

Towards Data-Driven Pre-Operative Evaluation of Lung Cancer Patients: The Case of Smart Mask

Brianna Myers¹, Jaskaran Atwal Nahal¹, Chai Yang¹, Lisa Brown², Soheil Ghiasi¹, Andre Knoesen¹

¹*Department of Electrical & Computer Engineering, UC Davis*

²*Department of Surgery and Comprehensive Cancer Center, UC Davis*

Abstract— Lung cancer is the number one cause of cancer deaths. Many early stage lung cancer patients have a resectable tumor, however, their cardiopulmonary function needs to be properly evaluated before they are deemed operative candidates. Pulmonary function is assessed via spirometry and diffusion capacity. If these are below a certain threshold, cardiopulmonary exercise testing (CPET) is recommended. CPET is expensive, labor intensive, and sometimes ineffective since the patient is unable to fully participate due to comorbidities, such as limited mobility. In addition, CPET is done using a set of physical activities that may or may not be relevant to the patient's typical activities.

This paper presents steps towards developing a solution to address this gap. Specifically, we present OOCOO, a mobile mask system designed to measure oxygen and carbon dioxide levels in respiration, as well as activity levels. Unlike state of practice, oxygen, carbon dioxide, and activity data can be continuously measured over a long period of time in the patient's environment of choice. The mask is capable of wireless data transfer to commodity smartphones. We have carried out initial work on development of an Android application to capture, analyze, and share the data with authorized entities.

I. INTRODUCTION

Non-small cell lung cancer (NSCLC) is the number one cause of cancer deaths in both men and women, accounting for approximately 27% of such deaths [1]. Many patients with early stage lung cancer have a tumor that is resectable, but may not be operative candidates due to co-morbidities or inadequate pulmonary function.

Accurate assessment of the risk of morbidity and mortality prior to curative resection for lung cancer is important for several reasons. First, preoperative assessment allows for appropriate treatment recommendation to the patient. If the patient is not a surgical candidate, an alternative therapy such as stereotactic ablative radiotherapy (SABR) may be a better option. Second, knowledge of a patient's risk for surgery allows for an informed preoperative discussion between the surgeon and the patient.

Our underlying observation is that the advances in information technology can be utilized to develop continuous, inexpensive, in-home, and patient-centric mechanisms for evaluation of patient's pulmonary function. Specifically, we set out to develop a light mobile mask that can be worn for most of the day to collect various respiratory parameters of interest, such as oxygen and carbon dioxide quantities, respiratory rate and flow, as well as, patient's physical activity.

In this paper, we present our initial mask prototype, which is capable of measuring oxygen and carbon dioxide in a subject's respiration. Moreover, the mask can measure the subject's activity at the same time, using an embedded accelerometer. We also developed a smartphone application to collect the data from the mask, and to potentially share the data with authorized entities, including automated analysis and archival services, via the cloud.

II. PULMONARY FUNCTION TEST FOR PATIENT EVALUATION: STATE OF PRACTICE AND ITS LIMITATIONS

The role of preoperative pulmonary function testing prior to lung resection has been well developed. Patients undergo spirometry and diffusion testing, which yield FEV₁ and DLCO measures, respectively. FEV₁ denotes the forced expiratory volume that the patient can exhale in one second. DLCO refers to the diffusing capacity of the lung for carbon monoxide, which provides an estimate of how efficiently gases are exchanged at the alveolar-capillary membrane. Pulmonary function testing provides raw values for these measures, which are then compared against data of other individuals of the same age, height, and gender to determine the relative standing of the patient's pulmonary function.

Both FEV₁ and DLCO are independent predictors of morbidity and mortality after lung resection for NSCLC [2,3]. If the predicted postoperative FEV₁ and/or DLCO, which are typically linearly scaled down from preoperative measurements with respect to the bronchopulmonary segments that are to be resected, place the individual in the bottom 40% of the reference population, guidelines recommend that the patient undergo cardiopulmonary exercise testing (CPET) for further evaluation [4].

CPET is a clinically-administered test in which, the patient is asked to run on a treadmill while a plethora of cumbersome sensors, including a face mask, are attached to her [19]. The mask and its connected tubing pass the subject's intake and outtake breaths through a bulky expensive machine that measures oxygen and carbon dioxide quantities, as well as, respiratory rate and flow (minute ventilation). The exercise workload is incrementally increased until the patient achieves her maximum heart rate. The data from various sources, such as heart rate, minute ventilation, carbon dioxide production per minute, and oxygen uptake per minute, are fused to determine the maximal oxygen consumption (VO₂ max). VO₂ max has been shown to stratify patients according to risk of morbidity and mortality after lung resection [5].

