



Development of First Proto-Types of a Low-Cost Computer based Solid-State Spirometer for Application in Rural Health-Care Centres across India

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1. INTRODUCTION

• Historical Perspective

Indians are genetically at higher risk of developing cardio and pulmonary diseases. Being a developing country, India lacks even basic health-care infrastructure in its far flung rural villages. With the gradual progress in development meaning life-style related diseases like heart-disease, diabetes, renal diseases etc. have taken a toll on the population. Compounding the problems of wide-spread poverty with

an increase in life-style related diseases necessitates a greater budgetary allocation needed for providing primary health-care. On an average 30% of Indians suffer from various cardio-vascular & pulmonary diseases. Latest statistics reveal that roughly 27 % of India's population falls under the below poverty line category. With the slow pace of economic growth seen in recent years India has not been able to fund rural health-care and poverty alleviation schemes with generous budgets.

• Objectives

Our research is directed towards bridging the cost divide in providing much needed basic health-care for our less-fortunate countrymen living in rural India. As a precursor to providing diagnostic indicators for various diseases, a Spirometer forms an integral piece of equipment to be installed in village health-care centres across India.

• Comparative Statement

Commercially available Spirometers are expensive to be procured for every village clinic considering there are 5,93,731 villages across the Indian sub-continent. An indigenous initiative to develop diagnostic equipment will go a long way in providing sustained supply of health-care equipment for the country.

• Concept and Realization

Spirometry is the technique of measuring the respiratory function of humans. It is most commonly referred to as pulmonary function tests (PFTs) in diagnostic parlance. PFTs employed for measuring lung function parameters like total lung volume, air flow rate and velocity during the inhalation / exhalation cycles give an indicator of lung muscle integrity. These vital parameters are crucial in diagnosing respiratory diseases like asthma, pulmonary fibrosis, cystic fibrosis, and COPD. The outputs of spirometry are generally referred to as pneumotachographs which contain graphical illustrations of Flow-rate versus Volume, Volume versus time & Flow-rate versus time. Commercially available spirometers in the market are often exorbitantly expensive and not within the reach of

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allow these physicians to make more quantitative assessments of their patients' pulmonary health. A training program that would instruct and motivate patients through the Spirometric tests would further

augment the accuracy of clinical diagnosis. Figure 1 example of a test spirogram. The various lung diseases vis-à-vis the indicative figures of Spirometry parameters are enlisted in Table-1.

Table 1 : Tabular form of various diseases versus the indicative (qualitative) figures of Spirometry Parameters

Sr. No.	Diagnosis	Forced Expiration Volume for one second FEV1 (Litres)	Forced Vital Capacity FVC (Litres)	FEV1/FVC
1	Normal Person	Normal	Normal	Normal
2	Airway Obstruction	Low	Normal / Low	Low
3	Airway Restriction	Normal	Low	Low
4	Combination of Obstruction / Restriction	Low	Low	Low

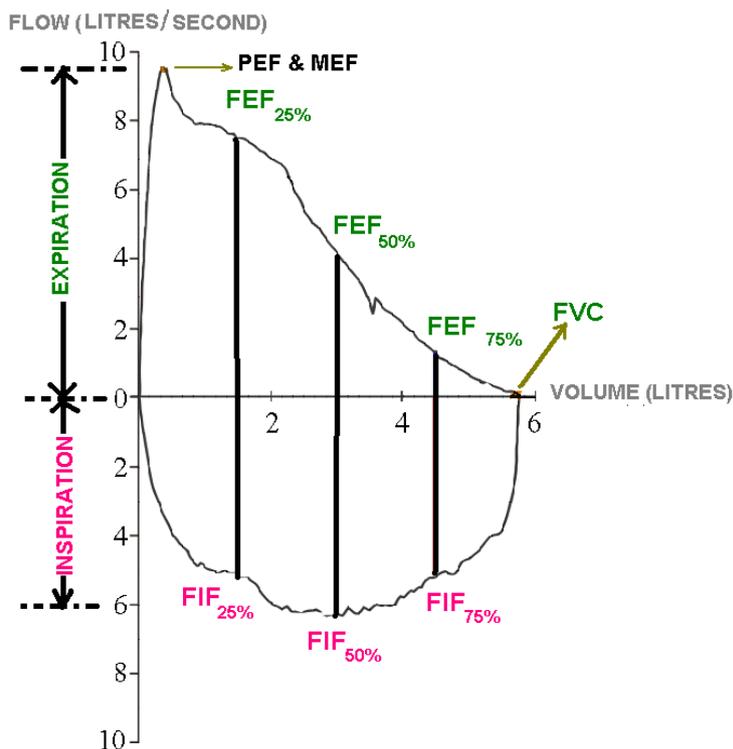


Figure 1 : Graphical illustration of a sample Spirogram

SDI Diagnostic, MicroDirect, and Welch Allyn are among some of the commercial manufacturers of spirometers. SDI Diagnostic manufactures six different spirometers ranging from \$995 to \$2395. The Spirolab II is a top of the line spirometer with salient features touch screen, Bluetooth, and a bidirectional turbine with a price tag of \$2395. Among the commercial brands MicroDirect spirometers are comparatively affordable with a price of \$1419.55. Summarily, nearly all spirometers in the market are far too expensive for use in developing countries.

