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The Second Wind

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The Second Wind

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Client: Dr. Rajeev Bhatia

Biomedical Engineering Design 4800:492-001

Honors Project Report

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Table of Contents

Table of Contents	1
1. Abstract	3
2. Description of the Project Problem	3
3. Background	3
4. Design Requirements	4
5. Testing	4
6. Business Aspects	4
6.1 Competition	4
6.2 Advantages	5
6.3 Market Analysis	5
7. Final Implementation	5
7.1 The Mechanical System	5
7.2 The Electrical System	6
7.3 The Software	6
8. Deliverables	6
9. Scope of Work Excluded	7
10. Performance Test Results	7
11. Progress	8
12. Individual Contributions	8
13. Financial Considerations	9
14. Summary Feasibility Discussion	9
15. Future Work	9
15.1 Downsizing	9
15.2 Durability	9
15.3 Accuracy	9
16. Discussion	10
16.1 Issues	10
16.2 Workload	10
16.3 Purchasing	10
16.4 Testing	10
16.5 Report writing	10

16.6 Mentorship	11
16.7 Lessons learned	11
16.8 Improvement of the course	11
17. References	12
18. Appendices	13
Appendix A: CAD Drawings in inches	13
Appendix B: Circuit Drawing	19
Appendix C: Design Testing Matrices	20
Appendix D: ANSYS Finite Element Analysis	24
Appendix E: Device Comparison Test Outputs (Validation Tests 1.1-1.3)	25
Appendix F: Fully Assembled Device	32

1. Abstract

The Second Wind device is a set of sensors and a data processing unit capable of recording data necessary to conduct a simplified version of a complex cardiopulmonary stress test (CPET). This data includes VO_2 , VCO_2 , ventilation, and pulse oximetry data. VO_2 and VCO_2 are the percent, by volume, of oxygen and carbon dioxide in the patient's breath, spirometry is the measure of air flow, and the pulse oximetry data includes heart rate (HR) and percent oxygen in the blood (SpO_2). In addition, the device was designed to be portable, so this test could be run from patients' homes or other smaller facilities rather than the usual hospital setting.

2. Description of the Project Problem

Medical professionals in pediatric respiratory care facilities must be prepared to diagnose and treat many respiratory complications within their patient population. One of the tools used is the complex cardiopulmonary stress testing. The test is noninvasive and typically performed in a hospital respiratory therapy center [4]. However, there can be difficulties scheduling around students' academic calendars as well as parents' calendars. Dr. Rajeev Bhatia, the client for this project, is the Medical Director of the Clinical Exercise Physiology Lab at Akron Children's Hospital as well as a Pediatric Pulmonologist. With his assistance, we have worked to design *The Second Wind*: a portable measurement device for use at home that records a patient's VO_2 , VCO_2 , ventilation, heart rate, and percent oxygen in blood during an exercise test and exports the data as graphs for the physician.

There are four advantages of portability for a ventilation device. The first is that patients would no longer need undergo the burden of traveling to a hospital or medical facility to perform the test. Second, patients can plan their tests around their own schedules. Third, doctors like Dr. Bhatia can monitor more patients' progress within less time. Instead of the process of scheduling 1 patient at a time to perform the full test in the hospital, a nurse or technician from a medical device company can monitor and help perform the test outside of the hospital. Finally, patients can experience less anxiety by performing their tests in the comfort of a familiar environment.

3. Background

Over forty million people have been diagnosed with respiratory diseases in the United States alone; many of whom are children suffering from ailments such as chronic obstructive pulmonary disease, asthma, and other similar diseases [2]. One method of tracking a patient's respiratory health is through an CPET. The device used for this test obtains VCO_2 , VO_2 , ventilation, and pulse oximetry data. Additionally there are other variables that the hospital device measures but were considered to be out of scope for *The Second Wind* due to time and budget considerations. The test itself is a 25-minute examination of a patient's breathing while performing exercise on either a treadmill or a stationary bicycle. Throughout the test, the difficulty of the exercise is increased by incrementally increasing speed and incline/resistance depending on whether a treadmill or stationary bicycle is used for the test. The doctor can then

analyze the graphs to monitor and make decisions for the patient. *The Second Wind* has been designed to help pediatric respiratory patients by providing an at-home version of a full hospital test. These at-home tests would not be an alternative for the full test but rather a supplement. For the purpose of this project, this paper will only discuss tests conducted on a treadmill.

4.Design Requirements

The team interviewed the client and collected a list of customer requirements. These were then translated into project requirements and used to set validation criteria. A complete list of customer requirements and project requirements can be found in appendix C. The top priorities of the project were to develop a portable device to measure VO_2 , VCO_2 , ventilation and pulse oximetry data. The device must create graphs using the collected data and export the graphs thereafter. The required graphs were as follows: Max Pred VO_2 (HR vs VO_2), Max Pred HR (HR) and VO_2/HR vs VO_2 , VCO_2 vs VO_2 , ventilation exhaled (VE) vs VCO_2 , VE/VO_2 and VE/VCO_2 vs VO_2 , VE vs VO_2 , and SpO_2 vs VO_2 . The device must be portable, therefore it must be small and light enough to be easily transported by only one person from home to home. Additionally, the prototype must cost less than the \$500.00 budget given.

5.Testing

The primary testing was to ensure that the data from *The Second Wind* was comparable to the data of the hospital device. To do this, a volunteer performed identical exercise test protocols at two separate times, once with the hospital equipment and once with *The Second Wind*. This testing ensured no differences due to different patients performing the tests. The data collected was processed and graphs were generated outlining the test. Dr. Bhatia considered the two sets of data comparable in terms of the values being recorded and the trends the data showed. In the end, Dr. Bhatia deemed the data from *The Second Wind* to be comparable within an acceptable margin of error to the hospital data. A full list of tests performed and their results can be found in both the Verification Testing Matrix and the Validation Testing Matrix in Appendix C. Additionally, graphs outlining the results of the comparison, listed as Tests 1.1-1.3 in the Validation Testing Matrix, can be found in Appendix E.

6.Business Aspects

6.1 Competition

The device has a minimal market competition. Of similar products, our device is one of few that meets the criteria set by our client. Although there are other devices on the market, we are going to focus on the two that come closest to accomplishing our client's criteria.

The VO_2 Master Pro is a device that measures VO_2 and ventilation, but not VCO_2 of the user. The device is fully portable, able to be taken outside, connects to a cellphone via bluetooth, and gives the user live data feedback. The market for this device consists of mainly athletes monitoring their performance, and costs the user \$5,000 [1].

The other device that performs a function similar to ours is the CardioCoach, which only measures VO_2 output. This device is designed for home and gym use, but is not portable and requires the user to be connected to large device. It is used to “[check] fitness based on oxygen consumption”. The company, KORR Medical Technologies Inc., markets this device to athletes and fitness trainers to monitor users while they exercise on a treadmill or bike in a gym setting and costs \$12,000 [3].

6.2 Advantages

The Second Wind has the ability to measure VCO_2 , VO_2 , ventilation and pulse oximetry data. This makes our product stand out from the competition. The VO_2 Master Pro is fully portable, but does not record all of the data that are needed for a respiratory test. Our device is portable, and measures all the data needed for a simplified CPET. *The Second Wind* then utilizes the BioRadio as a wireless transmitter to send raw data via bluetooth to a computer, with a 10 second delay for live data. Data captured in this way is then saved to a location of the user’s choosing on the computer being used.

6.3 Market Analysis

Upon first inspection, the market for *The Second Wind* is the healthcare industry. More specifically, respiratory care specialists who provide care and monitoring for either a large volume of patients or with patients that cannot easily access testing facilities and therefore would prefer a technician to make a home visit. *The Second Wind* could easily become standard equipment in any given hospital, care center, rehabilitation center, or any medical center or institution that is concerned with respiratory health.

While this could be a substantial market for *The Second Wind*, there is also great potential in the athletic training market. *The Second Wind* could be a relatively affordable alternative to equipment currently on the market. Eventually, *The Second Wind* could be sold to and distributed by Durable Medical Equipment (DME) companies in order to enlarge product reach and even transform *The Second Wind* into a ‘household name’ of hospitals and care facilities globally.

7.Final Implementation

The final design can be split up into three main parts, the mechanical system, electrical system, and the software. Fully assembled and worn device can be seen in Appendix F.

7.1 The Mechanical System

In the mechanical system, the headset is made of three adjustable elastic straps which allow for a tight fit on many different head shapes and sizes, as well as two plastic pieces which hold the straps in place and support the mounting arms. The mounting arms consist of two 3D printed arms that slant inwards in order to follow the curve of the patients face, see the *Full Mount Assembly* in Appendix A for reference. The arms can be broken down into two pieces by removing a locking pin, in order to allow for better ease of transport. The end of the arms have slots that allow for the adjustment of the spirometer holder, for different body sizes, which keeps the spirometer and other sensors in a stable position relative to the head. On the inlet of the

spirometer, the spit catcher and mouthpiece are attached and rest near the patient's mouth. The outlet of the spirometer has the mount for the CO₂ and O₂ sensor attached and the connection is sealed with a rubber gasket both in order to prevent leaks and to more securely hold the sensors in place. The last part of the mechanical system is the chest mount that consists of a metal plate with two straps that go vertically over the patient's shoulders and one that goes horizontally around the patient's chest. Attached to the metal plate is a piece of PVC pipe which is used to support the spirometer so that it does not fall during movement while exercising. The pipe has an adjustable angle which can be changed by adjusting the tightness of a screw at the bottom. The drawings for the full system can be found in Appendix A.

7.2 The Electrical System

A full diagram of the electrical system can be found in Appendix B. The system consists of an arduino, which is used to provide a constant voltage of 5V to the O₂ sensor and 3.3V to the CO₂ sensor. The CO₂ sensor used is the ExplorIR®-W 100% CO₂ Sensor and the O₂ sensor is the UV Flux 25% Oxygen Smart Sensor. These sensors were chosen because they were small enough to fit in a mount at the end of the device and were able to be purchased within budget. The sensors feed their voltage output data to the BioRadio through a pair of voltage dividers consisting of two one mega-ohm resistors. The divider is necessary because the sensors output voltage up to 3V while the BioRadio can only process up to 2V. The BioRadio feeds the data to the computer in real time during the test through bluetooth.

7.3 The Software

The software portion of the design consists first of the BioRadio BioCapture software which captures %O₂, %CO₂, ventilation, and pulse oximetry directly from the device. From there this data is imported to the data processing application created for *The Second Wind* in Matlab. In the data processing application, the raw data is analyzed and filtered to produce VO₂ and VCO₂ data [5]. Within the application, users can choose to view the data received in the form of a variety of different graphs before the data is exported to ensure everything is appearing as it should. Additionally, here the user can input the date, name of the patient, height, weight and other such data to be included in the .zip that is output from the application. Once the data has been processed and exported, all data on the application itself is deleted as to protect the patient's information.

