expected pulmonary function test (PFT) results for each of the patterns, are listed in Annex C of ISO 26782. These patterns would be delivered in an environmental chamber which could apply a variety of atmospheric pressures and humidity levels to simulate the different environments the spirometer would be used in.

Although it would yield a great degree of credibility to our design, it is not financially feasible to purchase the recommended equipment for validating our spirometer. An example of a computer-driven air source is the Pulmonary Waveform Generator manufactured by MH Custom Design & Mfg. L.C. More information on this equipment can be found on their website [http://www.mhcdesign.com/products.html]. A better alternative for validating our spirometer at

a variety of flows would be to use an air supply that could deliver a known volumetric flow. Although we have not located such equipment on campus at this time, we will continue to question various faculty members to see if they have such equipment for us to borrow.

NLHEP Guidelines

The National Lung Health Education Program (NLHEP) has a list checklist procedure that they use to validate commercial spirometers. The review procedure put forth by the NLHEP contains an extensive list of features designated as either required or optional. Optional features are also graded on a scale from 1-5, with 5 being the best. The highest score a spirometer can achieve in their grading is 100. The NLHEP will only evaluate spirometers that have verified they meet the standards put forth by the ATS for accuracy and repeatability. To prove the spirometer's performance, the NLHEP requires a printout of the results of the spirometer's testing using a computer-driven syringe and the 24 ATS specified waveforms. Copy of the pre-marketing 510k approval letter from the FDA must also be submitted to the NLHEP before they will consider reviewing a device. Because of these high requirements, it is unlikely that our spirometer will ever be put through an official NLHEP review. However, the checklist of features they inspect has been published, so we can verify that our spirometer would meet their requirements.

IEC 60601-1

The International Electrotechnical Commission (IEC) produced a document describing the physical requirements for electrical medical devices. This document was not specific to spirometers and included much information not relevant to our design. However, this document did contain requirements for the mechanical strength of specific aspects of our spirometer, such as the handle, as well as describe an important testing procedure for testing the durability of our spirometer. These requirements and the associated testing protocol are located in Section 4, Clauses 21-24 of the IEC document.

ISO 10993

This document published by the International Organization for Standardization contains requirements for biocompatibility of medical devices. According to this document, our spirometer will be classified as a "Surface-Contacting Device" with Limited Exposure. With such a classification, the document recommends that our device be tested for Cytotoxicity, Sensitization and Irritation. The procedures for these recommended tests are described in the ISO documents 10993-5 and 10993-10. The document also notes that the testing requirements recommended are not always necessary or practical, and that proof of biocompatibility of similar devices can negate the need for testing. Because a spirometer is a common medical device with very minimal risk to the user, extensive biocompatibility testing will not be necessary. To ensure the safety of our design, we only need to ensure that the materials used in the final product will not cause an adverse reaction to the user. The low-cost plastic materials we have been using (polycarbonate, polypropylene, etc.) meet this requirement, and continuing to use similar materials in the future will give our device the required biocompatibility.

Ethical Considerations

The development of any medical device brings with it certain ethical issues that must be considered throughout the design and validation processes. The end product should be developed to be universally available, so certain populations are not selectively excluded from the benefits

that may be found in using the device. The device should be designed so as to provide minimal risks to patients who use it. For example, patients who use the device should not be subjected to potentially hazardous materials. All testing should be conducted in an impartial manner, and results should be accurately presented. Lastly, clinical testing and validation of the device should be conducted in a manner approved by an IRB.

Design Progression

Spring 2009

During the spring 2009 semester, we designed and built a Venturi-type spirometer that had a constriction-based resistive element in the spirometer. The small pressure drop was measurable, but because air flow through the spirometer was turbulent, we observed a quadratic pressure-flow relationship (Figure 4).

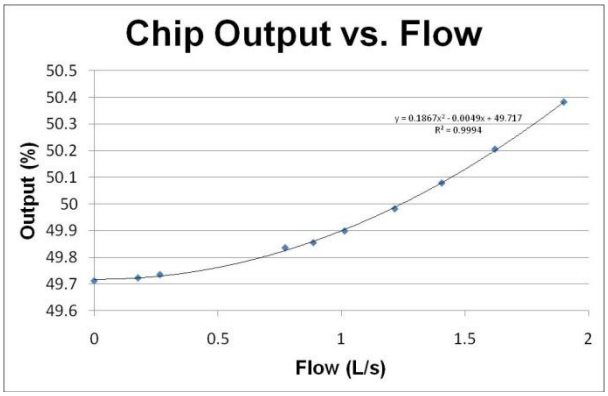

Figure 4: Quadratic pressure/flow relationship for Venturi spirometer

The prototypes we built used polyvinylchloride (PVC) and nylon because of the low cost of these materials and ease of manufacturing. These materials are also durable and easy to disinfect. This prototype also featured a disposable cardboard mouthpiece to help protect the user from communicable diseases for the low cost of $0.07 per mouthpiece.

The prototype incorporated as many of the principles of universal design as possible, including equivalent means of use for all users. The T-shape would encourage the user to maintain an upright posture, allowing for more accurate measurements and potentially fewer repetitions due to poor results. By reducing the number of measurements needed to achieve adequate results, less physical effort would be required from the user. Additionally, the safety, comfort, ease of use, productivity, and aesthetics were all considered in our design.

Summer 2009

The main drawback of the Venturi design presented at the conclusion of the Spring 2009 semester was that pressure and flow were not linearly related. Thus, one of the goals for the summer of 2009 was to design and build a spirometer that accomplished a linear flow-pressure relationship. After researching current industry designs, three models were envisioned that could theoretically accomplish this. The first was a Fleisch-type spirometer that possesses a system of capillaries inside the spirometer body (see Figure 5). The capillaries act to facilitate laminar flow by greatly decreasing the radius of pipe that the fluid flows through. In addition, the system of

capillaries also adds a resistive element to the spirometer to generate a measureable differential pressure. This system is currently used in the Vitalograph Pneumotrac and the Burdick Presto spirometers.

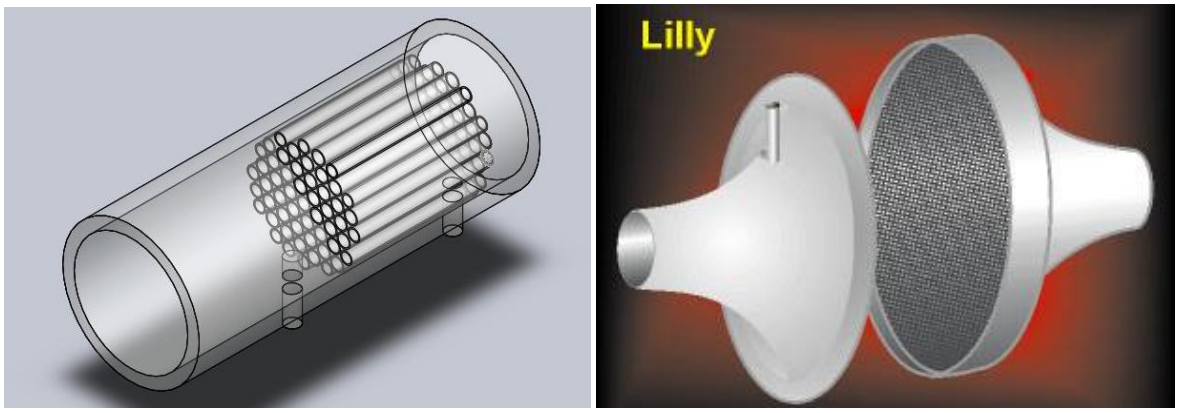

Figure 5 Examples of Fleisch (left) and Lilly (right) spirometers.[13] The pressure drop is measured across the resistive element, being either the capillary tubes or the fine screen mesh.