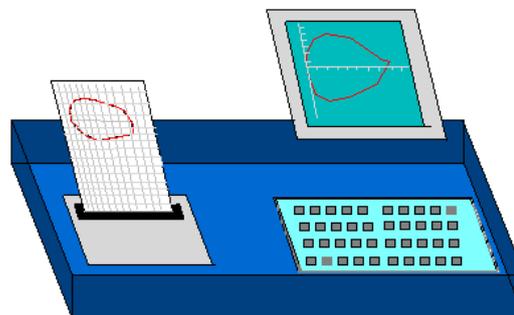


Figure 2 : Illustration of a commercially available Spirometer

There are various approaches to designing Spirometers viz. solid-state pressure sensor approach, volume based sensor approach, Convective heat



transfer, turbine based anemometer design & Air flow acoustics approach. The solid-state pressure sensor approach will be discussed extensively in the later sections. Volume based spirometers work on the principle of measurement of air volume through downward displacement of water. The merits of this approach are its simple design, low cost & a permanent mouth-piece design. 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 is quite large in size in comparison to the other designs. The chamber would have to expand to a volume of at least eight liters according to these 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.

Hot-wire based spirometers are based on the principle of Convective heat transfer. The rate of cooling is proportional to the rate of flow of fluid through the hot-wire sensor [10]. The value of h depends on the fluid mass flux (density * velocity) and dimension of sensor. The function between h and velocity can be experimentally determined by best fitting the parameters in modified King's law for free convection heat transfer at low Reynolds number (R_e) in a long cylindrical structure.

$$\text{Resistance of hot-wire sensor: } R_s = Ae^{\frac{B}{T_s}} \quad (1)$$

$$\text{Power Delivered to Sensor: } P = hS(T_s - T_f) \quad (2)$$

Where:

- B = a material dependent constant;
- T_s = temperature of the sensor in K;
- R = resistance at temperature T_s
- T_o = reference temperature in K
- R = resistance at temperature T_o
- T_f = Fluid temperature
- h = heat transfer coefficient referred to the sensor surface in W/m^2K
- S = surface area of the sensor.

$$h = C_o + C_1 v^n \quad (3)$$

The hot-wire sensor (Japanese CHEST M.I. INC., Hi- 501) is placed on one arm of Whetstone bridge and excited with constant voltage without negative feedback. The output signal is amplified and digitized by ADC of Lab-VIEW system or prototype system.

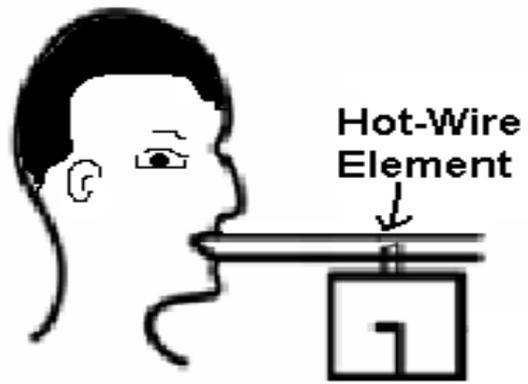


Figure 3 : Illustration of hot-wire based Spirometry technique

The air turbine based spirometers are based on the principle of direct proportionality of rotation speed on flow rate. Some of the demerits of this approach are friction related drag leading to inaccurate results at the fag ends of the respiratory cycle. Hence this leads to a non-linearity of rotation speed at the beginning and end of the breathing cycle.

II. DESIGN OF PRESSURE SENSOR BASED SPIROMETER SYSTEM

a) Principles of Fluid Dynamics

Total Pressure of a fluid flowing through a tube is the sum of the static and dynamic components. Static component of pressure is essentially the pressure exerted on the walls of the tube when the fluid is at rest (velocity = 0 m/s) whereas the dynamic component gives the pressure exerted by fluid when in motion. The dynamic pressure is dimensionally referred to as the change in kinetic energy per unit volume. Our spirometer system is designed to work on the principle of measurement of dynamic pressure of a fluid when it traverses a tube.

$$\text{Dynamic Pressure: } P = \frac{1}{2} \rho v^2 \quad (4)$$

Where: ρ = Density of Air at 300° K
 v = Velocity of flow of fluid

Once the dynamic pressure is extracted from the sensor, the Velocity of flow can be determined using equation 4.

$$\text{Flow-rate: } F = A \times \text{Velocity} \quad (5)$$

Where: A = Area of cross-section of tube

Total Volume of air can be determined by equation 6.

$$\text{Volume of Air: } V = \int_{t1}^{t2} F \cdot dt \quad (6)$$

The illustration in figure 4 shows the functional block diagram of the devised spirometer system. The first block is concentrated on the front-end of the system, in this case, the mouthpiece device. The second block is dedicated to the sensing device, in this case a FREESCALE Semiconductors Inc. dual port, MEMS

based pressure sensor (MPXV2010DP). The third level is reserved for the analog signal conditioning function. The fourth and fifth modules contribute towards signal digitization and ultimate display of the output of the system.

