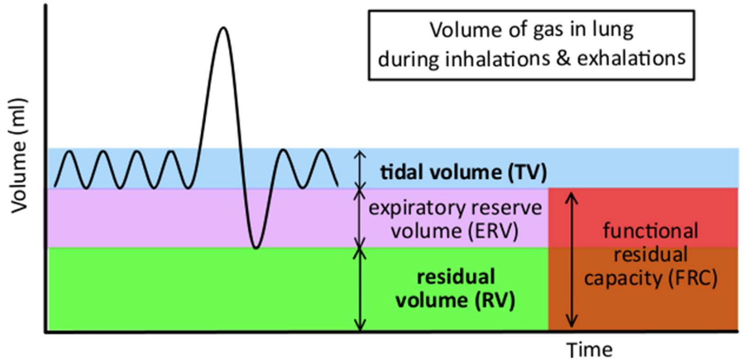
breath

a siprometer for
low-income areas

Introduction

Context of Use



There are many chronic obstructive pulmonary diseases (COPD), such as asthma and tuberculosis, in developing countries. To assess the severity, diagnose the type of COPD and treat the patient, it is important to get spirometric data, which include different lung volumes. However, medical instruments used to measure lung volumes are limited in low income countries. The design challenge is to improve the measurement of lung size, tidal volume (TV) and residual volume (RV), in low income settings.

Specifications

(The device must ...)

Function and Performance

Measure tidal volume and residual volume
Typical Tidal Volume Range: 0.2 - 1 L
Typical Residual Volume Range: 1- 8 L

Maintain accuracy
Deviation within 0.5% of expected

Produce accurate measurements
Tidal volume accuracy: +/- 1 mL (0.1%)
Residual volume accuracy: +/- 8 mL (0.1%)

Able to yield reproducible and multiple results
Minimum of three readings with 3% or 0.05 mL deviation

User Experience, Size, Ergonomics

Present necessary information and results clearly
Visual and text (Graphical format of Flow [L/s] versus Volume[L]), lines superimposed)

Be easy and straightforward to use
Maximum time for instructing patient: 5 mins
Max. time taken for measurement: 10 mins

Easy to calibrate
Minimize quantity of mechanical parts

Be portable (light and of adequate size to carry around). *Max. weight: 11 kg (20% of average body weight)*
Max. size:215.9 x 482.6 x 342.9 mm (size of average. backpack)

The device must be comfortable to use.
Use standard mouthpiece size

Not require user's forced effort during measurement
Higher sensitivity of the device - minimum flow rate that can be detected: 5 L/min

Not be invasive
Must not invade user's privacy in any way

Maintenance

Be easy to repair.
Time taken to disassemble/assemble modular design components < 3 mins

Be durable, robust
Life of 2 years (with min. of 5 uses per day)

Hygiene

Microbiologically safe (such that the air in device must not be breathed by other users)
Material used must be non-toxic and no moisture must be trapped in possible tubes/ mouthpiece

Easy to disinfect
Takes max 3 mins to disassemble and reassemble for cleaning

Context

Be suitable for low income settings (countries eligible in receiving funding as Official Development Assistance)
The device must not need special supplies. If extra supplies are required, use existing/standard supplies.

Be easy to power
Ability to function w/ power constraints

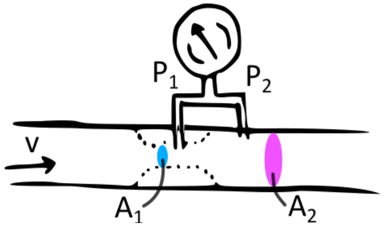
Be affordable/low cost
Must be less than £ 5000

Survive certain environmental conditions
Must protect from dust. Electronics should protect from water/rain. (IP54 - protect from interfering dust and splash of water from any direction.)

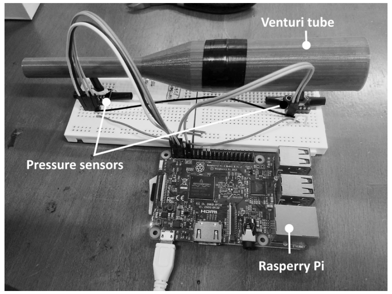
Initial Concepts

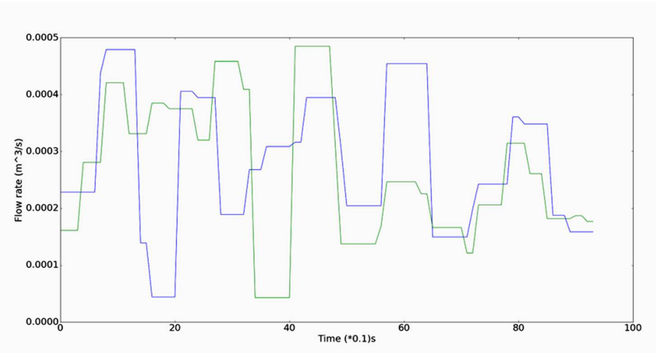
TV Measurement

Venturi Tube



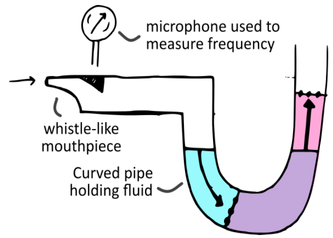
Mouthpieces Prototype

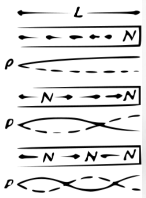


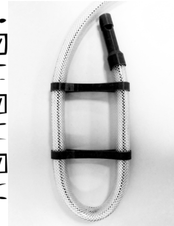


Principle: flow creates pressure difference in a venturi tube
Testing equipment: 3D printed tube, two pressure sensor, Raspberry Pi, MATLAB
Concept evaluation: concept was proved, but it is not a innovative concept.

U-pipe Whistle



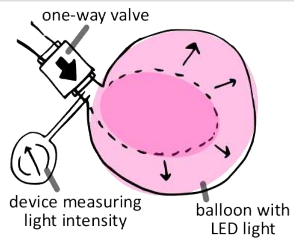


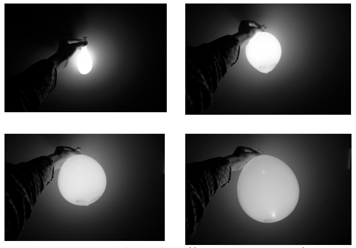


(chosen concept)

Principle: flow changes level of water and different air vibration generates higher frequencies (see picture below)
Testing equipment: 3D printed whistle, 3D pirinted tube holders, water, PVC tube
Concept evaluation: concept was disproved, but it is highly innovative and could be developed.