A second design alternative was the Lilly-type spirometer. Instead of using a series of capillaries like the Fleisch spirometer, the Lilly design utilizes a fine screen as a resistive element capable of creating laminar air flow. The typical Lilly design features a flange or bell shape as seen in Figure 5. By expanding the diameter of the spirometer where the screen is located, the design allows air to move at a much slower velocity through the screen to encourage laminar flow. The Lilly design is currently used by the Jaeger MSC-PC and Hans Rudolf 100-HR spirometer systems. However, this bell shape is difficult to manufacture and make into a portable device. For this reason, our third design alternative consisted of a Lilly-type spirometer that held a constant diameter throughout the entire length of the spirometer.

To assess the characteristics of the various design options, we manufactured one of each of the designs and tested their performance on two characteristics: 1) Ability to generate laminar flow (indicated by a linear flow-pressure relationship) and 2) The responsiveness of the model, indicated by the magnitude of the pressure drop through the spirometer. These three models were also compared to the most advanced version of the Venturi-type spirometer we manufactured. We also considered manufacturing and cleaning of the spirometer when making design considerations (Table 4).

Categories	Weight	Fleisch	Lilly with bell	Lilly without bell	Venturi
Low resistance	25	15	20	18	24
Material cost	5	4	3	4	5
Ease of cleaning	20	18	10	15	19
Ease of manufacture	15	12	7	12	14
Pressure vs. flow linearity (R^2 value in Excel)	35	25	30	20	5
Total	100	**74**	70	69	67

Table 4**:** A design matrix evaluating the physical characteristics of 3 different spirometer options.

During the summer, we were unable to manufacture a spirometer capillary system capable of meeting the required characteristic of a flow-pressure linearity regression coefficient greater than 0.99. Capillary materials that were tested included polypropylene coffee straws and polycarbonate hematocrit tubes.

Fall 2009

Hardware Development

During the Fall 2009 semester, we obtained an tested a capillary system made of cordierite manufactured by Corning. These capillaries were square with side length 1.168 mm and the system had a porosity (φ) of 83%.[14]

Reynolds number is a dimensionless quantity that characterizes the fluid flow through a pipe or other similar opening. A fluid is considered to have laminar flow if the Reynolds number is calculated to be < 2000. To utilize Reynolds number and quantify our spirometer's ability to facilitate laminar flow, the maximal velocity through the spirometer needed to be determined. We calculated velocity through the spirometer according to $v = \frac{F_{max}}{1000\pi\varphi r^2}$ where v is air velocity in $\frac{\text{m}}{\text{s}}$, φ is surface area porosity, and r is the spirometer radius in m. F_{max} is assumed to be 14 $\frac{L}{s}$, and the conversion unit for the constant 1000 is $\frac{L}{m^3}$. The above formula uses porosity to determine the effective cross-sectional area open for air flow. From this corrected area the effective spirometer body diameter can also be derived. This maximal velocity was applied to the calculation of Reynolds number (Re) according to $Re = \frac{d_c v}{\nu}$ where d_c is the hydraulic diameter of the capillary, v is air velocity, and ν is kinematic viscosity, equal to 1.678×10^{-5} Pa·s.[15] The entrance length required for laminar flow was found according to $l_e = 0.06\, Re * d_c$ where l_e is the entrance length in meters. This distance is the theoretical distance air needs to travel after an obstruction (in our case the capillary system) before the flow is laminar. Laminar air flow causes the flow-pressure relationship to be linear, which was our goal in revising our spirometer design.

We considered standard cordierite diameters of 2.54 cm (1 in), 3.18 cm (1.25 in), and 3.81 cm (1.5 in) because these would be most compatible with a PVC shell (Table 5).

Spirometer diameter (cm)	Effective diameter (cm)	Velocity (m/s)	*Re*	Entrance length (cm)
2.54	2.31	33.3	2317	16.24
3.18	2.89	21.3	1483	10.39
3.81	3.47	14.8	1030	7.22

Table 5: Calculated entrance lengths for spirometers

The spirometer diameter of 1.5 inches was chosen because it yielded the lowest entrance length. Furthermore, minimizing reduce flow impedance is important to maintain an accurate signal and to meet American Thoracic Society requirements, and this is accomplished by increasing the spirometer diameter. For a capillary system that was 5.08 cm (2 in) long, we recorded resistance values of less than 20 Pa·s/L, which is much less than the 150 Pa·s/L stipulated by the ATS.

Moreover, a flow-pressure linear trend line should have a high regression coefficient, ideally >0.99. Because the cordierite is the most expensive piece in the spirometer, it is

important to keep the amount of material in each spirometer low. Testing of the 1.5" diameter capillaries showed the regression coefficients for flow-pressure linear trend lines were 0.9936 and 0.9961 for 1" and 2" capillary lengths respectively (see *Prototype Testing* section). Even though tested capillary were smaller than the length of 7.22 cm (2.84 in) from the entrance length calculation, the high regression coefficients suggest that a fully developed laminar flow profile is not necessary to obtain sufficient flow-pressure linearity. It may also be possible to correct some non-linearity with appropriate calibration methods.

A capillary core length of 3.81 cm (1.5 in) was chosen because we wanted to minimize the amount of cordierite in the spirometer for cost and size reductions, but also show good linearity at high flows. Extending the length beyond 1.5" would have marginal flow-pressure linearity benefits that fail to outweigh the increase in cost and bulk. Dimensions of our final spirometer design that feature this core are illustrated in Figure 6:

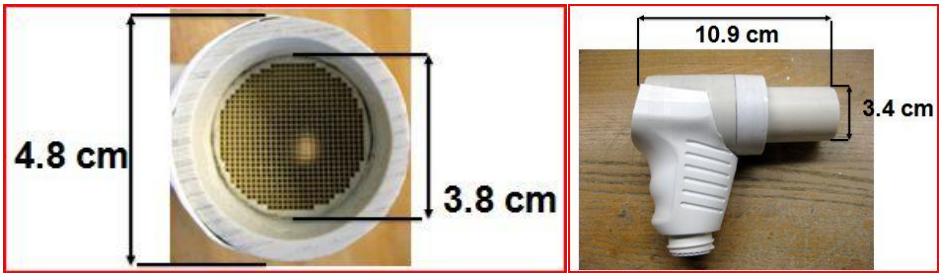

Figure 6: Top and side views of the spirometer with an appropriate core. A mouthpiece can be fitted into the front of the spirometer.

The final spirometer design achieves a linear flow-pressure relationship ($R^2 > 0.996$), meaning that it is more accurate at measuring low flows than our previous Venturi-type model. Two features of the design that have been maintained throughout the design process are the disposable cardboard mouthpieces for preventing transmission of disease, and the T-shaped handle for ergonomics.

Calibration Procedure

A 3 liter syringe is the industry standard tool used to perform calibration. ATS standards recommend that physicians use this syringe daily to calibrate the spirometer based on volume. Although most spirometers use pressure to measure flow through the spirometer and perform calculations to achieve volume data, flow-based calibration devices are not commonly utilized in clinical settings. Therefore, we sought to develop a method that would be capable of calibrating our spirometer's flow and volume measurements using only a 3 L syringe. To accomplish this, we used the methods described by Yeh, *et al.* (1982)[16] Using this method, a 3 liter syringe is plunged multiple times through the spirometer at slow, medium and fast rates, and weighted averaging is used to determine the conductance (flow/pressure) throughout the spectrum flows. Conductance values are stored in an array and used to convert the pressure data output from the spirometer into flow rates. Using this method, Yeh, *et al*. showed they were able to achieve an accuracy of ±0.5% of 3 liters after using 100 plunges of the syringe to calculate the conductance array.[16] A MATLAB program was written to perform the calibration math and store the conductance array as a text file for use in the Java-based software.