8.Deliverables

The deliverables are listed as follows:

- CO₂ sensor - measures %CO₂ in air
- O₂ sensor - measures %O₂ in air
- Mount for CO₂ and O₂ sensors - connects CO₂ and O₂ sensors to the main assembly
- Arduino - acts as device power supply
- Custom circuit board - steps down the output voltage of CO₂ and O₂ sensors

- Box for holding Arduino and circuit board - ensures power supply is completely contained
- Mouthpiece - Primary patient interface
- Head mount - Supports and positions the device
- Chest mount - Supports the device and prevents device rotation
- Data processing software - processes raw data into graphs that are exported into a .zip file

9.Scope of Work Excluded

The test *The Second Wind* has been designed to perform is a simplified version of a full CPET. A full CPET includes the following measures in addition to the values *The Second Wind* acquires: peak oxygen content, ventilatory anaerobic threshold, maximum heart rate, heart rate reserve, blood pressure, O₂ pulse (VO₂/HR), and ventilatory reserve [6]. Working with our client, we decided that due to the fact *The Second Wind* performs a supplementary role, the full test and all variables would not be necessary. Only the most important variables for the test, as ranked by our client, were chosen to be used in the final design. These variables being VO₂, VCO₂, ventilation, HR, and SpO₂. While not measure directly, both the maximum heart rate and O₂ pulse are values that can be calculated from the data acquired.

Original aspects of the project that had to be removed due to time and budget constraints are as follows. Firstly, the current version of the device is unable to calculate VO₂ Max, a datapoint useful in determining respiratory health. While this datapoint is important for the physician, it is often more useful to have a trained specialist locate this point on their own because a program could often falsely identify it. Secondly, as opposed to *The Second Wind* data processor collecting data directly from the BioRadio, we are currently gathering data with the BioRadio data capture software and then uploading that data to the data processor. This is due to the fact that, in the future, the device will be made smaller and not depend on the BioRadio. Therefore it is preferable that the data processor not be dependent on any BioRadio hardware or software.

10.Performance Test Results

As mentioned above in section 5, Testing, the data gathered from *The Second Wind* was deemed to be acceptable. While the data was not perfect, it was within the needs established for an at-home device. The error that was still present in *The Second Wind* was primarily due to electrical and mechanical noise, making the data difficult to analyze. In future versions of the design, it is recommended that noise from static and noise created at connection boundaries be dampened both physically and in the data processor to get clearer outputs. Additionally, while only one data point per second was the minimum required for the CO₂ and O₂ sensors, higher sampling rates would continue to make the data more accurate.

The headmount model was analyzed using a finite element method analysis program known as ANSYS version 17.2. It was modeled as a static structural model with fixed supports

on the inside of the head mount clovers. A force of 7 pounds was applied to the top face of the spirometer mount. The material properties of the model had the Young's Modulus and poisson's ratio of the Raptor PLA plastic used when the head mount was printed. The model solutions for displacement and equivalent stress were calculated. These figures are located in Appendix D. The maximum stress did not exceed the materials given yield strength. Therefore, the material should not break under the normal load of the device. This analysis was done in place of potentially destructive testing to prevent any damage that may have come to the device.

11. Progress

The Second Wind progressed significantly this year. The main objective was translating required specifications into a proof of concept. Nearly all of the original requirements were met with the first prototype and the device met all of the functional requirements. However, there were some alterations to the design of the head mounting device. While 3-D printed material could handle the forces applied to it without breaking the elastic adjustable straps stretched under the weight of the device, the stretching resulted in the displacement of the mouthpiece for the device. To correct, an additional chest mount was created to assist in the fixation of the device. In a future iteration, the chest mount could be taken out of the design making the device even more comfortable and easier to assemble.

12. Individual Contributions

The Second Wind team consists of the following:

Captain: Dana Faulkner

Modeling Engineer: Kyle Christie

Software Engineering: Logan Neidert

Electrical Engineering: Jacob Heiss

Financial Management: Alexandria Smith

These titles show the main tasks each team member focused on throughout development. However, as a small design team, our tasks overlapped immensely. Dana was the appointed leader of the team keeping the team on time for deadlines, she kept everything organized for the team with meeting times and what we should be working on. She also was the head of concept generation that we finalized for the second semester. Kyle mainly dealt with the finalized prototype idea, modeling it in SolidWorks, fine tuning the physical design, and then making adjustments when problems were found with the device. Logan wrote the software that performed the calculations on the data collected and displayed the final version to the user for their ease of viewing. He also performed research on the existing hospital device to ensure necessary design considerations were met to make the *The Second Wind* yielded similar data to the pre-existing hospital device. Jacob designed the electrical system for the device, including the specifications and performance of the sensors, the connections between sensors, power supply, and physical data collection. He additionally acted as the main point of communication

between the design team and Dr. Bhatia. Alex mainly handled the documentation of the device, the work done by the design team, and the DHF. She also made the purchase requisitions that were needed during the time of creation.

13. Financial Considerations

For the prototype, there are components that would not be present in a final product. These components include a chest mount, a BioRadio, and BioRadio specific spirometer and pulse oximetry sensor. To replace the BioRadio, an Arduino board can be used directly with a spirometer as well as an O₂ and CO₂ sensor. These changes would reduce the production cost greatly, and also reduce the weight of the product by allowing for a much smaller spirometer.

14. Summary Feasibility Discussion

The client's need was a device that could be used in a home setting that collects similar data to the hospital version (VO₂, VCO₂, ventilation) and displays graphs for the physician to check the progress of the recovering patients without a hospital visit. The device does fulfill this need in the scope for this project at this time. Our product is a prototype due to the fact that it can be made smaller and use a different spirometer that would not require the addition of the BioRadio.

15. Future Work

15.1 Downsizing

In future iterations of *The Second Wind*, the size and weight of the device, will continue to shrink. The spirometer that is currently used can be changed to one that is much smaller. The device arms can be made smaller as well. With further development, the overall weight of the device can be reduced. The amount of wiring will also decrease when the BioRadio and BioRadio components are removed so that the only necessary wires would be going to one Arduino. This will also decrease the likelihood of users tripping or getting caught in the wires, or even accidentally detaching wires from the device.

15.2 Durability

Many parts of the device are made of 100% infill Raptor PLA, so the yield strength and life time of the device is much lower than that of metal or injection molded parts. Considering this, the durability would increase with the use of stronger materials.

15.3 Accuracy

The device currently has sensors that operate at 1 Hz. There is a short warm up time before the test should be administered to allow the sensors to stabilize. Additionally, there is a lag time in data collection due to the interfacing with the BioRadio. In future iterations, a design team could obtain sensors that are able to collect more data points per second to give more accurate data.

16. Discussion

16.1 Issues

There were a few problems when we began to work on the device. The first version of the headset was not able to support the weight of the sensors. The solution was to add a second post on the temples to prevent rotation and fix the angle. However, when the issue persisted, a chest harness and support pole, used to hold the spirometer and prevent device rotation, were added to counteract the torsion. Additionally, the BioRadio is limited to a maximum input voltage of 2 volts, but the O₂ and CO₂ sensors can produce up to 3 volts. The sensors were chosen primarily due to their sampling rates and data collection ranges. Output voltage was not a major criteria because it is easy to adjust given the proper materials. To solve this problem, we used a voltage divider to step down the signal voltage.

16.2 Workload

In the first semester we met once a week in person for a short time, and held virtual meetings over Discord, an application with features such as voice channels and messaging threads. This section of the design process was discussion based and did not require physical assembly time. For the majority of the second semester we continued to meet 2-3 times per week as smaller sub-groups working on separate tasks, and at least once per week as the full group. The division of labor in the first semester initially consisted of all team members researching our product. In the second semester, Kyle, Alex, and Dana worked on the headset and Logan and Jacob worked on the software and electrical parts of the device.

16.3 Purchasing

The main purchasing obstacle that was encountered over the course of the project was that the cost of the two sensors used was the majority of the budget. Because of this, the team had to be very mindful of the remaining budget.

16.4 Testing

The initial test of the device was jogging in place to make sure that the system did not fall apart as a patient was moving. The device was able to pick up signal but there was a lot of noise that was soon mitigated within the data processor through the use of a low-pass filter. The next test was a comparison of the hospital's device with *The Second Wind* using the same exercise type and test protocol to compare the data. This was accomplished by performing a full exercise test to exhaustion first at Akron Children's Hospital and at The University of Akron Student Wellness and Recreation Center.

16.5 Report writing

The report was written in combination by all of the members of the team. Each of us worked on sections based on our area of expertise in regards to the project. The report was then edited by each team member to ensure that it was accurate.

16.6 Mentorship

Other than from our client, Dr. Rajeev Bhatia, we did not receive any guidance from outside our department. Dr. James Keszenheimer helped the group decide on an initial direction

for a project. Additionally, he gave advice on how data could be collected as well as any other additional issues we had. Stephen Paterson assisted in regards to SolidWorks drawings to be printed successfully from the free 3D printing resources available to students at Bierce Library.

16.7 Lessons learned

A lesson that we learned is that clear and concise communication with your client is mandatory for efficiency in the overall design process. Regular updates are important to keep them informed about the progress of the device. We also learned to pay careful attention to dimensions in order to decrease time changing the dimensions of parts in drawings and reprinting parts. Thus, decreasing the overall build time.

16.8 Improvement of the course

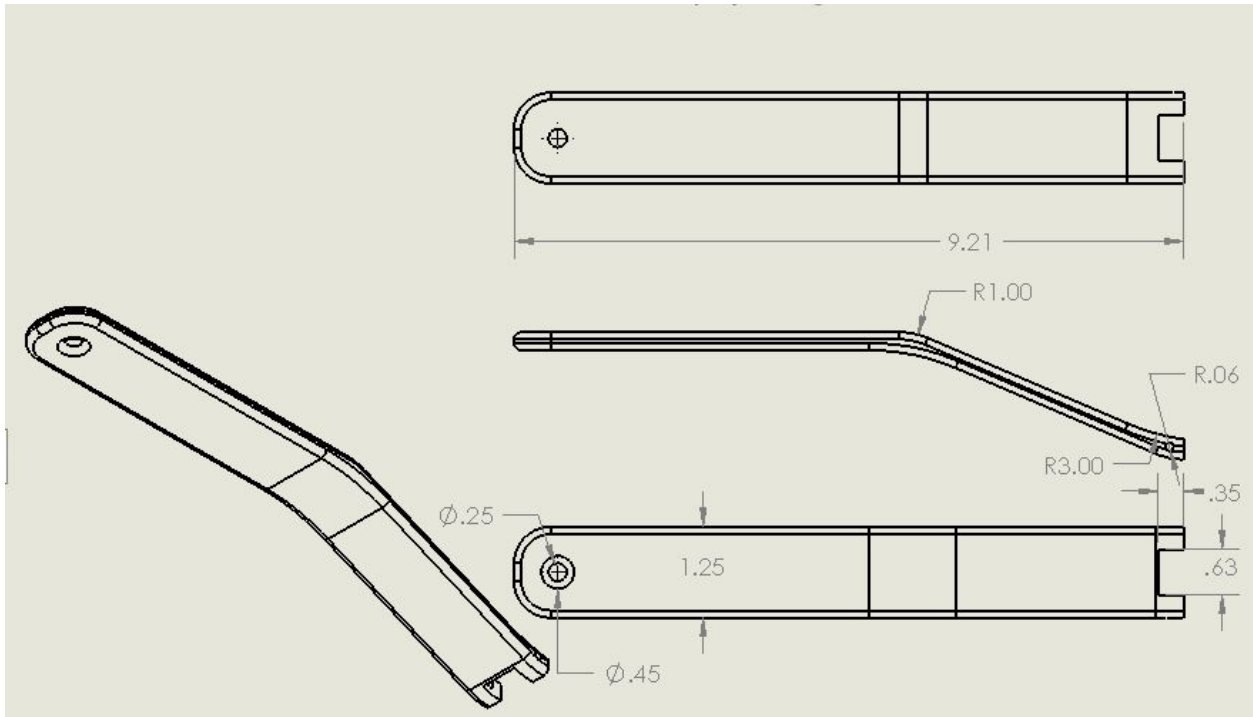
Given the way this course is set up, we were able to complete the project in time for Capstone day. The first semester mainly consisted of research, concept development, design matrices, and planning. Since there was not much physical construction in the first semester, it felt very slow and relatively calm with a lot of focus on the textbook, which we feel may have affected our judgement regarding how long the device would take to fully design, build, and test. While we were still able to complete the project in time for the deadline, we think that more heavily emphasizing the need for prototypes during the early stages of the design process may help students. Also, we feel that although the textbook was very helpful, it may have been better to have more homework assignments that directly related to our individual projects rather than based off of book examples. This way, students could learn the same concepts and techniques taught in the textbook while also getting timely feedback on real documents that could be included in their project.