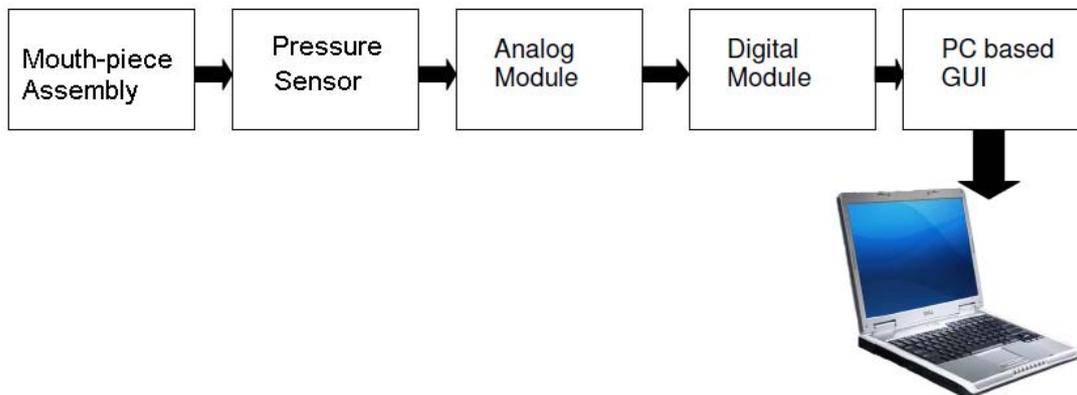


Figure 4 : Functional block diagram of the complete Spirometry System

b) Sensor Calibration

Prior to making any measurement, the pressure sensor needs to be calibrated for its performance. A FLUKE Inc. blood pressure simulator (BP-PUMP2) has been employed for applying a fixed quantum of static pressure on the sensor ports. The positive side port was calibrated first by connecting to the simulator. The applied pressure was varied from 6.7 kPa to 13.3 kPa and the voltage at the output of the analog circuit (described in section II c) was measured. This output voltage was normalized by subtracting the mid-point

potential of 5V (Maximum input swing for ADC) with the output value. This results in a range of voltage values from 0 to 5 V with 2.5V as centre value. The pressure to voltage conversion factor (+ve & -ve ports) was also calculated from the formula given in Table-2. This factor was crucial in deducing the pressure value from the output of the ADC. Alternately, the applied pressure was calibrated using a sphygmomanometer in parallel with the fluke BP simulator and the deviation of pressure values was found to be 1.55% between the mercury readings and our system.

Table 2 : Calibration values for positive side port of sensor

Sr. No.	Pressure (applied) (kPa)	Output Voltage "V _P " (+ve Port) (Volts)	Normalized Voltage (V _P - 2.5) (+ve Port) (Volts)	Pressure to Voltage conversion factor [Pressure / (V _P - 2.5)] (kPa / Volts)	Average Conversion factor (kPa / Volts)
1	6.7	3.28	0.78	8.58974	8.3907
2	8	3.41	0.91	8.79121	
3	9.3	3.64	1.14	8.15789	
4	10.6	3.79	1.29	8.21705	
5	12	3.95	1.45	8.27586	
6	13.3	4.1	1.6	8.3125	

Table 3 : Calibration values for negative side port of sensor

Sr. No.	Pressure (applied) (kPa)	Output Voltage "V _N " (-ve Port) (Volts)	Normalized Voltage (2.5-V _N) (-ve Port) (Volts)	Pressure to Voltage conversion factor [Pressure / (2.5-V _N)] (kPa / Volts)	Average Conversion factor (kPa / Volts)
1	6.7	1.83	0.67	10.00	9.75734
2	8	1.68	0.82	9.7561	
3	9.3	1.54	0.96	9.6875	
4	10.6	1.40	1.1	9.63636	
5	12	1.27	1.23	9.7561	
6	13.3	1.13	1.37	9.70803	