Software Development

A computer interface was written in Java that accepts pressure data from the microcontroller in packets at a sample rate of 100 Hz and decodes the bits into numeric values. The calibration algorithm described above is used to convert pressure values into flows, and trapezoidal numerical integration calculates volume data from flow. Flow and volume data is graphed in real-time within the Java application. A screenshot of the graphs displayed by the software is shown in Figure A1 of Appendix A.

The software is currently run from within the Eclipse IDE. After initiating a test, the software records data for 2 seconds and calculates the average value to be used as a baseline measurement. Following the baseline calibration, the graphs begin to display the flow and volume data in real time. Once this graphing has begun, the software will run for 6 seconds, during which time the user should perform the spirometric maneuver. After 6 seconds, data acquisition is halted, and the total volume accumulated during the maneuver is printed on the screen alongside the graphs.

Circuitry Component Selection and Development

iLite Signal Conditioner

The ZMD31014, commonly known as the "iLite", is a low-cost signal conditioner tailored for use with bridge-type sensors. The iLite is capable of performing A/D conversion, low-noise amplification, temperature and linearity correction, as well as numerous other functions. The chip takes analog input from a sensor and converts it to a digital signal to be sent via I2C to other integrated components. With a cost of less than $2/chip, the iLite provides a large amount of practical function to our design without dramatically increasing costs.

In our spirometer, the analog voltage output from the spirometer will be directly connected to the iLite for signal conditioning and amplification. By incorporating the iLite into the design, we are able to eliminate many external trimming components (such as op-amps, resistors and capacitors) that would normally be needed to obtain a clear signal from our sensor. The iLite also provides easy adjustment of the gain and offset values through writing coefficients to the EEPROM rather than requiring manual switching of physical components.

Microcontroller Selection - PIC18F13K50

The PIC18F13K50 microcontroller is low-cost and offers the capability of converting data between the I2C and USB protocols. It is USB 2.0 compliant and can be programmed using a programmer that operates on USB. This chip costs less than $2.00 in quantities over 100 and can operate at temperatures between -40°C and 85°C. This chip was chosen because it is one of the lowest-cost chips capable of conversion from I2C to USB.

Another alternative we considered was using a very inexpensive and basic microcontroller in conjunction with a chip made by FTDI that performs the I2C to USB conversion. The FTDI chip utilizes drivers that recognize the incoming USB signal as a virtual COM port on the computer. However, using this component would still require a microcontroller to synchronize the FTDI and iLite chips. This design was not pursued because of additional cost and complexity.

Currently, the PIC microcontroller is located on the development board provided by the manufacturer. We have fabricated a printed circuit board that would be populated by the microcontroller, iLite chip, and several other components. The board design includes a 6-pin

programming header so code can be updated on the microcontroller after being soldered to the board. See Figure A2 in Appendix A for the schematics and board design developed in EAGLE.

The microcontroller can be programmed in C using the MPLAB Integrated Development Environment (IDE) and the C18 Compiler provided by Microchip. The USB framework provided by Microchip was used and extensively modified this semester to develop the code required for it to function on our PCB. Functions that were developed include the capability to connect to a computer via a USB connection, emulation of a serial port (a virtual COM port), and transmission of data stored in the microcontroller's memory over the USB connection that displays in HyperTerminal.

Final Design

The final design for the system is illustrated in Figure 7.

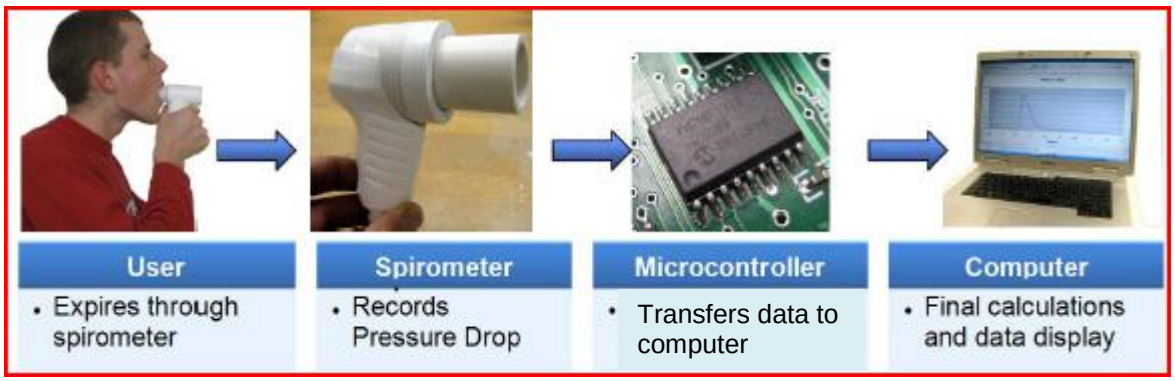

Figure 7: Schematic of spirometer system. The user exhales into a spirometer and the Honeywell 24PCEFA6D pressure sensor measures a pressure drop across the spirometer's resistive element. The ZMD 31014 signal conditioner chip performs analog to digital conversion, and the PIC18F13K50 microcontroller facilitates conversion of data and transfer to a computer. Software in the computer performs calibration-based numerical scaling and integration, and it displays data in real-time. A user interface and user-motivation animations are intended to be a part of the final design, but they were not implemented this semester.

The system was designed to include minimal components to lower cost and reduce the number of potential pieces in which the user/technician would encounter errors. However, accuracy of the signal and an aesthetic real-time display is vital, and the components included in the design are both necessary and sufficient to meet this requirement.

Prototype Testing

iLite Signal Drift

If the spirometer is not routinely calibrated, signal drift has the potential to reduce test repeatability over time. A major goal of our design is to minimize calibration; therefore, we must ensure tha signal drift will not have any significant effect on the accuracy and repeatability of results. One reason for including the iLite signal conditioner into our design is due to its ability to compensate for drift by periodically taking auto-zero measurements and performing adjustment to its output.[17] To confirm the iLite's stability over time, the signal conditioner was left running for a period of approximately 8 hours, during which the output was collected at a frequency of 1/8 Hz. The plot of the iLite's output over time is shown in Figure 8, from which

the correction capability of the iLite is apparent. Over the course of the test, the signal drifted approximately 0.1%; thus, drift will be negligible in its effect on our spirometer's repeatability.

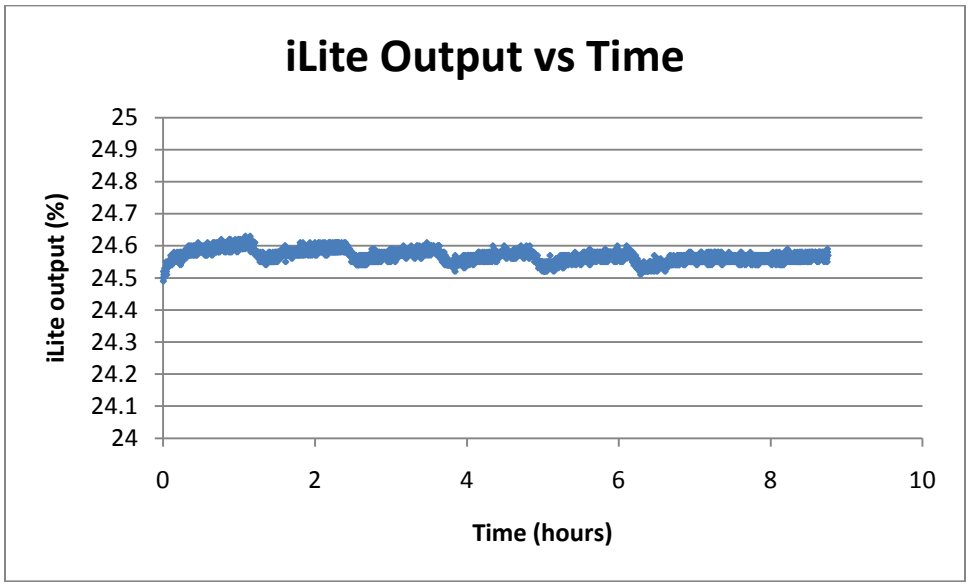

Figure 8: A plot of the iLite's output over a period of ~ 8 hours. Samples were taken every 8 seconds for the duration of the test. The iLite compensates for the slow drift upward by performing periodic auto-zero corrections, which are visible on the plot as the rapid downward curves.