17. References

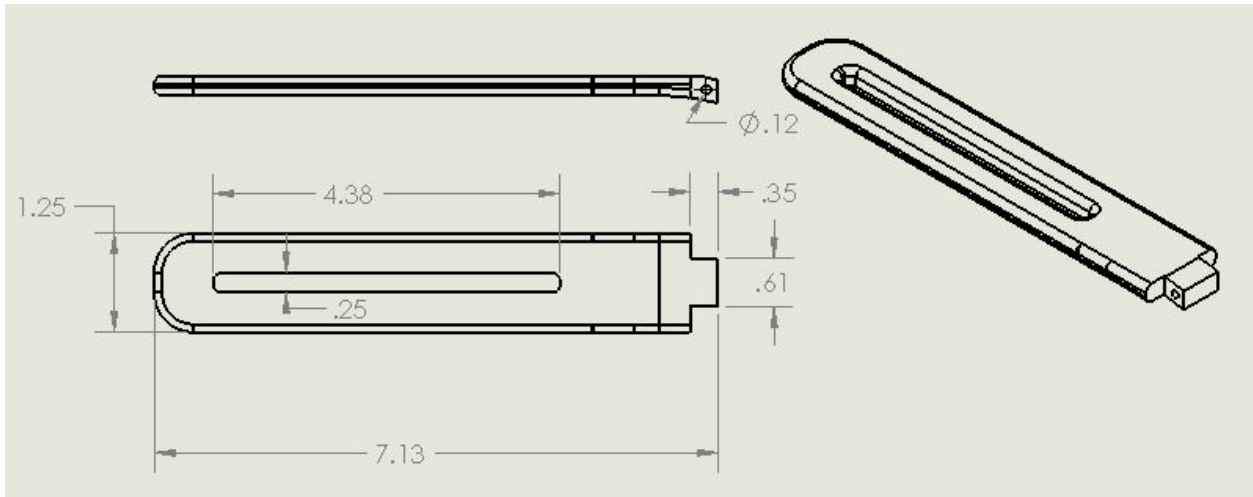
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18.Apendices

