SpiroSense

Developing a Deskilled Spirometer for Primary Care and At-Home Settings

Presented By:
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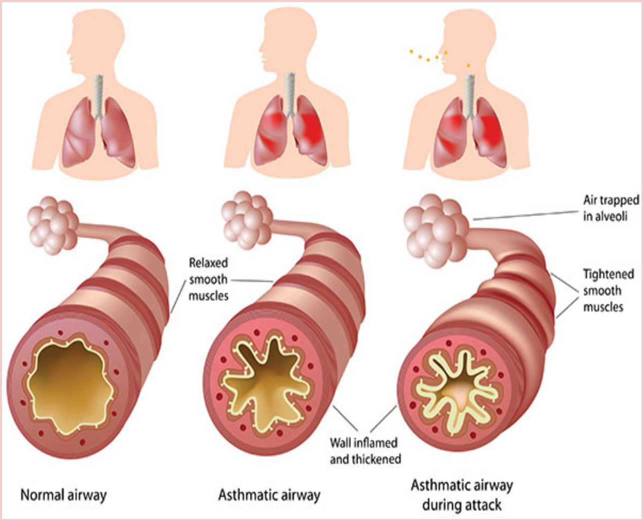
The Clinical Background and Standard of Care

Clinical Background

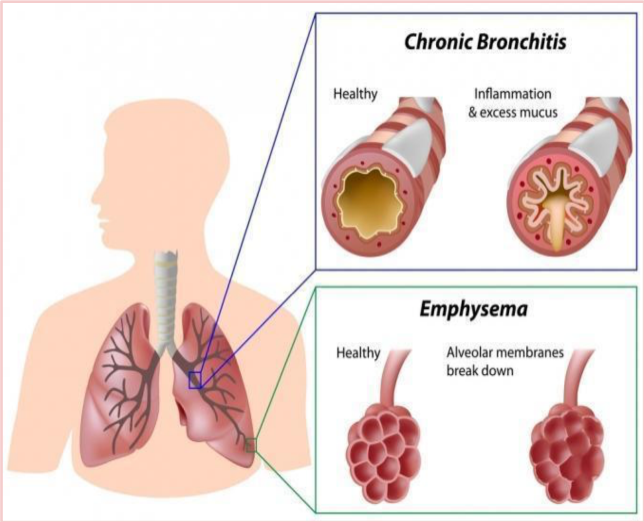
Asthma



300 million affected globally[1]

250,000 deaths annually [1]

Chronic Obstructive Pulmonary Disease (COPD)



210 million affected globally[2]

3 million deaths annually[2]

- **3rd leading cause of death** in the U.S.
- Cost the U.S. **$95 billion annually**
- Roughly **50%** of affected patients go **undiagnosed**

The Clinical Problem

About **50%** of Americans living with chronic obstructive lung diseases are **undiagnosed**, so they are **not getting proper treament**

WHY?

Diagnostic equipment is expensive

Complexity of equipment contributes to lack of presence in primary care

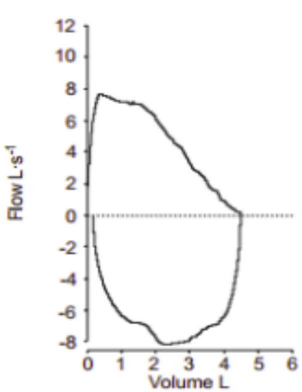
In the domestic healthcare market, there is a need for a low-cost and deskilled spirometer to better inform affected patients and their providers on the necessity of treatment.

Spirometry

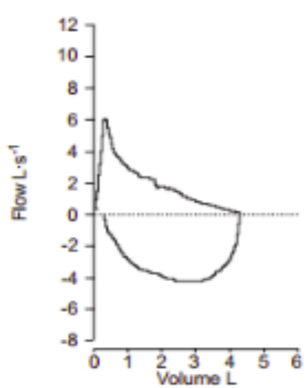
Patient Inhales Deeply → **Patient Exhales for 6 seconds** → **Patient Quickly Inhales to Capacity**

This is repeated until 3 valid trials are obtained

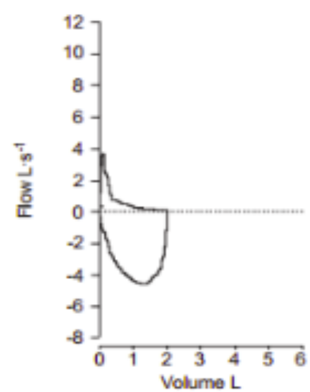
RESULTS



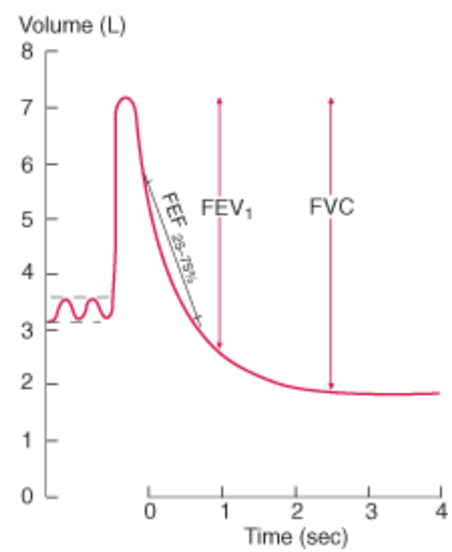
Healthy patient



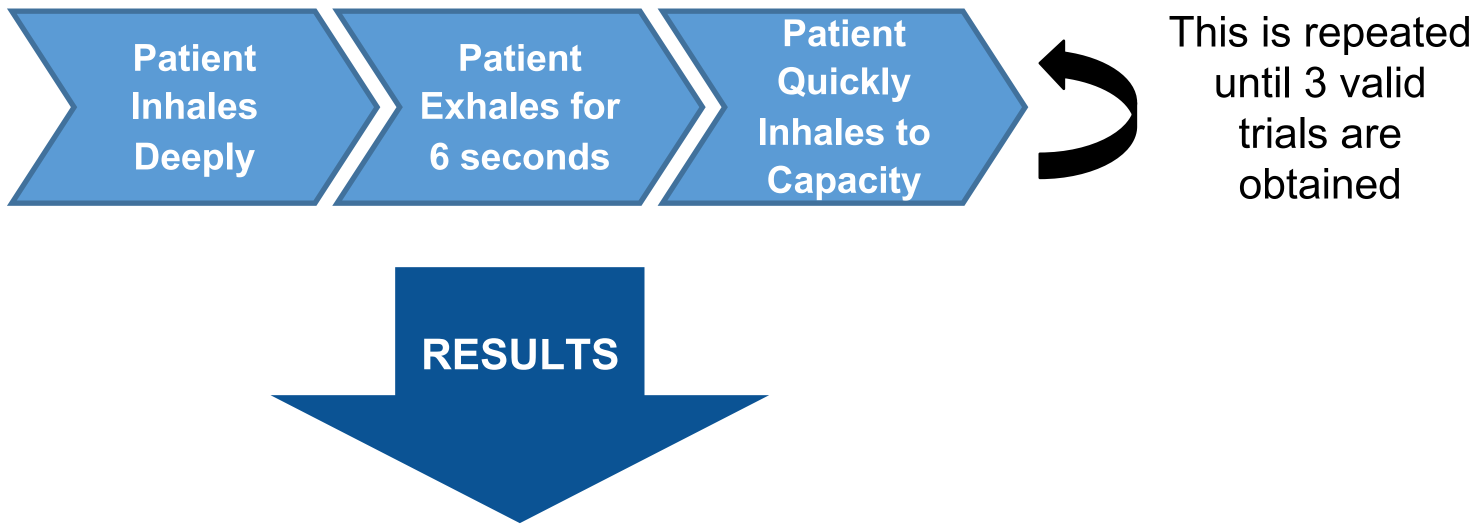
Asthma



COPD



Spirometry



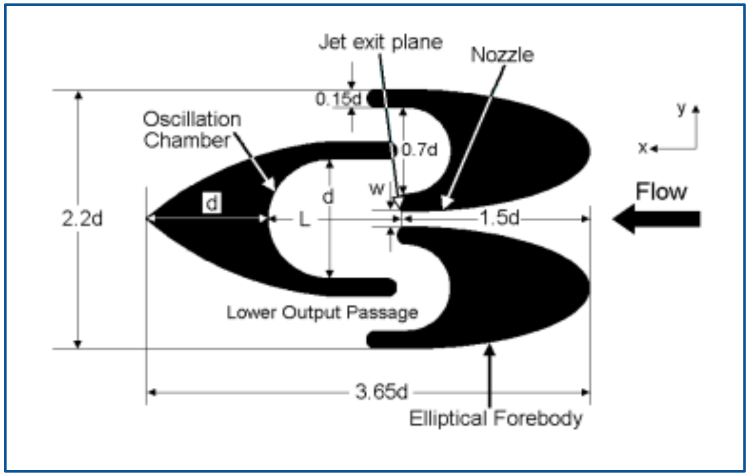
Spirometry is the **<u>standard of care</u>** for pulmonary diagnosis.
Spirometry is expensive and is often not available in primary care settings.