Linearity Testing

The linearity of the pressure-flow relationship is a key determinant of the low flow sensitivity of a spirometer design. Therefore, a majority of the testing was designed to assess this relationship. The testing apparatus utilized the air valves found in the basement of the Engineering Centers Building to generate constant airflows. A plenum was used to equalize the air flow across the entire cross-sectional area of the spirometer. The spirometer was connected to the plenum via a PVC pipe that also helped to allow even air flow across the cross-section. The velocity of the air leaving the spirometer was measured using an anemometer, and velocity was converted to a volumetric flow rate by multiplying by the cross-sectional area of the rear of the spirometer. The pressure drop caused by air flow was measured by the pressure sensor, converted to a digital signal by the iLite, and output to a computer using the iLite's development software. Figure 9 shows a diagram of the testing setup used for linearity testing.

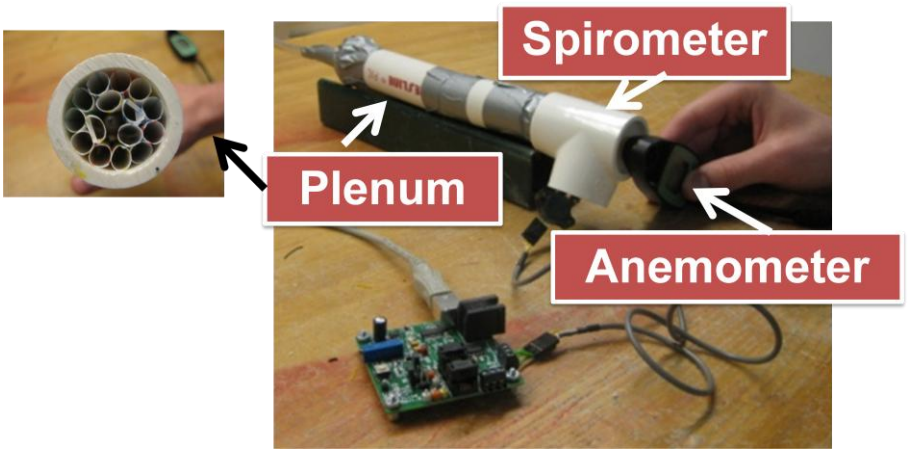

Figure 9: A diagram of the linearity testing setup.

With this setup, various air flows were passed through the spirometer, and the output from the iLite was measured for approximately 10 seconds at 100 Hz at each flow rate. This output data was averaged and plotted against the flow rate in Excel, and the linearity was assessed by fitting a linear trendline to the data. The various prototypes designed throughout the semester were all evaluated using this setup, and the results from the linearity testing was the primary criteria used to determine the optimal capillary length and spirometer body diameter.

The initial prototype used square cordierite capillaries (side length 1.168 mm) with an overall body diameter of 1" were tested with capillary lengths of 1 and 2". Figure 10 shows the pressure-flow curves for these two systems. As seen from Figure 10, neither 1 nor 2" long capillaries were able to facilitate a truly linear flow-pressure curve. However, the 2" length did show a more linear response, indicating the importance of capillary length in the ability of the spirometer to achieve laminar flow.

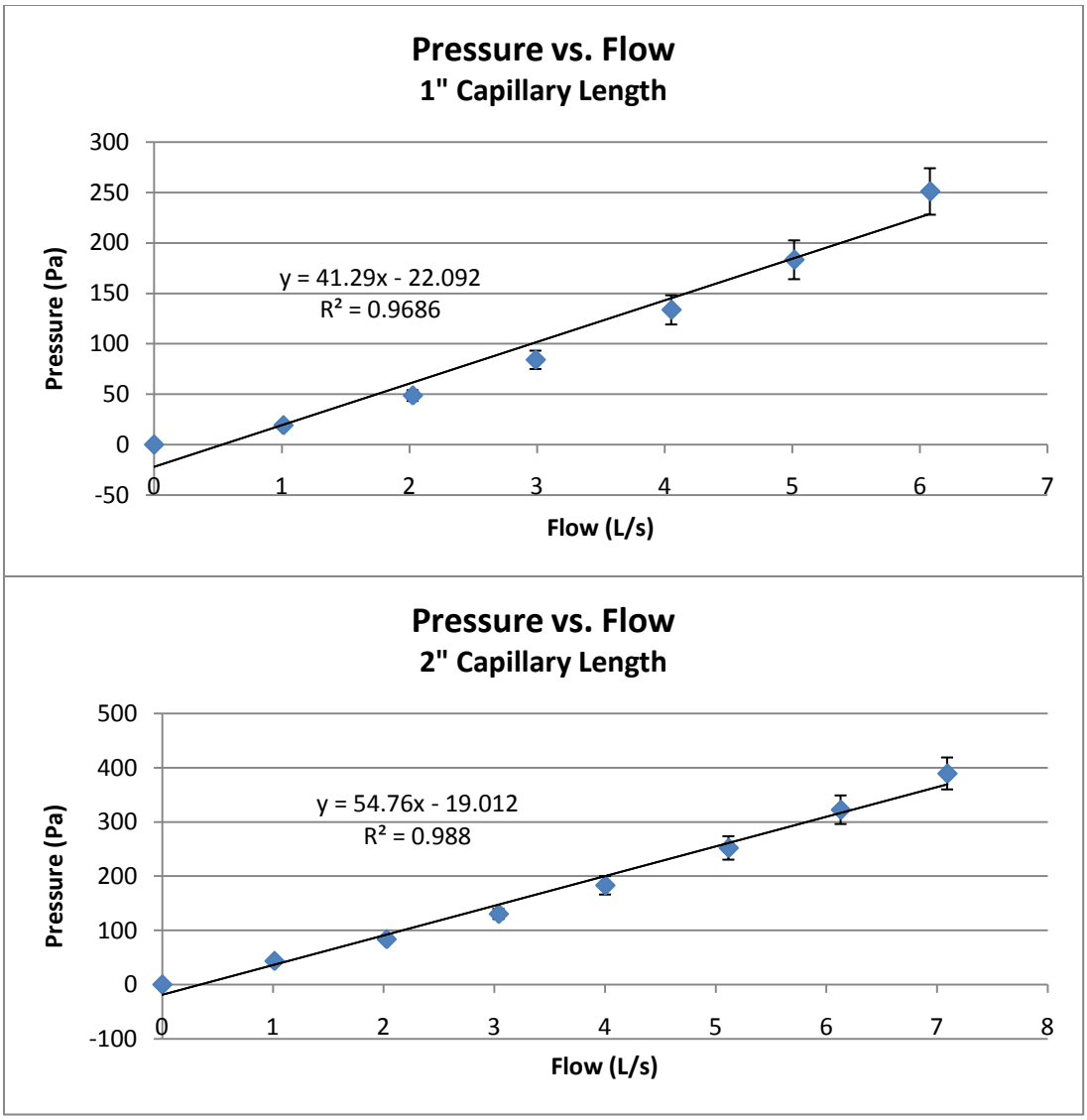

Figure 10: The pressure vs. flow relationship for a spirometer with a 1" diameter capillary system at lengths of 1" (top) and 2" (bottom).