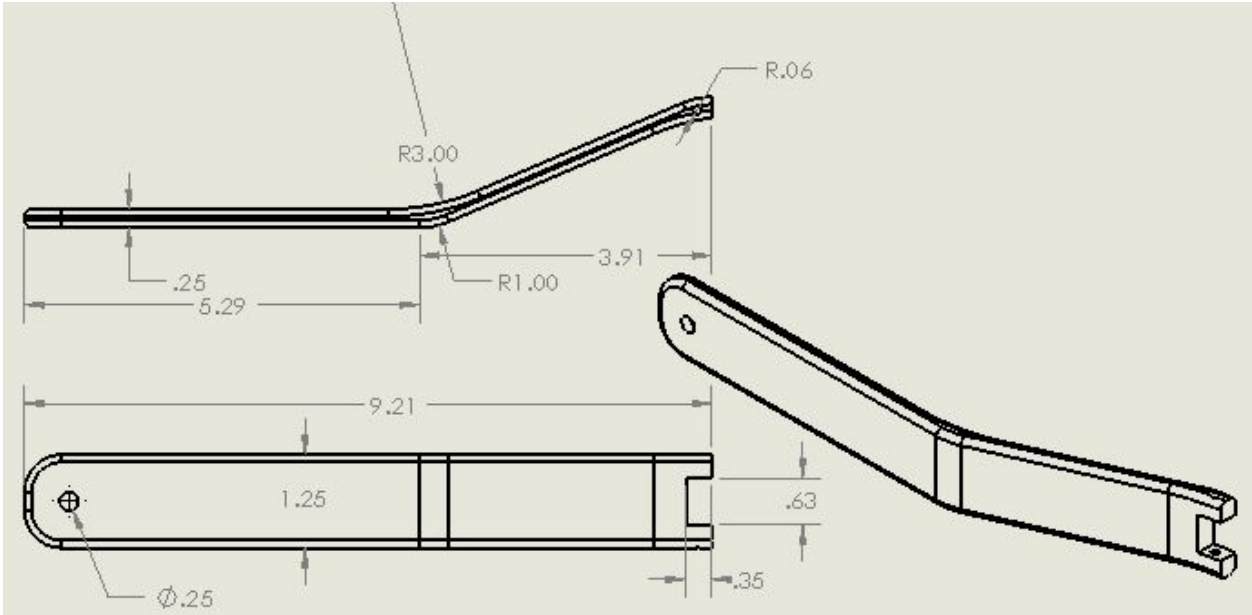
Appendix A: CAD Drawings in inches



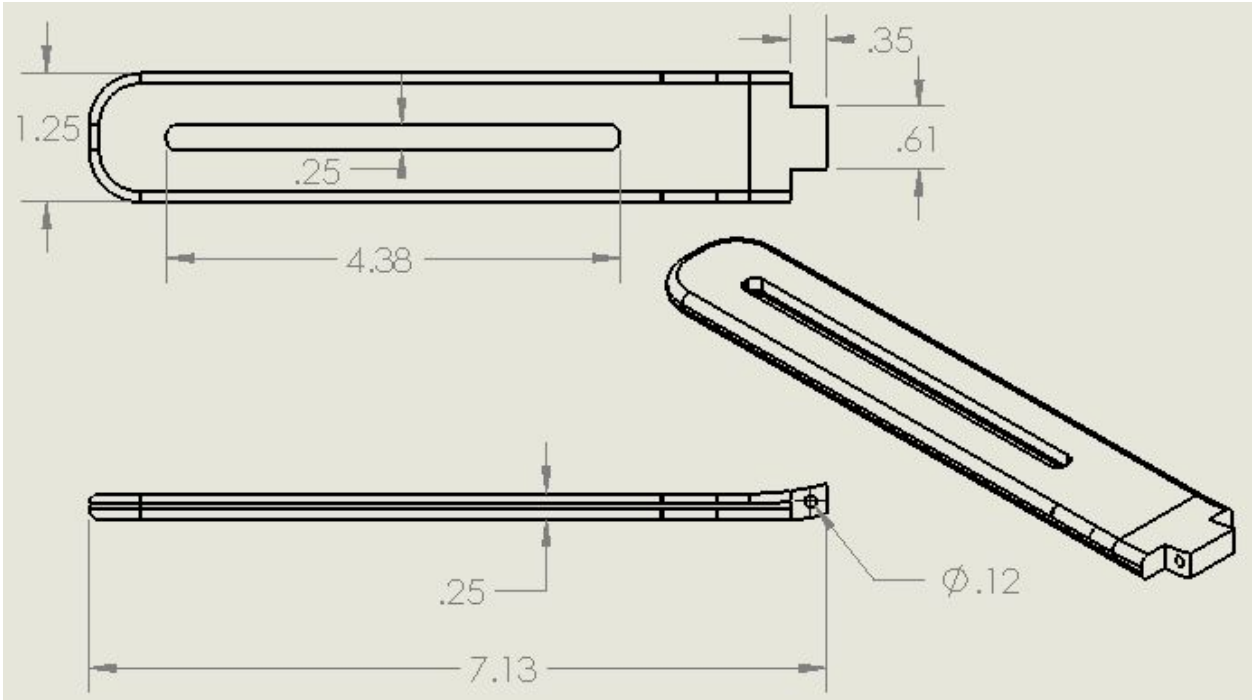
Left Distal Arm Segment



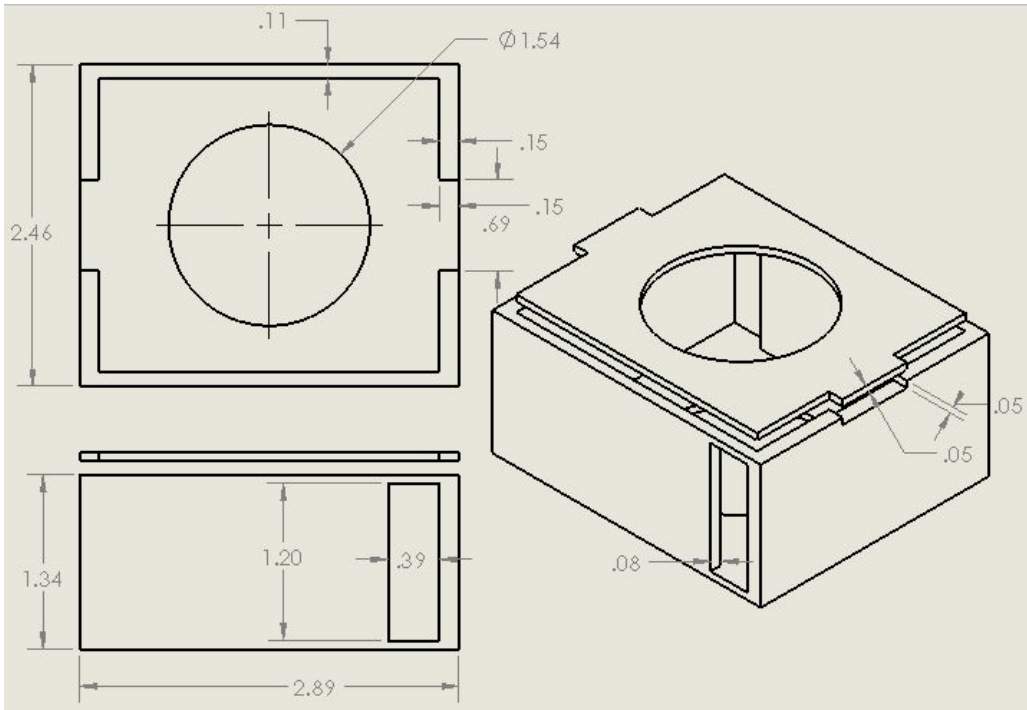
Left Proximal Arm Segment



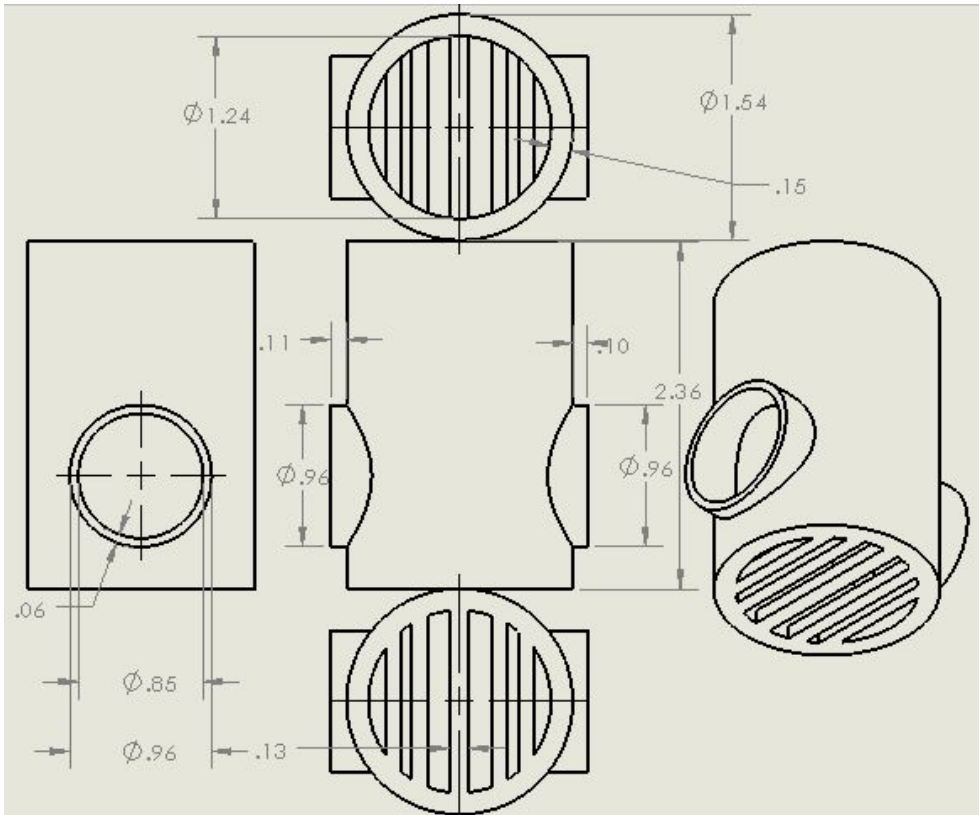
Right Distal Arm Segment



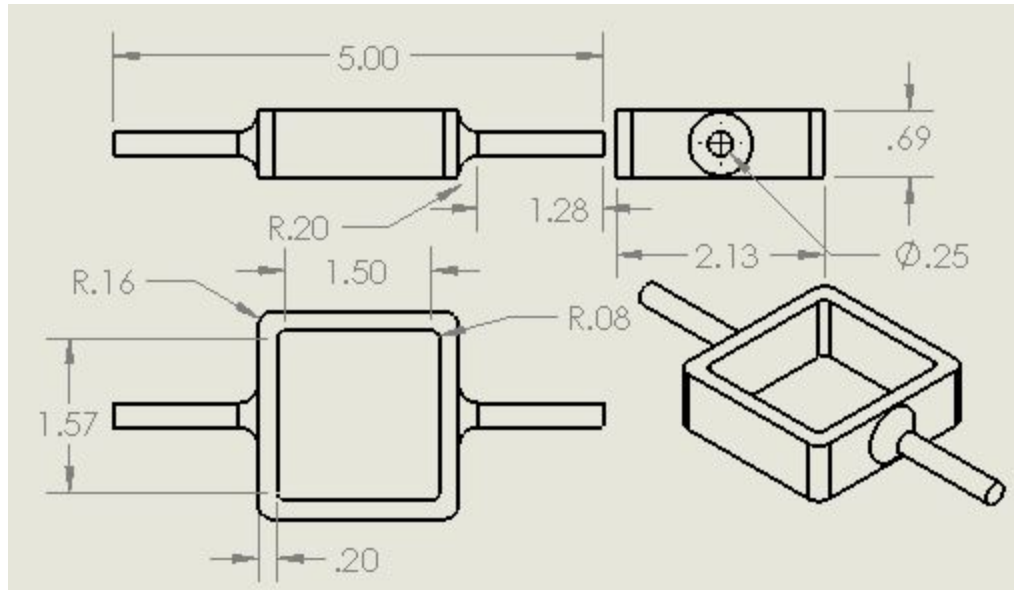
Right Proximal Arm Segment



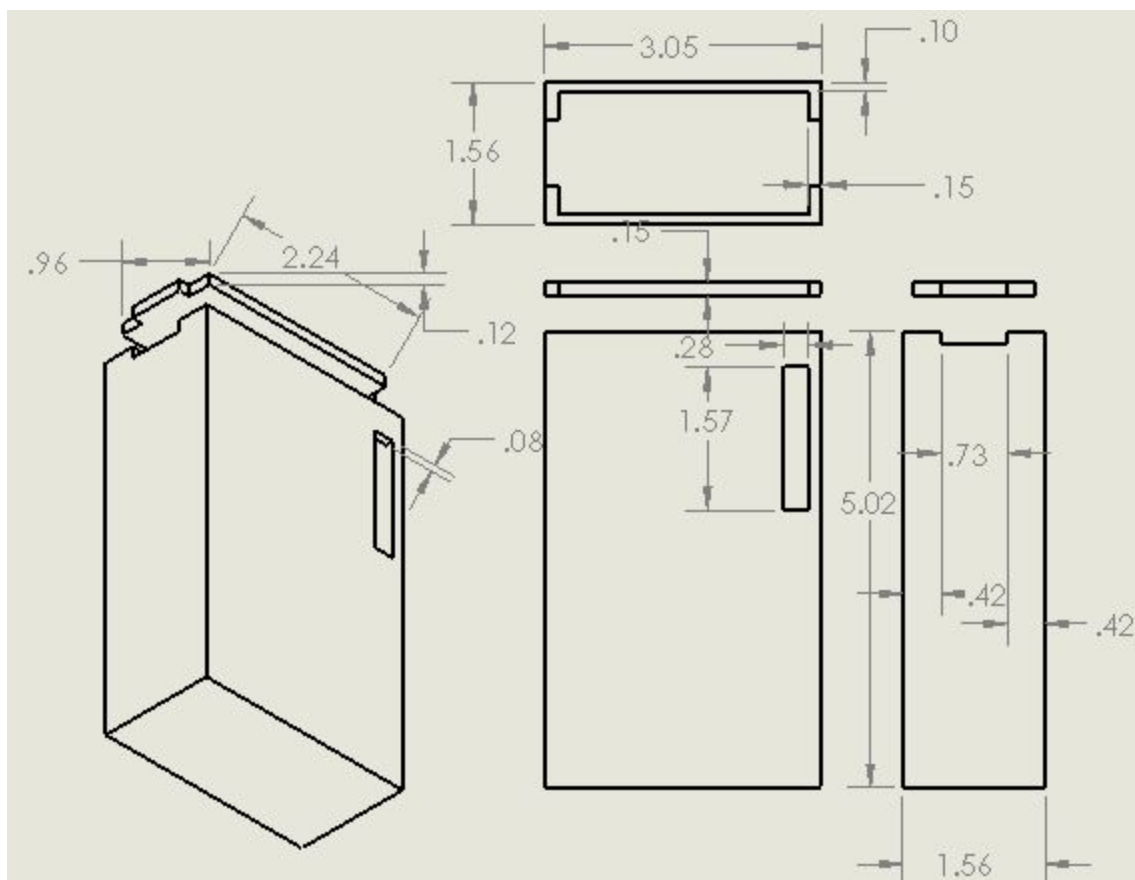
Sensor Safety Box



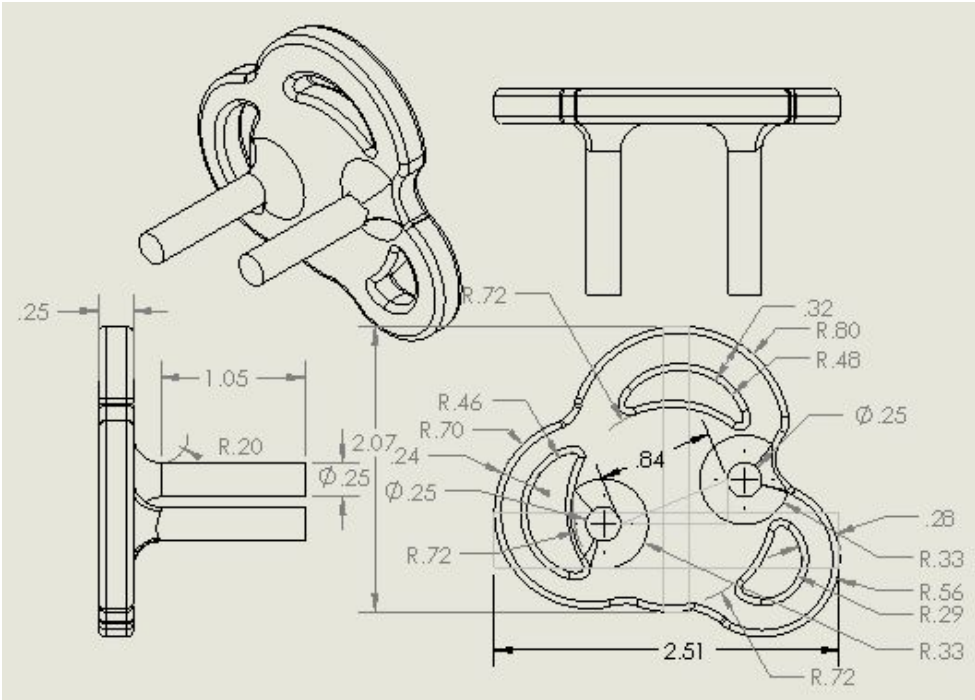
Sensor Mount



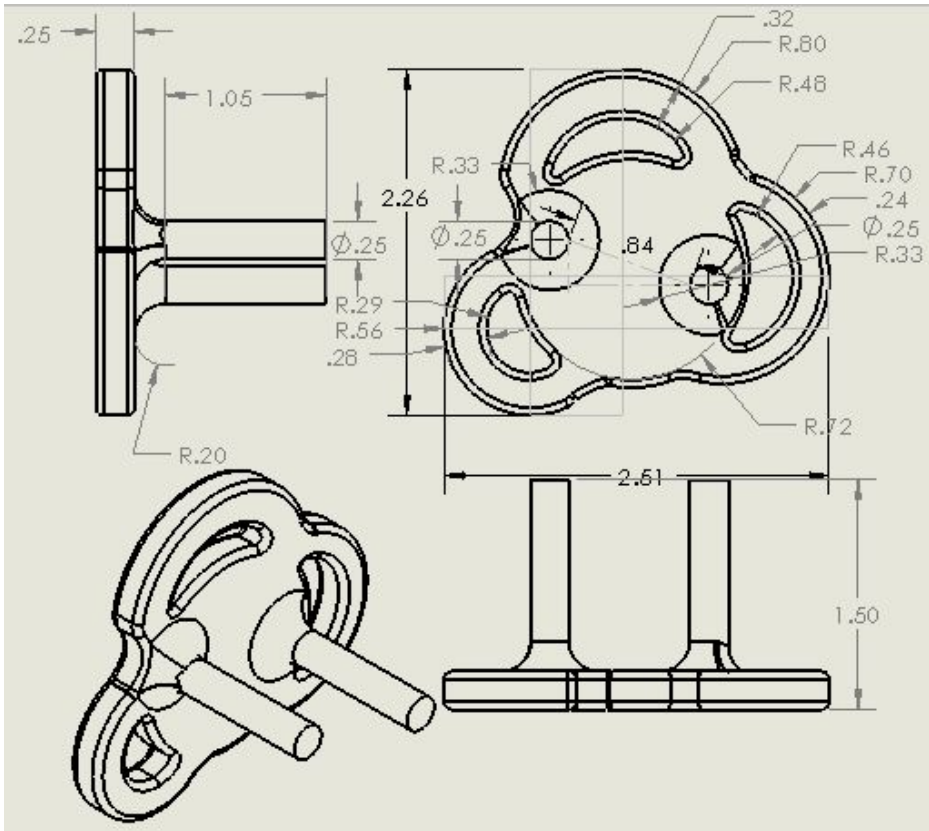
Spirometer Mount



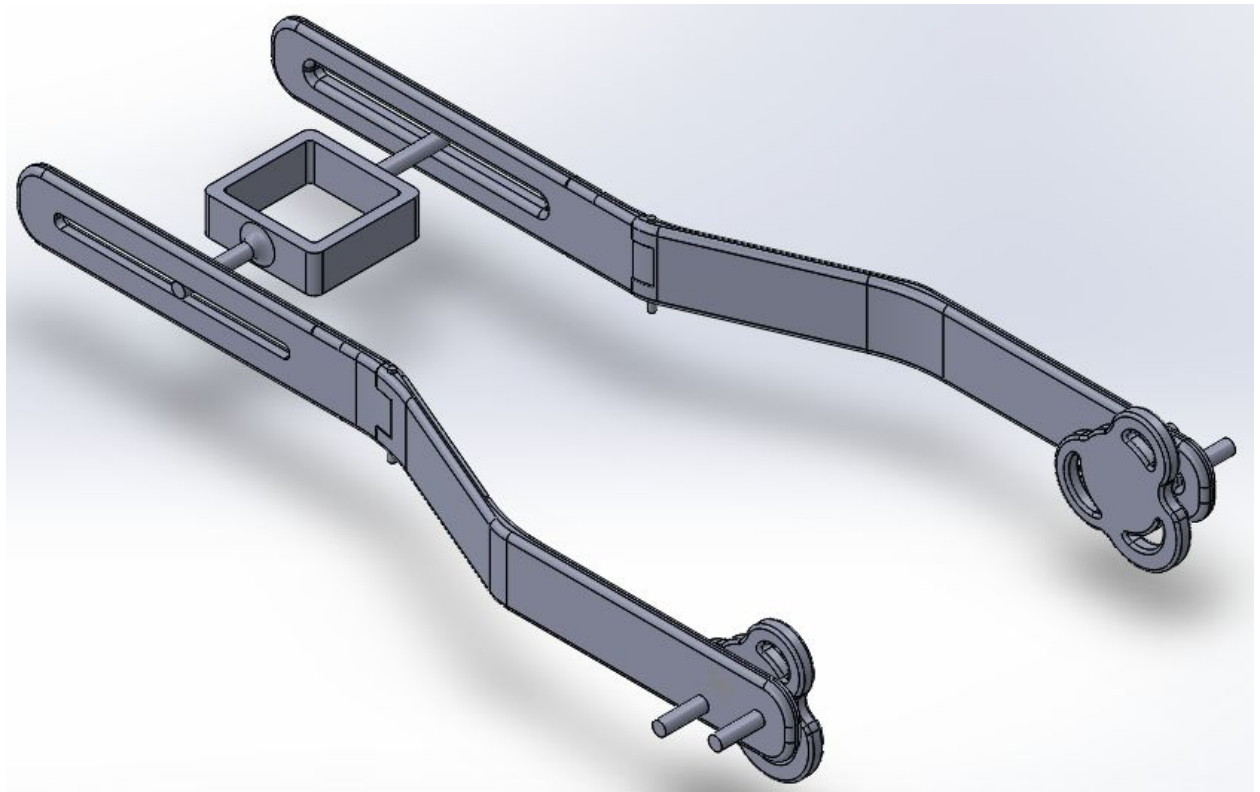
Arduino Safety Box



Left Temple Mount

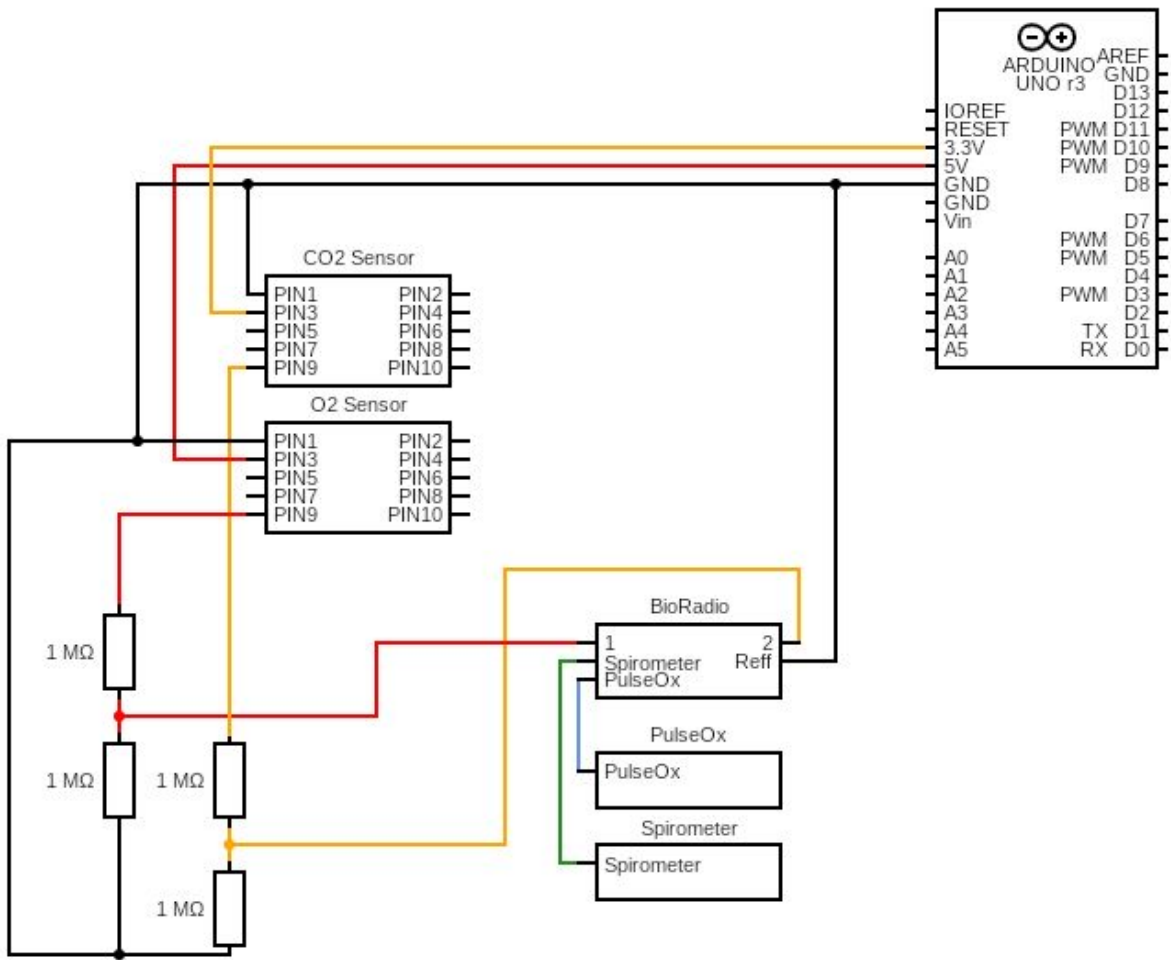


Right Temple Mount



Full Mount Assembly

Appendix B: Circuit Drawing



The Second Wind Electrical Schematic

Appendix C: Design Testing Matrices

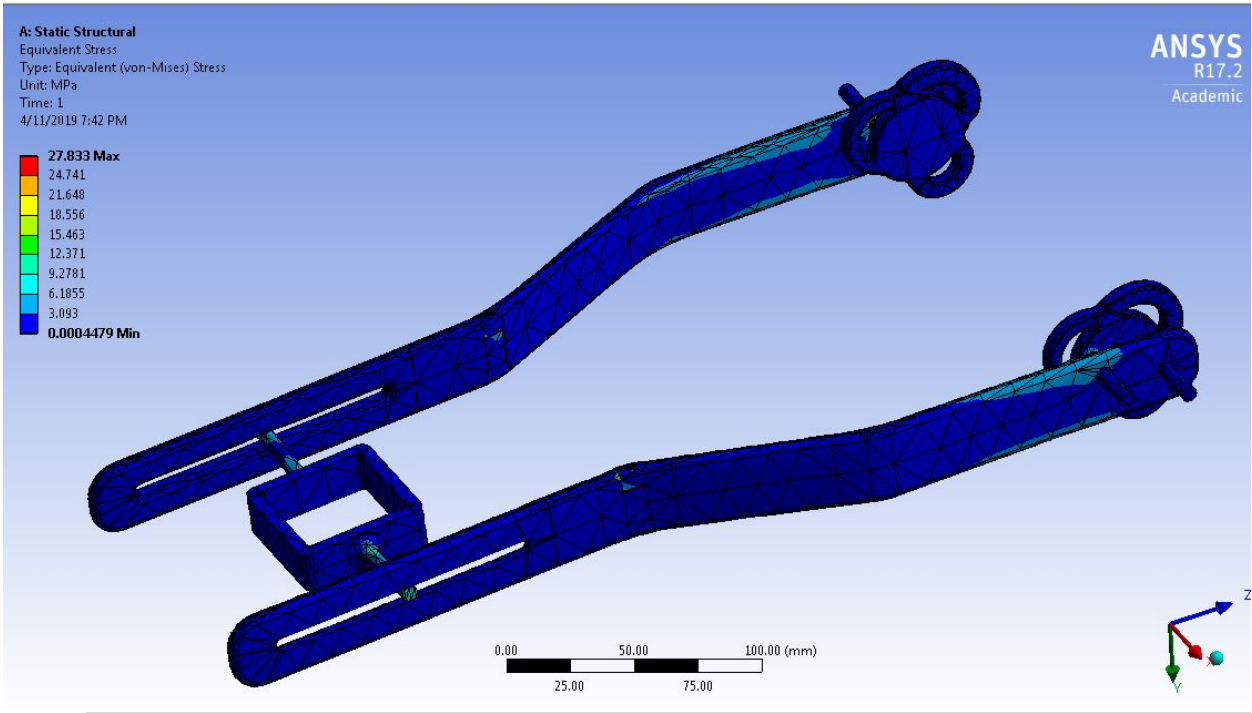
Verification Testing Matrix						
Test Number	Customer Requirements	Product Requirements	Design Inputs	Test Methodology	Acceptance Criteria	Results
1.1	Measures VO2 and VCO2	Measures % oxygen in air	O2 sensor has a sampling rate of at least 1 data point per second	Check sensor documentation	Pass if the sampling rate of the O2 sensor is at least 1Hz	Pass
1.2		Measures % carbon dioxide in air	CO2 sensor has a sampling rate of at least 1 data point per second	Check sensor documentation	Pass if the sampling rate of the CO2 sensor is at least 1Hz	Pass
1.3		Measures air flow rate	Device includes a spirometer with a sampling rate of at least 1 data point per second	Check sensor documentation	Pass if the sampling rate of the spirometer is at least 1Hz	Pass
2.1	Collects pulse oximetry data	Measures heart rate	Heart rate monitor has a sampling rate of at least 1 data point per second	Check sensor documentation	Pass if the sampling rate of the heart rate monitor is at least 1Hz	Pass
2.2		Measures SpO2	SpO2 sensor has a sampling rate of at least 1 data point per second	Check sensor documentation	Pass if the sampling rate of the SpO2 sensor is at least 1Hz	Pass
3.1	Be portable	Can be easily transported	Disassembled device assembly can fit within an 18"x13"x5.5" space	Measure	Pass if the device fits within an 18"x13"x5.5" space when disassembled	Pass
3.2		Is lightweight	Device does not exceed 10 lbs	Measure	Pass if the device weight is less than or equal to 10lbs	Pass