Our Solution

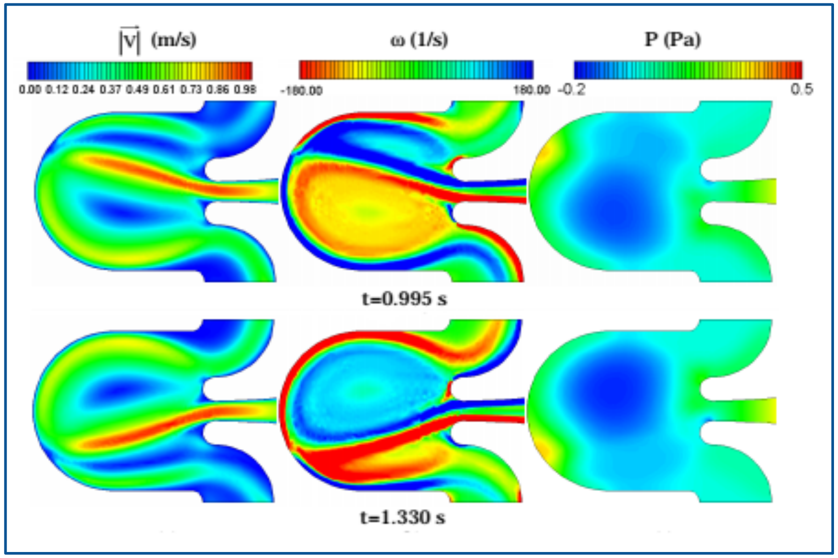
Measuring Flow: Oscillatory Flowmeter

Target-Based Fluidic Oscillators

1. Jet oscillation driven by the unsteady motion of the counter-rotating vortices
2. Frequency varies linearly in a wide range of Reynold's numbers

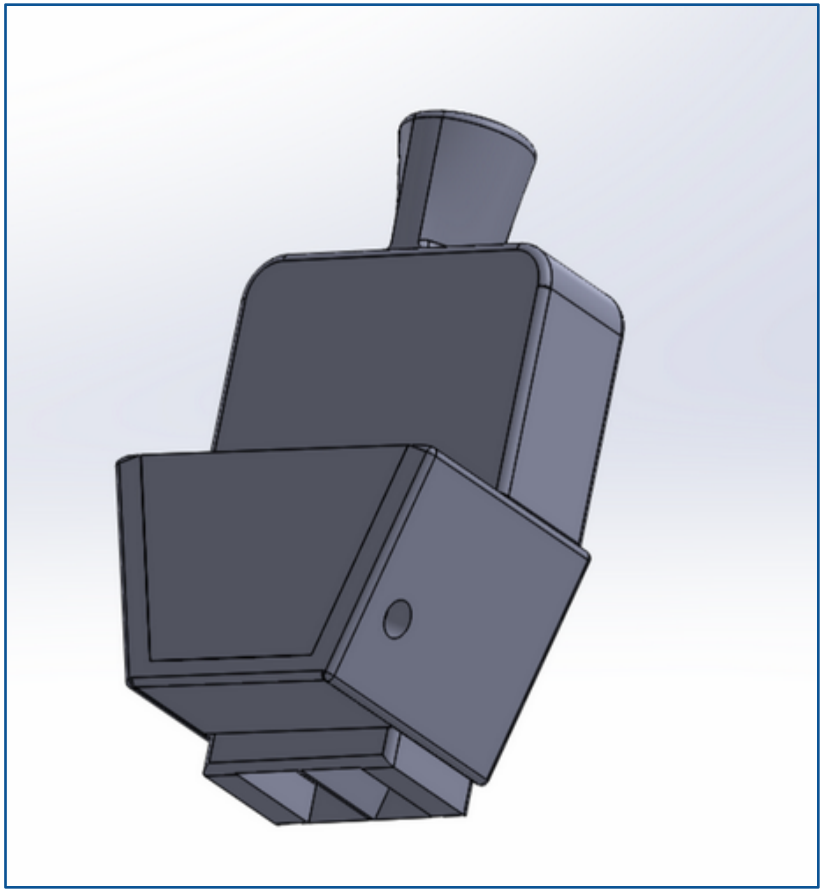


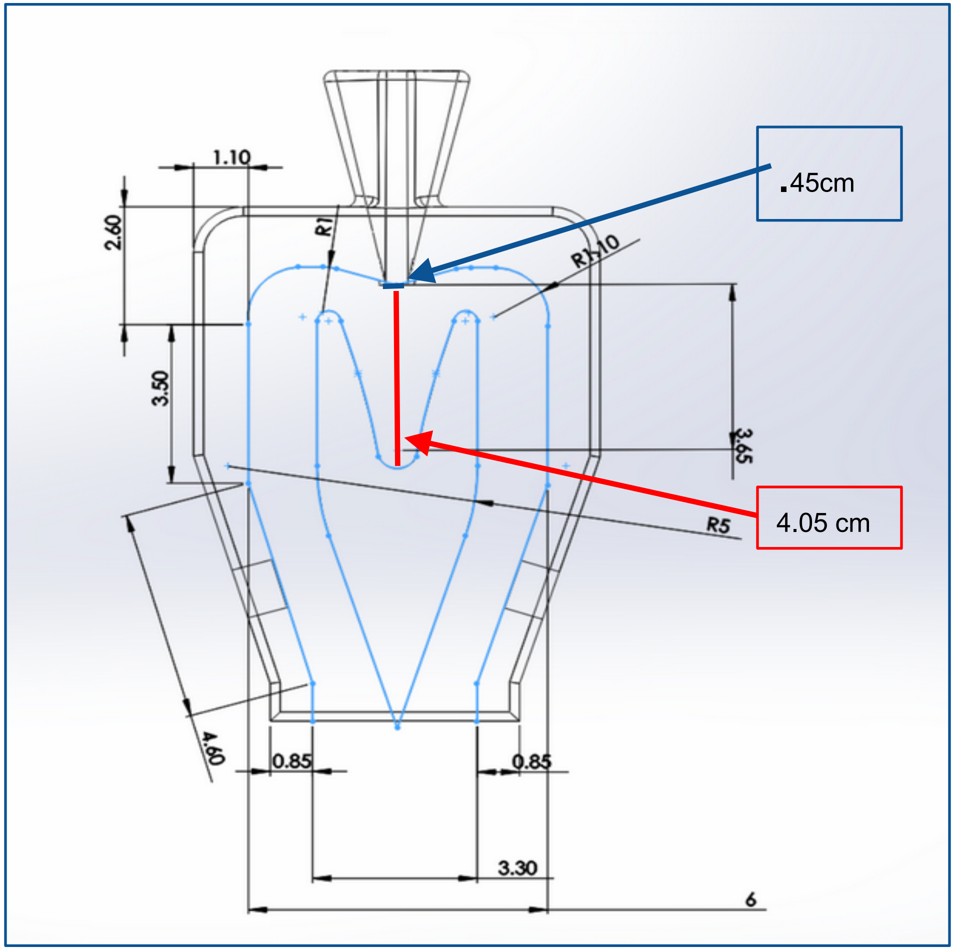
The nozzle width at the jet exit plane is w and the distance between the jet exit plane and the oscillation chamber wall (L) is 9w. [7]



Flow Visualization

SpiroSense





Android Application

http://invis.io/2C2ESIE9U

Competitive Advantage

Non-disposable / reusable and disinfectable

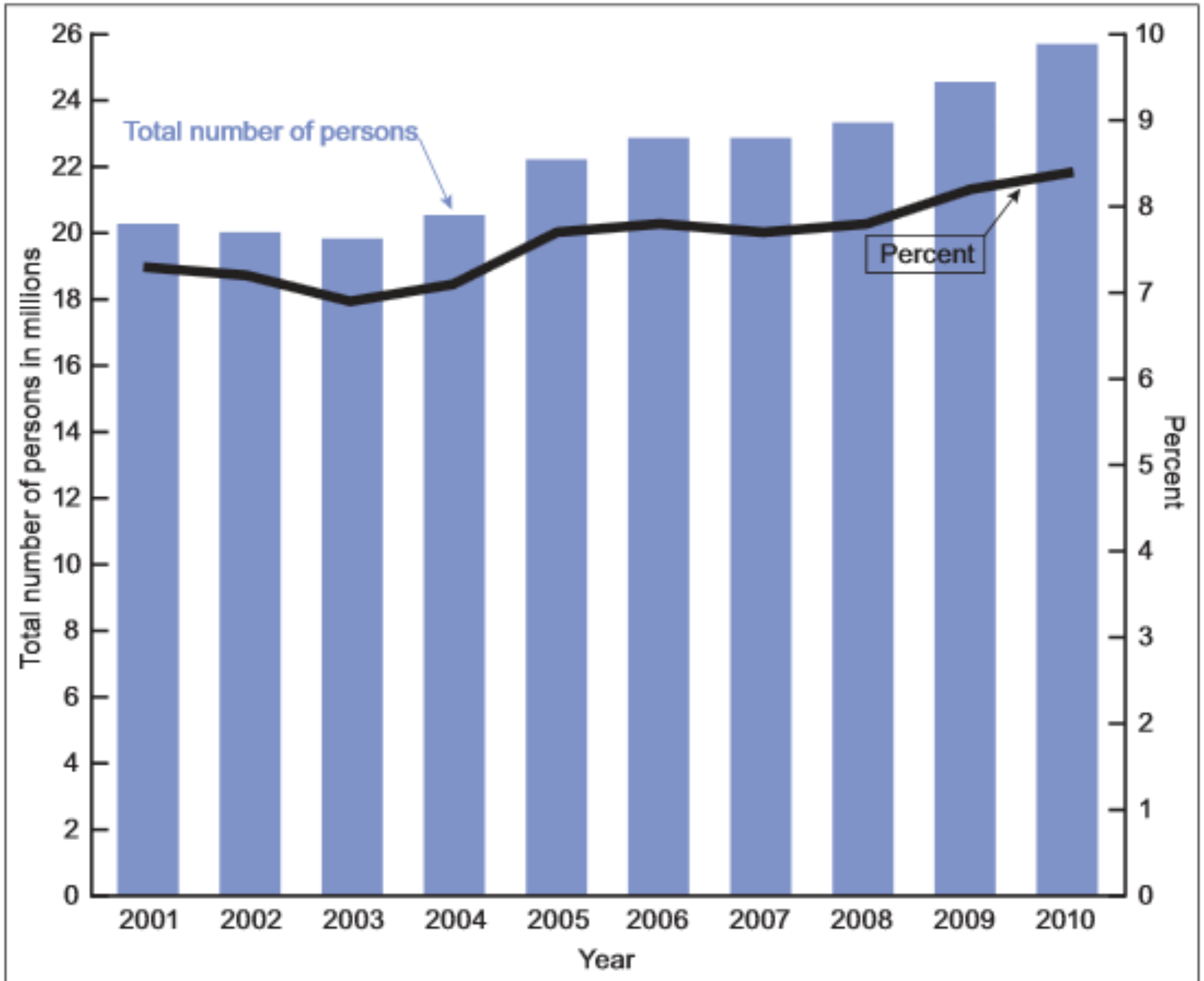
Accurately measure pulmonary function: Sensitivity within 3.5% margin of error