A larger spirometer body diameter allows for lower air velocities at a given flow rate, which improves laminar flow. Therefore, a capillary system utilizing the previous capillaries and spanning a 1.5" body diameter was tested in an effort to generate greater linearity. These systems were also tested at lengths of 1" and 2", and the pressure-flow curves for these models are shown below in Figure 11. Additionally, the previous testing system we found unable to generate air flows high enough to cover the entire span required by ATS standards. To achieve higher flows, we attached two different air valves together prior to connection to the plenum. This setup was successful at generating higher air flows, but also caused considerably higher variability in the air flow. The uneven flow rates are shown by the higher standard deviations in the data, especially at high air flows, compared to prior testing.

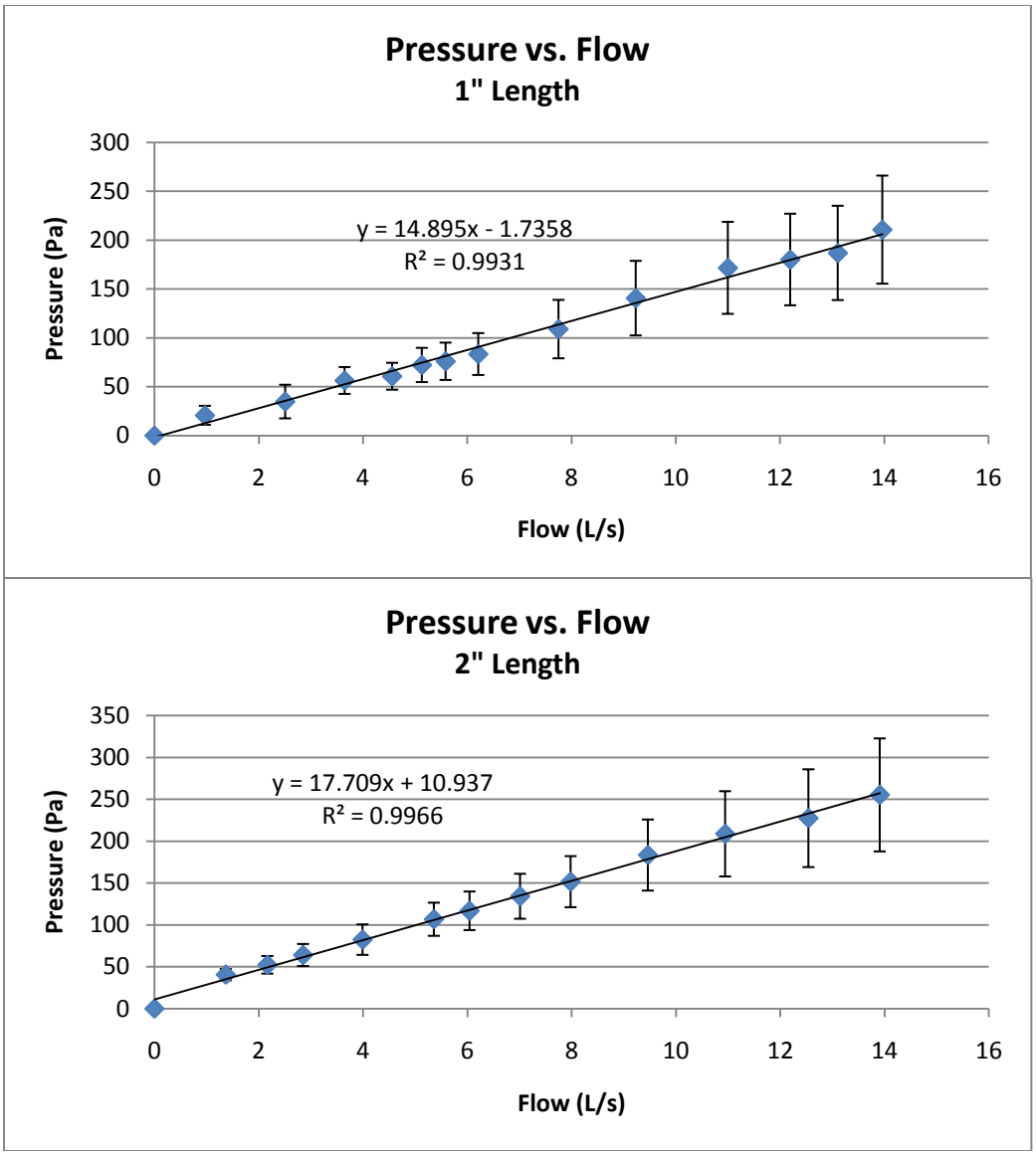

Figure 11: Pressure vs. flow plots for spirometer models utilizing 1.5" diameter capillary systems at with capillary lengths of 1 and 2 inches.

Table 6 below shows the compiled results from all of the linearity testing performed on the various prototypes.

Capillary system diameter (Inches)	**Capillary length (Inches)**	**Pressure vs. Flow linear slope ($Pa/L \cdot s^{-1}$)**	**R^2 of linear trend line**	**Maximum pressure drop (Pa)**	**Maximum resistance ($Pa/L \cdot s^{-1)}$**
1"	1"	41.29	0.9686	251.05	41.29
1"	2"	54.76	0.9880	389.47	54.9
1.5"	1"	14.90	0.9931	210.82	15.09
1.5"	2"	17.71	0.9966	255.2	18.35

Table 6: A summary of the linearity testing performed on 4 different spirometer prototypes.

Humidity Testing

Repeated exhalations through a spirometer can cause condensation to form on the resistive element, causing increased resistance and measurement error. Condensation is especially a problem for Lilly-type designs which utilize a very fine wire mesh, as well as Fleisch designs that utilize metal capillaries.[18] Because our spirometer does not utilize a heating element, we needed to ensure that its function would not be compromised after exposure to warm, humid air. After measuring the average output in the absence of air flow, a fixed flow of ~4 L/s was run through the dry spirometer while recording the output from the iLite for about 10 seconds. Then, a steam cleaner was used to thoroughly steam the spirometer body and simulate multiple exhalations. The spirometer body was reconnected to the airflow and the new output from the iLite was again measured for ~10 seconds. The output from each trial was averaged and the standard deviation of the measurements was calculated. Figure 12 shows a comparison of the average output at 0 L/s, the dry spirometer body at 4 L/s, and the output at 4 L/s post-steaming. As seen on Figure 12, the average output from the iLite was slightly higher than the dry reading, but considerably less than the standard deviation of the data set, indicating no significant difference between the measurements.

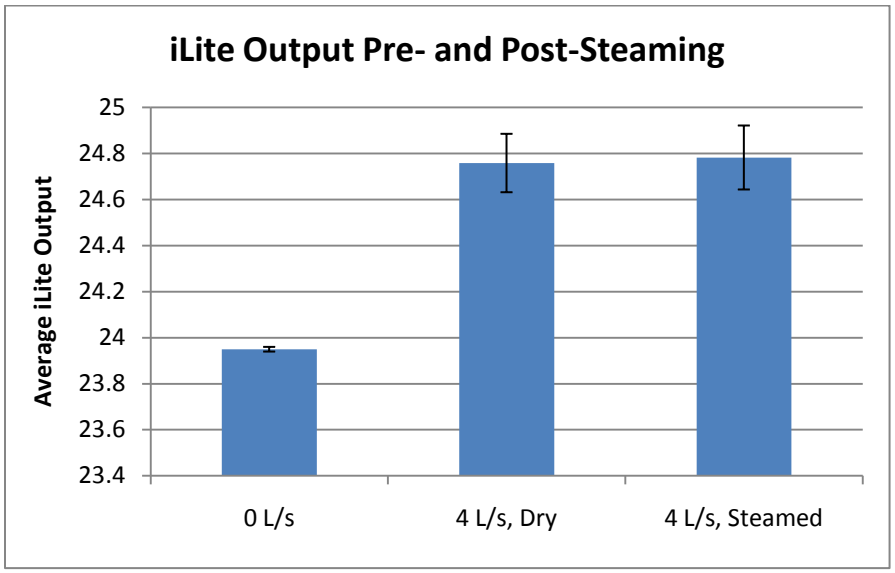

Figure 12: The average iLite output recorded from fixed flow rates of a dry and steamed spirometer body.