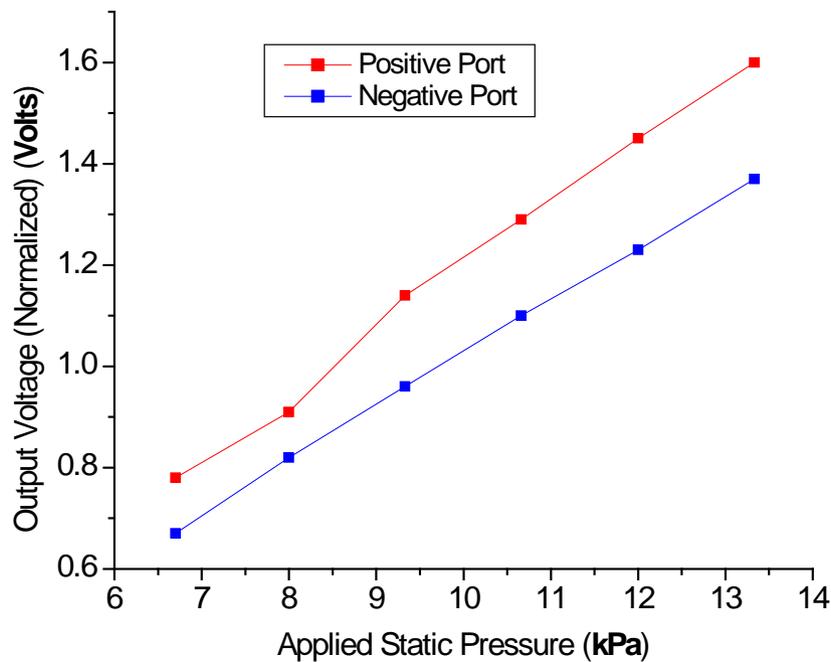


Fig. 5 : Normalized output voltage versus applied static pressure

c) Analog signal conditioning module

The analog circuit (Fig. 6-a) for the Spirometry system consists of instrumentation amplifier (AD624) in conjunction with an OPAMP. The output of the IA is then coupled as input to a general purpose OPAMP (AD713) for further amplification to give a signal large enough to drive the input to an ADC in the digital micro-controller module. Presently, the total gain of the system is 55. Gain can be tuned depending on the value of the output signal from the pressure sensor and the ADC input range. Additionally, level-shifting block is added at the output to prevent the negative drift of output voltage from the negative pressure port of the sensor. This level

shifter is designed with a single low power, low leakage current Quad OPAMP (LMC 6044) in a summation configuration. The input reference voltage is fixed at the mid-gap of the ADC range of 5V. The reference voltage of 2.5V is supplied by a potential divider arrangement consisting of two 1MΩ resistors. The mid-point of the divider is connected to a buffer for voltage stability and the output of the buffer is connected to the non-inverting terminal of the level shifter OPAMP. A photographic illustration of the realization of the analog circuit over multipurpose PCB is shown in figure 6-b.

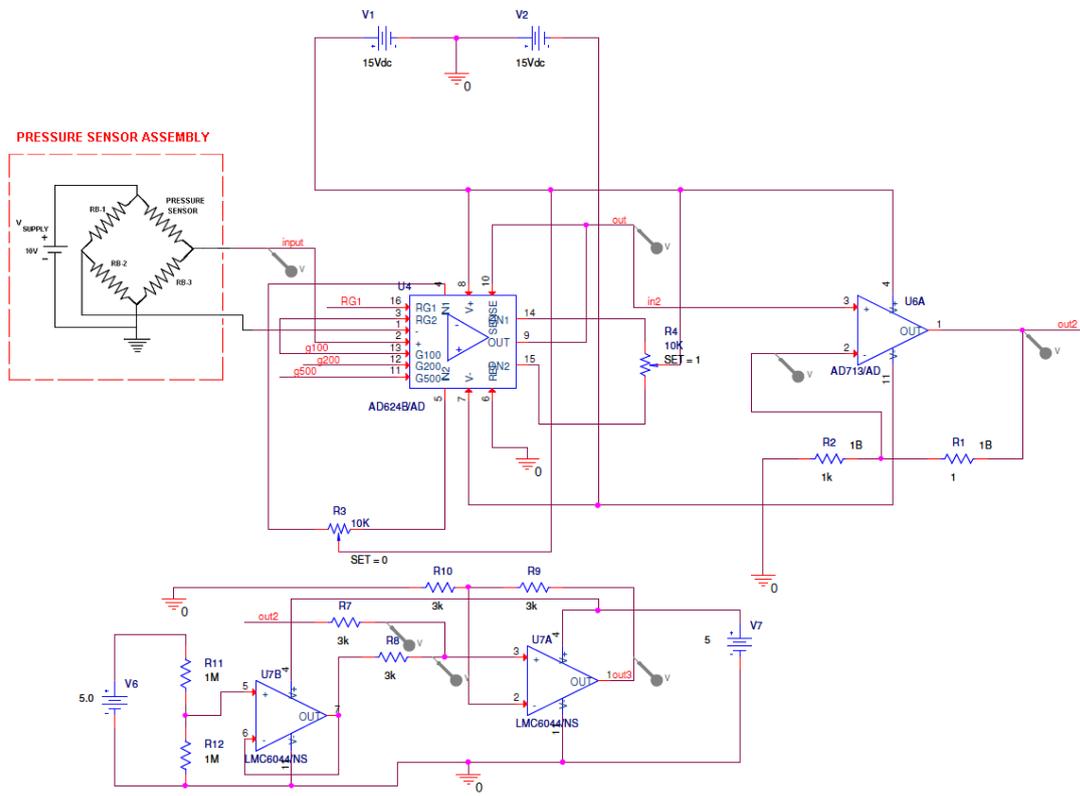


Fig. 6 (a) : Schematic diagram of the Analog signal conditional module

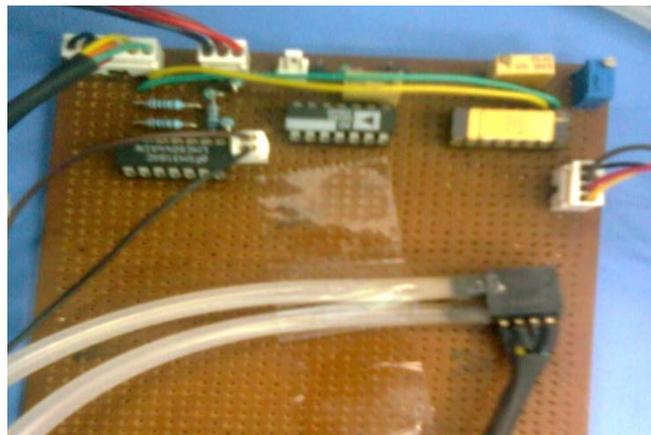


Fig. 6 (b) : Photograph of the realization of the analog circuit over multipurpose PCB

