MedRhythms Auditory Device

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1. The Problem

Problem Statement

We must address the lack of neurologic music therapy treatment compliance for patients suffering from dysarthria as a result of neurological injury (TBI and stroke) or neurodegenerative conditions (Parkinson's and MS) in order to improve respiratory capacity and endurance. These patients struggle to comply with their breathing exercises as the current solutions are not entertaining, don't provide feedback, and have no aspects of entrainment.

Population

The patient population can be broken down into primary and secondary users. The primary users are patients with dysarthria. Dysarthria is the difficulty of breathing and loss of control of muscles used for speaking. In the US alone, about 7.5 million people struggle to use their voices.[1] It can be caused by neurological trauma like TBI and stroke, or neurodegenerative conditions like Parkinson's and MS. These are the patients who will directly be interfacing with the product. The secondary users are the NMTs or the neurologic music therapists. They will be teaching patients how to use the device and accessing data stored after use to advance patient treatment plans.

Problem (User Needs)

Through conversations with the NMTs and our client about the pain points of current solutions and their desired specifications, we compiled the following design criteria:

1. **Function** - Does the device serve its intended purpose?
    a. Differentiates between an inhale and an exhale.
    b. Measures speed of breath.
    c. Measures length of breath.
    d. Allows for device calibration.
    e. Allows for changes in resistance level.

2. **Compliance** - How does the device improve user experience to increase patient compliance?
    a. Audio entrainment - beats displayed on GUI align with beats per minute of chosen song. Overlaid metronome audibly queues the patient to inhale and exhale on beat.
    b. Entertaining - experience mimics "guitar hero" through selection of preferred song and inclusion of visual notes that inform breathing rate.

c. Provide immediate feedback to the patient - patient's breath is displayed on GUI in real-time.
d. Store and send long-term feedback - patient's average inhale/exhale duration, number of great breaths, and other pertinent summary metrics can be stored after each session on a local computer.

3. **Physical needs -** How does the device address ergonomics and patient safety?
    a. Safe to use - no physical risk associated with using this device.
    b. Easy to use - patients with dysarthria can complete exercises without additional assistance. Software can be easily installed.
    c. Sterility - all parts exposed to breath can be quickly sterilized between sessions.
    d. Durability - minimal to no damage if device is dropped or shaken (i.e., device maintains functionality).
    e. Runtime - battery can withstand multiple sessions without dying.
    f. Low cost - price is affordable for dysarthria patients with existing medical bills.

Expected Outcomes (societal / cultural impact / global reach)

This device is made for patients who develop dysarthria as a result of neurological trauma or neurodegenerative diseases. Nearly 1 million people in the US live with multiple sclerosis (MS), 1 million in the US live with Parkinson's, and nearly 1.5 Americans in the US sustain a traumatic brain injury (TBI).[2,3,4] This accounts for 3.5 million of the patients that suffer from dysarthria. We expect that this device could be used to treat a number of respiratory conditions in the future.

Our targeted societal impact is to improve quality of life for patients with dysarthria who struggle to communicate with loved ones. Having a tool that is fun, motivating, and has the power to restore communication and respiratory function could significantly impact the lives of these patients and their families.

With a few modifications, this device population could be extended to children with asthma. Asthma affects nearly 5.1 million children under the age of 18 in the US.[5] Prescribed breath exercises may increase children's lung capacity and improve asthma symptoms. Additionally, any patient who has undergone anesthesia from surgery must perform breath exercises with an incentive spirometer to prevent lung collapse. The absence of entrainment and entertaining patient feedback contributes to a lack of compliance among these patients, making our device a strong candidate for this population.

The future implications of this device span different age groups, diseases, and populations. However, the immediate clinical impact is to improve the lung capacity and respiratory endurance of dysarthria patients and help them regain their communication and quality of life.

2. The Background

Entrainment breathing exercises, which involve the synchronization of breath to an external perceived rhythm, have been shown to improve multiple symptoms of dysarthria. Speech and singing utilize muscles of respiration and articulation and contain elements of rhythm, pitch, tempo, and diction. As such, rhythm is used as a stimulus that automatically accesses and syncs with motor areas in the brain and leads to subconscious improvement in motor control.

Existing products / solutions for this problem

Figure 1: Image of The Breather device by PN Medical

Entrainment and breathing devices have been shown to improve symptoms of dysarthria. The Breather is a commonly used device on the market that can be purchased on Amazon for a relatively cheap price (~$40) and is easily accessible by both NMTs and patients. The Breather has 6 Inspiratory settings and 5 Expiratory settings. Its dimensions are small and it is relatively easy to hold in the hand, weighing 0.1 lbs. It is recommended to do 2 sets of 10 breaths twice a day, 6 days a week.[6]

Patient compliance with this device remains low, especially among our target population. The lack of real-time feedback from the Breather is discouraging and tiring for these patients who spend years in therapy. Additionally, the absence of long-term feedback makes it difficult for NMTs to track patient progress and advance treatment plans accordingly.

Figure 2: Image of the Pulmonica by Harmonica Techs

The Pulmonica combines entrainment with the Breather concept. This device costs $100 on Amazon and is relatively lightweight and portable. According to NMTs, the music generated by the Pulmonica is unpleasant, as patients often lack previous experience playing a harmonica. There is no real-time feedback or option to adjust resistance, making it impossible to advance patient training programs. Additionally, after talking with NMTs we found that most patients struggle to fit their mouths around the mouthpiece. Overall, compliance with this solution remains low.[7]

Overview of pertinent IP landscape

Trade Secrets, Copyrights, and FTOs: No known relevant or pertinent trade secrets or copyrights. No FTOs were found.

Patents: Through a patent search we found 6 relevant and registered patents. Some share our concept of connecting a USB cable to a computer or phone. However, all are different enough from our design, and are in preliminary stages. See the following six below:

1. "Lung instrument training device and method"[8]
2. "Smart respiration training machine"[9]
3. "Portable respiration training device system and thereof methods"[10]
4. "Medical breathing training ware"[11]
5. "A kind of respiratory training device"[12]
6. "Breathing and respiratory muscle training method and system" [13]

3. Specifications and Constraints

Table 1: House of Quality, Specifications 1-9

		Spec #1	Spec #2	Spec #3	Spec #4	Spec #5	Spec #6	Spec #7	Spec #8	Spec #9
Priority	CUSTOMER REQUIREMENTS/NEEDS	No sharp edges, shock risk, etc.	Accuracy of inhale/exhale categorization	Accuracy of placement of breaths into different speed categories	Accuracy of breath length detection, as compared to stopwatch	Time to disassemble, sterilize, and re-assemble device	NMT rating of entrainment incorporation	Subject rating of entertainment value	Time to provide visual feedback	Ability to store & email feedback file on computer after session
1	Safe to use	X				X				
2	Differentiate between inhale and exhale		X							
3	Measure speed of breaths		X	X						
4	Measure length of breaths				X					
5	Sterility					X				
6	Audio entrainment						X			
7	Entertaining							X		
8	Provide immediate feedback to patient			X	X				X	
9	Store and send long-term feedback			X	X					X
10	Change breathing resistance level									
11	Device calibration		X							
12	Easy to use									
13	High durability									
14	Long runtime									
15	Low cost									
	Competitive Values	Yes	100%	N/A	N/A	< 10 minutes	0/5	0/5	N/A	No
	Marginal Value	Yes	90%	90%	p > 0.05	< 10 minutes	4/5	4/5	< 2 seconds	Yes
	Ideal Value	Yes	95%	95%	p > 0.05	< 5 minutes	5/5	5/5	< 1 second	Yes

Table 2: House of Quality, Specifications 10-17

		Spec #10	Spec #11	Spec #12	Spec #13	Spec #14	Spec #15	Spec #16	Spec #17
Priority	CUSTOMER REQUIREMENTS/NEEDS	Wind speed change for consecutive resistance holes	Accuracy of max speed reading post-calibration	NMT and subject rating of ease of use	Subject rating of ease of software installation	Subject rating of ease of cleaning	Height to survive drop test	Battery Life	Total cost
1	Safe to use								
2	Differentiate between inhale and exhale								
3	Measure speed of breaths								
4	Measure length of breaths								
5	Sterility					X			
6	Audio entrainment								
7	Entertaining								
8	Provide immediate feedback to patient								
9	Store and send long-term feedback			X					
10	Change breathing resistance level	X		X					
11	Device calibration		X	X					
12	Easy to use			X	X	X			
13	High durability						X		
14	Long runtime							X	
15	Low cost								X
	Competitive Values	Unknown	N/A	Unkown	N/A	N/A	Unknown	N/A	< $50
	Marginal Value	> 0.5 m/s	90%	4/5	4/5	4/5	> 3 feet	> 10 hours	< $50
	Ideal Value	> 1 m/s	95%	5/5	5/5	5/5	> 5 feet	> 20 hours	< $20

4. Final Design (Technical Documents)

Engineering drawings, 3D CAD model renderings

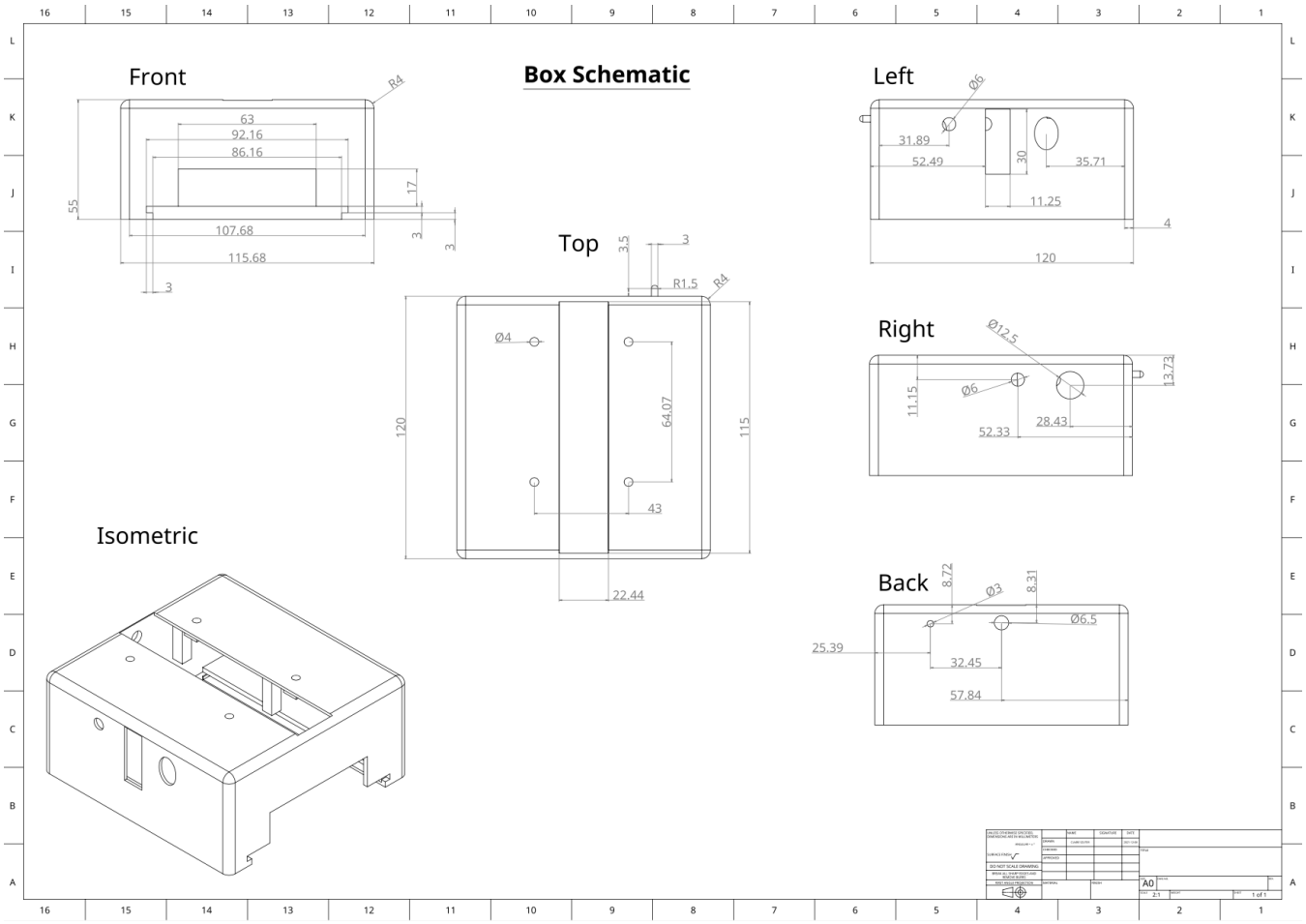

Figure 3: CAD mechanical drawing of the box enclosure. Views are labelled.