Robustness: No moving parts and minimum calibration

Market Analysis

Market Analysis

Prevalence of Asthma in U.S.



NOTES: Percentages are age adjusted to the standard 2000 U.S. population. See Table 1 for underlying data.
SOURCE: CDC/NCHS, National Health Interview Survey.

Market Analysis

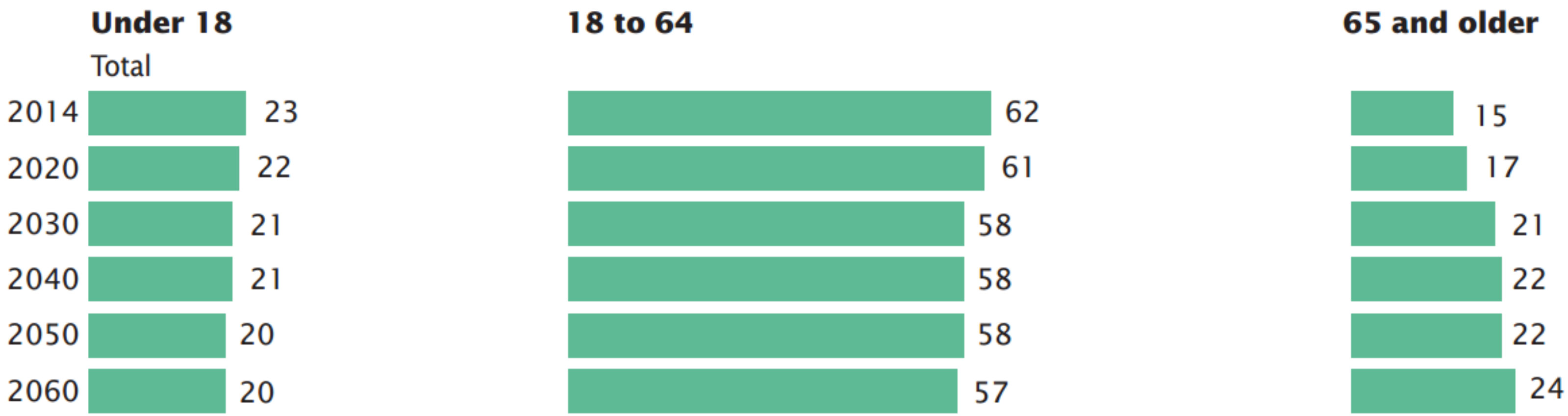
- All patients living with asthma and/or COPD are part of SpiroSense's potential market
- Secondary market is pulmonologists or primary care physicians who want to bring affordable spirometry to their clinics, where it is otherwise unavailable
- Chronic conditions account for 75-80% of all U.S. healthcare spending annually, so the opportunity for devices that measure these conditions is appealing
- 7-10% of people with chronic lung conditions used some kind of monitoring equipment in 2012

Industry Report

Industry Report

- Home health monitoring expected to increase as aging population grows

Age Distribution of the Population by Nativity: 2014 to 2060
(Percent of group's total population)

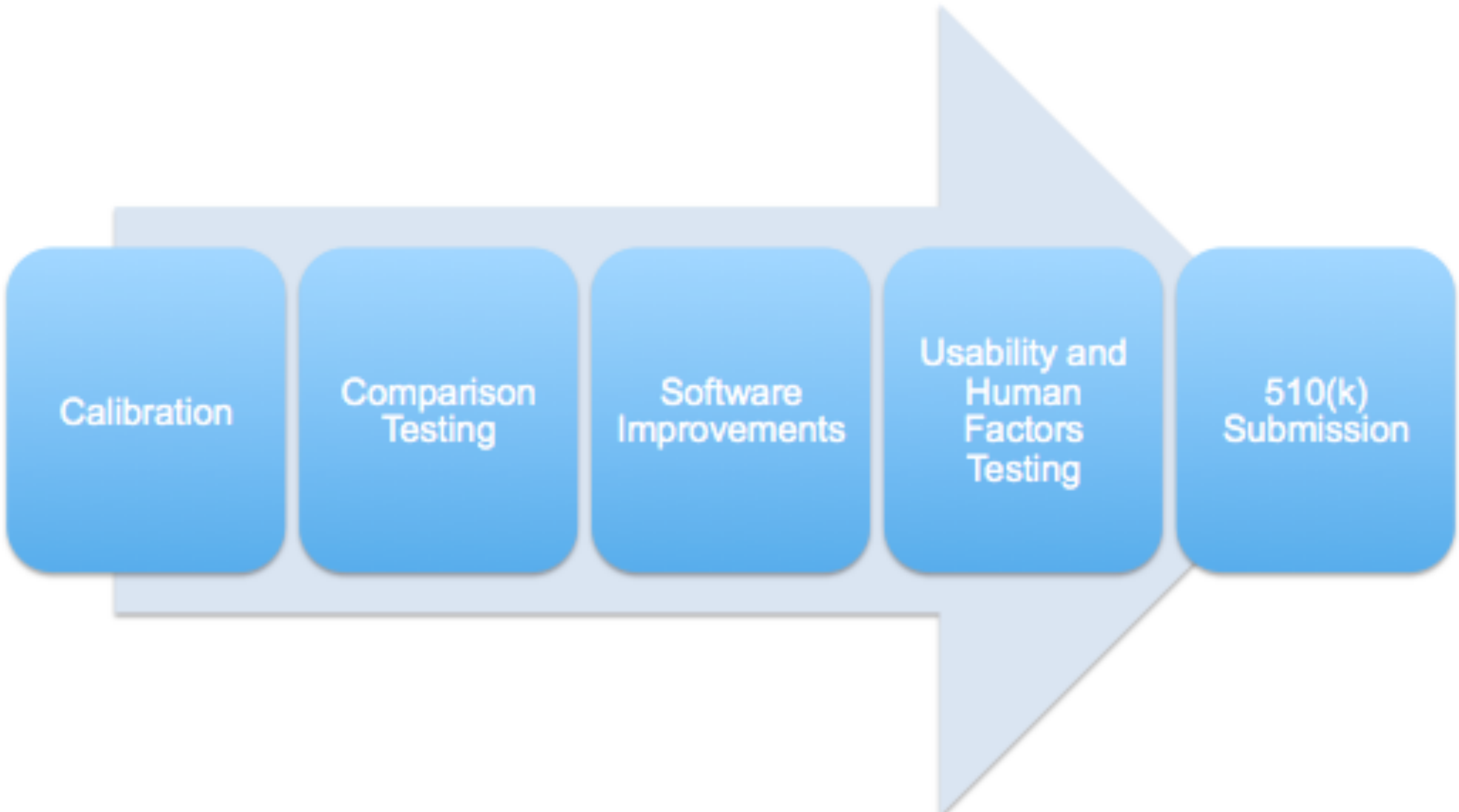


Note: The percentages for each group in each year may not add to 100 due to rounding.
Source: U.S. Census Bureau, 2014 National Projections.

- In 2014: industry generated $74.8 Billion in revenue with a growth rate of 3.6%
- Currently industry is fragmented by small, private companies which makes the barrier to entry low

Operational Plan

Operational Plan



Thank You!