Balloon with LED





Principle: flow changes volume inside the balloon, resulting in changes in wall thicknes, thus light intensity of the LED inside will be changed
Testing equipment: balloon, white LED, Photohshop
Concept evaluation: hard to keep manufacturing consistency. Low accuracy.

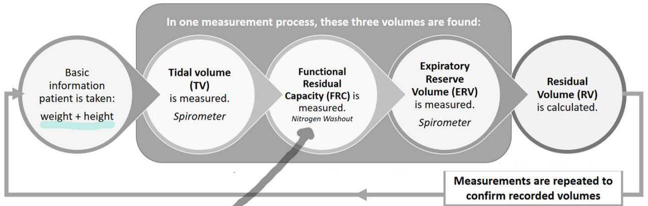
RV Measurement

Nitrogen Washout

After assessing each of the existing residual volume measurement methods, the nitrogen washout method was chosen.

Whole Body Plethysmography	Helium dilution	Nitrogen washout
• Very expensive • High degree of maintenance • Not suitable for widespread use	• Requires a special gas mixture • Not suitable for low income settings	• Only requires oxygen cylinder • Widely available for low-income settings • Requires no effort (quiet breathing)

Nitrogen washout is where 100% oxygen is inhaled to "washout" the nitrogen (N2) in the lungs. By knowing the volume of N2 in the lungs, the residual volume can be calculated.



$$FRC = \frac{V_{N2W} - V_{N2T}}{F_{iN2} - F_{fN2}}$$

V_{N2W}: N_2 volume washed out
V_{N2T}: N_2 volume from tissue.
F_{iN2}: the initial fractional concentration of N_2
F_{fN2}: the final fractional concentration of N_2

$V_{N2T} = \frac{BSA \times 96.5 + 35}{0.8}$, where

$$BSA = 0.007184 \times weight^{0.425} \times height^{0.725}$$

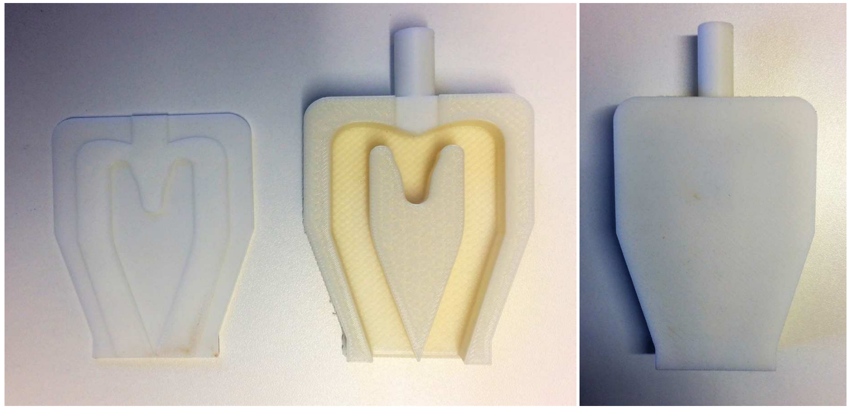
Although a N_2 analyser is the most direct way to measure the N_2 concentration, because it is expensive, **an oxygen (O_2) sensor and a carbon dioxide (CO_2) sensor** are used instead. The use of two sensors make the results more accurate.

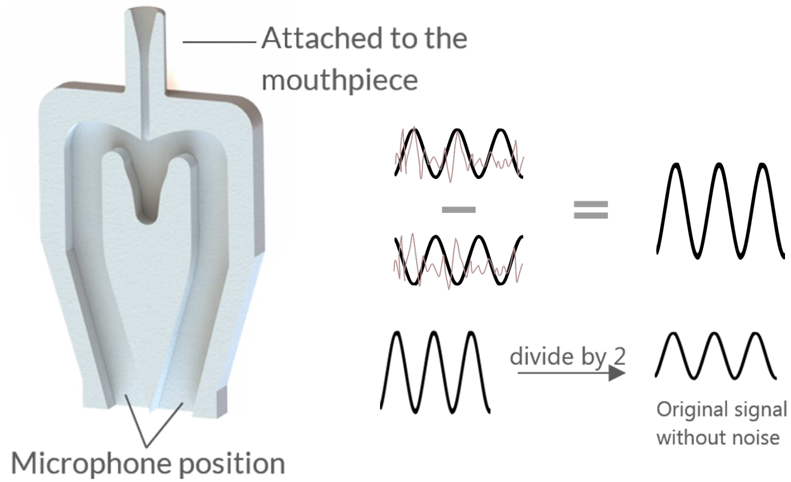
Measuring volumes...
From speaking to Dr. Simon Ward and research, this is how the tidal volume and residual volume are measured.

SpiroSense Inspired Design

SpiroSense is an inexpensive spirometer designed and developed by a group biomedical engineering students in John Hopkins.

The working principle is to have two channels inside a closed chamber, so that the vibration of the flow will generate two sound signals with same frequency but 180 degree phase difference. Therefore, the noise cancellation can be done by subtracting the two signals. The original sound signal can then be obtained by dividing the result by two.

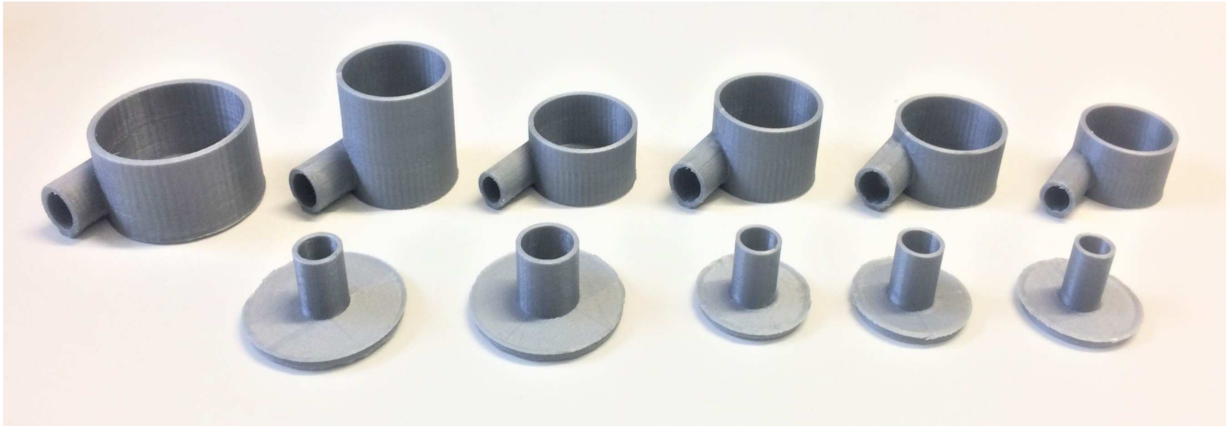




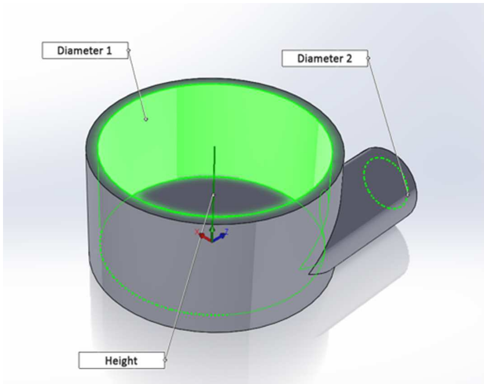
Vortex Whistle

The vortex whistle idea was the first idea to replace the initial U-shape whistle concept. Due to the difficulty of noise cancellation in a vortex whistle, the SpiroSense Inspired Design was been used as the initial idea. However, after realising the risk of the idea and cost of the two microphones, vortex whistle concept was been revisited and developed.