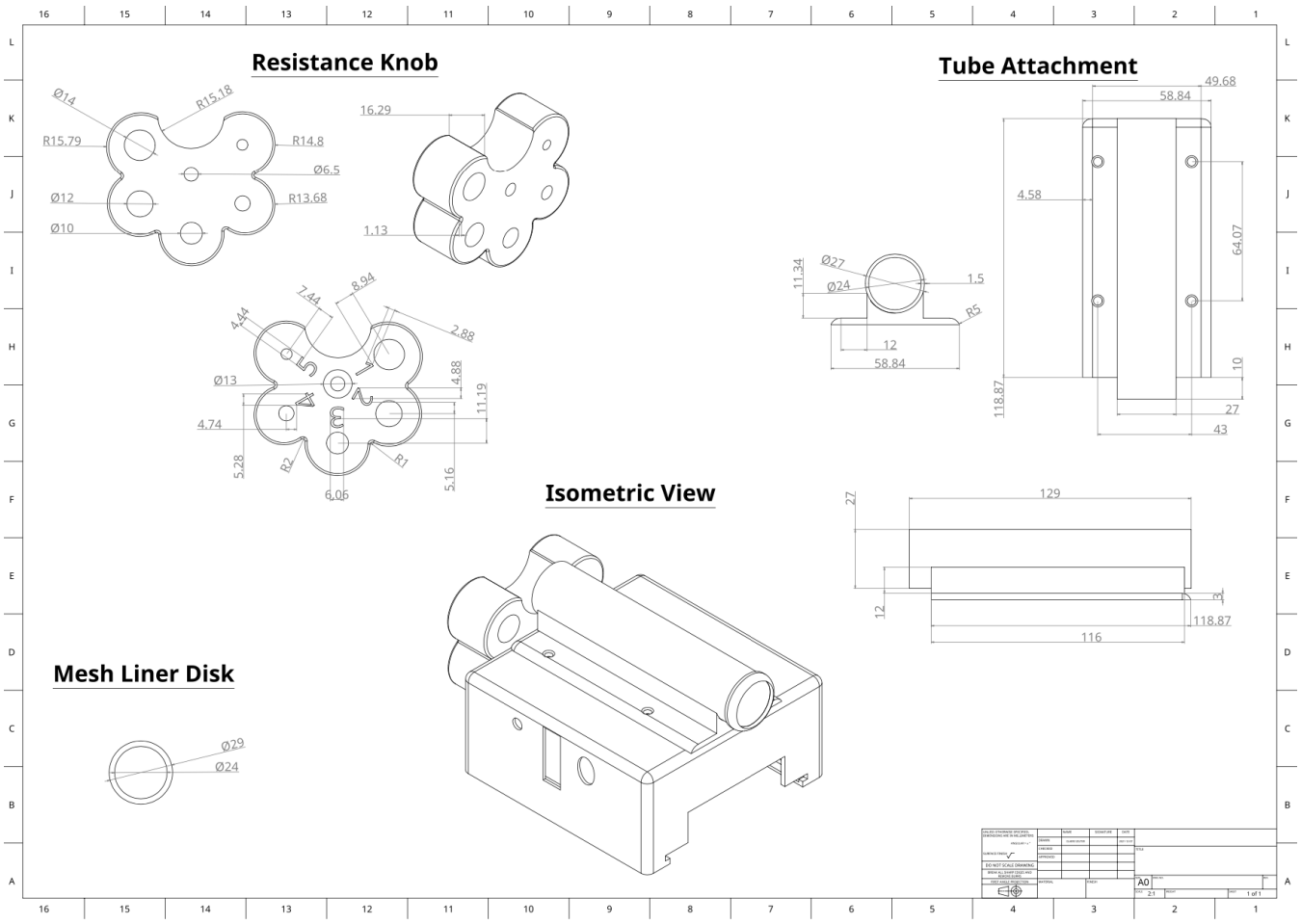

Figure 4: CAD mechanical drawing of the resistance knob, the mesh liner disk, and the tube attachment. Views are labelled, and an assembled isometric view can be seen at the bottom for reference.

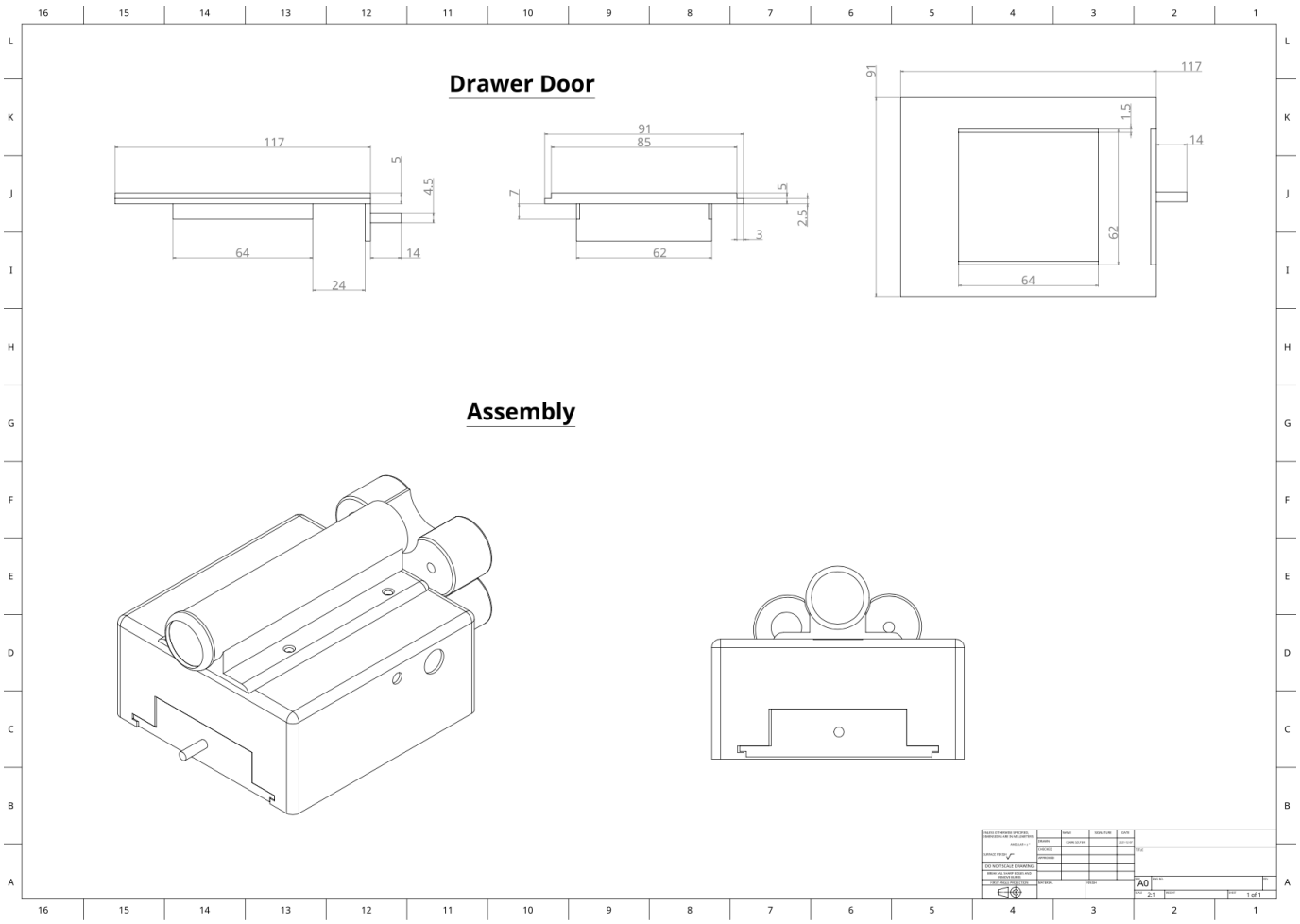

Figure 5: CAD mechanical drawing of the battery drawer door. Views are labelled, and a complete assembled isometric view can be seen at the bottom for reference.

Electronics schematics

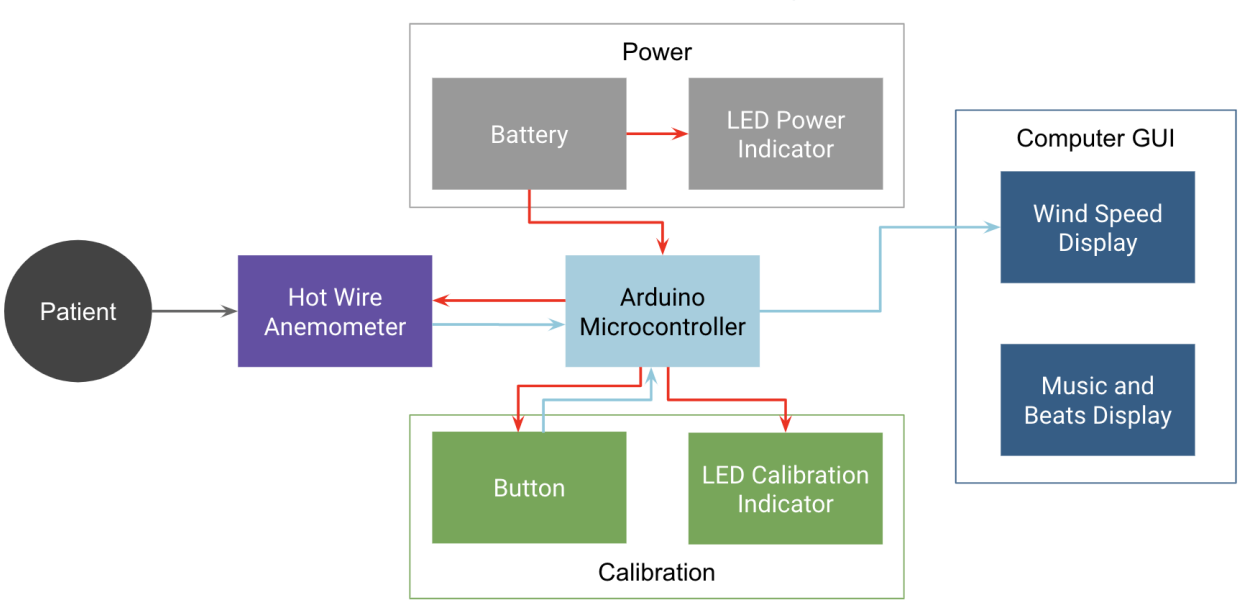

Figure 6: Circuit block diagram of the electronics. This shows both functionality and component connections. The grey arrow represents a breath, the red arrows represent power, and the blue arrows represent signal/information.

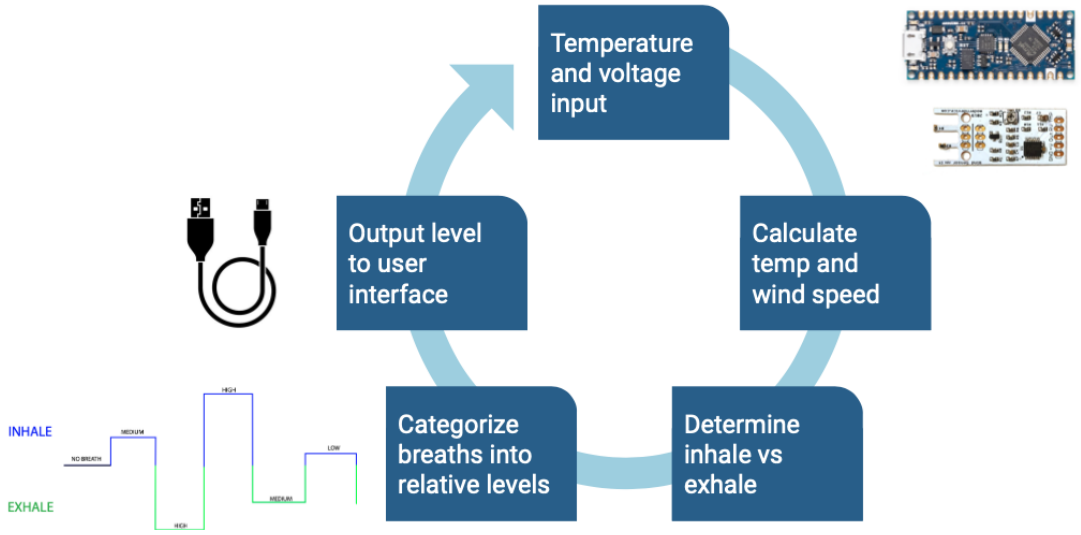

Figure 7: Sensor data flowchart that shows the cycle of the sensor in communication with the GUI.