Appendix

References

1. Masoli M, Fabian D, Holt S, Beasley R. *Global Burden of Asthma*. 2004. http://www.ginasthma.org/local/uploads/files/GINABurdenReport_1.pdf
2. Burden of COPD. (2015, March 9). Retrieved from http://www.who.int/respiratory/copd/burden/en/
3. Yannawar AN, Chopra RK, Pandharkar VD, Patel CS. *Prevalence of Undiagnosed COPD In Western Indian Population*. Am J Respir Crit Care Med. 185;2012:A6028
4. The top 10 causes of death. (2014 May). Retrieved from http://www.who.int/mediacentre/factsheets/fs310/en/
5. Das J,, et al. *In urban and rural India, a standardized patient study showed low levels of provider training and huge quality gaps*. Health Affairs 31.12 (2012): 2774-2784.
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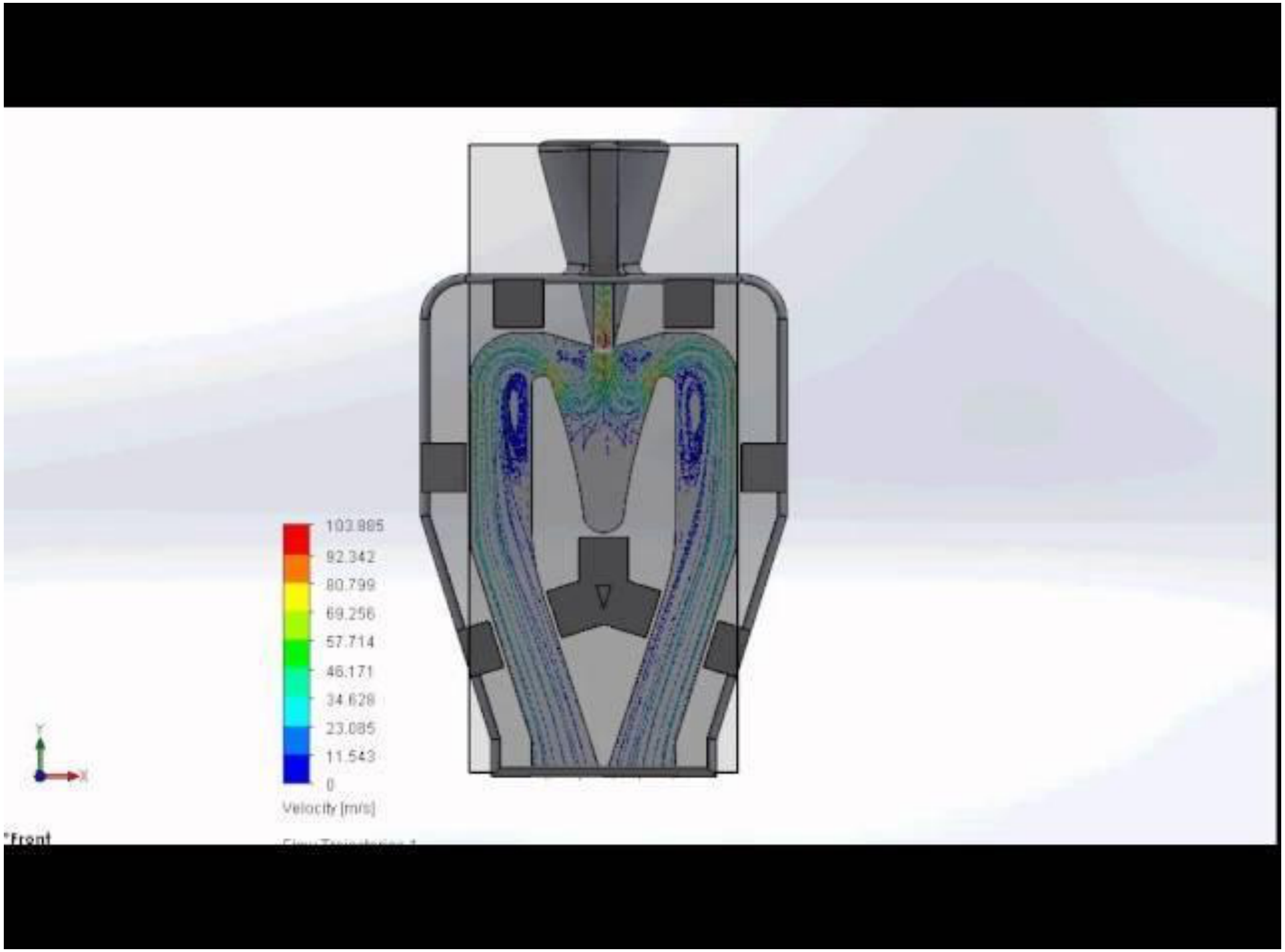
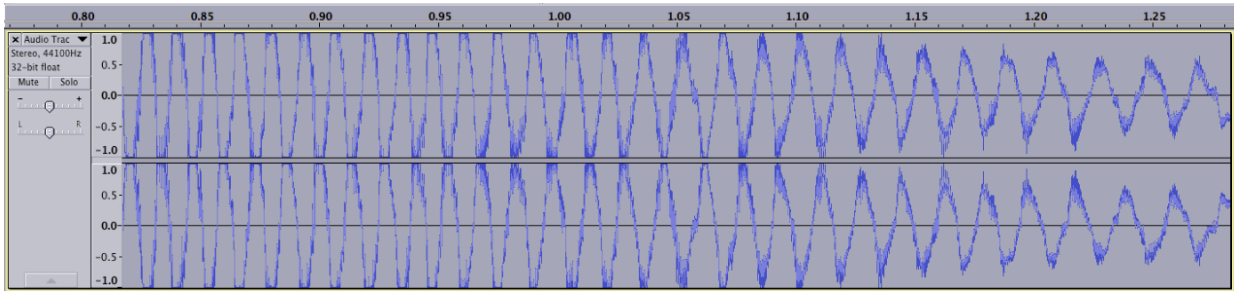
7. Uzol O, Camci C. *Experimental and Computational Visualization and Frequency Measurements of the Jet Oscillation inside a Fluidic Oscillator*. 4th International Symposium on Particle Image Velocimetry. Gottingen, Germany. 2001, September 17-19.

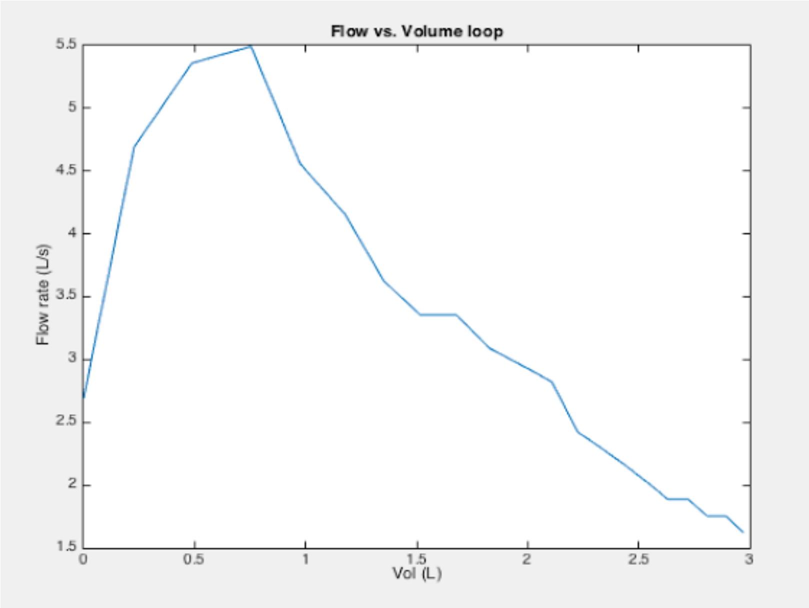
Flow Simulation



Signal Processing

Initial Audio Recording





Flow-Volume Loop

Disinfection Protocol

Two part device: fluidic oscillator detachable from electronics for disinfection.