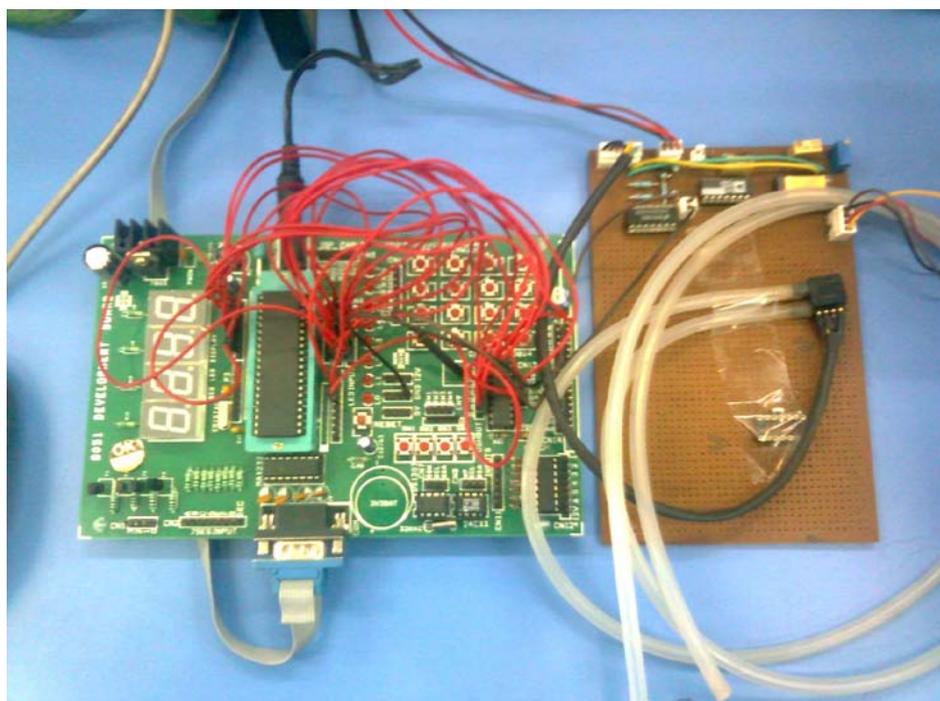


Figure 6 (c) : Photograph of the complete analog & digital setup

d) *Design of micro-controller firmware*

A digital module (Fig. 6-c) consisting of the analog to digital converter (ADC0804), RS-232 interface & microcontroller (89V51RD2) was employed to convert the analog signal to a digital output and send data in digital form to the computer via the RS-232 port. The sampling frequency of the ADC was set at 700 Hz for digitizing the input signal. Since the input signal is of very low frequency (<10Hz), a sampling frequency of 700Hz is enough to give good real time performance.

The flow of the implemented micro-controller firmware program has been illustrated in figure 7. To begin with, the read, write & interrupt pins of the ADC were assigned to P2⁵ (Pin-5 of Port-2), P2⁶ & P2⁷ of the micro-controller. The next step was to initialize the counter and assign pin-0 of Port 3 to a variable called LED which would then be called after conversion is performed. The next block of the flow chart is dedicated for setting the buffer for transferring data to serial port. Then comes the block for setting parameters for beginning the conversion cycle for the ADC to Read/Write and transmit. The subsequent block for setting the timer interrupt for a sampling frequency of 700 Hz, calling the ADC from the timer interrupt ensuring a timer synchronized conversion & setting the output to toggle the port assigned to variable LED. The subsequent blocks are dedicated to setting the timer 1 in mode 2 for a baud rate of 9600 bps, enabling interrupt and starting timer.

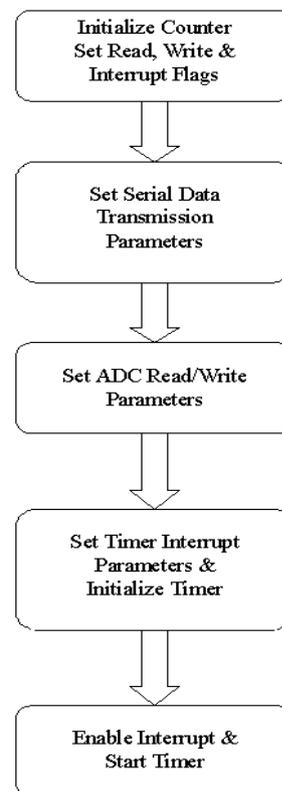


Figure 7: Flow chart of the implemented micro-controller program

e) *Design of Computer Software*

The digital module sends data to the computer, which then had to be interpreted and plotted. For this purpose an interface program has been coded using the Lab-Windows software. Some of the salient features of the developed GUI software are as follows:

- Real-time acquisition and display of data
- Facility to print output panel in PDF format
- Ability to save plotted data in raw ASCII format
- Facility to enter patient name in panel
- Control of acquisition and display by use of Stop and Resume buttons
- Display of raw ADC data in Decimal format
- Display of ADC input voltage in real time graph & mean voltage in numeric format.
- Display of mean values of Pressure, Flow-rate (m^3/s & Litre/s), Volume, Full Vital Capacity (FVC), Forced Expiration Flow (FEF 100%), & Forced Expiration Volume (FEV).
- Real-time graphical output of Pressure v/s time, Flow-rate (Litre/s) v/s time, Flow-rate v/s Volume (Spirograph).