4.1	Be usable by a 10-21-year-old	Is safe for the user	Mouthpiece has no sharp edges	Visual inspection	Fail if mouthpiece has any sharp edges; pass otherwise	Pass
4.2			Mouthpiece is made from medical grade silicone	Check material documentation	Pass if mouthpiece is made from medical grade silicone	Pass
4.3			All wires are insulated so no metal is exposed	Visual inspection	Pass if no metal is exposed	Pass
4.4			Power supply has a casing that separates it from the user	Visual inspection	Pass if power supply is not exposed to the user	Pass
4.5		Is durable	3D printed parts have 100% infill	Check material documentation	Fail if infill is any less than 100% infill; pass otherwise	Pass
4.6			Main Assembly components do not separate with 2lb of force applied	Force testing	Pass if all components remain attached to the main assembly when subject to a 2lb force	Pass
4.7			Device can survive a drop of 6 feet	Drop Test	Pass if device exhibits no component damage or failure after a drop of 6 feet in height	Not Performed
4.8		Can be worn by 10-21-year-olds	Headset is adjustable from minimum of 18 inch to maximum of 22 inch circumference	Measure	Pass if headset can adjust from between 18-20 inch circumference	Pass

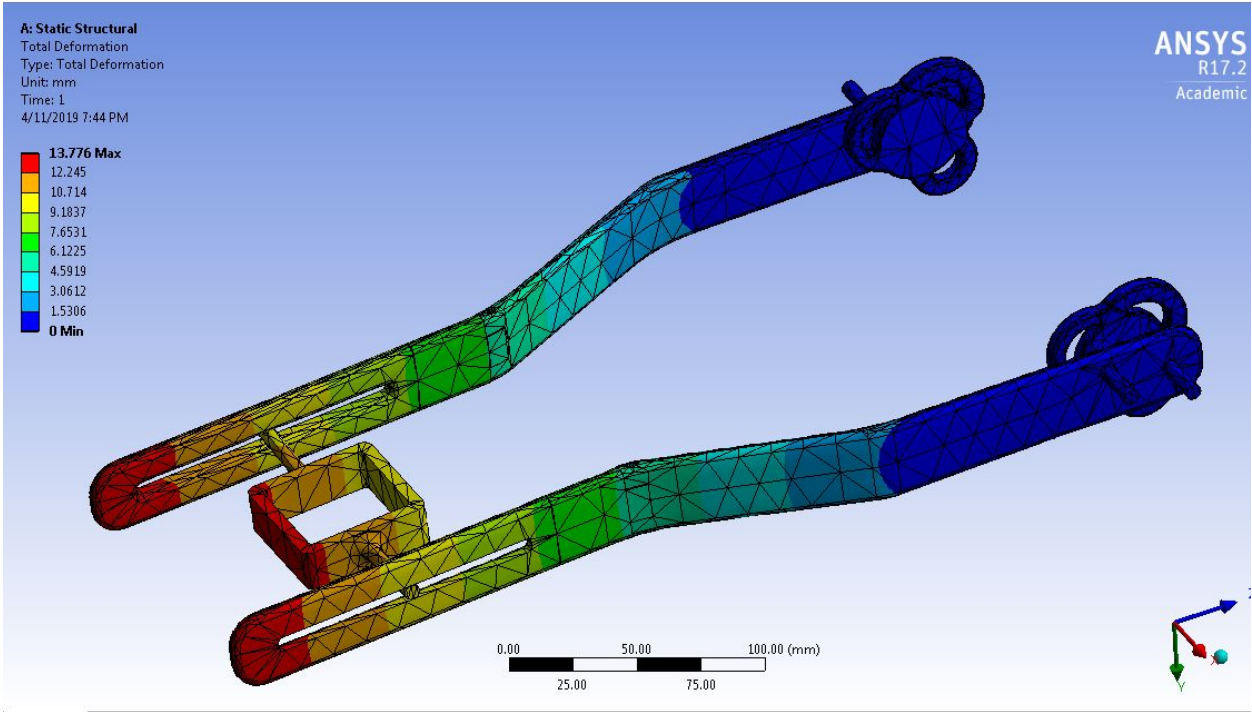
4.9			Chest mount is adjustable from minimum of 24 inch to maximum of 42 inch circumference	Measure	Pass if chest mount can adjust from between 24-42 inch circumference	Pass
5.1	Record and graph data	Data from the device can be gathered wirelessly	Device is Bluetooth compatible	Check BioRadio documentation	Pass if device has Bluetooth compatibility	Pass
5.2		Device itself does not store data	No data storage unit present on the device	Visual inspection	Pass if no data storage devices are present on the device	Pass
5.3			Data processor does not have a storage capability	Visual inspection	Pass if all data imported to the data processor is removed once the application is closed	Pass
5.4		Long battery life	Power supply has a life of at least 3 hours	Test through use until failure	Pass if all sources of power have a battery life of at least 3 hours	Pass

Validation Testing Matrix				
Test Number	Customer Requirements	Test Methodology	Acceptance Criteria	Results
1.1	Measures VO2 and VCO2	Test through comparison against hospital device	Pass if VO2 and VCO2 data from the device are reasonably comparable as determined by Dr. Bhatia	Pass
1.2	Collects pulse oximetry data		Pass if pulse oximetry data from the device are reasonably comparable as determined by Dr. Bhatia	Pass
1.3	Record and graph data		Pass if all graphs output from the data processor are reasonably comparable as determined by Dr. Bhatia	Pass
2.1	Measures VO2 and VCO2	Test through simulated use	Pass if VO2 and VCO2 data can be obtained from the device	Pass
2.2	Collects pulse oximetry data		Pass if pulse oximetry data can be obtained from the device	Pass
2.3	Be portable		Pass if device can be worn by a single person without assistance when fully assembled	Pass
2.4	Be usable by a 10-21-year-old		Pass if device can be worn by users at both ends of the age spectrum	Pass
2.5	Record and graph data		Pass if the data processor can output all the necessary graphs (full list of graphs located in testing protocol)	Pass
2.6	Have data exportable to flash drive		Pass if graphs created by the data processor can be exported as a .zip file	Pass
3.1	Budget of \$500	Check budget Documentation	Pass if total amount spent from budget is less than \$500	Pass