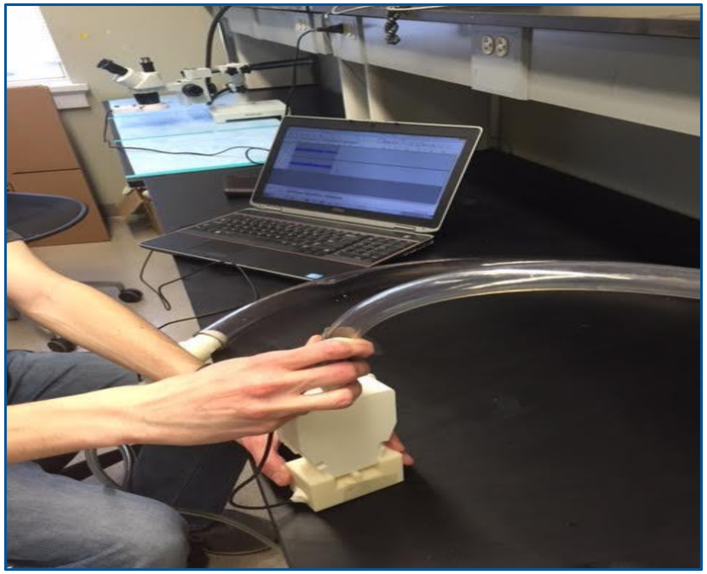
Jhpiego Standards

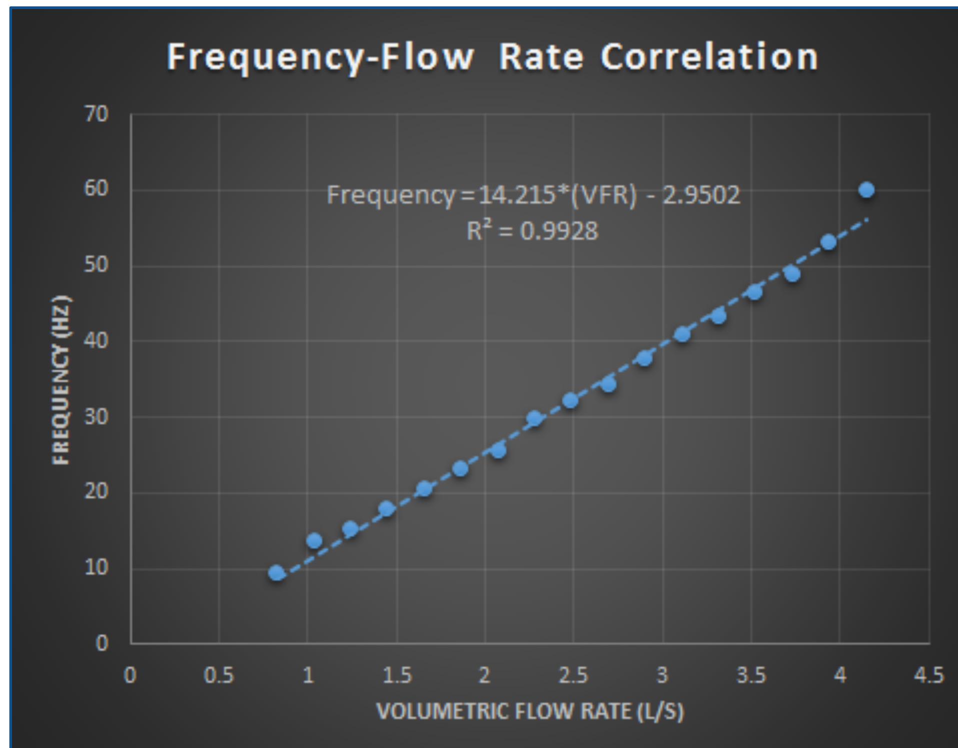
Decontamination: Soak 10 minutes in Cl solution

Cleaning: Wash thoroughly in soap and water

High Level Disinfection: Soak 20 minutes in Cl solution

Frequency vs. Flow Rate Correlation





Temperature and Humidity

The calculations of the effects on air of temperature and humidity can be calculated directly (see appendix)

The change in Reynold's number is directly proportional to kinematic viscosity

Per Dr. Katz, " The increase in density by humidity is at most ~ 10% (note that exhaled air is humid, and nearly at body temperature). So, as long as the device is still operating using air, and using exhaled air, it should be fine."

Gas Conversion Factors

TABLE 4.2 Gas Conversion Factors (Volume and Flow)

To convert from	To	Multiply by: Formula	Multiply by: Typical value
ATPS	BTPS	$\frac{BP - pH_2O}{BP - 47} \cdot \frac{310}{273 + T}$	1.080
	STPD	$\frac{BP - pH_2O}{760} \cdot \frac{273}{273 + T}$	0.892
	ATPD	$\frac{BP - pH_2O}{BP}$	0.971
ATPD	BTPS	$\frac{BP}{BP - 47} \cdot \frac{310}{273 + T}$	1.113
	STPD	$\frac{BP}{760} \cdot \frac{273}{273 + T}$	0.919
	ATPS	$\frac{BP}{BP - pH_2O}$	1.030
BTPS	STPD	$\frac{BP - 47}{760} \cdot \frac{273}{310}$	0.826
	ATPS	$\frac{BP - 47}{BP - pH_2O} \cdot \frac{273 + T}{310}$	0.926
	ATPD	$\frac{BP - 47}{BP} \cdot \frac{273 + T}{310}$	0.899
STPD	BTPS	$\frac{760}{BP - 47} \cdot \frac{310}{273}$	1.210
	ATPS	$\frac{760}{BP - pH_2O} \cdot \frac{273 + T}{273}$	1.121
	ATPD	$\frac{760}{BP} \cdot \frac{273 + T}{273}$	1.088

BP = barometric pressure
T = temperature (°C)
ATPS = ambient temperature and pressure, saturated
ATPD = ambient temperature and pressure, dry
STPD = standard temperature and pressure, dry
BTPS = body temperature and pressure, saturated

The "typical values" assume a barometric pressure of 760 mmHg and a temperature of 24°C. Standard pressure is 760 mmHg and standard temperature is 0°C (= 273 K). Body temperature is 37°C (= 310 K).

$$P_{H_2O} = 14.47 - 0.705T + 0.0428T^2$$

where P_{H_2O} is partial pressure of water vap or (mmHg) and T is temperature (degrees Celsius)

*different conversion factors for inhalation and exhalation, patient recording and calibration syringe

Shade, David M., and Arthur T. Johnson. "Chapter 4: Design of Respiratory Devices." Biomedical Engineering and Design Handbook. By Myer Kutz. New York: McGraw-Hill, 2009. N. pag. Print.

Temperature and Humidity

	Temperature vs. Viscosity			
	Temperature (F)	Dynamic Viscosity	Kinematic Viscosity	
	80	3.86	1.69	
	90	3.90	1.74	
	100	3.94	1.79	
	120	4.02	1.89	
	Max % Increase	**4%**	**12%**	

	Dry Air	Moist Air
Equation	$\rho_\alpha = \frac{0.0035\rho_a}{T}$ Where ρ_α is density (kg/m³), ρ_a is partial pressure of air (P_a, N/m²), and T is Temperature in Kelvins	$\rho = \rho_{da}\frac{(1+x)}{(1+1.609x)}$ Where ρ is density (kg/m³), x is specific humidity (kg/kg), and ρ_{da} is the pressure in the dry air (Pa)

Prototype Design

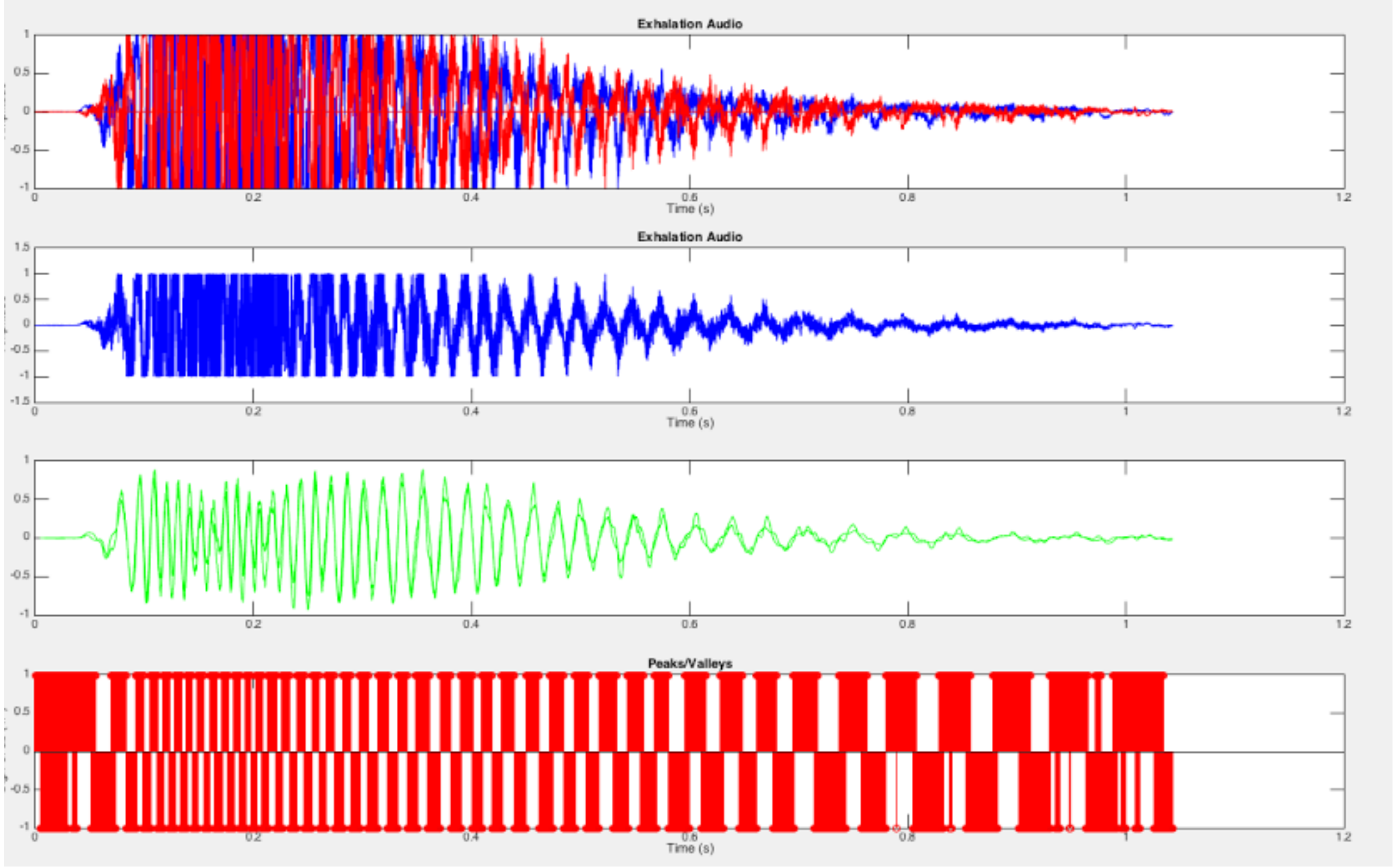
The Evolution of SpiroSense

Current Prototype

Device Validation

Trial	Collected FVC	%Error
1	2.55	0.15
2	2.52	0.16
3	2.661	0.113
4	2.716	0.094666667
5	2.753	0.082333333
6	2.513	0.162333333
7	2.588	0.137333333
8	2.724	0.092
9	2.753	0.082333333
10	2.726	0.091333333
Avg	**2.6504**	**0.116533333**
St. Dev.	**0.098012698**	