The spirometer system including the software has been tested with an indigenously designed prototype mouthpiece. The system has been tested on a real human subject and results are discussed in the following section. Figure 8 shows a snapshot of the function panel of the designed software. The spirograph shows a value of volume, which is having a zero error of 2 litres, which meant that the actual total volume of air inhaled/exhaled is roughly 6 litres. The software also allows for entering calibrated zero-error values of pressure and voltage making it highly versatile. It also features a real-time display of digitized voltage for cross-checking of output data.

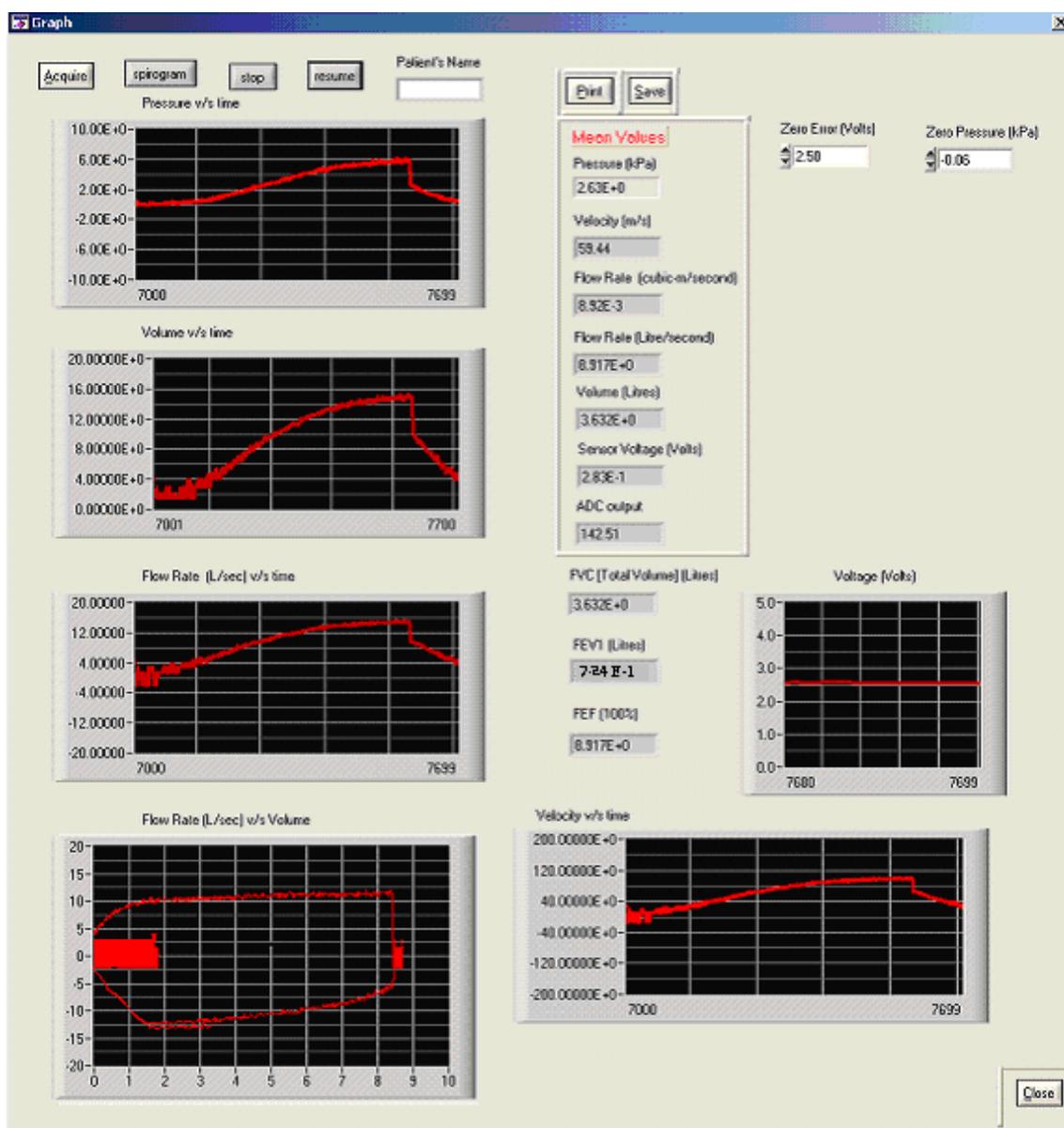


Figure 8 : Snapshot of the GUI program for the Spirometer System showing a sample Spirograph taken for a human subject