Due to "the frequency of the vortex whistle sound is linearly proportional to the breathing amount" (Watanabe K., Sato H. 1994. *Vortex Whistle as a Flow Meter*. p2), further exploration was carried out. Vortex whistles with different geometries were 3D printed. Frequency response was obtained and the dimensions were finalised by trial and error. After talking to Dr Lorenzo Picinali, the final solution to eliminate noise was to attach a piezoelectric transducer at the back of the whistle. This solution allows all components inside the spirometer to be stationary, making the device more compact and also easier to be cleaned.



Height	20	30	15	15	15	20
Diameter 1	30	30	30	30	25	40
Diameter 2	10	10	10	8	8	10



Work-like Prototype

MATLAB Codes

```
fs = 22050;
N = 1024;
T = 5;
max_frequency = [];
figure(1)
t = timer('TimerFcn', 'stat=false;','StartDelay',5);
start(t)
```

settings for performing Fast Fourier Transform

```
stat=true;
dispTime = 5;
while(stat==true)
    ti = title(num2str(dispTime,'Blow in: %d'));
    set(ti, 'FontSize', 20);
    pause(1)
    dispTime = dispTime - 1;
end
ti = title('Blow NOW');
set(ti, 'FontSize', 20);
recObj = audiorecorder(fs,8,1);
recordblocking(recObj, T);
sig = getaudiodata(recObj);
df = fs/N;
f = 0:df:fs/2;
```

setting up the recorder

```
for i=0:(T*20)
    signal = sig(1+i*N:(i+1)*N);
    fftMag =( abs(fft(signal)) );
    Y = fftMag(1:length(f));
    [A, B] = max(Y);
    max_frequency = [max_frequency, B];
    plot(f, Y/(N)*2);
end
```

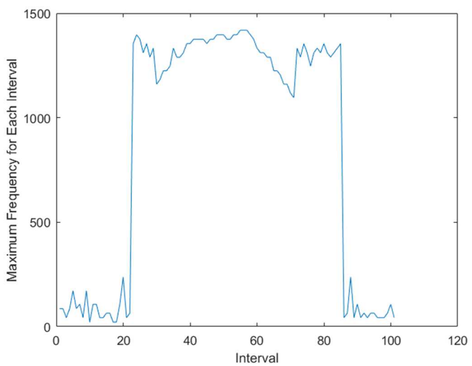
Fast Fourier Transform for plotting frequency

obtaining the maximum frequency

```
figure(22)
plot(max_frequency*11025/513)
xlabel('Interval')
ylabel('Maximum Frequency for Each Interval')
area = sum(max_frequency)
```

plotting the maximum frequency

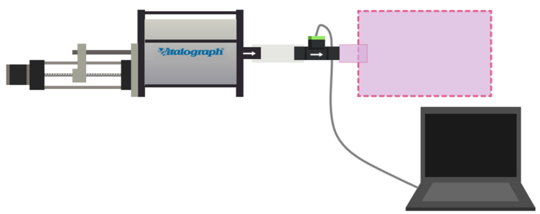
MATLAB Results



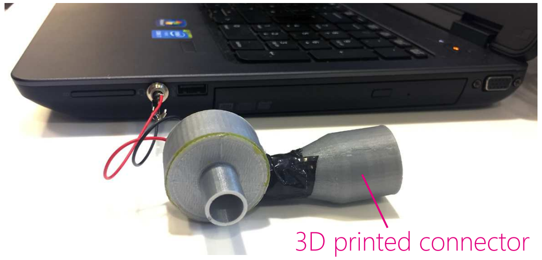

```
>> test

area =

   3995
```

integrated the result was obtained, which was then used to compare with the reading from Sensirion.

Calibration



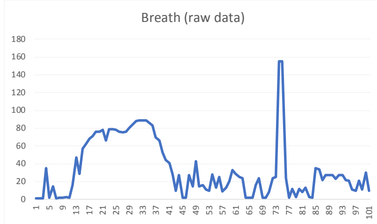
The testing rig used for initial calibration was set up as shown. (picture adapted from 'EDP 2017 Spirometer Calibration and Test Rig INSTRUCTIONS')

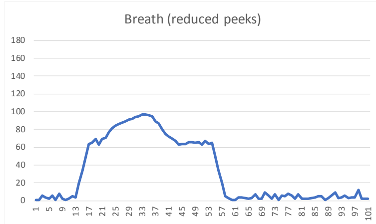


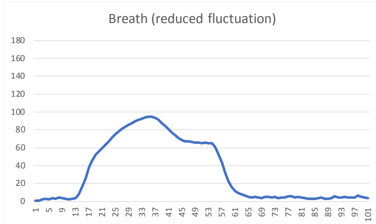
Calibration of *breath* relied on the physical phenomenon that mass flow at every point in a closed pipe must be the same. Thus, the work-like prototype was connected airtightly to a Sensirion Mass Flow Meter SFM3000 with a custom designed and 3D printed connector (as shown previously). As the flow through the two instruments was exactly the same, readings of both would be identical. The initial plan was to use standard flow rates from the testing rig. However, the vibration generated by the stepper was picked up by the piezoelectric microphone, making the calibration unreliable. As a second solution, human breathing was used and data gathered by both sensors were analysed.

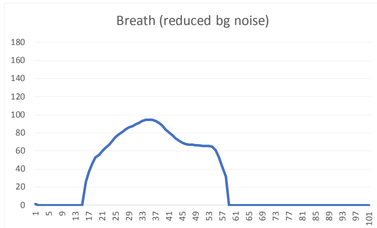
Data plots of the instruments looked similar. However, readings from *breath* were much noisier. Thus, to reduce errors, a filtering process was developed, which resulted in better quality results. First, unrealistic changes between data pieces were deleted, and all peaks from the set were removed. Then, by implementing a lowpass filter, the plot was smoothened. Finally, to reduce cumulative error, intervals below a certain flow rate threshold were deleted. Through these steps, data plots measured by the two devices became similar in terms of shape, but still had to be scaled. While experiments were carried out, the scaling factor was determined to be varying in an interval of 20%, rather than staying constant in all cases.