Matlab Graphs



Predicted PFT Values and Disease Staging

FVC = 0.1524*Height(inches) - 0.0214*Age(years) - 4.6500 [Men]
FVC = 0.1247*Height(inches) - 0.0216*Age(years) - 3.5900 [Women]

FEV1 = 0.1052*Height(inches) - 0.0244*Age(years) - 2.1900 [Men]
FEV1 = 0.0869*Height(inches) - 0.0255*Age(years) - 1.5780 [Women]

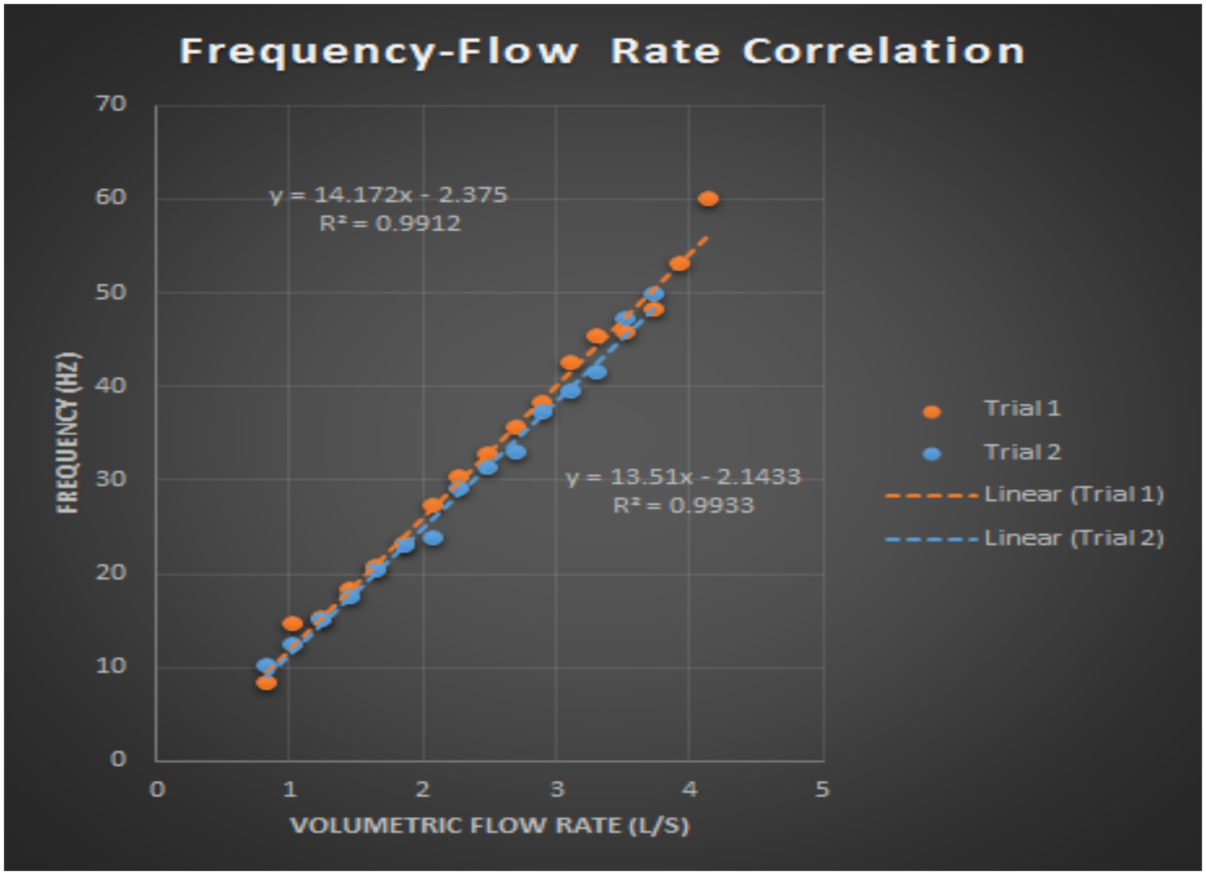
FEV1% = Predicted FEV1 / Predicted FVC

(Crapo Standards for Predicted PFT Values;
http://www.hopkinsmedicine.org/pftlab/predeqns.html)

Stage I	Mild COPD	FEV1/FVC<0.70	$FEV_1 \geq$ 80% normal
Stage II	Moderate COPD	FEV1/FVC<0.70	FEV_1 50-79% normal
Stage III	Severe COPD	FEV1/FVC<0.70	FEV_1 30-49% normal
Stage IV	Very Severe COPD	FEV1/FVC<0.70	FEV_1 <30% normal, or <50% normal with chronic respiratory failure present*

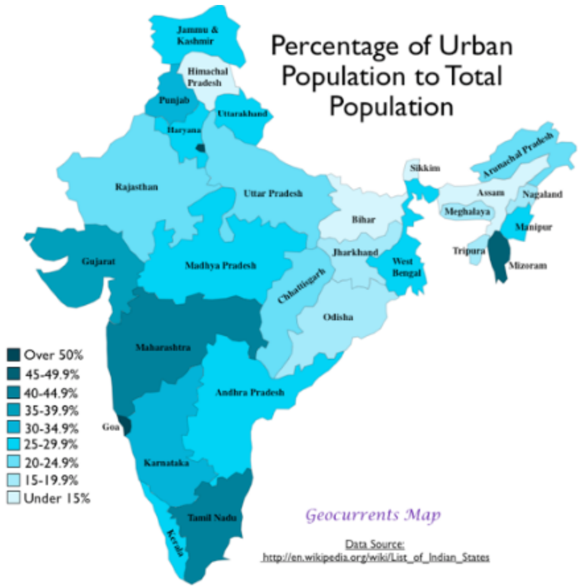
Global Initiative for Chronic Obstructive Lung Disease (GOLD) Classifications

Additional Frequency-VFR Correlation Testing



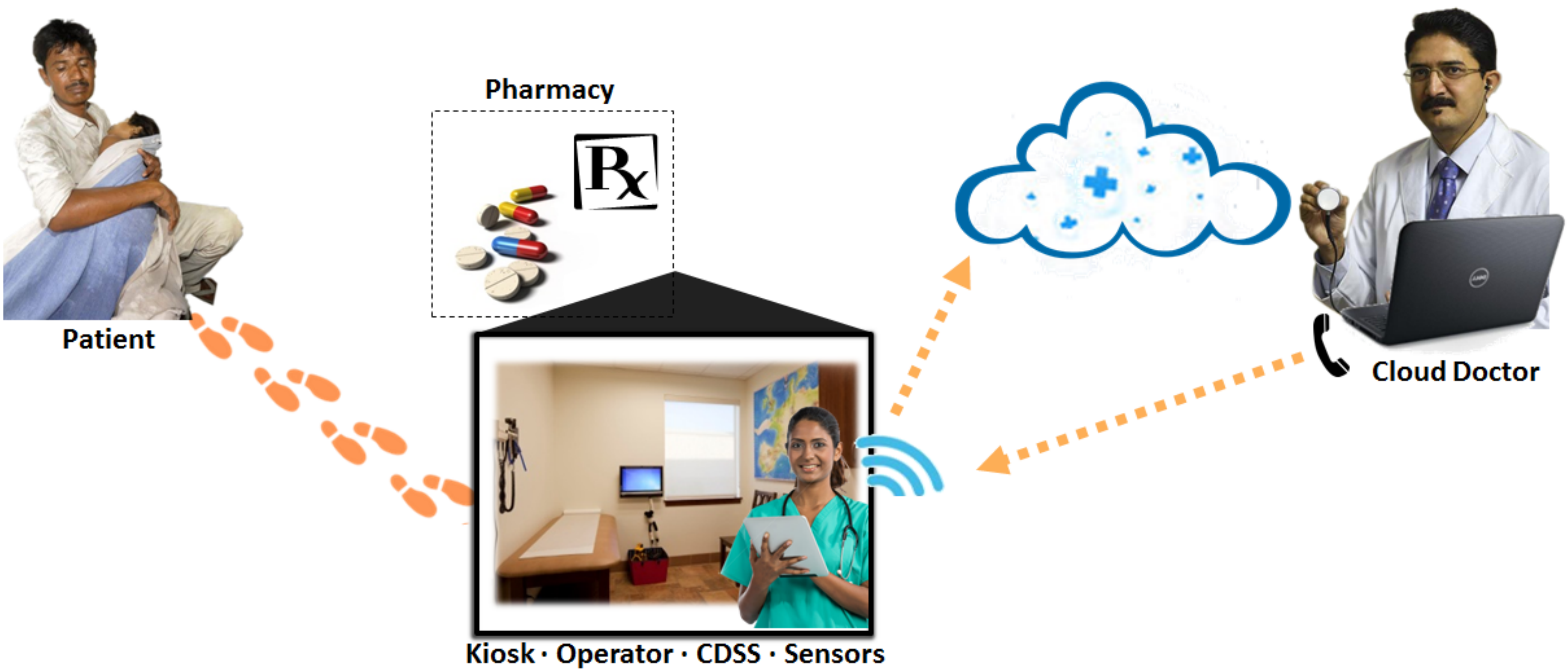
Background in India

- 70% of India's population live in non-urban areas
- 60% rural population lives on less than 35Rs (0.57USD)/day