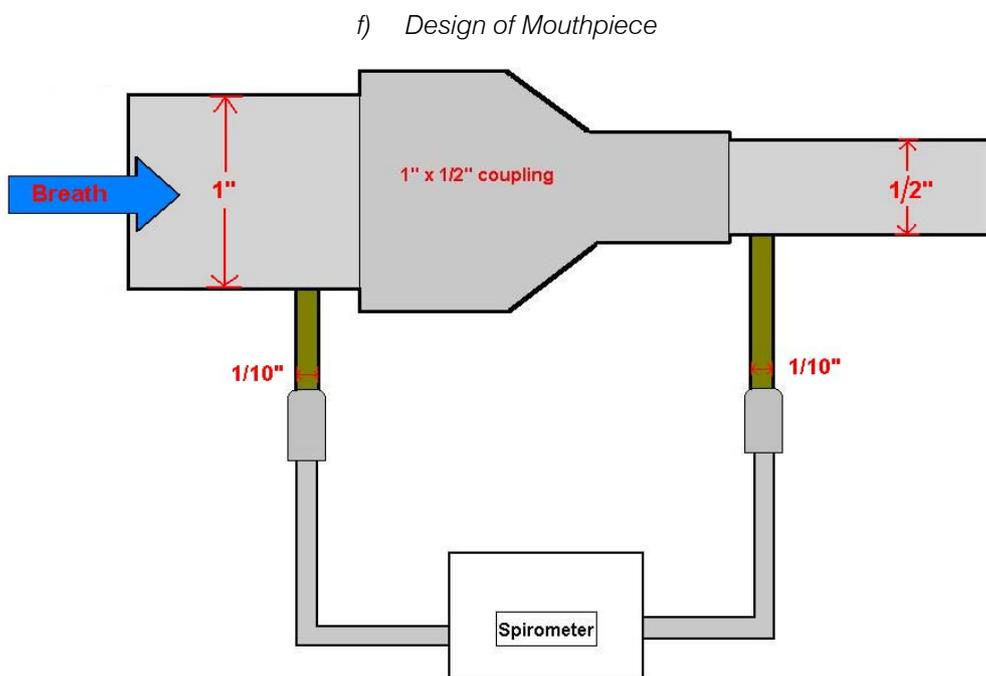


Figure 9 (a) : Illustration depicting the designed mouthpiece with dimensions

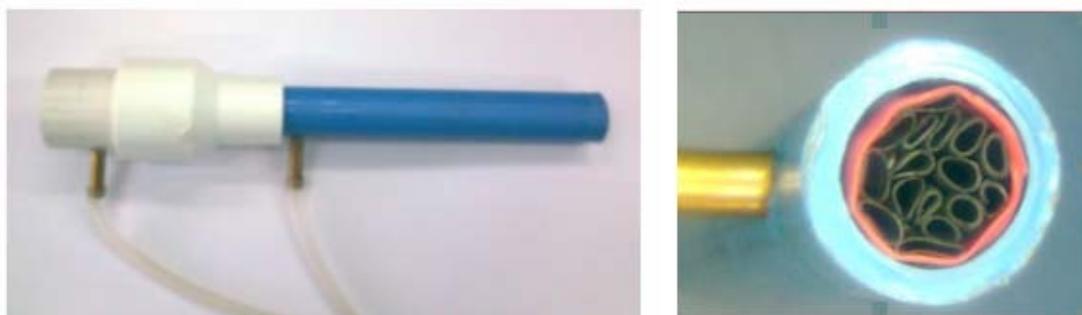


Figure 9 (b) : Photograph of the fabricated mouthpiece (left) and cross-section showing the laminar flow resistor (right)

The first proto-type of the spirometer mouthpiece has been designed and fabricated using in-house facilities. The mouthpiece has been designed for a 50% drop in pressure across its length. The design essentially consists of two PVC pipes connected via a coupling. The tube facing the patient was of 1 inch diameter which was connected to a 1" to 0.5" reduction coupling. The latter end of this coupling was connected to a 0.5" PVC pipe. The pressure sensing ports connecting the pressure sensor with the mouthpiece were fixed at either ends of the coupling assembly in a linear and coplanar fashion. There is a Fleisch type air resistance assembly that converts the turbulent flow input from the patient to laminar flow for better sensing accuracy (figure 9-b) and it is placed in the space between the sensing ports. The patient blows air from the left end (Fig. 9-a) resulting in a pressure difference between the ports which is in-turn sensed by the silicon pressure sensor and converted to meaningful output by the system.

III. RESULTS & DISCUSSIONS

The completely developed spirometer assembly together with mouthpiece, analog & digital modules, and software was tested with a human subject. The subject was instructed to follow the standard breathing maneuvers and the data was acquired for real-time calculation of spirometry parameters. The zero-error/tolerance values for various parameters are listed in table 4 below. The area of cross-section of the mouthpiece was $1.5 \times 10^{-4} \text{ m}^2$. Mean values of air velocity, flow-rate & total volume were extracted for each respiratory cycle and tabulated in table 5. The measured volume was correlated with a standard calibration syringe. As seen from figure 10, the air velocity has a direct proportionality w.r.t the flow-rate. A respiratory cycle is such that the velocity and flow-rate are continuously varying functions of time. A time integration of the flow-rate will yield the cumulative volume in one respiratory cycle. The plot in figure 11

exhibits a near linear dependence of the displaced air volume on the flow-rate thereby confirming that the data is taken from a single person, as over a short duration of time, the physical status of the individual remains practically constant.