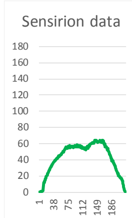
In order to determine the exhaled volume, area under the data plot was numerically integrated, and the result was converted to litres, using the equation of given for the SFM3000.

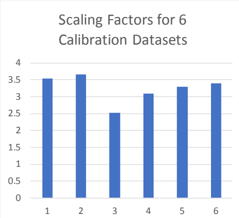






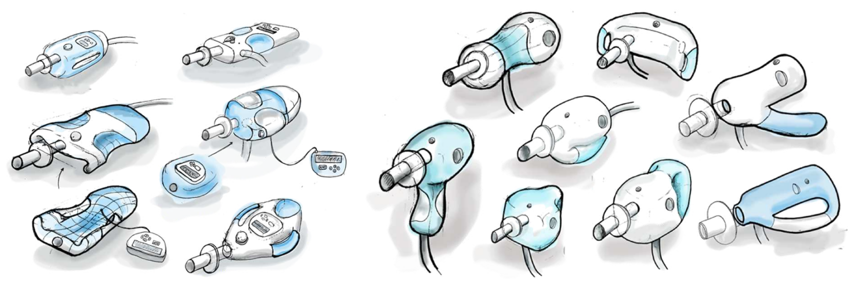






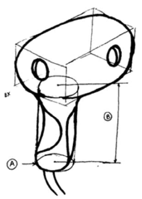
Look-like Prototype

Form and Aesthetics Exploration



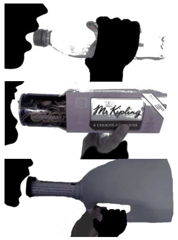
Sketches were made of different inspired forms. Organic shapes were mainly explored to make the device look more comfortable to use and to give a more friendly aesthetics. Like most medical devices, white is the chosen main colour. The colour, white, is associated with purity and cleanliness. The holding positions in the design are highlighted by colour accents in the sketches.

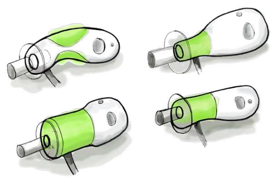
Human Factors and User Testing



Anthropometric Data
(Pheasant, 2003.)

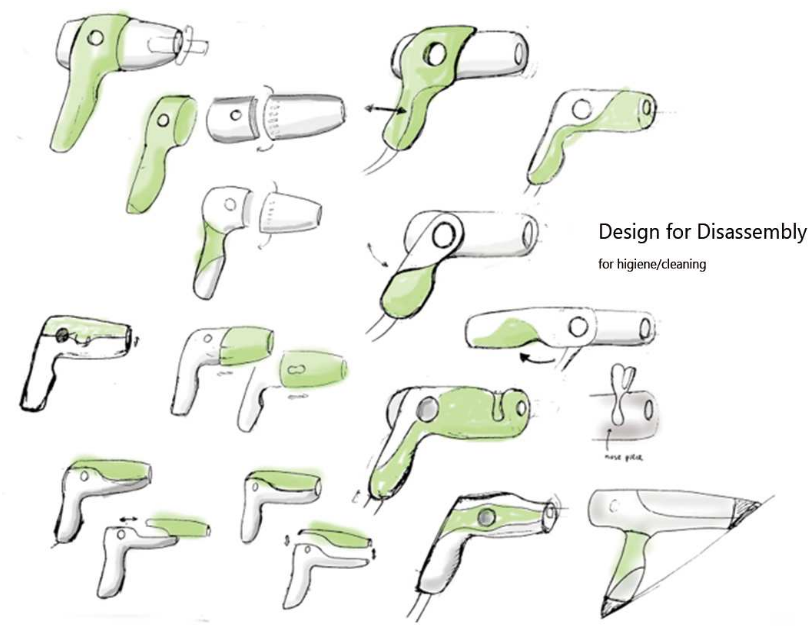
	Men		Women	
	5%	95%	5%	95%
Palm length	98	116	89	105
Max. grip diameter	45	59	43	53

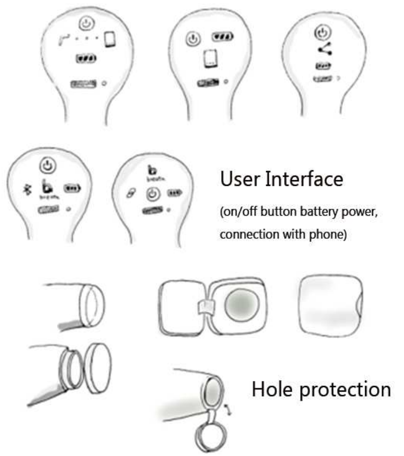


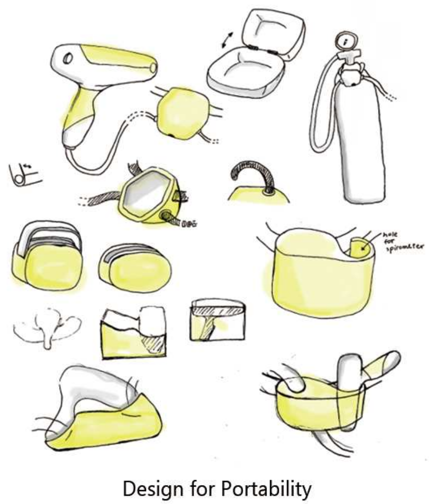


Through user testing low-fidelity prototypes, various holding positions were explored. Different easy-to-manufacture angles for the handles (vertical, 30° from vertical, 45° from vertical and 60° from vertical) were tested. After user testing, it was found that the handle with 30° from vertical was the most comfortable. Different handle shapes were created using blue foam based on anthropometric data. The handles were tested until an optimum shape and size was decided.

Detailed Design







A hair-dryer-like shape was chosen for the device as it is the easiest shape to implement the chosen handle shape and orientation.

Design for disassembly
Different disassembly methods (e.g. sliding, opening, unscrewing) for daily disinfecting and maintenance were investigated.

User interface
The device would be controlled by a mobile phone application. It can lower the cost and make the device lighter, more portable and more convenient to use. The device itself will have one on-and-off button, two indicators with one showing the amount of power remaining in the device and the other showing the connection status between the device and the mobile app.