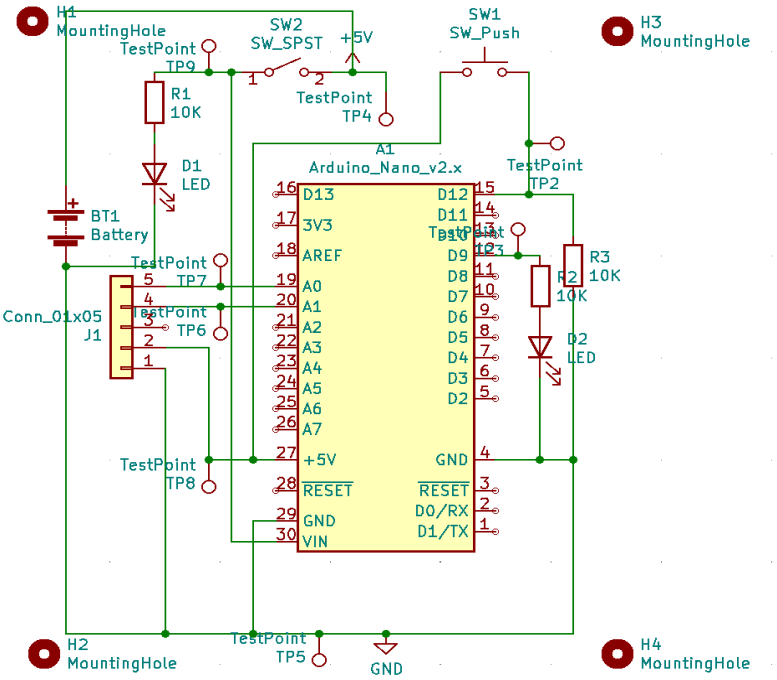

Figure 8: Full-size circuit schematic with labels and values.

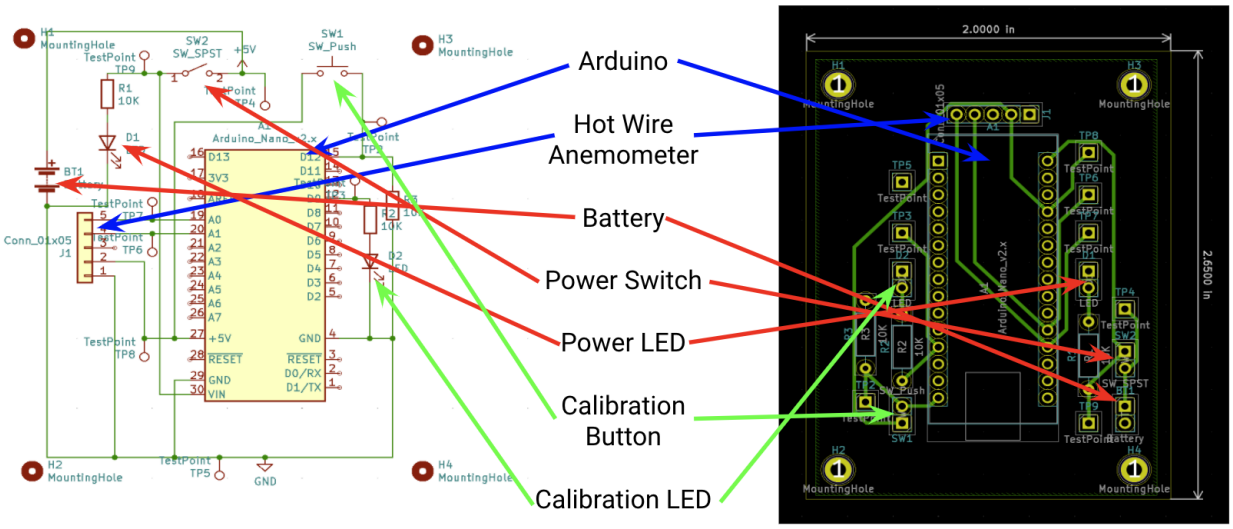

Figure 9: Circuit schematic mapped to the PCB schematic. This includes labels and component values.

PCB layout

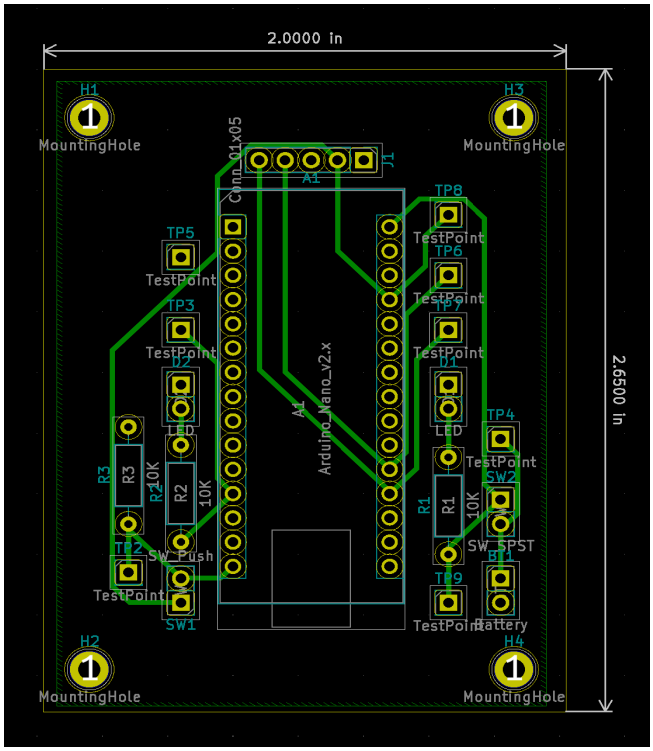

Figure 10: Full size schematic for the PCB with relevant labels, mounting features, and dimensions.

Software flowcharts (Reference to git repositories)

Git repository with detailed ReadMe including instructions on how to use software can be found at: https://github.com/haleyelena/474-Project

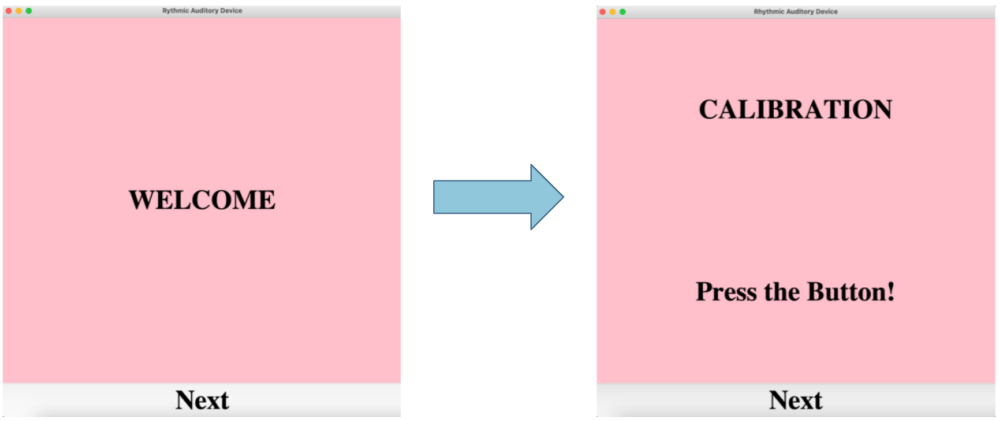

Figure 11. Welcome Page and Calibration Page of final GUI.

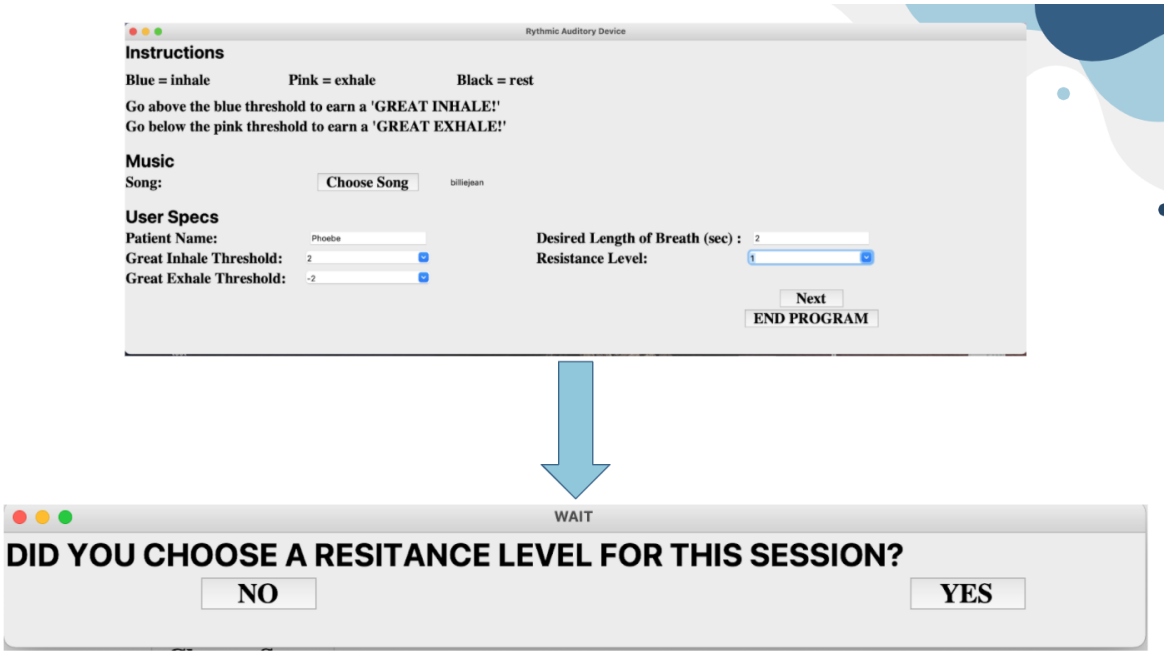

Figure 12. Menu Page and Warning Popup of final GUI.

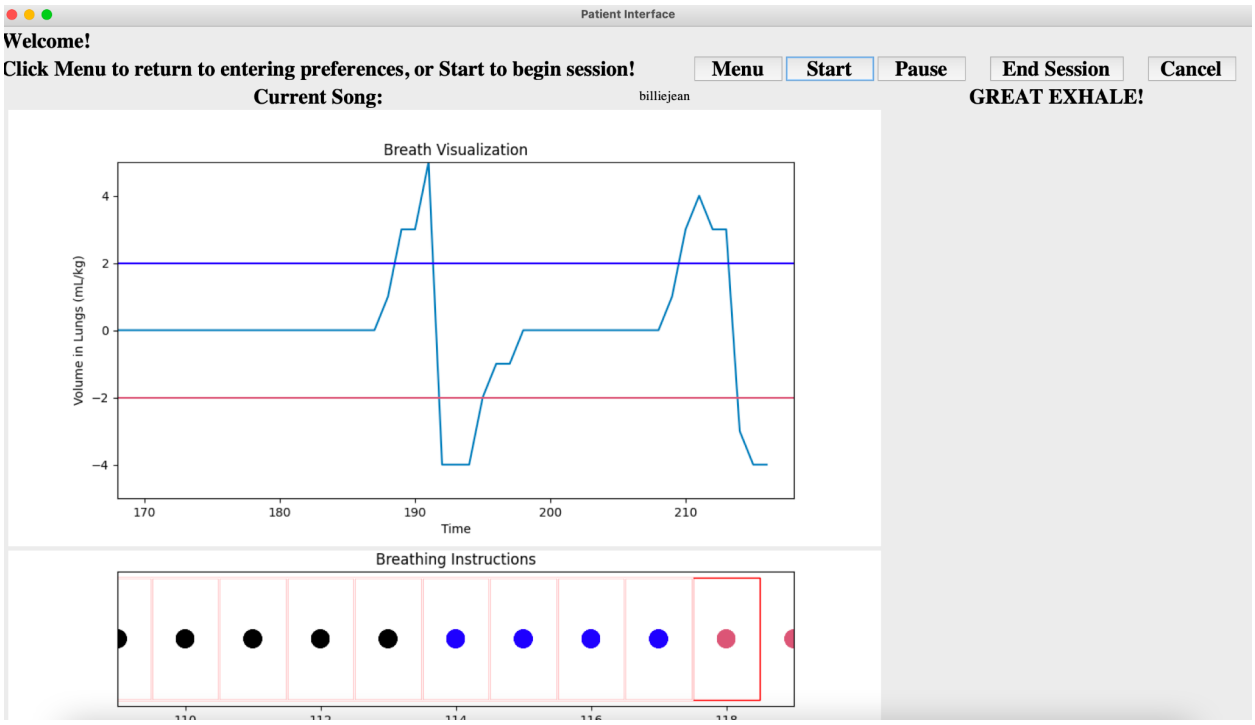

Figure 13. Main Page of final GUI.