Table 4 : Tolerance values of various parameters

Parameter	Value
Pressure	0.06 kPa
Volume	0.8 Litres
Velocity	1 m/s
Flow-rate	0.15 L/s

Table 5 : Spirometric Test Results (mean values)

Sr. No.	Velocity m/s	Flow-rate Litre/s	Volume Litres
1	44	6.6	3.13
2	53.9	8.08	3.97
3	65.07	9.75	4.74
4	67.1	10.15	5.04
5	75.18	11.38	5.49
6	82.3	12.35	6.23
7	86.09	12.91	6.48

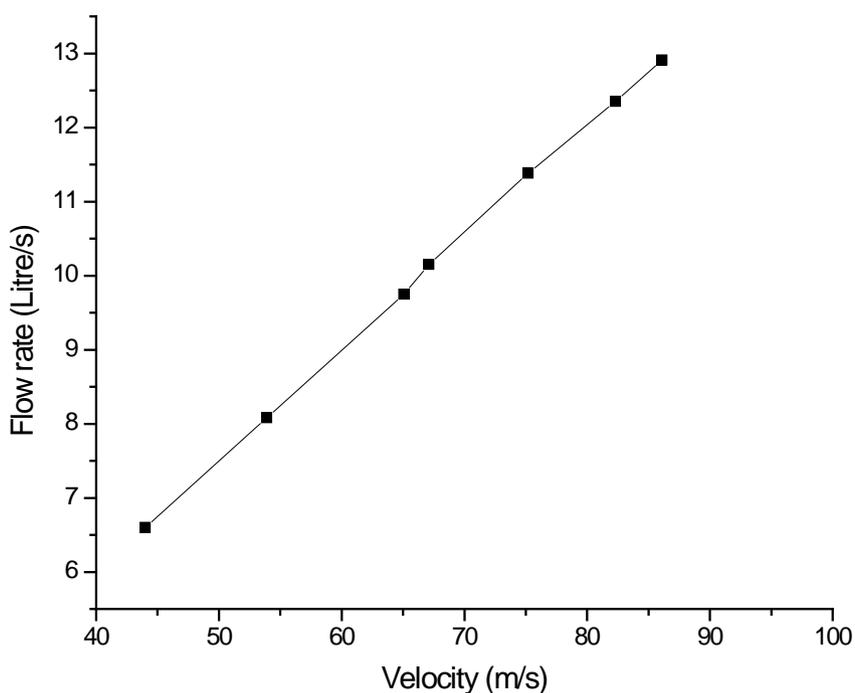


Figure 10 : Plot showing the Velocity versus Flow-rate proportionality



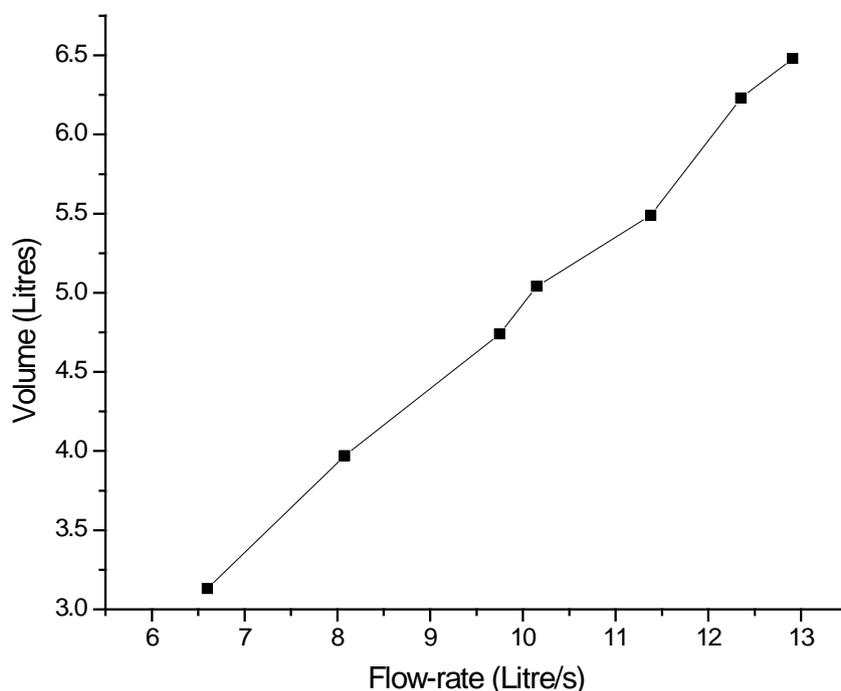


Figure 11: Plot depicting Volume versus Flow-rate for a human subject over various respiratory cycles

IV. CONCLUSIONS

The solid-state sensor approach to realizing a spirometer system has been employed with good degree of success. The pressure sensor has been extensively characterized with calibrated amounts of static pressure and the pressure to voltage conversion factor has been empirically estimated. The analog circuit has been designed with great care to prevent any non-linearity in operation. Micro-controller firmware program has been designed with a view to minimize conversion losses and give real-time data at the output. The computer software has been developed with a view to display significant Spirometric data in real-time. This software has also been designed with a user-friendly approach in mind and gives a fair deal of control to the operator. An indigenous design of a proto-type mouthpiece has been able to achieve good results. Preliminary test results have indicated that the system has performed with a great degree of accuracy. Hence, the first principle's approach to realizing of a Spirometer using a solid-state pressure sensor has succeeded. Extensive trials need to be performed on human subjects to gather statistical data for further analysis.

V. ACKNOWLEDGMENTS

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