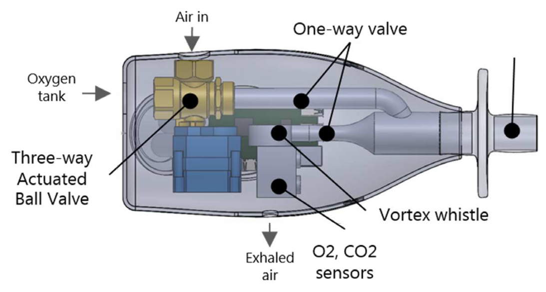
Sketches were made to explore the clearest way to present the three interface components.

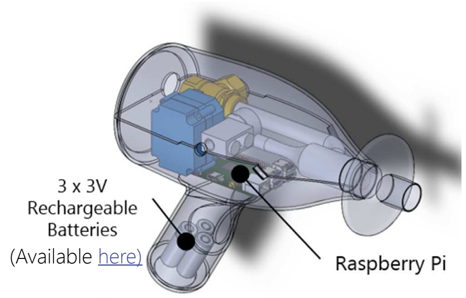
Design for portability
Sketches were made to investigate how to make the design more portable. The option of separating the device into two components to make the device lighter for the user to hold was considered, but later disregarded. A one-component device is easier to transport as there would be less items for the medical staffs to look after, so the decision was made.

Look-like Prototype

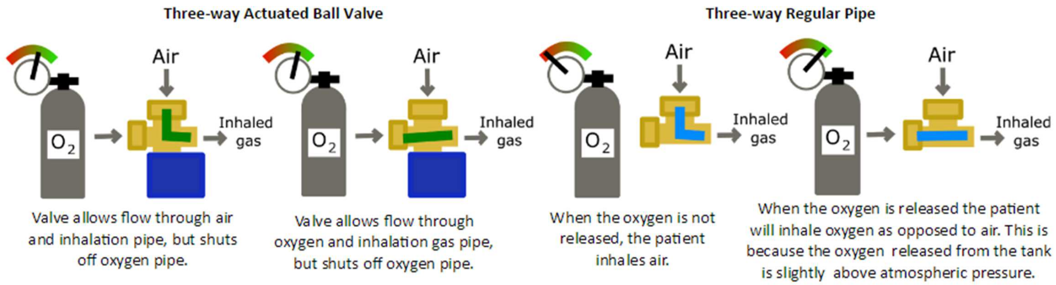
Final Iteration

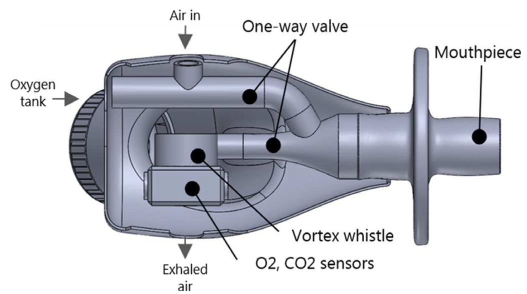
Once a basic form was decided from the many sketches and user testing, a CAD of the design was created to ensure that the technical components can fit into the design.

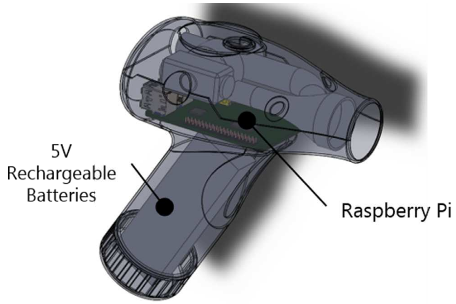




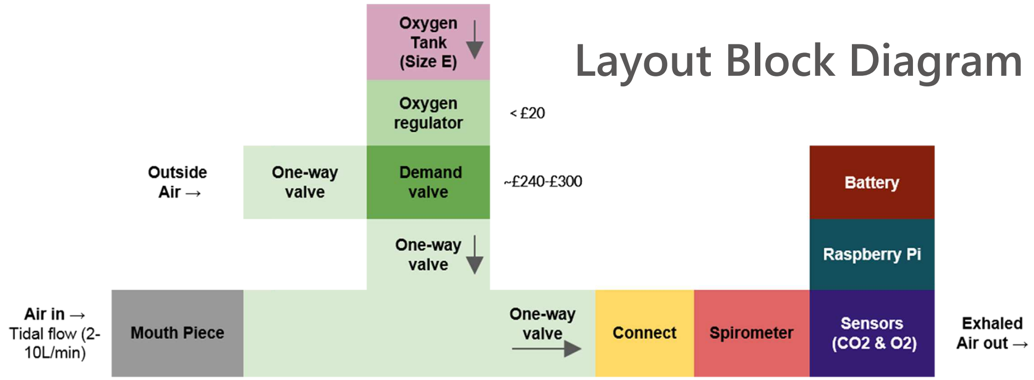
After fitting all the components, the design revealed to be very big and, potentially, very heavy. This was because of the three-way actuated ball valve, which switches the patient between inhaling normal air, when TV and ERV are being measured, and oxygen, when FRC is being measured. To reduce the size, the actuated valve was replaced with a three-way regular pipe. The diagram shows how it works.







To summarise the technical components in the device, below is a block diagram showcasing the layout of the components and details of some of the components.



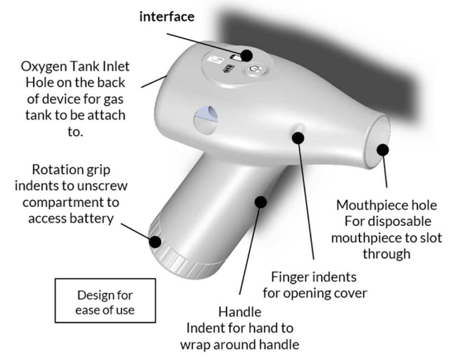
-Component details -

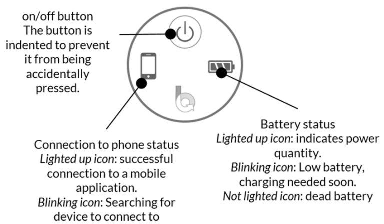
If other costs, such as production costs, were to be considered, the total price of the device can be estimated as less than 10 pounds, which is significantly cheaper than an existing device, which costs approximately £30, 000 (EasyOne Pro LAB Spirometer).