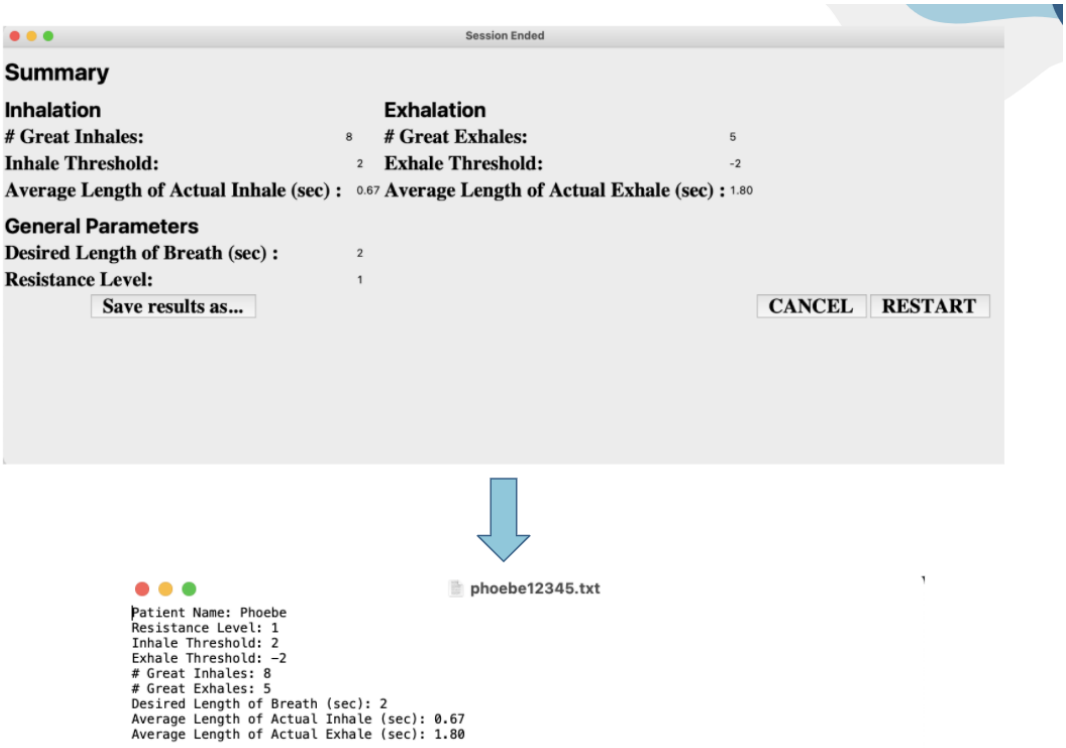

Figure 14. Summary Page of final GUI and output text file.

5. Testing to Specification

In this section we explore the testing of the three core design criteria: Function, Compliance, and Physical Needs. Each test was designed to determine whether or not our design specifications were met given the competitive, marginal, and ideal values. Testing and Results are summarized below.

Schematics / drawings for testing devices

Many of the testing procedures were done by having users breathe into the device and monitoring the GUI and/or a stopwatch. An example of this is the length of inhale/exhale test, for which a schematic is shown below.

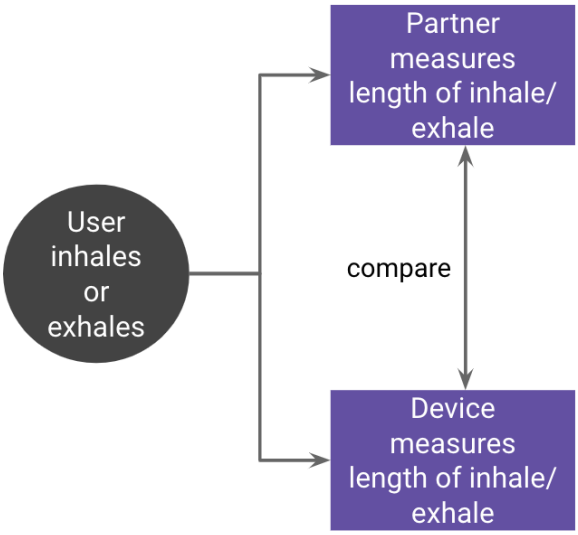

Figure 15: Testing procedure schematic for determining accuracy of length of breath measurement

Some of the testing procedures were done by using an air-hose that can be adjusted to release air slower or faster, shown in Figure 16 below.

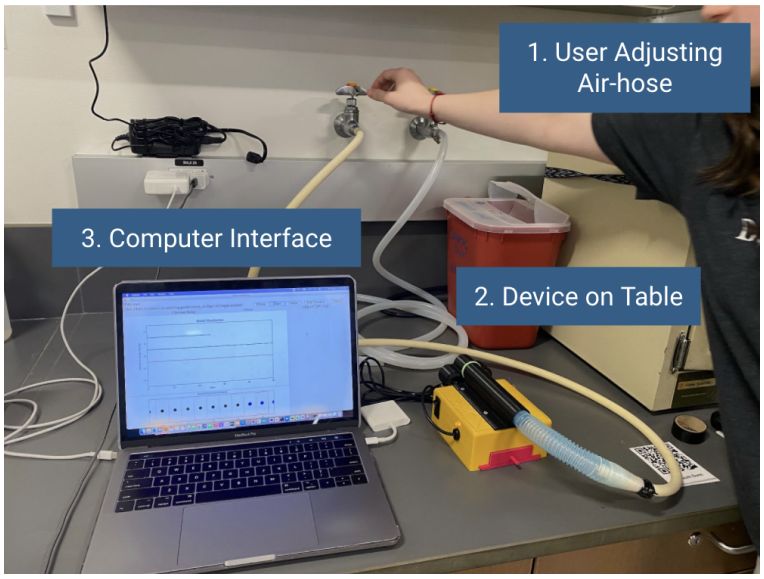

Figure 16: Image of testing procedure with air-hose

For other tests, a vane anemometer was used to measure real wind speed and to categorize it into a particular wind speed "level," which was then compared to the level output on the GUI. A schematic of this is shown below.

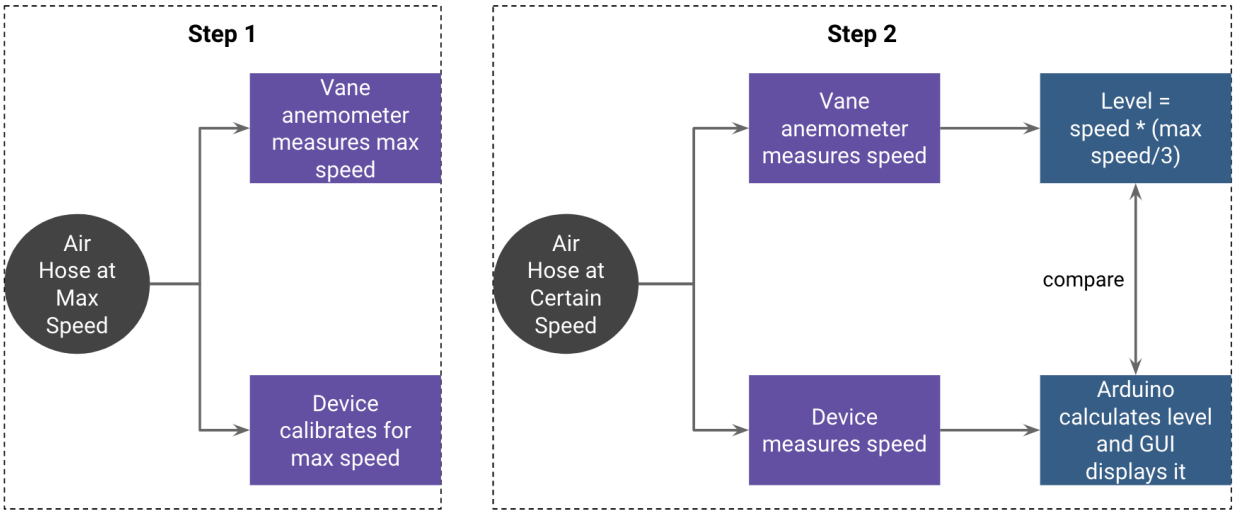

Figure 17: Testing procedure schematic for determining accuracy of wind speed level

The vane anemometer was also used to measure the output wind speed for each resistance hole in order to determine if higher resistances truly occluded more air flow. A schematic of this is shown below.

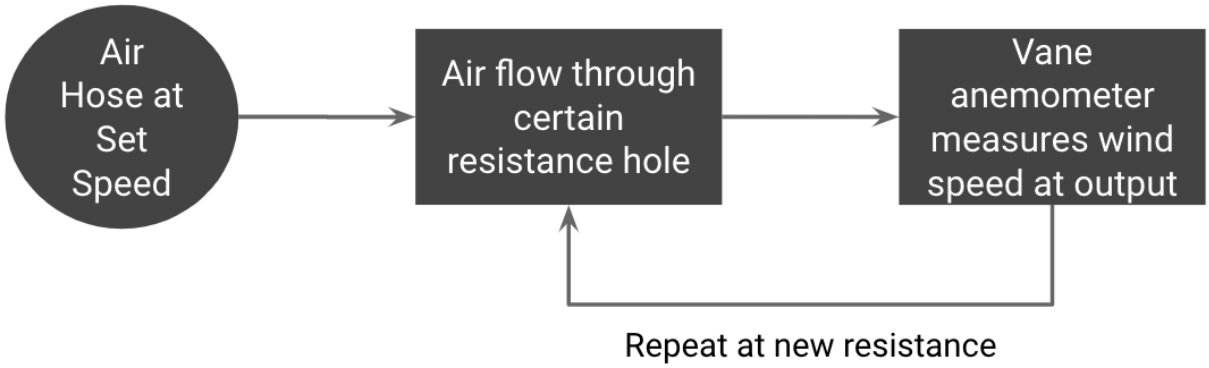

Figure 18: Testing procedure schematic for determining output wind speed for different resistances

Testing procedures / data collection

Table 3: Testing methods (green = completed)

User Need	Key Specification	Testing Methods
Differentiate between inhale and exhale	Accuracy of inhale/ exhale categorization	Observe the GUI as 3 subjects perform 10 breaths and determine the percentage of inhales & exhales that are categorized correctly.

Measure speed of breath	Accuracy of placement of breaths into different speed categories	Set the air hose at 3 different wind speeds corresponding to a level 1, 2, and 3. Observe the GUI at each of these wind speeds for 10 Serial prints and determine the percentage of correctly classified outputs.
Device calibration	Accuracy of max speed reading post-calibration	Calibrate device by using a constant flow rate from the air hose. When the program begins, determine if the GUI prints a constant level 3 corresponding to the constant flow rate at which we calibrated for 20 Serial prints.
Measure length of breath	Accuracy of breath length detection	Have subject breath into the device such that they achieve 10 “Great Inhales” and 10 “Great Exhales”. As soon as the subject passes the threshold corresponding to a great breath, begin a phone timer until the subject’s breath dips below the threshold. Compare the timer readings to the GUI summary metrics “Average Length of Actual Exhale” and “Average Length of Actual Inhale.”
Change breathing resistance level	Wind speed change for consecutive resistances	Measure wind speed with vane anemometer at end of breathing tube with the mesh filter for each resistance level. Determine average difference in wind speed between each resistance level.
Audio entrainment	User-defined scale of how well device incorporates entrainment rated by NMTs	Have 5 NMTs rate our device for its incorporation of entrainment on a scale of 1-5, with 5 being the highest degree of entrainment.
Entertaining	User-defined scale of how entertaining device use is rated by subjects	Have 5 random subjects rate our device for its level of entertainment on a scale of 1-5, with 5 being "Very “Entertaining".
Provide immediate feedback to patient	Time to provide visual feedback	Change air hose speed from various levels and measure time for the GUI to reflect this change in level 5 times for each trial.*
		Have a subject alternate their inhales and exhales for 10 breaths and measure time for the GUI to reflect change (i.e., positive to negative output or vice versa).
Store and send long-term feedback	Ability to store & email feedback file on computer after session	Perform 5 breathing sessions and check if patient feedback is stored after each session.**
Easy to use,	User-defined scale	Have 5 NMTs rate our device for its ease of use, software

install, and clean	for ease rated by NMTs and other subjects	installation, and cleaning on a scale of 1-5, with 5 being the easiest.
Sterility	Time to disassemble, sterilize and re-assemble device	Measure time to disassemble device components susceptible to contamination, sterilize them, and re-assemble.
High durability	Survives drop test > 3 ft	Drop device from a height of 3 feet and examine for damage.
Runtime	Battery life	Test current draw of circuit using power supply.
Low cost	Total cost	Calculate bill of materials

* The delays were measured when transitioned from speed 1 to 0, 2 to 0, 3 to 0, and 0 to 3. It was too difficult to accurately change the wind speed from 0 to 1 or 0 to 2 because the air hose could not be turned to a fine enough degree.
** The "send email" functionality has not yet been developed, so only the storing functionality was tested.