Appendix D: ANSYS Finite Element Analysis

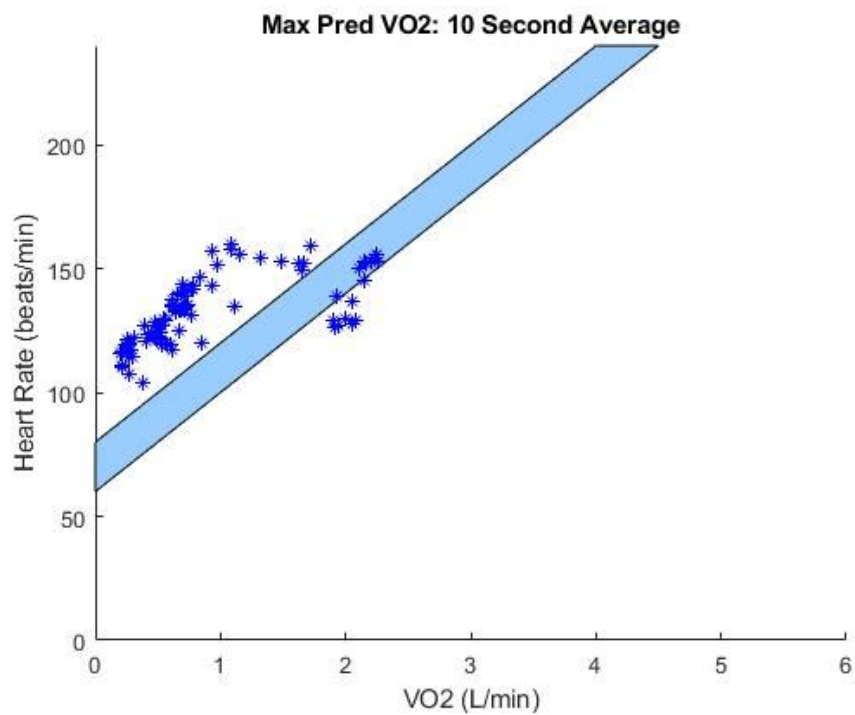


Head Mount Equivalent Stress - Finite Element Analysis

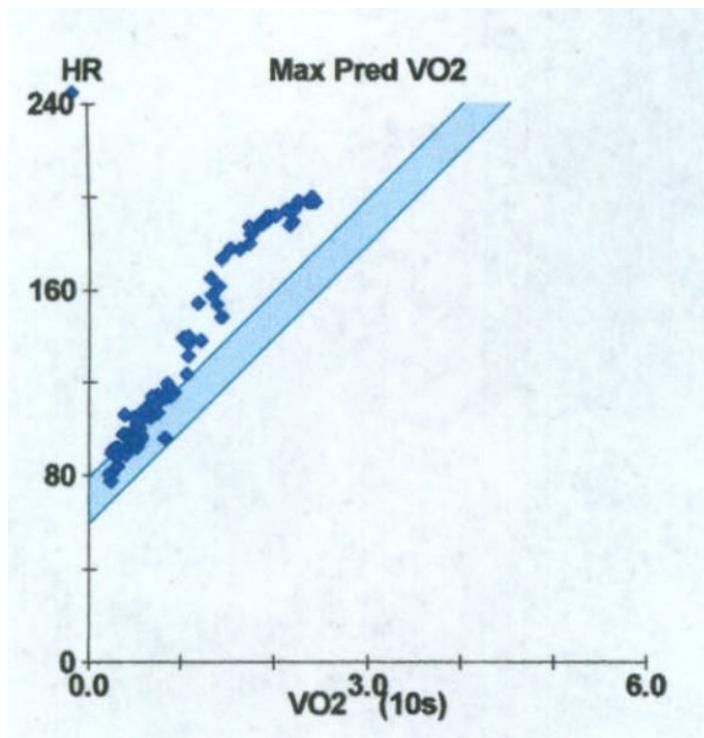


Head Mount Total Deformation - Finite Element Analysis

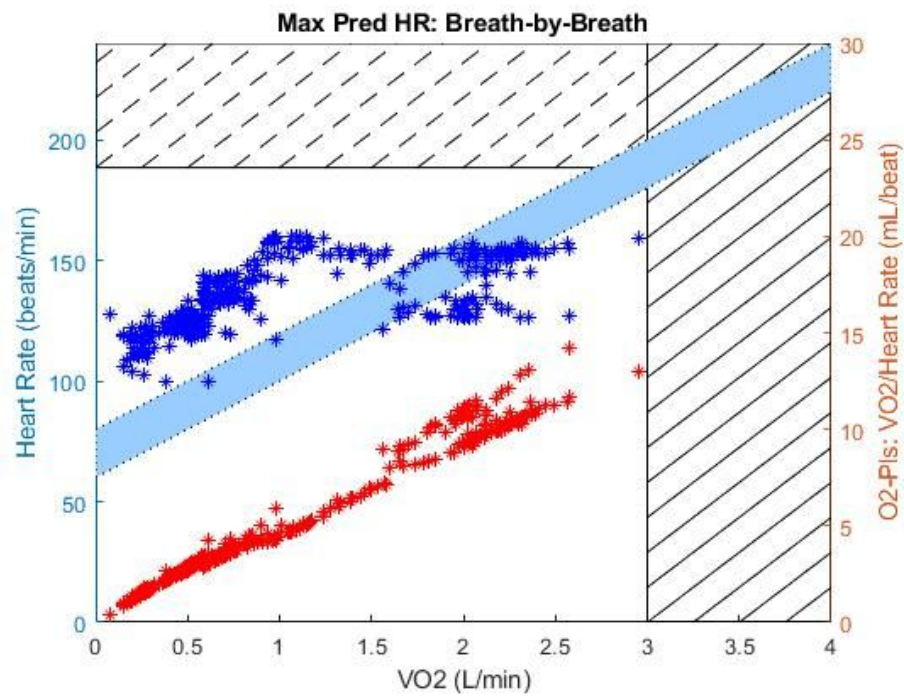
Appendix E: Device Comparison Test Outputs (Validation Tests 1.1-1.3)