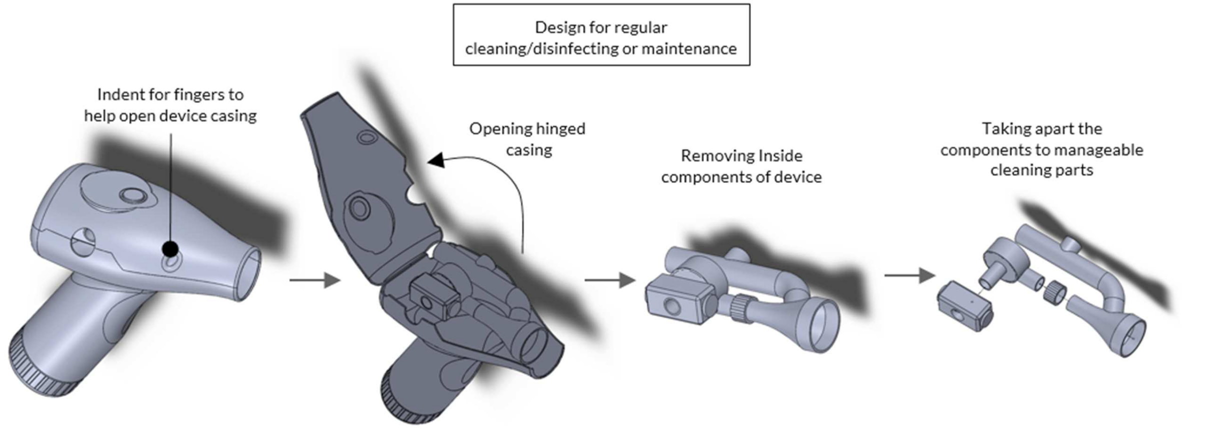
Look-like Prototype

Final Design Details

Detailed features of the design, which gives affordance to the user, were shown in the labelled CAD diagrams below.







After ensuring that the basic material requirements listed below were reached, an Ashby plot was created using CES Edupack plotting price against density to minimise the cost and the weight of the device. The lighter the product the easier it is to carry.

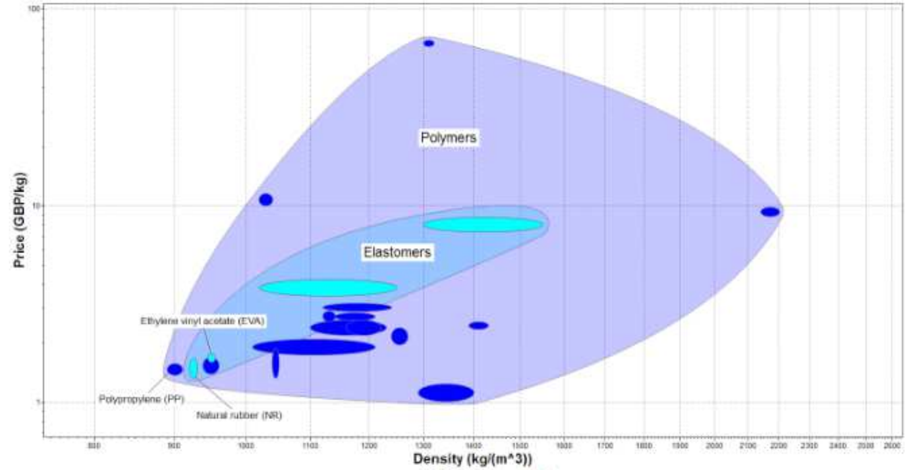
Requirements:

Good electrical insulator
Suitable for medical devices
(biomedical & biocompatible material)
Non-brittle
Durability
Easy to mass produce
Water resistant

Design for environment

Design for Low cost

Design for portability

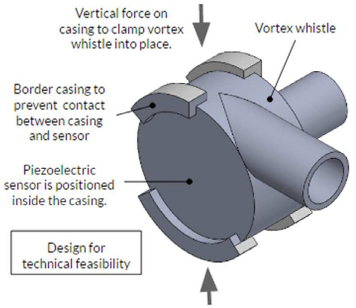


(CES Edupack)

Polypropylene was identified as the optimum material for the device's body. To make certain areas of the device easier to grip, an elastomer material will also be used and was chosen as well. Although natural rubber had the lowest density and price, because it has poor UV resistance, ethylene vinyl acetate (aka EVA), was chosen instead. EVA and polypropylene are materials that can be easily formed by injection moulding during mass production.

Impact Reduction

The work-like prototype uses a sensitive piezoelectric transducer, which detects vibrations. To prevent the piezoelectric from detecting movements of the device, the device stands on the handle such that the sensor is never parallel to the surface. The sensor will be enclosed inside the vortex whistle and the casing will only touch the border of the whistle as seen in the CAD diagram.