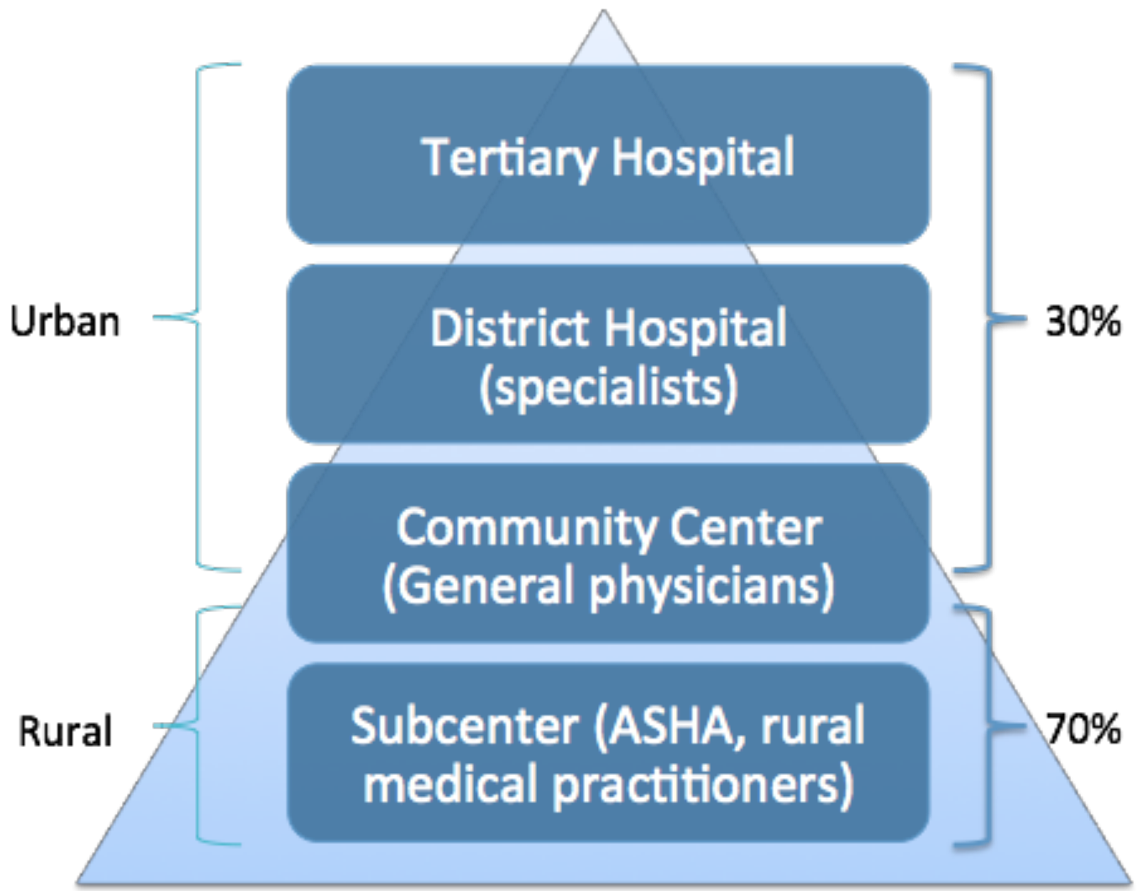


http://geocurrents.info/wp-content/uploads/2013/05/India-Urbanization-Fertility-Map.png

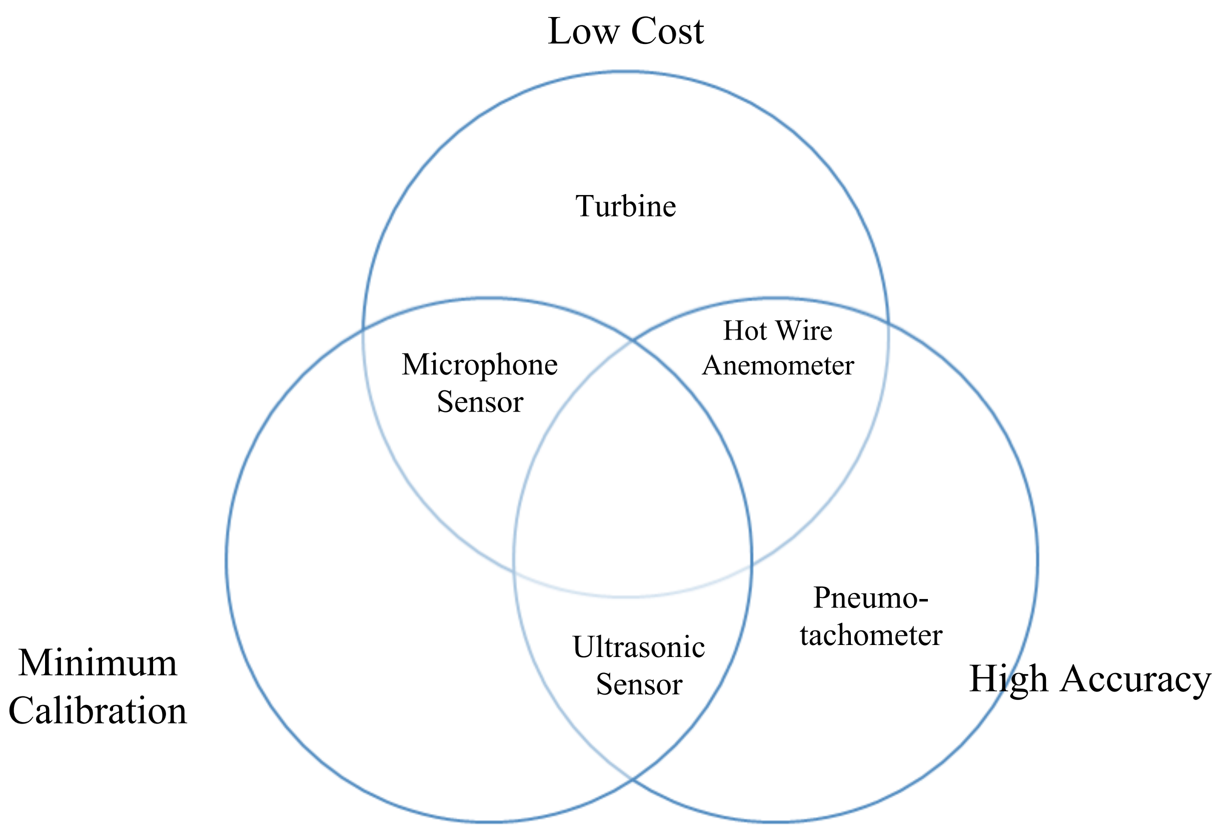
The Kiosk Model



Access to Healthcare in India

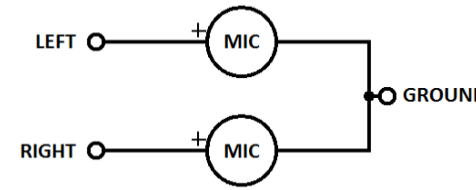


Existing Methods



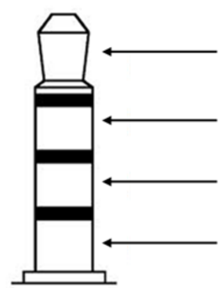
Powering The Device

Plug-In Power



9V Battery Power

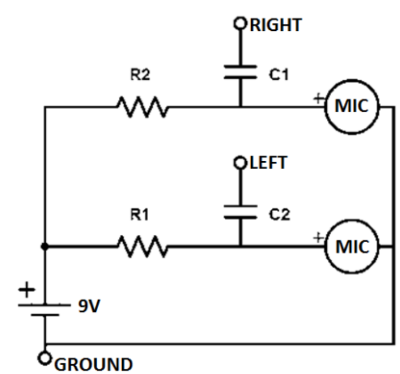
3.5mm TRRS



OMTP	CTIA
Left	Left
Right	Right
Microphone	Ground
Ground	Microphone

LG, Samsung, Nokia, Motorola, Asia

Apple, HTC, Microsoft, US/Europe



	Wire Anemometer	Ultrasound	Microphone alone	Microphone w/ fluidic oscillator	Pneumotachometer	Turbine
Advantages	A test of various spirometer method accuracies showed hot-wire is very consistently accurate after frequency-specific adjustment (needed for all methods). Hot wire anemometry exhibits stable performance characteristics across the range of temperature, humidity, Fio2, and inspiratory/expiratory ratios encountered clinically, has a small dead space, is unaffected by mean airway pressure, and is therefore suitable for clinical applications.	Ultrasonic spirometers transmit a signal between two transducers and the transit time, which is affected by airflow between the sensors, is related to flow velocity. The transit time is independent of the acoustic velocity of the medium. This method has no moving parts, requires no calibration, is accurate and precise, and is temperature independent. It may be low-cost depending on which types of sensors are needed. It is simple and can record both inhalation and exhalation.	Low-cost and simple. May not need additional material/equipment so the cost is even lower than it would be with a fluidic oscillator. If used without a mouthpiece, there would not be any sterilization necessary.	Not much evidence on this being used other than in the heart-shaped fluidic oscillator spirometer. If it works, the advantage is that it can be used to measure flow throughout complete exhalation, there are no moving parts so it should be durable,and it does not require calibration.	Pneumotachometers harness a pressure differential created by flow passing through capillaries (mesh). You can then apply Bernoulli's equation to this pressure drop to get the air flow, which is generally linearly correlated with this pressure drop. Pneumotachs can be accurate and can be variable in size depending on their intended environment use.	Turbine spirometers are cheap, simple to use and are often unaffected by changes in atmospheric conditions. Since they do not have to be heated, they have better linear and higher ranges of flow when compared to pneumotachometers.