Liquid Degradation

The typical method for cleaning the inside of the spirometer will be to submerse it in a liquid disinfectant solution such as 95% ethanol. The cordierite manufacturer had not done extensive testing regarding liquid degradation, though representatives have said that it should not degrade with exposure to ethanol or standard disinfectant concentrations of bleach. As added validation, we performed basic liquid degradation tests by submerging a section of the cordierite capillaries in water for ~10 minutes. At the end of the test duration, close visual inspection of both the capillaries and the water did not show any signs of physical degradation of the material.

Calibration Assessment

Using the calibration program written in MATLAB (see *Calibration Procedure* section), data from 30 plunges of a 3 liter syringe was gathered. 10 plunges each were performed at slow, medium and fast rates, and the resulting conductance array was stored in MATLAB. Next, an additional 30 plunges were performed and the conductance array determined by the previous set of measurements was applied to convert the measurements into flow and volume data. The results of the volume calculations for the 30 measurements are shown below in Figure 13.

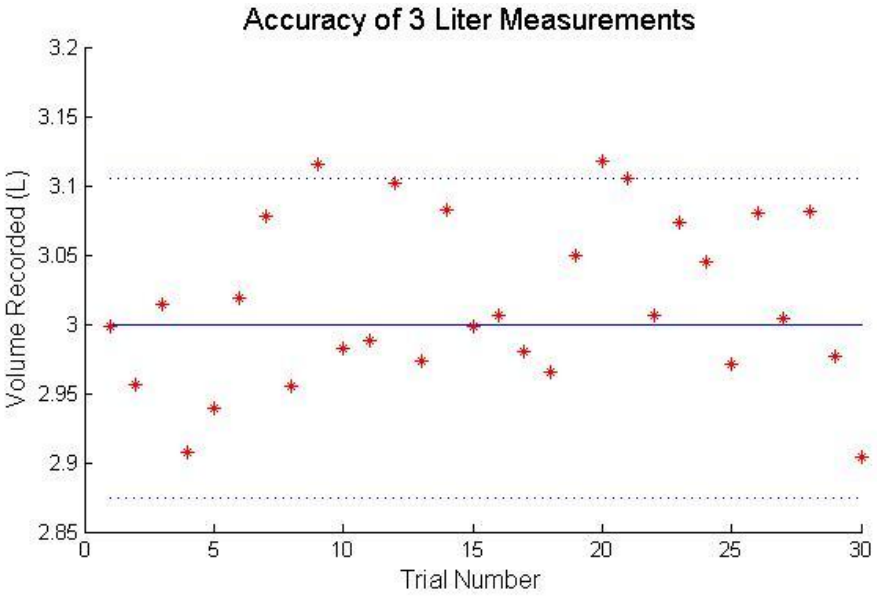

Figure 13: The volume measurements recorded (post-calibration) from 30 plunges of a 3 L syringe. The dotted lines indicate ±3.5% of 3 L; therefore, all points between the dotted lines (n=28) meet ATS standards.

As seen in the figure, 28 of the 30 measurements fell within 3.5% of 3 L, the ATS requirement for volume measurement accuracy. Although a very high accuracy was exhibited for this calibration when recording 3 L volumes, we noted that measuring larger volumes that are typical of human lung capacity seemed to be less precise.

The results from our calibration validation were also analyzed using statistical analysis. A two-tailed Student's t-test gave $t(29)=1.42$, $p=0.16$ with a null hypothesis that measured volume is 3 liters. These results suggest that our spirometer is fairly accurate at measuring the 3 L volume.

Future Work

There are several key things that we plan on implementing in the final semester of this project. First and foremost we are going to complete the necessary documentation and file for clinical testing with the Institutional Review Board (IRB). This will be first on the list due to the time-consuming nature of the approval process. We have also completed a majority of the Invention Disclosure Report (IDR) and are intending on submitting it to WARF once we have made all final adjustments to our spirometer's dimensions and materials.

Because our device will most likely be sanitized using a solution of ethanol, we plan on doing degradation tests with the cordierite core and ethanol solutions. The manufacturer has informed us that no testing to date on the durability of the cordierite core in ethanol. Other

testing of the cordierite core will also be performed, such as its durability in poor transportation conditions similar to developing nations. We will also ensure our device meets the standards described above, particularly those in ISO 26782.

Additionally, we plan on implementing our coaching program into the software that was developed to display the flow and volume data. This coaching software will include video tutorials on how to perform the spirometric procedure. These videos will also cover things to avoid during the procedure such as poor posture and coughing. Along with the volume and flow vs. time graphs are currently developed, the next version of software will include a flow -volume graph. There will also be an incentive screen that will feature a boat or something similar moving across the screen to promote maximal effort from the user during the maneuver. This incentive screen should also incorporate visual and audio feedback to further encourage the user to keep blowing and give their maximal effort throughout the duration of the trial.

A printed circuit board (PCB) allows the electrical components of a device to be mounted in a compact fashion that eliminates connecting wires. Complete schematics and a PCB design containing all the components required for the spirometer's function was developed and is shown in Appendix A. This design was printed and components were ordered to populate the board. However, the board was not assembled or tested due to time constraints as well as incomplete microcontroller programming that is required for the PCB to function. An immediate focus for the upcoming semester is to populate and test the PCB design and determine if any revisions need to be made to improve its functionality.

Much progress was made this semester in the development of the PIC microcontroller code. Although the current code is capable of transmitting data via USB, the code has not been developed that can acquire data from the iLite using the I^2C protocol. After succeeding in acquiring data from the iLite and transmitting it such that it can be viewed in HyperTerminal, the code may need to be modified to fit the Java software framework currently used to display the data. Finally, a few minor settings, such as input specification and clock multiplying, will need to be adjusted as the target microcontroller will be found

The current calibration procedure utilizing a MATLAB code will need to be modified to provide greater accuracy for large volumes as well as integrate the program into the existing Java-based graphing software. First, we hope to significantly improve its accuracy by using more advanced function-fitting methods. Such methods are well-illustrated by Ohya, et al.[19] and by Strömberg and Grönkvist.[20] Specifically, implementing more advanced mathematics such as Fourier transforms will allow the calibration to maintain its accuracy to volumes far beyond 3 liters. Once the calibration program has been validated by comparison testing with commercial spirometers, the code will be written into our Java software to eliminate the use of MATLAB.

Once we have IRB approval to conduct clinical testing, we will validate our design against commercial spirometers. This will allow us to prove that our device is capable of being used as a diagnostic tool as it is intended. All aspects of the design, including hardware function and durability, ease of cleaning, accuracy and repeatability will be thoroughly assessed Clinical testing will also allow us to determine if our coaching software is affective in replacing a trained technician to encourage the user through the maneuver. Clinical testing will be held as the "gold-standard" for our spirometer's validation, and it is our ultimate goal for the Spring 2010 semester.