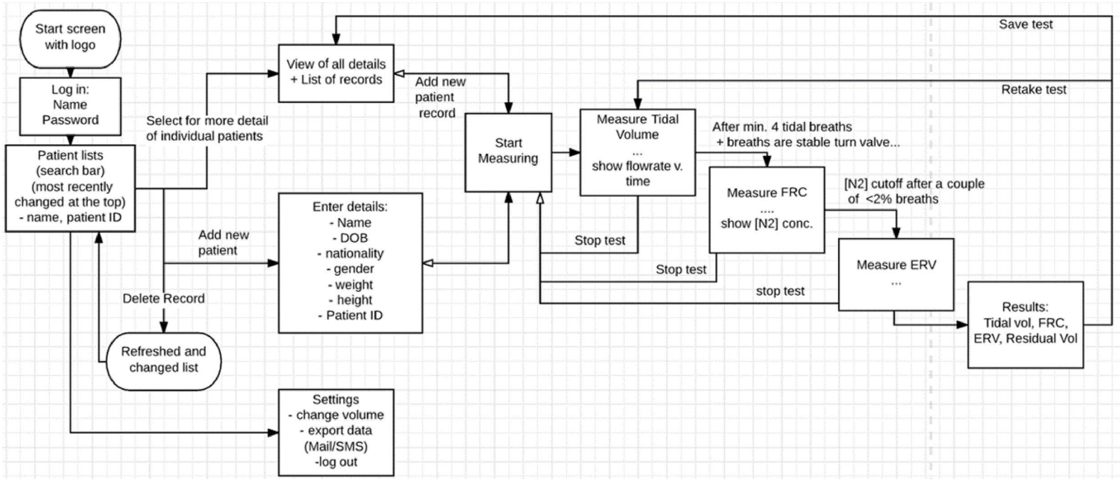


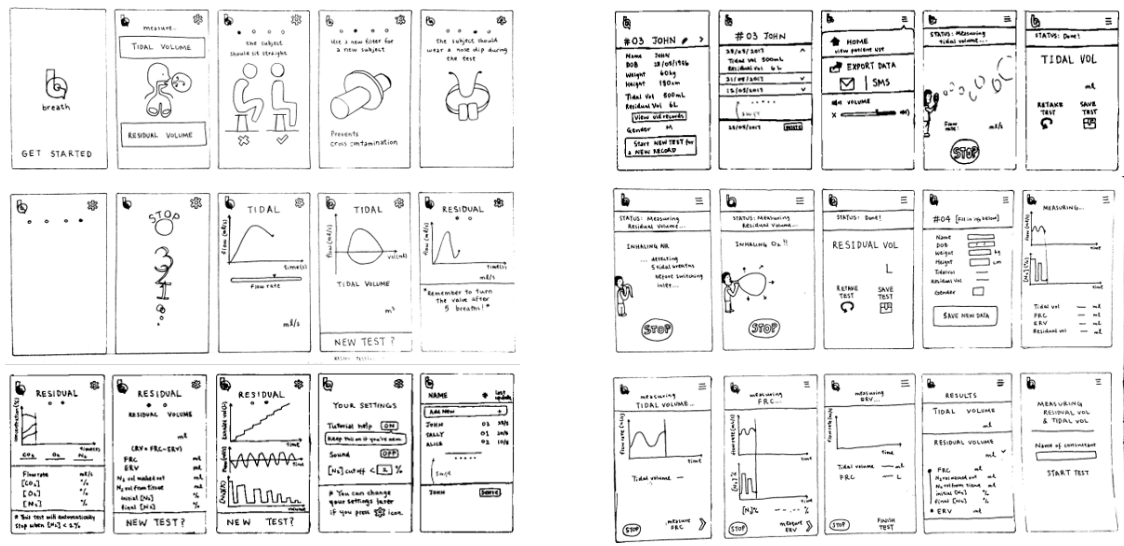
User Interface

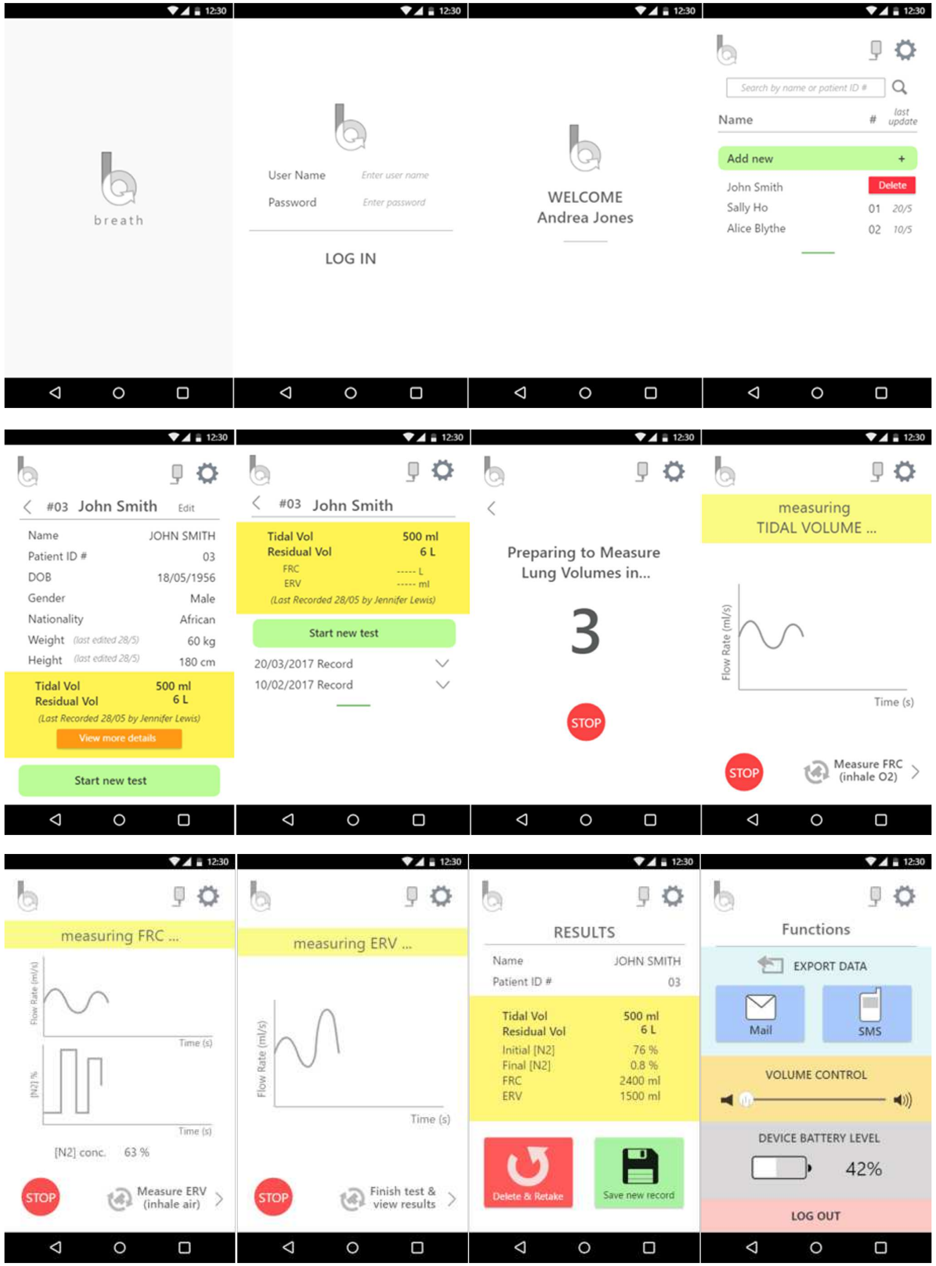
Initially, the interface was designed such that two separate measurements were done to measure tidal volume and residual volume. After getting feedback from Dr. Simon Ward, the flow chart was iterated until the final one shown was created.

Feedback from Dr. Ward:

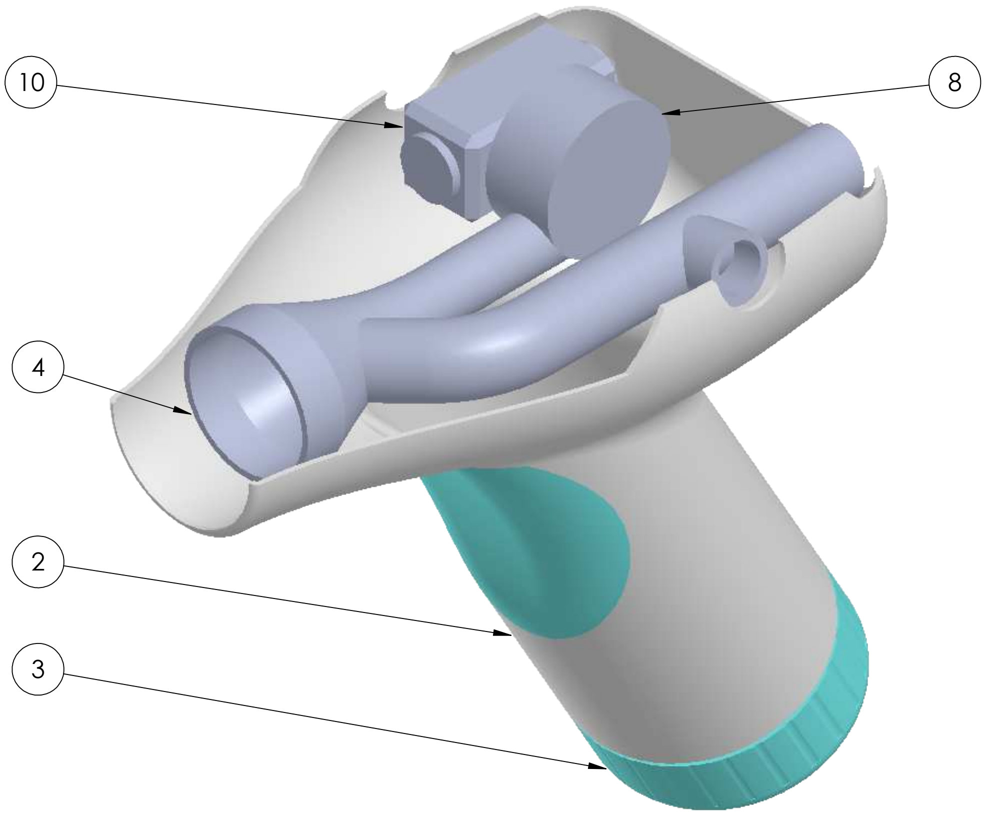
1. Tidal volume and residual volume are usually measured together one after the other as one measurement
2. Important patient details that the interface should record
3. A recording system for medical staff is needed