	Wire Anemometer	Ultrasound	Microphone alone	Microphone w/ fluidic oscillator	Pneumotachometer	Turbine
Disadvantages	Sensitivity to gas composition and gas temperature. The calibration curve is nonlinear and cannot be easily extrapolated beyond its calibration range. Calibration of a hot-wire sensor is necessary for making accurate and reliable flow measurements. In the calibration process, reference velocities, Ur, are measured at various locations across the flow cross section, and the corresponding reference output voltages, Er, are obtained for all the measured data points. Subsequently, the resultant data pairs (Er, Ur) are plotted to obtain the calibration curve for the specific hot-wire sensor. The calibration method shown in this paper involves use of a closed loop wind tunnel. It is recommended that a spirometer should be readjusted daily.	The resonant frequencies of the two transducers must be very close otherwise sensitivity will decrease. Sensors must be heated to around 40 degrees Celsius to prevent condensation from forming.	The last 3 seconds of exhalation as well as all of inhalation are inaudible (according to the SpiroSmart paper). Also, there may be issues with standardizing the distance from the person's mouth to the microphone and outside noise is a problem. You need complete silence in order to accurately record the sound of exhalation. The lack of a mouthpiece may decrease the accuracy of the signal due to interference from outside noise.	Requires sanitation (or disposable mouthpieces). Little evidence for clinical use of fluidic oscillator to measure lung function. Would probably need to validate this through testing.	Pneumotachs only provide accurate flow measurement with laminar flow. If turbulent flow is achieved, then the pressure gradient is no longer linearly correlated with the air flow. Additionally, the capillary gradient used to create the pressure differential is subject to alteration from contaminant accumulation and from condensation of water vapor - both of these increase resistance and alter the pressure differential - resulting in "drift" aka inaccurate measurements. Additionally, the characteristics of flow (when dealing with gas) are subject to alteration from viscosity and temperature of the gas, so if the pneumotach is used in hot environments the flow may no longer be linearly correlated to flow rate.	They may be inaccurate at both low and high flows; the vanes need to be lightweight to overcome inertia before they can begin to rotate and they may continue rotating after the flow has stopped. Additionally, vanes can become distorted at high flows and easily break. They are also susceptible to barometric pressure

Spirometry Measurements

FVC - Forced Vital Capacity - Volume of air that can forcibly be blown out after full inspiration (Liters)

FEV1 - Forced Expiratory Volume in 1 second - Volume of air that can forcibly be blown out in one second, after full inspiration (Liters)

FEF - Forced Expiratory Flow - Flow (or speed) of air coming out of the lung during the middle portion of a forced expiration (L/min or L/sec)

FIF - Forced Inspiratory Flow - Flow (or speed) of air coming entering the lung during the middle portion of a forced inspiration (L/min or L/sec)

PEF - Peak Expiratory Flow - Maximal flow (or speed) achieved during the maximally forced expiration initiated at full inspiration (L/min or L/sec)

TV - Tidal Volume - Amount of air inhaled and exhaled normally at rest (Liters)

TLC - Total Lung Capacity - Maximum volume of air present in the lungs (Liters)

SVC - Slow Vital Capacity - Maximum volume of air that can be exhaled slowly after slow maximum inhalation (Liters)

FET - Forced Expiratory Time - Length of the expiration (seconds)

Medications

- Albuterol (short acting beta agonist)
- Bitolterol (bronchodilator)
- Budesonide (steroid, bronchodilator)
- Doxofylline (antitussive)
- Ipratropium Bromide (bronchodilator)
- Montelukast (leukotriene receptor antagonist)
- Oxtriphylline (bronchodilator)
- Salmeterol (long acting beta agonist)

The Clinical Problem

Less than 20% of patients in rural India are **correctly diagnosed** with chronic lung conditions such as asthma and COPD[5,6]

WHY?

Diagnostic equipment is expensive

RMPs are not formally trained

Project Constraints and Goals

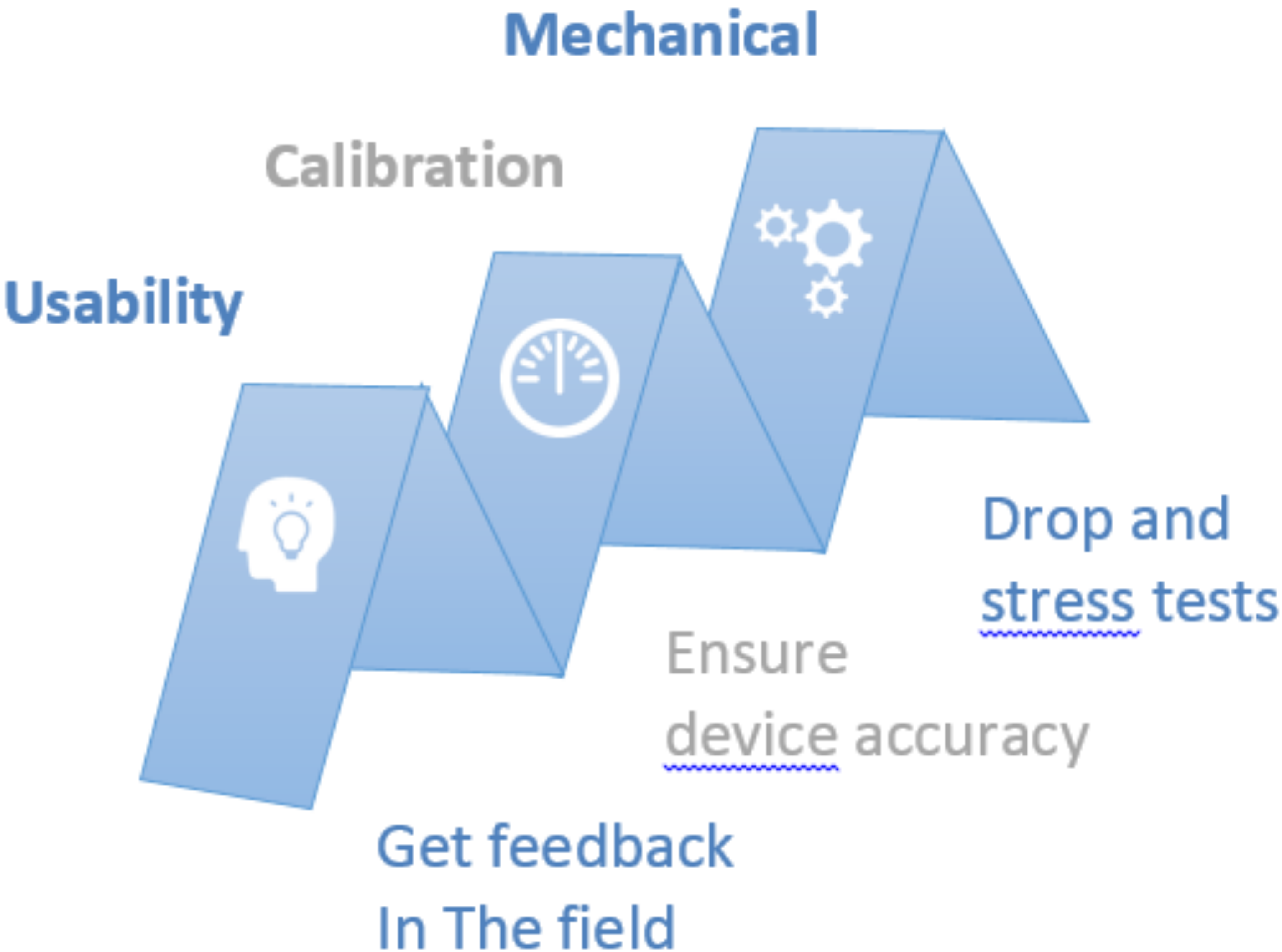
Design Constraints

- Measure flow rates within a 3.5% margin of error
- Require calibration frequency of at most once a week
- Cost less than $50 USD
- Have an operating range of 0-15 Liters/second
- Pickup oscillation frequencies as low as 20 Hz

Design Goals

- Easily usable for untrained medical assistants
- Have a durability lifetime of at least 5,000 uses
- Have a built-in trial validity algorithm
- Output data with a 25 mL volume resolution
- Easily sanitizable

Next Steps


Mechanical
Calibration
Usability
Drop and stress tests
Ensure device accuracy
Get feedback In The field

Prototype Budget

COMPONENT	COST
3D Printing (0.15kg@$53/kg PLA)	$8.00
Microphones (2@$0.92)	$1.84
Resistors/Capacitors (bulk)	$2.00
Wires	$0.50
3.5 mm Stereo Audio Wire	$4.77
9V Battery	$3.50
9V Battery Clip	$0.60
Total	**$21.21**

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- Dr. Joseph Katz
- Dr. Elizabeth Logsdon
- Dr. Andrea Prosperetti
- Dr. Satadal Saha
- Dr. Sumit Sengupta
- Chris Browne
- Anant Subramaniam