Results and Statistical Analysis

Table 4: Results of testing along with statistical analysis

User Need	Testing Methods	Results (AVG ± STDEV)	95% CI	Value Met
Differentiate inhale vs. exhale	Observe inhale/exhale	100 ± 0%	N/A	Ideal
Measure speed of breath	Use air hose at 3 wind speeds	100 ± 0%	N/A	Ideal
Measure length of breath	Compare length of great inhale/ exhale displayed on GUI vs. printed	$p_{inhale} = 0.82$ $p_{exhale} = 0.22$	N/A	Ideal
Device calibration	Ensure that only level 3 is printed to Serial monitor at calibrated max	2.95 ± 0.22 (95% accurate)	2.85–3.05	Ideal
Change breathing	Measure wind speed with vane anemometer	0.33 ± 0.19 m/s	0.06–0.79 m/s	Not Met

resistance level	at output for each resistance			
Provide immediate feedback to patient	Change air hose speed and measure time for GUI to reflect change 5 times for each level	1 → 0: 0.75 ± 0.23 sec 2 → 0: 1.17 ± 0.09 sec 3 → 0: 1.61 ± 0.17 sec 0 → 3: 2.18 ± 0.39 sec	0.00–0.40 s 1.09–1.25 s 1.46–1.77 s 1.84–2.52 s	Decrease: Marginal Increase: Not met
	Alternate inhale (I) & exhale (E) and measure time for GUI to reflect change 10 times	I → E: 1.24 ± 0.24 sec E → I: 1.00 ± 0.17 sec	0.66–2.14 s 0.38–1.68 s	Marginal
Store and send long-term feedback	Check if patient feedback stored after 5 sessions	Yes (5/5 stored)	N/A	Ideal
Sterility	Disassemble device components susceptible to contamination, sterilize them, and re-assemble	64.01 ± 0.22 min (Disassemble/assemble: 4.01 ± 0.22 min Autoclave: 60 min)	Dis/assemble: 3.82–4.21 min	Ideal
Runtime	Test current draw of circuit using power supply	51.9 hrs (2800 mAh / 54 mA)	N/A	Ideal
Low cost	Calculate bill of materials	$46.22	N/A	Marginal

We performed deeper statistical analysis to analyze the accuracy of our device in measuring breath duration. We had one subject exhale into the device 10 times while monitoring the patient GUI. As soon as the “Good Exhale” threshold line was exceeded, we started a timer. The timer was stopped when the subject’s breath dipped below the threshold line. This process was repeated with inhales. For each exhale or inhale, we compared the timer measurement with the “Average Length of Actual Exhale/Inhale” values output as summary metrics for that session. We then performed a two-sample, unpaired t-test with a significance level of 0.05 to determine if there is a statistically significant difference in the means of the two groups. The results of the test are shown in Table 6.

Table 5: Additional statistical analysis on length of breath testing

Type of Breath	Shapiro-Wilk Test for Normality (p-value)	Levene's Test for Equal Variance (p-value)	2-Tailed Unpaired T-test (p-value)	Statistical Difference
Exhale	Timer: 0.93 GUI: 0.86	0.67	0.82	No
Inhale	Timer: 0.10 GUI: 0.04	0.57	0.22	No

As shown in Table 6, we failed to reject the null hypothesis that the means of the two groups are equal. However, the failed normality assumption for the inhale GUI data limits the results of the study. Additionally, we correlated exhale/inhale duration measured via timer with that measured via GUI to determine how accurately the device detected breath length. These correlations are shown in the figure below. Both the exhale and inhale correlations had a line of best fit slope close to one, which indicates an almost 1:1 correlation between the timer and the GUI measurements. However, while the correlation for exhale duration had an R^2 value of 0.99, the correlation for inhale duration had a lower R^2 value of 0.66, indicating that the line of best fit did not fit the exhale data as well. Since many parts of this testing procedure were susceptible to human error, including variable breath durations and stopwatch reaction time, further trials should be conducted to validate these results.

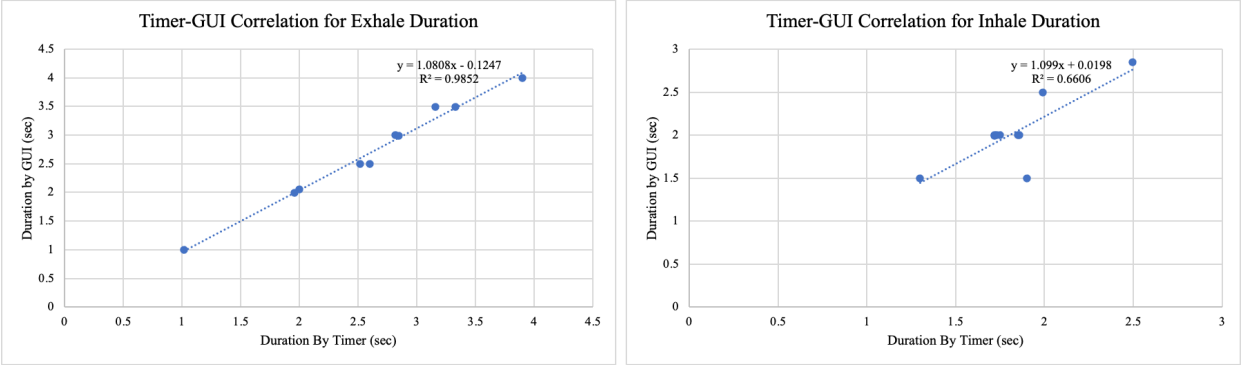

Figure 19: Correlations between timer- and GUI-recorded durations of exhales and inhales

Moreover, Bland-Altman plots were generated for exhale and inhale duration comparing results recorded with the timer versus the GUI. These plots are shown in the figure below. From these plots, it is clear that almost all of the data points showing the difference between the two recording methods fall within the limits of agreement, indicating that most of the variation was due to the testing methods themselves. This suggests that the GUI breath duration display shows little bias and is accurate with respect to the "gold standard" timer measurements.

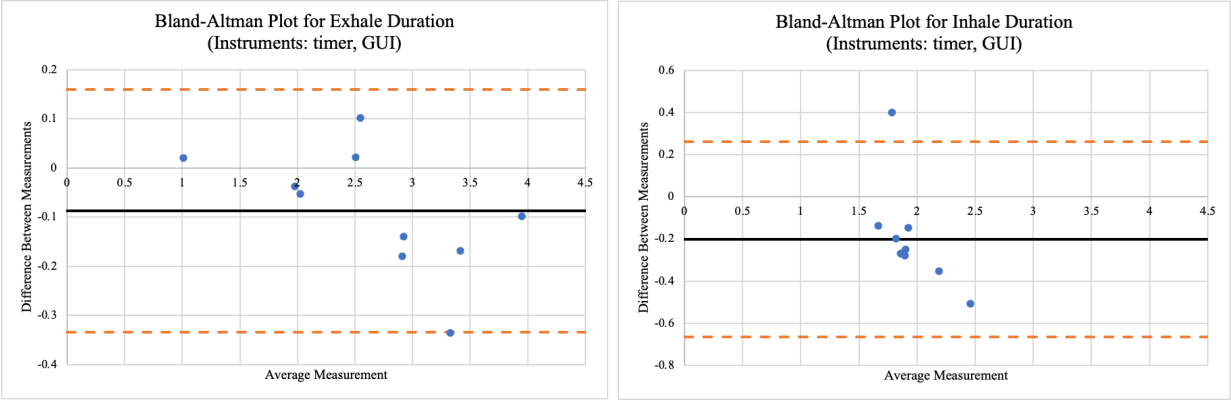

Figure 20: Bland-Altman plots for exhale and inhale duration as measured by a timer and by the GUI

To further test the immediacy of visual feedback, statistical analysis was done on the time for the Serial monitor to change from an inhale to exhale measurement. Bland-Altman plots in the below figure show the difference in this time, taken by a stopwatch, between consecutive measurements. Once again, since almost all of the data points fall within the limits of agreement, most of the variation is due to the stopwatch recording method itself, suggesting that the speed of visual feedback has little bias and is relatively precise.

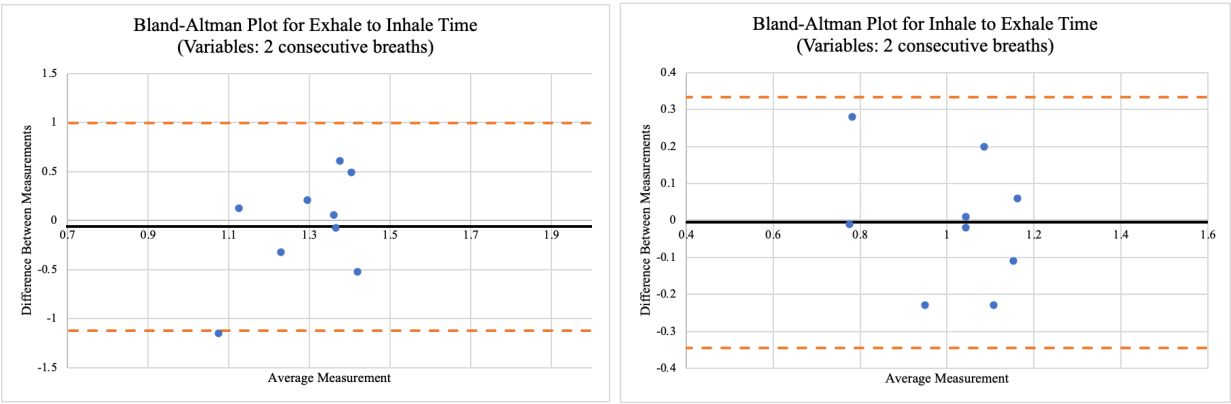

Figure 21: Bland-Altman plots for time change between exhale and inhale and vice versa, taking the average and difference between consecutive breaths

In order to calculate the total product cost of $46.22, a Bill of Materials (BOM) was generated, shown below in Table 6. The price of the laptop/computer used to install the software is not included in this BOM because our device includes only the physical components, including the mouthpiece, breathing tube, and box with the electrical component housing, and the GUI software.

Table 6: Bill of Materials

Component	Quantity	Cost	Total Cost
Wind Sensor Rev. C	1	$17.00	$17.00

PCB Board	0.221	$6.50	$1.44
Arduino Nano Every	1	$11.33	$11.33
Micro USB - USB Cable	1	$1.20	$1.20
10K Resistor	2	$0.07	$0.14
Yellow LED	1	$0.13	$0.13
Blue LED	1	$0.15	$0.15
AA Batteries	4	$0.26	$1.05
AA Battery Pack	1	$3.00	$3.00
SPST	1	$0.40	$0.40
Push button	1	$4.94	$4.94
Mesh Filter	0.002	$11.97	$0.02
Corrugated tubing	0.005	$19.58	$0.10
PLA	266.46	$0.02	$5.33
Total			**$46.22**

Software unit tests & System integration testing

Software unit tests were completed and passed for applicable functions in the repository. System integration testing was performed throughout the rest of the testing process, as discussed in all above testing procedures that utilized both the GUI and the mechanical/electrical components.

6. Design Iterations

Brainstormed solutions

Figure 22: All brainstormed solutions, unorganized

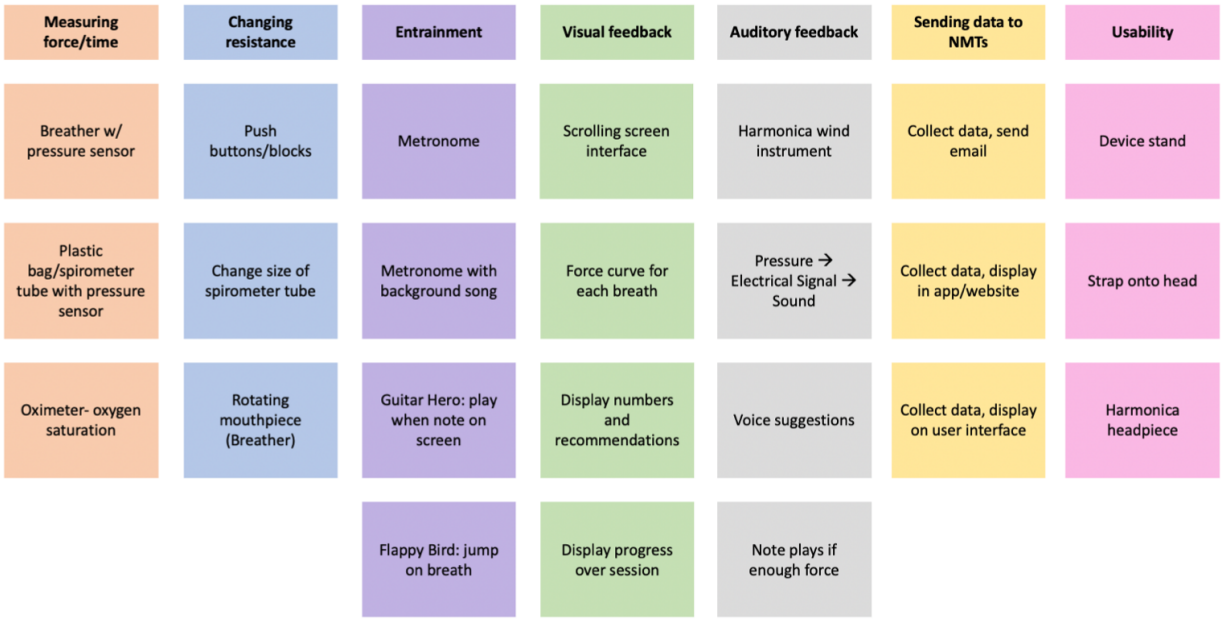

Figure 23: Organized brainstorm under the design blocks, however, unfiltered.