General Assembly Drawing



ITEM NO.	PART NAME	QTY.
1	CASE BOTTOM	1
2	HANDLE BATTERY LID	1
3	CASE LID (INCL. BUTTON AND INTERFACE ICONS)	1
4	THREE-WAY PIPE	1
5	MEDICAL SILICONE ONE-WAY VALVE	2
6	DEMAND VALVE	1
7	PIPE COUPLING	1
8	VORTEX WHISTLE PIPE	1
9	VORTEX WHISTLE	1
10	ELECTRICAL COMPONENTS (INCL. RASPBERRY PI, PIEZOELECTIRC TRANSDUCER AND GAS SENSORS)	1
11	7.4 V 2500MAH BATTERY	1

OVERALL DIMENSIONS

TOTAL LENGTH: 170 MM
TOTAL WIDTH: 92.3 MM
TOTAL HEIGHT: 172 MM

Designer: Group 6	Title: Breath	Scale: 1:1	Imperial College London Design Eng. Dpt.
Date of issue: 21/06/17	Document type General Assembly	Projection:	Module code: DE2 - EDP
Material: Polypropylene, Blue EVA	Mass: 296 g		

CAD Renders

Group Reflection

Fan Mo

Time management is important when working on a group project like *breath*, which lasts for about six months. At the beginning, I was responsible for setting out targets for group meerings and noting down the important outcome we had during the discussion. In the concept proving phase, I was involved in the venturi meter and balloon concepts. I worked with other members to interface the pressure sensor and the Raspberry Pi, and I was also responsible for carrying out rough tests on the balloon with LED by using Photoshop.

The second half of the project wast to produce a work-like and a look-like prototype, and I was involved in the work-like. Rather than using a Raspberry Pi, we decided to use MATLAB for easier signal processsing, because we wanted to see the exact graph rather than just t prove the concept could work. I also kept communicating with other sub-group to make sure each of us know how everything progressed. In the final stage, I curated, designed and edited this final portfolio by gathering everyone's contribution in this project together. I learned that although we usually tried to get everything done as soon as possible, some unexpected siuation still might happen. In the future projects, I will leave more time for each iterative process for reduing the risk of running out of time.

I was used to exploring the form and design of products, but this time I took the adventure of getting into the technical aspects of a product. I found it challenging, but I was pleased that we tried to tackle a difficult problem by using a relatively simple method (the piezoelectric transducer). I realised the importance of getting feedback from experts in different fields, like Dr Lorenzo Picinali for sound technology and Dr Simon Ward for the usage of the device.

Grace Chin

In the beginning of the project, I was mainly involved in proving the venturi-meter-based idea. Once a concept was chosen, I was one of two people responsible for the look-like prototype. This involved carrying out background research about the context of use, and technical information behind the nitrogen washout system. Although I was comfortable creating many sketches to communicate different forms and mechanism ideas for the design, I struggled in CAD and am thankful that other group members helped. In considering human factors, low-fidelity prototypes were made by shaping blue foam, anthropometric data were researched, and user testing was done. Originally, the big white blue foam model prototyped was going to be our final design, but after some input from group members, the design was scaled smaller and a rushed 3D print prototype of the final design was made. If I had more time, I would have increased the quality of the final prototype. Using Dr.Wards' feedback, I researched, sketched and made the user interface. Finally, I documented the look-like design development process in this portfolio.

Working as a group, we would weekly update each other on progression. Because the work-like and look-like design were dependent on each other, communication was very important. I learnt to accept that, although, development on the work-like would sometimes cause work done on the look-like redundant, it is all for the better of the overall product.

Norbert Weseley

Through the entire project, it was essential for us to work effectively as a team, as the volume and complexity of this design challenge was over the level of our individual knowledge and skills. Our main strategy was to divide problems into small tasks which then were allocated to sub-groups of our team based on interest and skillset. Pairs then worked on these blocks and presented results to the whole group in order to make decisions about next steps together, based on collective feedback. In the second term, sub-teams were selected for each concept to work on, where I was involved in the whistle idea and the venturi meter. In both cases I was responsible for general engineering solutions, CAD designs and 3D printing. However, after the conceputal phase, none of the concepts turned out to be a perfect solution, but we gathered a lot of experience and gained a thorough understanding of the challenge itself.

In the third term, there were two main sub-teams: a look-like and a work-like, where I was involved in the second. My duties were similar to those in the first period, but this time stakes were much higher as the prototype had to work at the end, thus we had to develop with a highly agile approach. This meant, that technologies we wanted to adapt and the design itself changed on a weekly basis, according to most recent results and feedback form experts. I found it both exciting and challenging to work on many ideas, trying to get familiar with new tech and implement it in a hurry. I learnt to accept that ideas can turn out to be unfeasible, thus it is important to collect as many as possible and keep track of each of them. I also learnt the importance of working in a team, thus if one of us gets stuck, or derails, others can help to get back on track, and constant communication and feedbacks are absolutely essential. Furthermore, I realised that my time management was rather poor during this project, so this is something I definitely need to work on.

Thomas Shakespeare

During the project, I went to the Royal Brompton Hospital and gained some information of lung volume measurement. I have attended several meetings and contributed some ideas here and there. I helped to make some of the blue foam prototypes used for human factors testing and have helped in creating the final CAD model.

I thoroughly enjoyed working as a group. It was a very rewarding experience.

breath