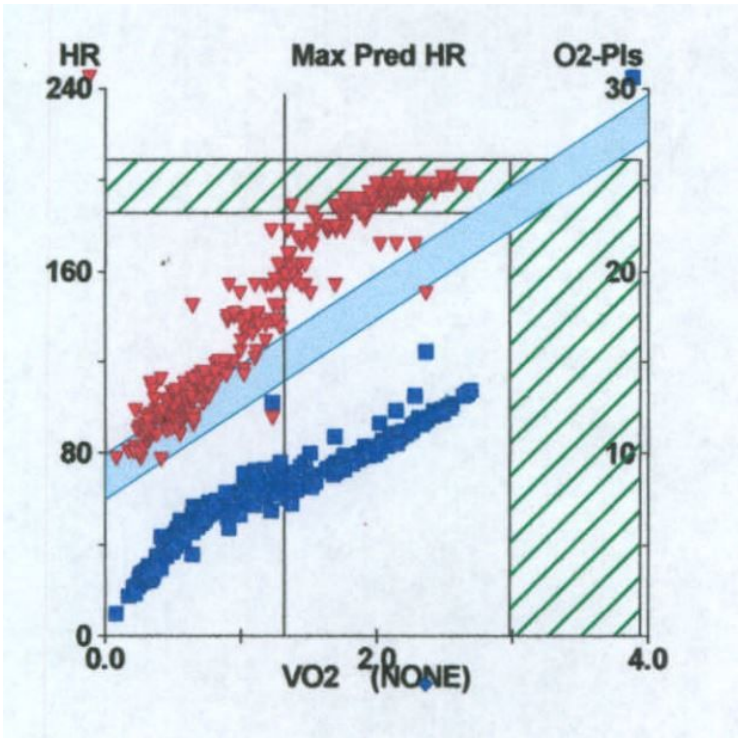
The Second Wind Max Pred VO₂



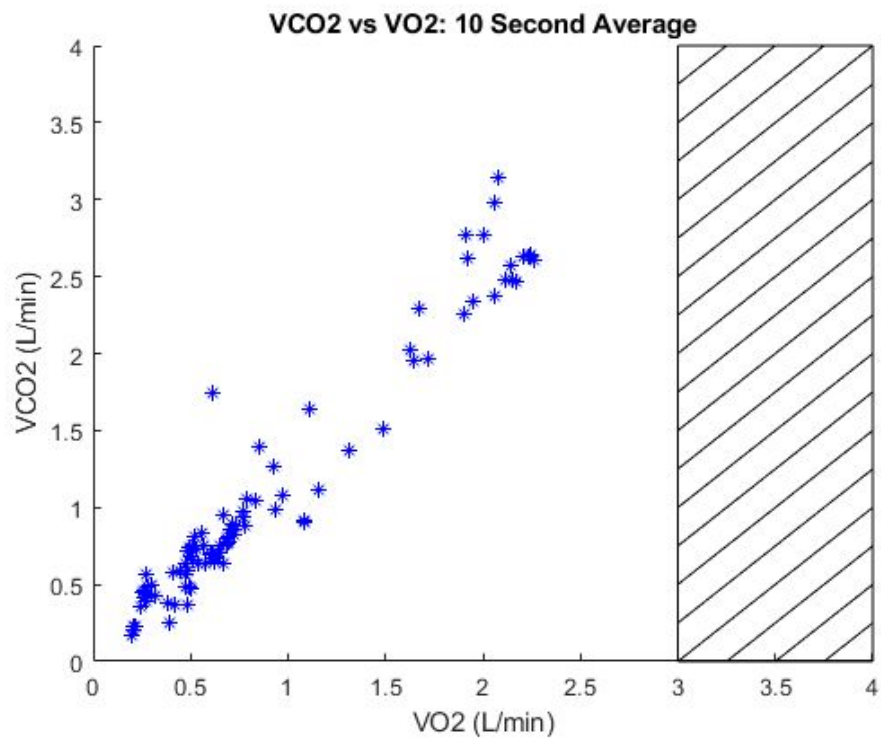
Hospital Max Pred VO₂



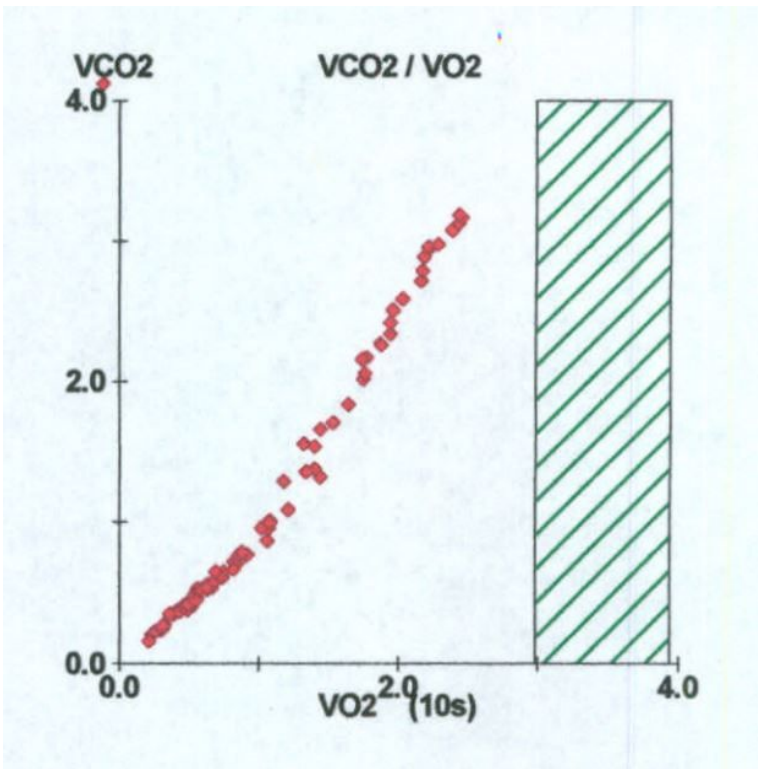
The Second Wind Max Pred HR



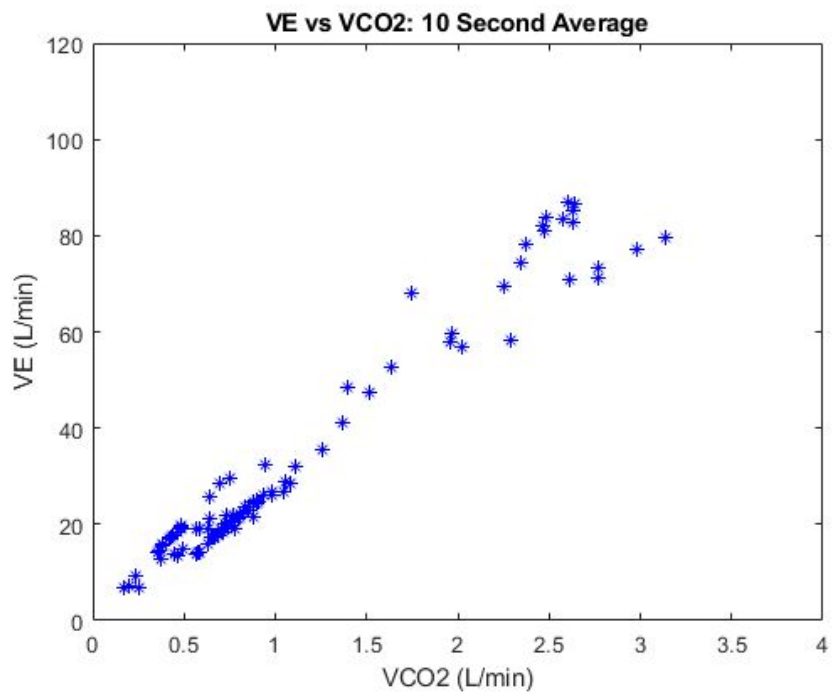
Hospital Max Pred HR



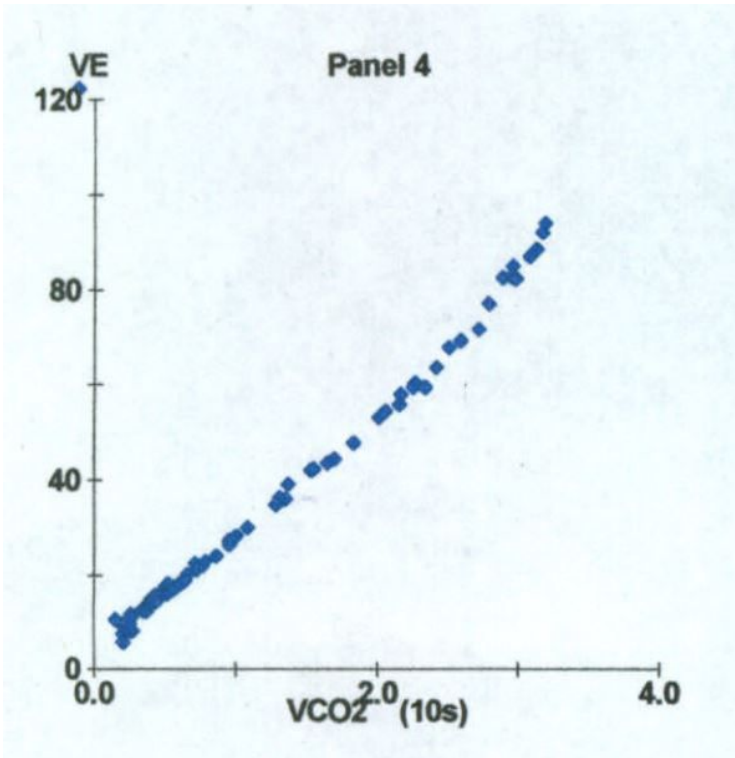
The Second Wind VCO₂ vs VO₂



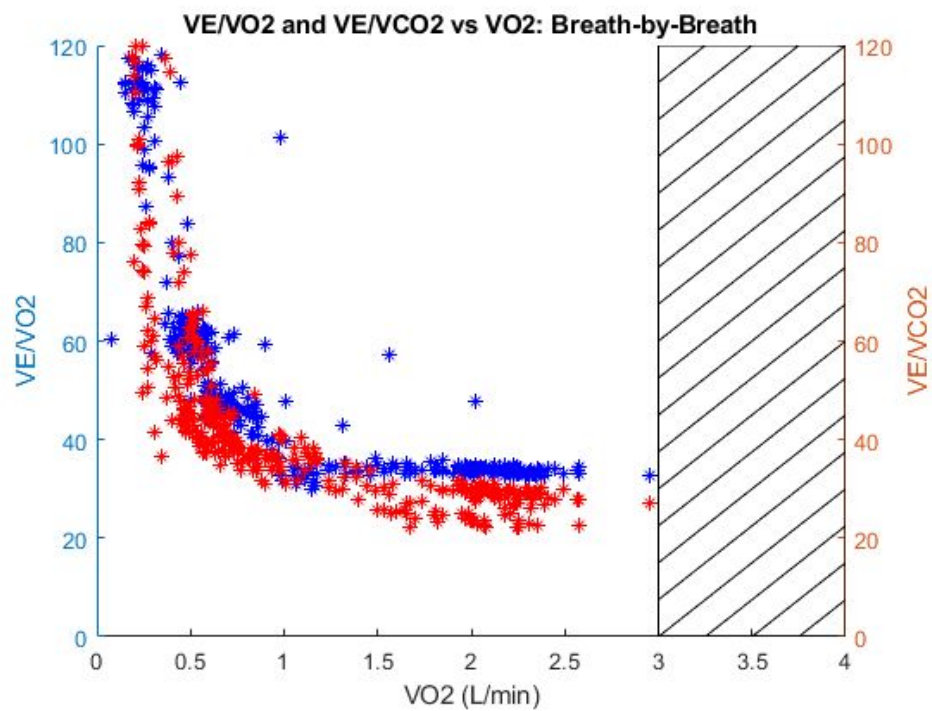
Hospital VCO₂ vs VO₂



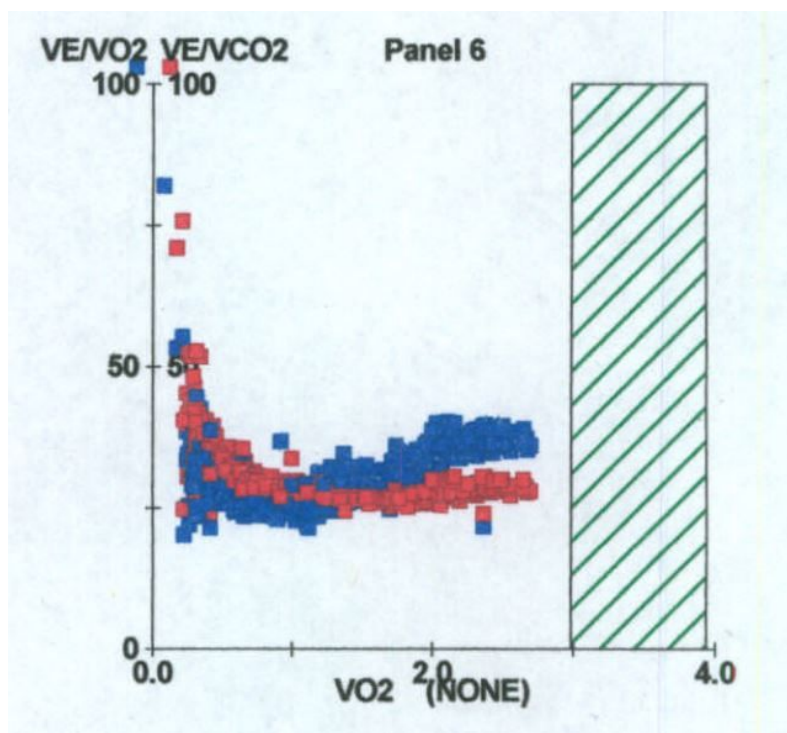
The Second Wind VE vs VCO₂



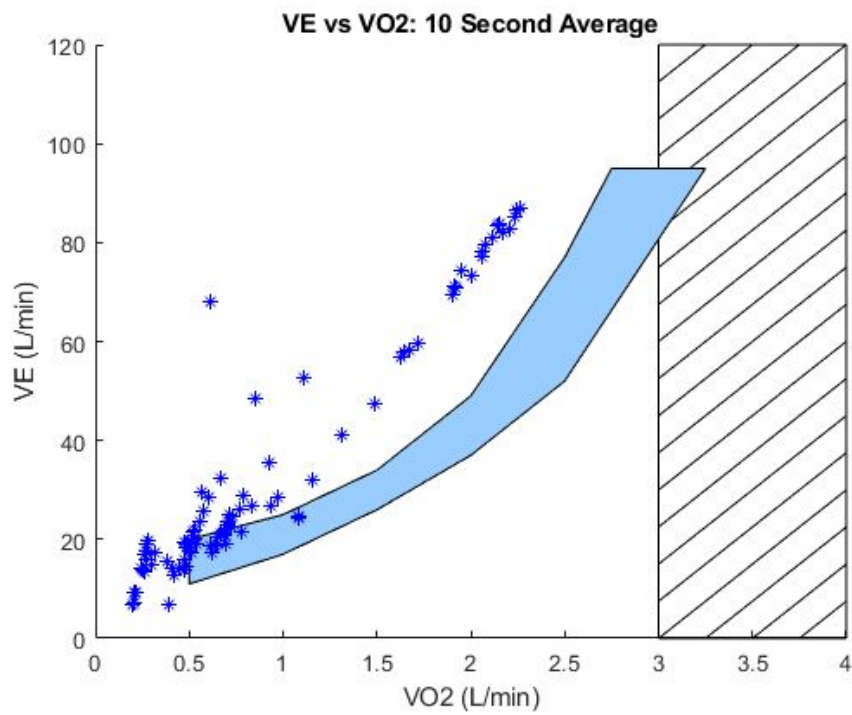
Hospital VE vs VCO₂



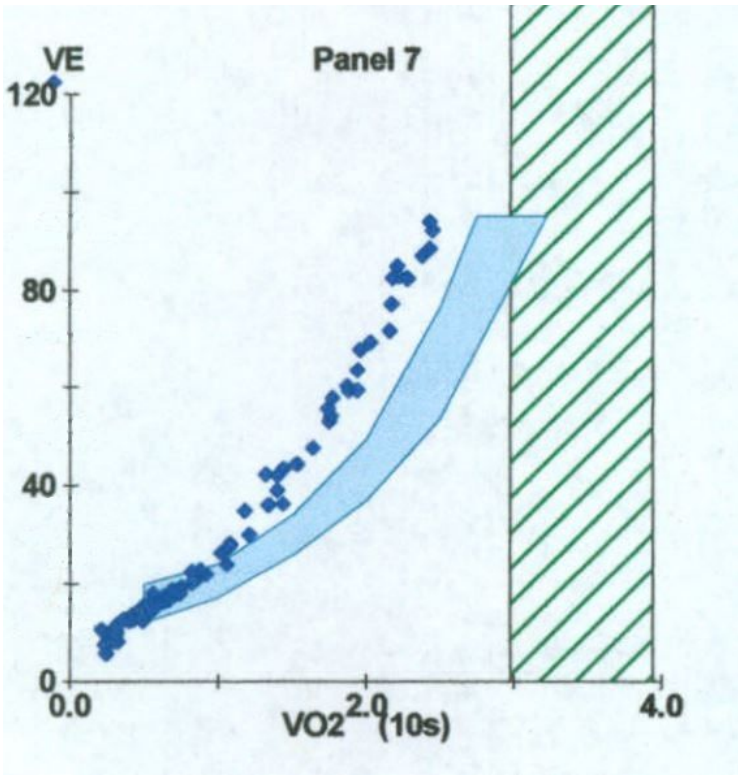
The Second Wind VE/VO₂ and VE/VCO₂ vs VO₂



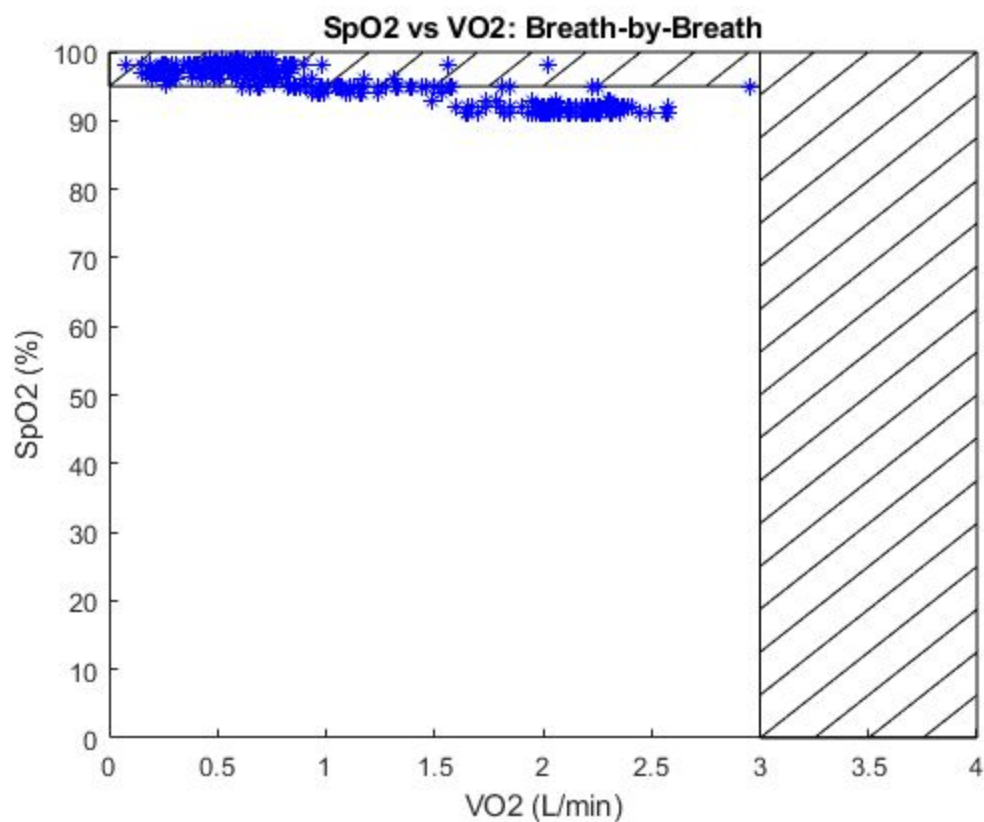
Hospital VE/VO₂ and VE/VCO₂ vs VO₂



The Second Wind VE vs VO₂



Hospital VE vs VO₂



The Second Wind SpO₂ vs VO₂

Note: SpO₂ vs VO₂ was not recorded for the in-hospital portion of the testing.

Appendix F: Fully Assembled Device



The Second Wind Fully Assembled and Worn