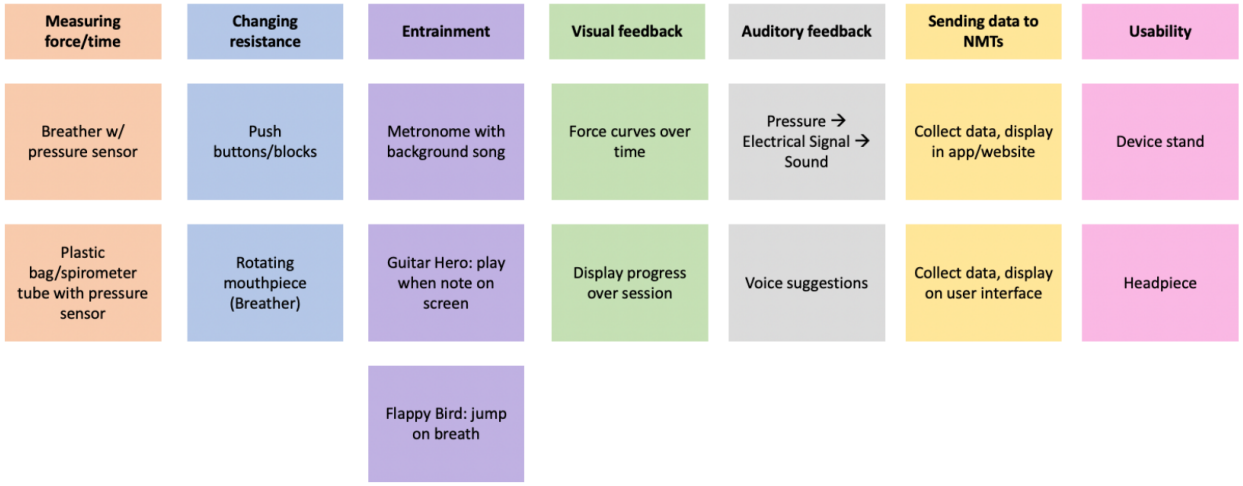

Figure 24: Organized brainstorm under the design blocks and filtered.

Decision matrices for major solutions that were pursued

These decision matrices were based off of our old user needs list. Although similar, it does vary slightly from our final user needs list. Below you will first find the primary user needs list used for scoring and the Pugh matrix used for scoring

<u>Primary User Needs:</u>

1. Improve breathing strength and cadence
    a. Discreetly modulate resistance
    b. Entrainment: tell user when and how long to breath on beat/rhythm
2. Provide feedback to patient
    a. Provide immediate visual and auditory feedback: duration, force, and recommendations
    b. Provide feedback about improvement over course of session
3. Store data and provide feedback to NMTs
    a. Collect and store average duration and force for each resistance for each session
    b. Readily display average data to NMTs
4. Ease of use
    a. Mouth fits fully around mouthpiece so patient cannot inhale through mouth
    b. User does not strain to put mouth around mouthpiece
    c. Adjustable/replaceable mouthpiece
    d. Patient does not have to hold device
    e. Battery is easily replaceable by NMTs/family members

5. Durability and cost
    a. Produce good sound quality
    b. Device should survive 3 ft drop
    c. Fully charged device should function for 2 hours
    d. Device should function for 2 years
    e. Affordable

Table 7: Pugh Matrix for score based decision making on our top brainstormed ideas

User Needs	Weight	Plastic bag spirometer tube w/ pressure sensor, rotating mouthpiece, flappy bird, display progress over session, electrical sound, collect data and display on app, head piece	Breather w/ pressure sensor, rotating mouthpiece, guitar hero, force curves over time, voice suggestions, collect data and display on app, head piece	Breather w/ pressure sensor, push buttons, metronome, force curves over time, voice suggestions, collect data display on user interface, device stand	Breather w/ pressure sensor, push buttons, metronome, display progress over session, electrical sound, collect data and display on user interface, device stand
Improve breathing strength and cadence	5	2	3	4	1
Provide feedback to patient	4	3	4	4	3
Store data and provide feedback to NMTs	2	4	3	3	3
Ease of use	3	1	3	4	4
Durability and Cost	1	2	3	4	4
Total		35	49	58	39

Low, mid, and high-fidelity prototypes

Ideation:

Our proposed solution for the low-fidelity prototype was a “Breather” w/ pressure sensor, push buttons, metronome, force curves over time, voice suggestions, collect data + display on user interface, and a device stand.

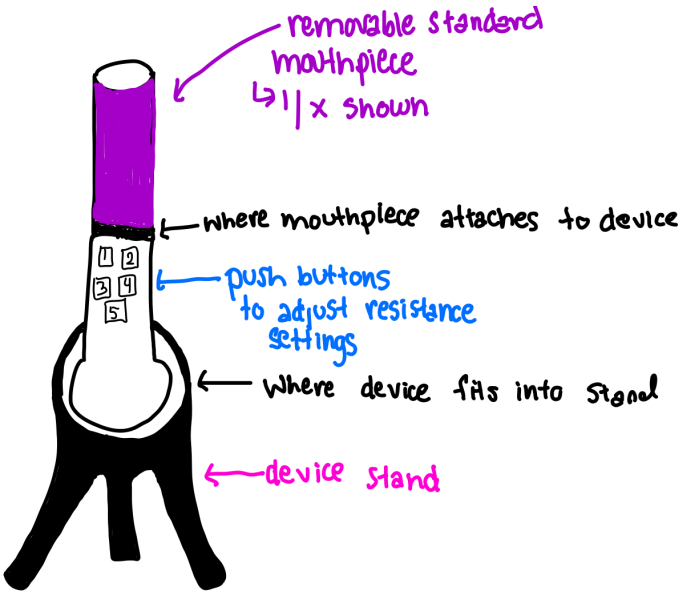

Figure 25: Proof of principle of the physical device

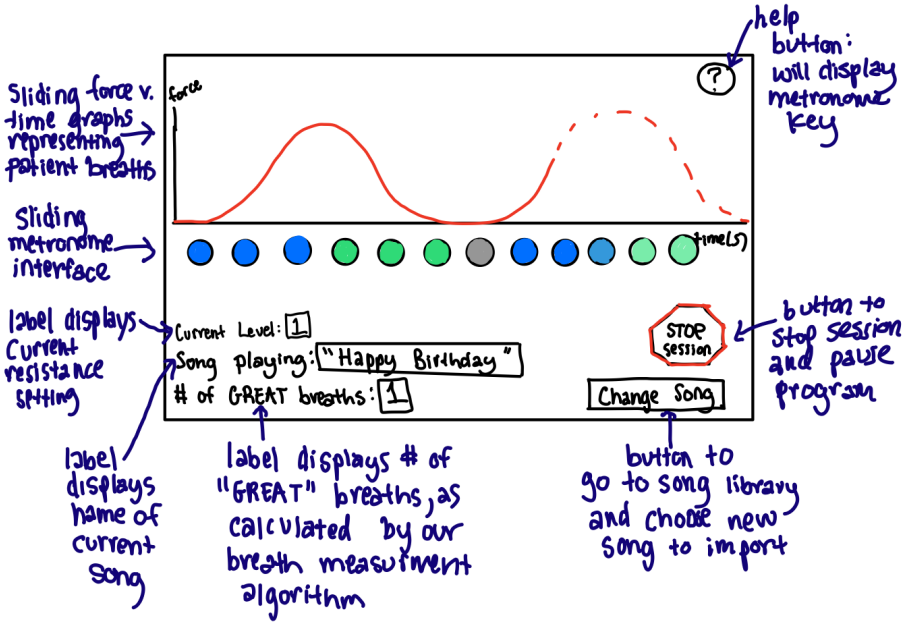

Figure 26: Proof of principle of program GUI

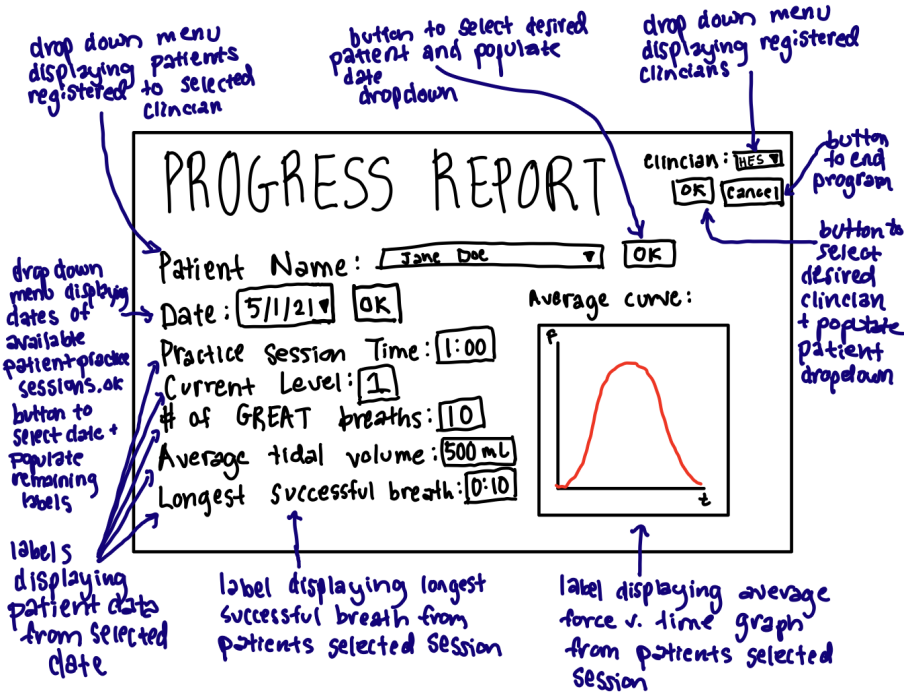

Figure 27: Proof of principle of GUI progress report

Low-Fidelity:

In the low-fidelity phase of prototyping, we create "looks like" and "feels like" prototypes of the device and GUI, seen below.

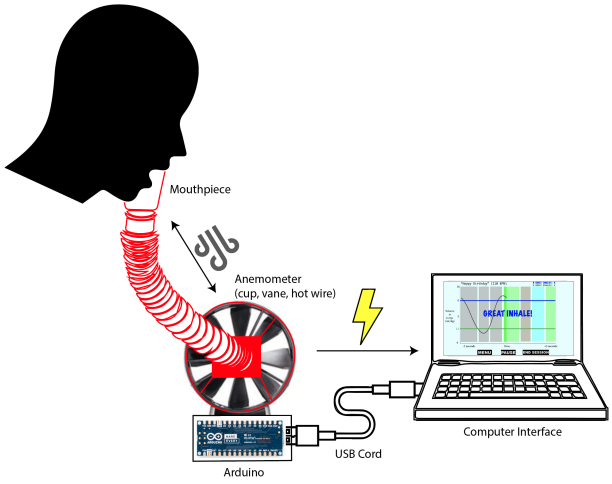

Figure 28: "Looks like" prototype of device, including mouthpiece, tube, anemometer, Arduino, USB cord and GUI

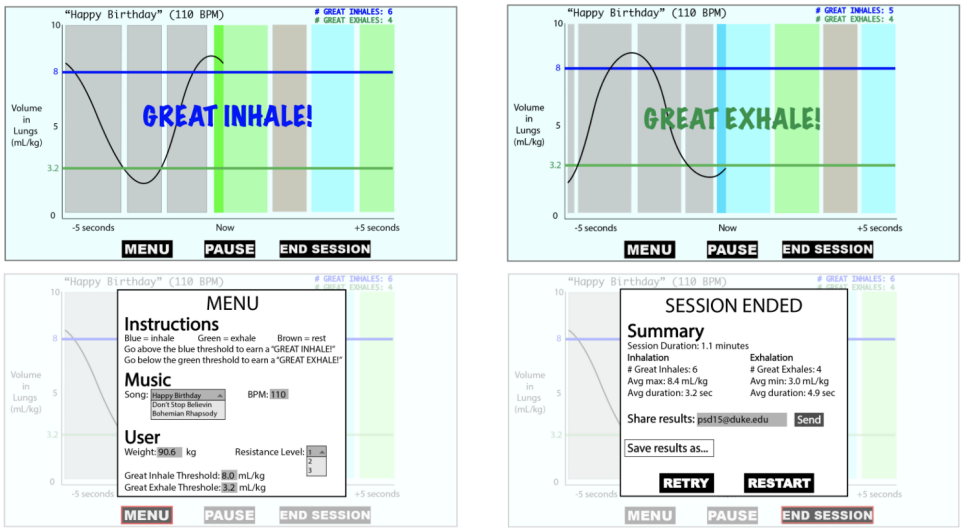

Figure 29: "Looks like" prototype of GUI, showing four different functionalities

Mid-Fidelity:

In the mid-fidelity phase of the prototype we continued making "feels like" prototypes and began making "works like" prototypes as well. For the electrical components, we decided on a sensor and using a microcontroller (Figure 30). For the Software components, very early stage GUI with placeholder buttons were created (Figure 31). For the CAD components, a very early stage enclosure was made on OnShape, however, the design was never printed (Figure 32).