Timeline of Future Work

Spring 2009	Developed reliable prototype that gives accurate and precise readings for a given flow rate and volume.
Summer 2009	Performed extensive pressure vs. flow testing. Refined design to improve linearity of pressure vs. flow for operation at low flows. Worked on developing open-source software to analyze and display data.
Fall 2009	Refined design to achieve a linearly correlated flow-pressure trend line. Developed calibration protocol and algorithm to improve accuracy and reliability for volume and flow rate. Verified refinements with volume accuracy testing. Tested temperature and humidity effects. Prepared design to meet requirements for clinical testing. Developed Java software to scale data and graph flow vs. time and volume vs. time curves in real-time.
Spring 2010	Establish human subjects protocol and file for clinical testing. Assemble PCB and test function to obtain a stand-alone device. Develop coaching audiovisuals and completely link patient blowing to coaching feedback; test effectiveness of coaching using commercial spirometers vs. our prototype. Perform testing on human subjects to ensure no other reliability problems from human use. Compare spirogram from clinical testing with spirometers on the market, improving spirometer design as necessary. Perform extensive clinical testing on humans, both healthy and with lung obstructions due to asthma or COPD. Prepare to mass-produce prototype.

Conclusion

The high cost of current spirometers has made them unaffordable to many physicians in emerging nations. Unfortunately, it is in these same locations that pulmonary disorders such as COPD are especially prevalent. Due to the need for spirometry equipment to diagnose and monitor respiratory function in developing countries, we sought to design a low-cost spirometer including coaching software. Revisions of our past work have allowed us to develop a model that has a linear pressure flow relationship (R^2>0.996), implement real time graphing of flow and volume data, and investigate calibration methods. This work was accomplished following good ethical protocol and included appropriate investigation into regulations affecting our design. Future work will be done to integrate motivational tools into the existing graphing software, improve the calibration algorithm, and ultimately test the overall function of our design with clinical testing.

Acknowledgements

We would like to give special thanks to David Hubanks, Eric Hoffman, and Isaac Wiedmann from ZMD who kindly donated us a signal conditioner and software. We also want to thank our client, Dr. David Van Sickle who has given us a lot of support on this project. Thanks also to Professor Mitch Tyler who served as our advisor and gave us invaluable guidance and to Amit Nimunkar, Jon Baran, Chris Esser, Peter Klomberg, Varuneshwar Gudisena, and Vikram Singh, who helped with logistics, PCB layout, and programming. With these people's help, we were able to design and build a solid proof of concept.

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APPENDIX A

Ergonomic Requirement –Youth Hand Measurements

Combined Sexes	Mean	SD
Inside Grip Diameter	3.79	0.28
Outside Grip Diameter	6.8	0.5
Hand Length	13.7	0.8
Hand Width	6.3	0.4
Males Only		
Inside Grip Diameter	3.81	0.3
Outside Grip Diameter	6.9	0.5
Hand Length	13.8	0.8
Hand Width	6.2	0.4
Females Only		
Inside Grip Diameter	3.77	0.27
Outside Grip Diameter	6.7	0.4
Hand Length	13.6	0.8
Hand Width	6.4	0.4

Table A1: Hand measurements taken from 8-year old children.[21]

Software Screenshot

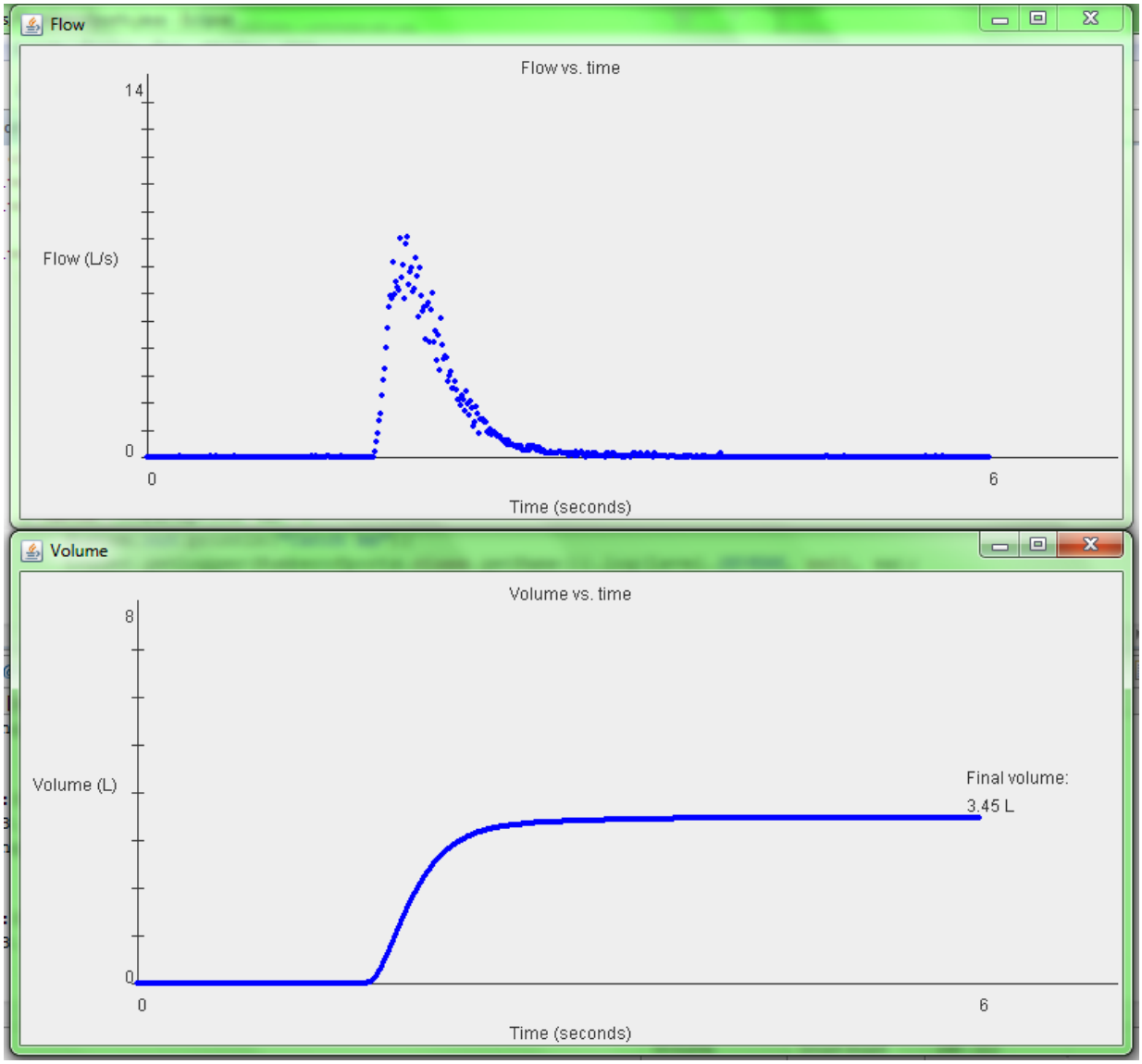

Figure A1: A screenshot of the graphs produced by the Java-based software. Both the flow-time and volume-time graphs are updated in real time throughout the maneuver. This screenshot was taken after completion of the maneuver, at which point the total volume exhaled by the user (FVC) is displayed at the right side of the volume-time graph.