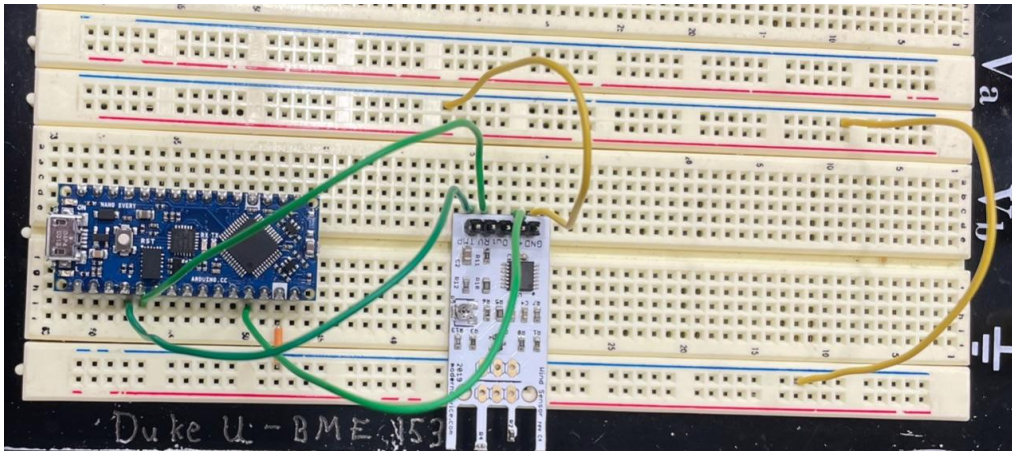

Figure 30: Mid-fidelity sensor and the Arduino

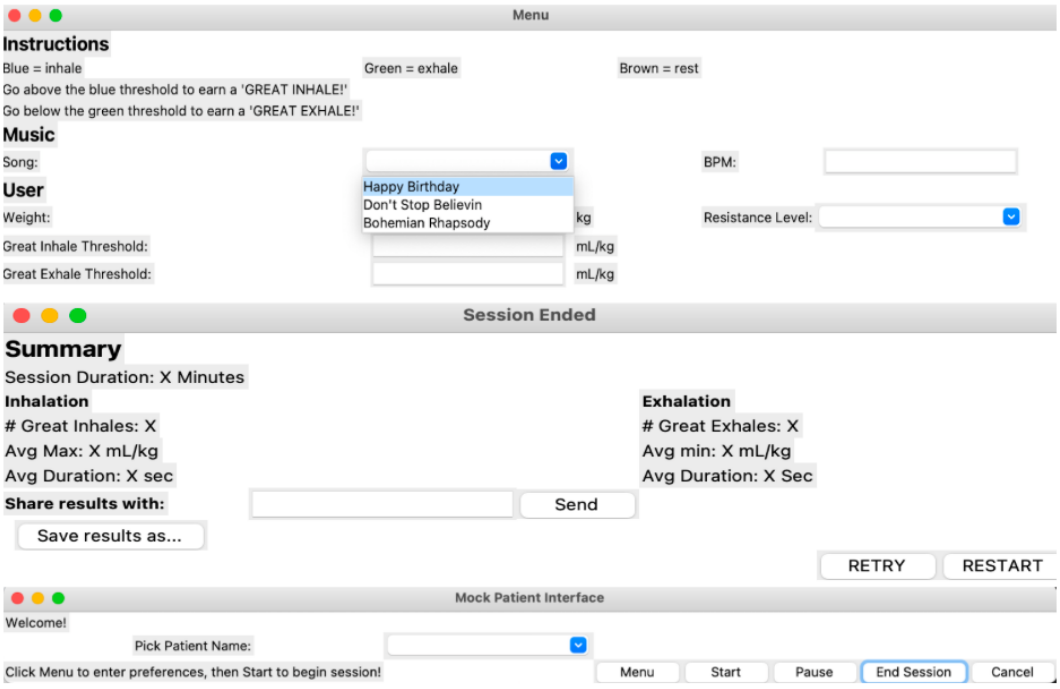

Figure 31: Mid-fidelity user GUI. Push buttons are just placeholders.

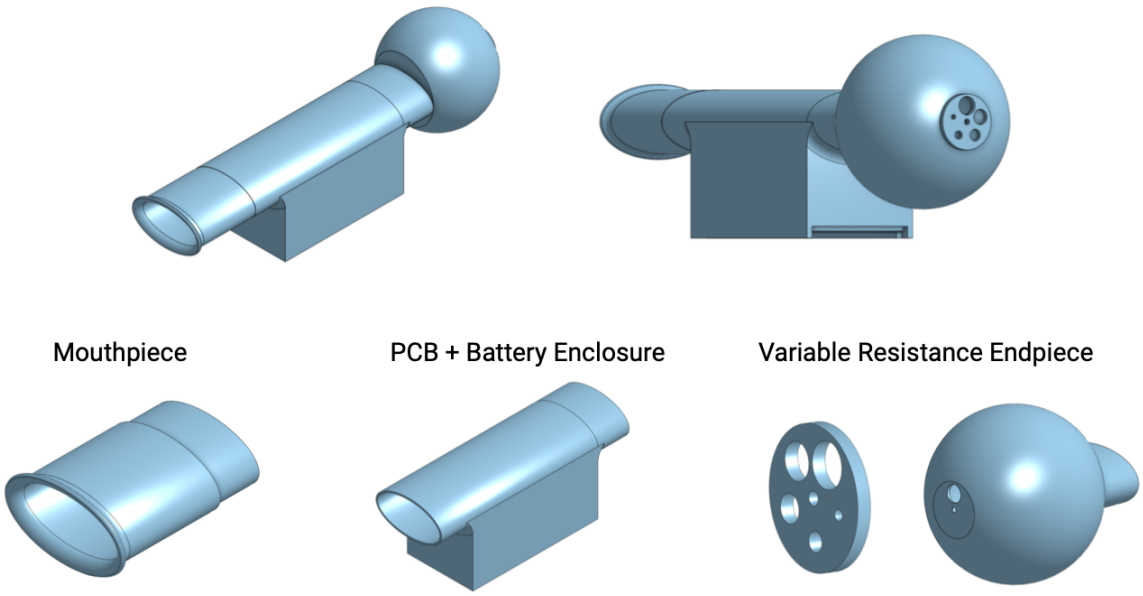

Figure 32: Mid-fidelity CAD design. Was never printed or tested.

High-Fidelity:

The high-fidelity prototype was close to the final design. The electrical, software, and CAD components were integrated together, shown fully functioning in the figure below. A long tube was used for ergonomic reasons, allowing the user to sit up right without craning their neck.

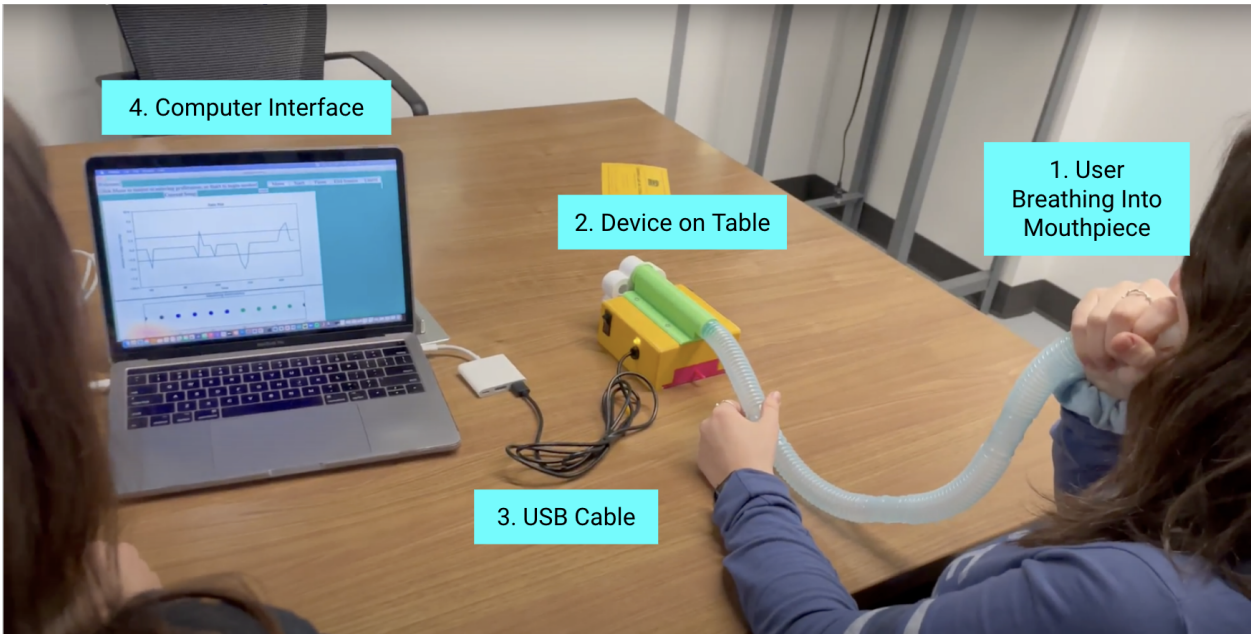

Figure 33: High-fidelity completed and assembled design.

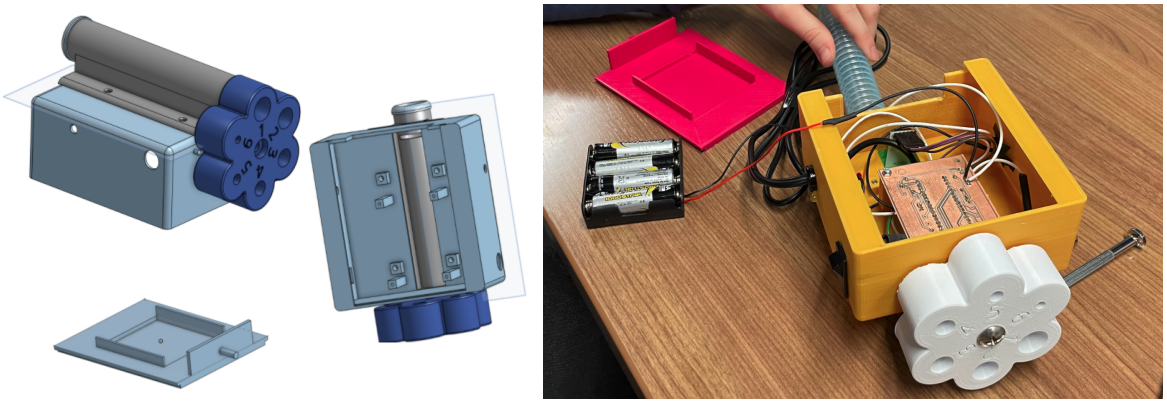

Figure 34: High-fidelity CAD design (left) and soldered PCB within enclosure (right).

Roadmap to Final Prototype:

The changes between the high-fidelity and final prototype were based on our discussions with the NMTs as well as with Dr. Palmeri after our high-fidelity presentation. Visual aspects (button sizes, colors, and text boxes) of the GUI made up most of the noticeable changes, as well as the minor CAD alterations to make the pieces easier to remove and clean. A shorter tube was used because preliminary testing revealed large inaccuracies since the temperature and wind speed of a breath changed drastically before reaching the sensor when a long tube was used. The final integrated design is shown below.

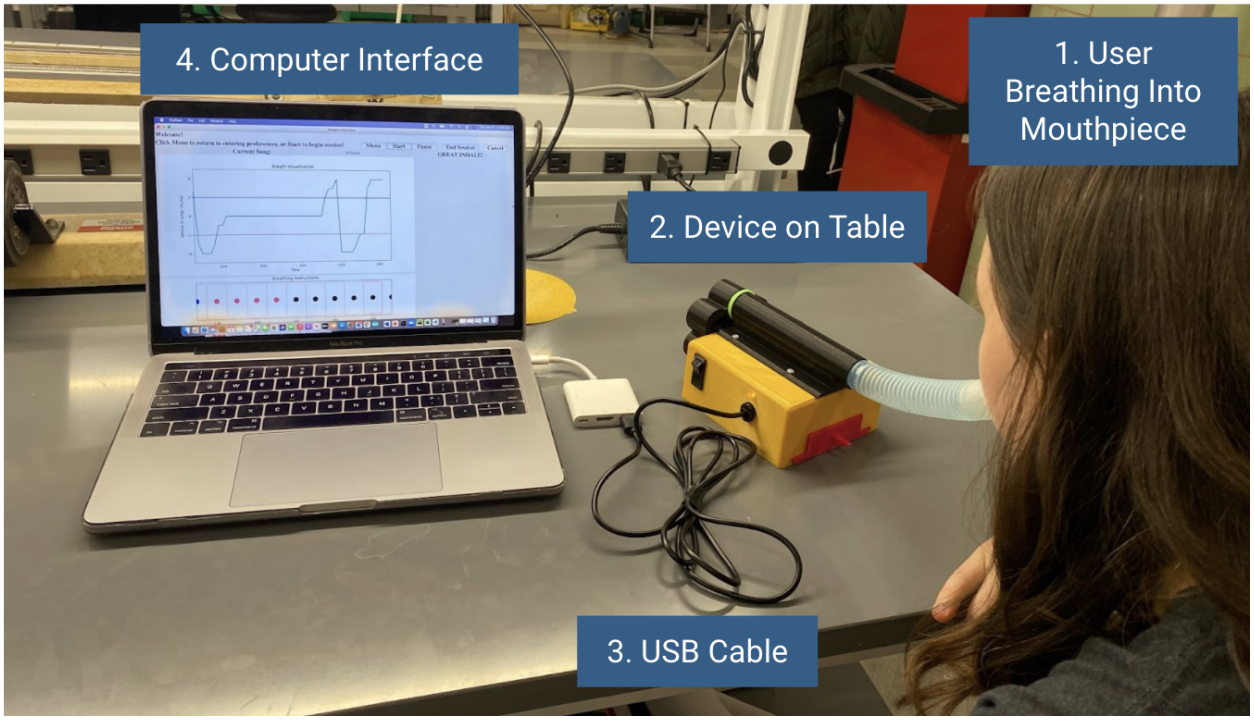

Figure 35: Final assembled design.

For a future design, a few improvements could be made. For the hardware, a more robust sensor that does not use temperature (which can fluctuate drastically between patients and uses) could be used to decrease feedback delay. For the GUI, an algorithm that crafts treatment plans based on results of previous sessions could be designed in addition to an algorithm that informs the patient if their breaths are on beat or not. A simple zip file and user guide could be created for easy software installation, and audio cues for inhaling and exhaling could be added to the GUI. Finally, given the difficulties with the tkinter GUI package, a different, more robust package could be used in the future. As for the enclosure, a stand could be designed to ensure that the patient does not have to crane their neck when the device is sitting on the table. Smaller resistance holes can be made to increase the force with which patients must breathe, and an encoder or motor could be used to electrically match the resistance level on the physical device and on the GUI. Finally, the sensor could be physically isolated in the housing to ensure quick and easy removal/replacement.

7. Regulatory (public health, safety, and welfare)

Hazard Analysis

Table 8: Hazard Analysis

Hazard	Cause(s)	Effect(s)	Probability of Occurrence	Severity	Risk Index	Acceptable?	Mitigation Plan
Patient inhales water droplets	Condensation in tube	Patient must cough up water	Occasional	3	11	Acceptable upon completion of quality assurance review	GUI asks patient to wash and dry tubing every 2 sessions
Choking hazard	Third party (child, pet) places object into box/tube	Patient has obstructed airway	Improbable	1	12	Acceptable upon completion of quality assurance review	Secure removable parts of device with child and pet-safe systems
Patient inhales hazardous particles	Mold, mildew, or viruses collect on filter and patient gets sick	Patient becomes ill	Occasional	2	10	Acceptable upon completion of quality assurance review	GUI asks patient to wash and dry tubing every 2 sessions and to replace filter every 2 weeks
Enclosure cuts patient	Piece of plastic is scraped off or inner component is too sharp while battery is being changed	Patient has a cut	Remote	3	14	Acceptable upon completion of quality assurance review	Bevel/fillet all sharp edges in and on device
Patient loses consciousness	Patient misreads or does not understand breathing instructions and breathes too much/ too little themselves	Patient could injure themselves	Remote	1	8	Undesirable: Written and reviewed decision required to proceed	Device detects if breaths have become too shallow, deep, or fast and encourages user to promptly stop using device
Burn hazard	If the wiring on the PCB	User receives a	Improbable	2	15	Acceptable upon	Ensure that no wires or

	comes loose, the Arduino can short and overheat the entire board and wiring. The patient has access and could accidentally touch these wires	minor burn				completion of quality assurance review	electrical components are accessible to user except for heat-wrapped wires attached to the battery pack
Shock hazard	If the wiring on the PCB comes loose, a circuit component can short and potentially shock a patient, if the patient attempts to access the component	User receives a minor shock	Improbable	2	15	Acceptable upon completion of quality assurance review	GUI encourages patient to turn off device when it is not in use

Failure Mode and Effect Analysis (FMEA) (safety)

Table 9: FMEA

Potential Failure Mode	**Cause(s)**	**Effect(s)**	**Probability of Occurrence**	**Severity**	**Risk Index**	**Acceptable?**	**Mitigation Plan**
Arduino or other circuit component blows out	Wire breaks loose from PCB or external component, or two metal components touch, shorting the circuit	Arduino or other circuit component heats up, device no longer functions as it should	Remote	3	14	Acceptable upon completion of quality assurance review	Ensure that all components are securely attached to the board and that heat shrink is used to prevent undesirable electrical connections
Connection between	Patient, physician, or	The Arduino	Improbable	3	17	Acceptable without	N/A

device and computer becomes loose	someone else shakes the wire too much and it disconnects from Arduino	does not send any Serial data to the computer				review	
Device breaks from a fall or being thrown	The loose wire could accidentally be pulled or tripped on and pull the device off the table. A child could also mistake the device as a toy and throw it around.	Wiring in the device comes loose and component shorts, so the device can no longer output accurate data to GUI. Filter or battery pack falls off and is not replaced.	Occasional	3	11	Acceptable upon completion of quality assurance review	Ensure that all components are secured to the box and cannot fall off via a fall. Create a user guide that explains what steps should be followed to re-set up device if parts fall out/off.
Hole in the tubing	Wear and tear or tubing could be punctured by a sharp object, like scissors	Lets air escape before reaching sensor, preventing accurate readings	Remote	3	14	Acceptable upon completion of quality assurance review	Provide extra tubing for patient to replace ripped tubing with
Beats on device speed up or slow down more than they should	Tkinter program malfunctions and prints beats at the wrong times	Patient cannot follow the prescribed beats, resulting in a lower session score than expected	Improbable	2	15	Acceptable upon completion of quality assurance review	User manual provides steps for resetting the program to fix GUI malfunctions
GUI does not output patient's true breaths (breath vs no breath, inhale vs exhale)	Device is not calibrated correctly or tkinter program malfunctions	GUI does not accurately capture good inhales/ exhales and outputs an incorrect	Remote	2	14	Acceptable upon completion of quality assurance review	GUI allows the user to restart the session and redo calibration. User manual provides steps for resetting

		session score					the program to fix GUI malfunctions
Resistance level is incorrect on device or GUI	Patient sets resistance number incorrectly on device or GUI	Session score is not accurate and NMTs prescribe wrong treatment plan	Occasional	3	11	Acceptable upon completion of quality assurance review	Before starting program, GUI aks if patient has selected correct resistance level

Fault Tree Analysis (top 3 risks)

The main overarching risk identified was a patient fainting or getting physically harmed in some way by the device. The three main risks leading to this are a patient choking or inhaling particles, a patient becoming overly exerted during breathing exercises, and a patient getting burned or shocked by electrical components. A Fault Tree Analysis is shown below.

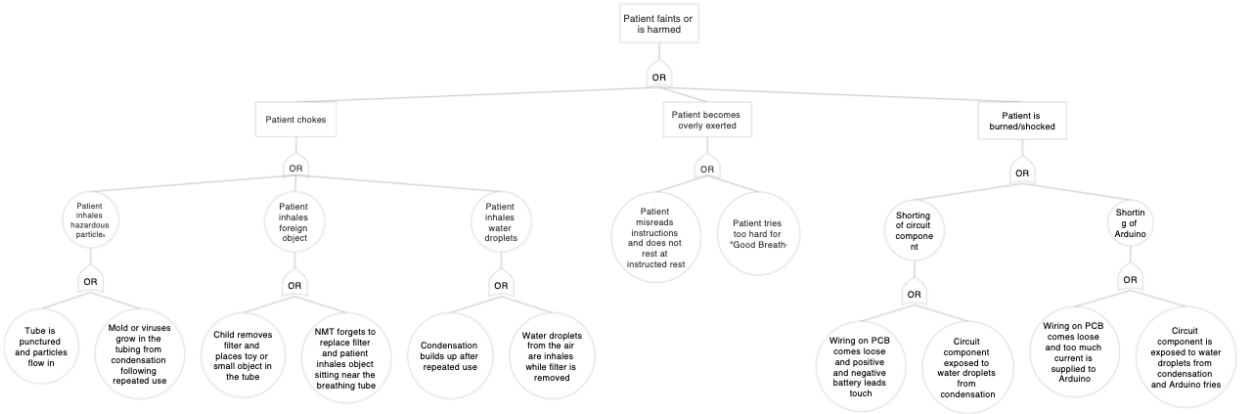

Figure 36: Fault Tree Analysis with top three risks

Discussion of other regulatory considerations on a path to FDA 510k clearance

Public Safety

In order to address public safety concerns, the device has been evaluated according to ISO standards 60601 and 62304. Furthermore, a hazard analysis and failure mode and effects analysis were performed to identify and mitigate risks. FDA compliance is also necessary.

According to the FDA device database, the Breather is classified as a therapeutic incentive spirometer, which is a Class II device that qualifies for 510k clearance[14]. Our proposed design would also classify as a Class II device that qualifies for 510k clearance if we are able to

demonstrate significant equivalence to another U.S. marketed device. Due to the presence of numerous electronic incentive spirometers on the market, the likelihood of demonstrating that our device has the same intended use and technological characteristics of the predicate is high.

Additionally, our device would not require the pre-market authorization that is characteristic of Class III devices. Instead, it would rely heavily on a robust quality management system (QMS) that defines how parts are manufactured, purchased, and inspected prior to assembly. ISO 13485 defines the requirements for a QMS for electronic medical devices similar to our Class II device. Our QMS would need to take into account documentation requirements, management responsibility, quality policy regarding overall organization and distribution of our device, management reviews, product realization planning, customer-related processes, resource management, design and development processes with an emphasis on FMEA and hazard analysis, production and service provision, measurement analysis, and continuous improvement[15].

Public Health

Regaining of normal respiratory capacity and endurance is an important indication of recovery for our patient population. Despite prescriptions from a medical professional to perform incentive spirometry and other breathing exercises, compliance remains low among these patients due to a lack of appeal factors with the current on-market devices. Thus, patients suffering from dysarthria and other neurological conditions hampering respiratory function continue to suffer a decreased quality of life.

Our proposed solution to this problem cultivates a more enjoyable user experience through the use of entrainment and the inclusion of real-time and long-term patient feedback. Although we anticipate increased compliance will lead to improvements in respiratory capacity and endurance, a number of health risks could arise if the device is used improperly. For example, if the device filter is removed for cleaning and the NMT fails to replace it, the patient could ingest foreign particles through the end of the breathing tube. Patients could also be negatively affected if they misread breathing instructions and become overly exhausted during a session. However, by taking these potential risks and failure modes into account and performing the relevant FMEA and Hazard Risk Analysis, we can minimize these outcomes among the target population.

In order to test our device on the target population, we would require IRB oversight, as it would involve research and human subjects. Testing our device among patients with severe medical conditions and assessing its impact on their compliance levels and respiratory function falls under the category of “research on human subjects.”

Public Welfare:

We believe that by making the patient experience more enjoyable through real-time feedback and entrainment, patients will be more likely to engage in breathing exercises prescribed by medical professionals. No data is stored on the device, but rather it is saved in a

text file on the user's computer. Thus, there are no ethical concerns regarding data privacy. In the future, we intend on sending patient feedback following a session in an email to the NMTs, which would require further ethical considerations. In addition to the proposed immediate public health and safety concerns associated with our device, the design has the potential to mitigate stress associated with the NMTs having to constantly remind and explain to patients how to perform their exercises. We hope that by creating an entertaining, easy to use process, NMTs will no longer have to remind patients to use the device, and can devote more time to creating treatment plans based on patient improvement.

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