Schematics and PCB Layout

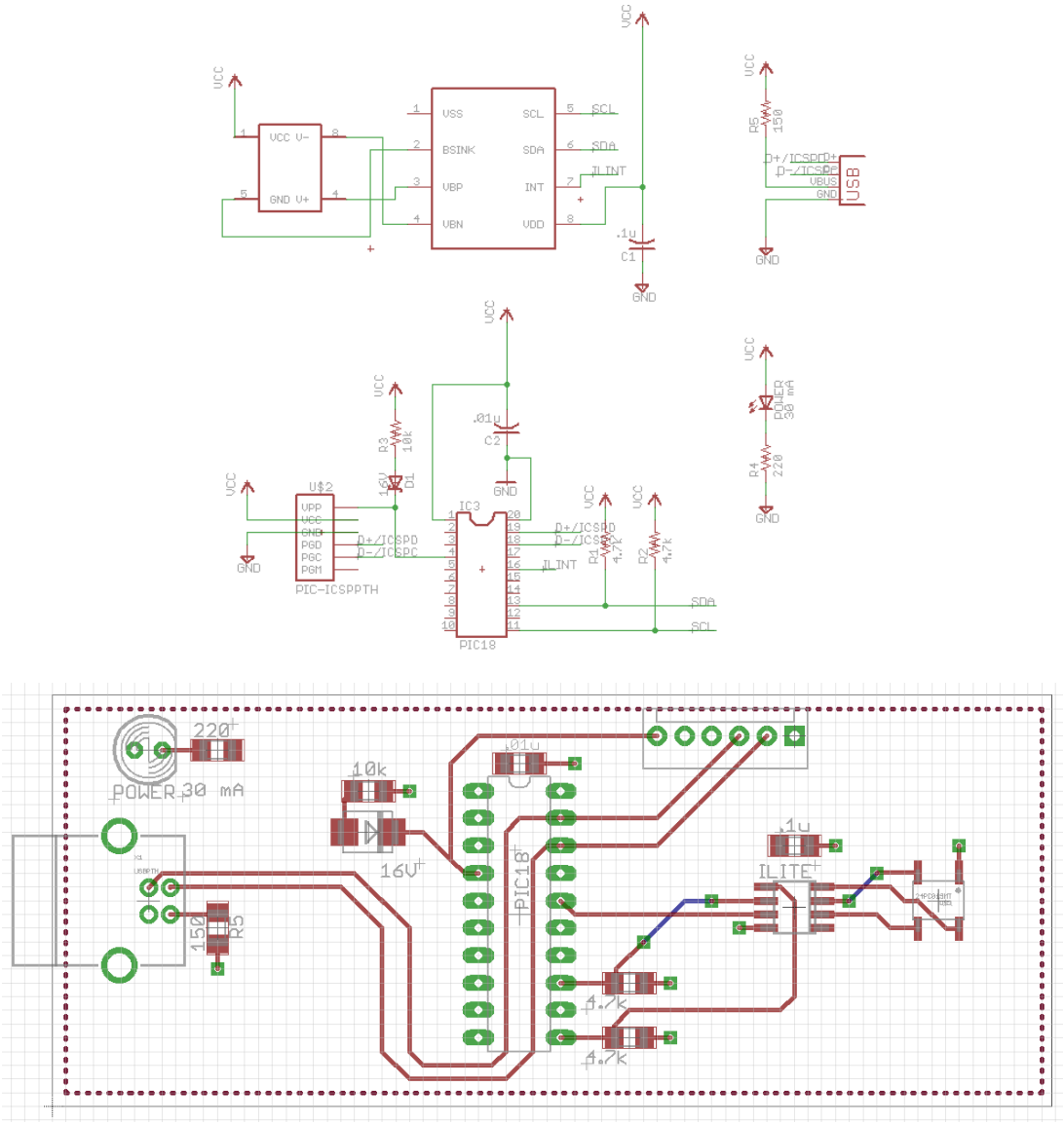

Figure A2: Diagram of the schematics (top) and PCB layout (bottom) developed this semester. EAGLE 5.6.0 light edition was used to generate these designs.

APPENDIX B – Product Design Specifications

Low-cost, Open-source Spirometer

Andrew Bremer, Andrew Dias, Jeremy Glynn, Jeremy Schaefer
Client: David Van Sickle, PhD
Advisor: Professor Mitch Tyler
Last Updated: 12/04/09

Background and Problem Statement: Spirometers are used to diagnose many pulmonary diseases including chronic respiratory diseases that affect approximately 500 million people worldwide. 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 disinfect
- Minimize calibration
- Simple and universal instructions for operation
- Graphically display results of FVC maneuver
    - FEV
    - FEV1
    - FEV1/FEV
    - FEV6
    - PEF
    - $FEF_{25\%-75\%}$
    - Time zero determined by back-extrapolation
- 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*

i. Spirometer: 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. The body should facilitate laminar air flow, and thus a linear flow/pressure relationship should be measured. The total resistance of the spirometer should be less than 0.15 kPa/L·sec at all flows between 0 and 14 L/s.

Device will need to withstand these pressures and air flows multiple times daily and still be able to function accurately. Spirometer must still function accurately after it or any accessories have been subjected to drop testing mandated by IEC 60601-1, pp 115-117. The handle must be able to withstand a force equal to 4 times the weight of the main body of the spirometer. If the spirometer is to be disassembled, markings should be clear to ensure correct reassembly or it should be impossible to assemble incorrectly.

ii. Hardware/software interface: Capable of sending pressure and temperature data each with 10 bit resolution at 100 Hz over USB. Should have duplex communication with the computer.

iii. Software: 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. Measurement display should be accurate to 0.01 L (L/s for flow). 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. Volume-time curves should be displayed with the aspect ratio of 1 L:1 sec, flow-time curve should have a ratio of 2 L/s to 1 L.

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. Mouthpieces or mouthpiece packaging must be labeled "single patient use." All parts that come into contact with bodily tissues, fluids or gasses must be deemed biocompatible as relevant to their function. Appropriate biocompatibility will be defined according to the protocol defined in ISO 10993-1, *Biological Evaluation of Medical Devices*. All components intended for reuse that come into contact with the patient must be capable of being cleaned and disinfected or cleaned and sterilized. Instruction manual should specify what should be disinfected or cleaned.

c. *Accuracy and Reliability*:
    i. *Spirometer* - The maximum error for volume readings must be <3% of the reading or .05 L, whichever is greater. Measurements must be repeatable enough such that when measuring a constant flow patterns, all readings fall within 3% or 0.05L of the mean of the readings, whichever is greater. Volume linearity error should not exceed 3% when measured at increments 0.4 to 0.6 L in size for the span of the measurement range (ISO 26782). Pressure vs. flow should fit a linear trendline with regression coefficient ≥ 0.98. Accuracy and reliability should be maintained with only initial factory-set calibration in varied temperature and humidity conditions. 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.
    ii. *Maneuver* - Repeatability of the spirometry maneuver should be graded by the system established by the ATS and described in *ATS/ERS Standardisation of Spirometry*, 2005 update. Standardized respiration coaching should ensure repeatable pulmonary measurements.
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. Unit should maintain performance requirements with multiple daily disinfecting procedures.
f. *Operating Environment*: The unit should maintain accurate function between 17° and 35° C, in relative humidity from 30% to 75%, and in ambient pressure 85 to 106 kPa. Exhaled air is assumed to be at body temperature (37°C) 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 is handheld and easily portable, measuring 10.2 cm (4 in) in length and 3.2 cm (1.25 in) in diameter.
i. *Weight*: The maximum weight for the unit is 500 grams (1.1 lb)
j. *Materials*: The chosen material for initial prototype is a PVC case with cordierite capillaries. The chosen materials are abuse-tolerant, easily manufactured on a mass scale, and water and heat resistant to deformity or breaking.
k. *Power*: Device must be powered via USB bus (maximum voltage 5 V, maximum current 100 mA).
l. *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. Direction of flow must be marked. Name, address, manufacture trademark, and model identification number or serial number should be visible on the spirometer.

Any markings on the spirometer must remain legible after cleaning, disinfecting, or rubbing. Method of disposal should be labeled in packaging.

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, in the motivational coaching software, in operation training software, and on the spirometer itself, must be conveyed in a universal fashion for multi-lingual understanding. An electronic copy of a user's manual should be included with the spirometer.
b. *Environmental impact*: Use, cleaning, and disposal of consumables should have minimal environmental impact.
c. *Customer*: Emerging nation healthcare practitioner
d. *Patient-related concerns*: Device mouthpiece should be replaced between uses
e. *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.