VO₂ max testing is expensive, labor intensive, and sometimes inaccurate if the patient is unable to fully participate due to co-morbidities, such as limited mobility [18]. In such cases, submaximal exercise testing, such as stair climbing, is sometimes used as a surrogate for CPET. The maximum altitude achieved during stair stepping is associated with cardiopulmonary complications and mortality [6]. Testing cardiopulmonary function via stair climbing is also limited by subjectivity in terms of duration of stair climbing, speed of ascent, number of steps per flight, height of each step, and criteria for stopping the test [4]. Furthermore, some patients are limited more by musculoskeletal or peripheral vascular diseases than cardiopulmonary disease; therefore, stair climbing ability in such patients will not accurately reflect cardiopulmonary function.

Since VO₂ max testing or stair climbing tests pose the aforementioned limitations and inaccuracies, physicians are less inclined to use these tests, and instead rely on their experience to estimate operative risk when assessing patients. Therefore, a solution for data-driven evaluation of pulmonary function in lung resection patients needs to be developed.

III. RELATED WORK

The ability to personally monitor your health with devices has become easier than ever with the development of many commercial activity trackers. Wearable devices, such as the various Fitbit wristbands, Misfit Shine, and the Lumo Back, are now commercially available for individuals to increase their physical health awareness [7].

The development of commercial wearable activity trackers can be extended to devices that are catered towards the specific needs of physicians and medical applications. For athletes to be successful, they must have an optimal combination of activity levels and respiration rates [12]. Athletes often complete testing to track their respiratory performance. Currently, the testing to measure a person's respiration performance is only available in laboratory settings. Often, the test equipment used in the determination of an individual's aerobic fitness level is uncomfortable and the lab environment obstructs natural results. A system comprised of two accelerometers worn around the upper torso has been recently developed to measure the respiration rate of athletes [11]. Systems of this type, which do not require laboratory testing or large test equipment, can enhance the accuracy of aerobic fitness level testing by creating a more comfortable and natural testing environment for individuals.

As a complement to the development of wearable devices, smartphones and mobile applications have become more integral to healthcare. Smartphones occupy a large role in our lives, and therefore offer a wealth of potential for healthcare providers about our personal lifestyles. A mobile application was created that extracts information about a user's phone usage to assist in medical diagnoses within the cognitive-behavioral domains [13]. Applications that offer information and insight about the lifestyles of patients can provide more accurate diagnoses and more effective treatments. Another mobile application has been developed to allow doctors to view multiple patient's vital signs through their smartphone [15].

There is also a current drive towards integrating Bluetooth into healthcare technology. One benefit of Bluetooth enabled healthcare is that it enables more extensive monitoring of patients from remote locations. Mobile applications that retrieve data via Bluetooth and transmit it to doctors through a cloud server allow doctors to view their patients' data, without the need for the patient to visit the doctor's office. Multiple cloud based monitoring systems with wearable sensors have been developed [14] [16] [17]. The sensors in the systems communicate to a smartphone through Bluetooth, and the smartphone transfers data to a medical management system through a cloud server.

Aging populations present a challenge for current healthcare systems to find more suitable methods to provide care for elderly [10]. The development of remote residential healthcare offers potential for improvement in preventative care for older persons. Similar to the cloud based wearable sensor systems, a residential activity monitoring system based on Bluetooth Low Energy (BLE) was developed to monitor elderly patients more effectively [9].

While some systems have taken advantage of Bluetooth communication and cloud servers for remote monitoring, other systems have used Bluetooth to control devices within the home. A Bluetooth-based system has been developed with a brain-computer interface that allows paralyzed patients to control devices in a smart living space with steady-state visually evoked potentials [8]. These types of systems can even enable paralyzed and currently disabled persons to live more independently. Such systems can significantly improve the efficiency and sustainability of healthcare systems.

IV. OOCOO SMART MASK

The system (OOCOO Smart Mask) outlined in this paper enables physicians to conveniently assess patients on their preoperative risk before lung resection surgery and their recovery after. The mask is a mobile system used to measure trends in the concentration of oxygen and carbon dioxide in a patient's respiration, along with their physical activity. Data from the mask is sent over BLE to a smart phone, where doctors can view data in real-time through the mobile application.

Since tubes and testing equipment can limit the testing locations and types of activities performed during testing, the mobile system allows doctors to conveniently test their patients in their own facilities, with the freedom to perform a variety of tests that are more tailored towards the patients needs. The development of a BLE mobile application also presents an opportunity for further development of the system as a remote at-home monitoring system, where doctors can view live data of patients while the patients complete their normal daily activities. Such systems can be used to easily track patients' recovery at home following operative procedures.

The respiration data collected by the mask correlates with physical activity intensity in a patient. The correlations can give insight into the pulmonary function of the patient. The data from the mask is an alternative or complement to current VO₂ max testing in prognosis and decision making for lung re-sectioning patients.

To select the oxygen and carbon dioxide sensors with acceptable concentration ranges for the mask, it is necessary to know the oxygen and carbon dioxide concentrations in the average human respiration. At rest, humans exhale 3.6% carbon dioxide and 16% oxygen on average. At higher levels of exertion, humans will exhale upwards of 7% carbon dioxide. The atmospheric concentrations of oxygen and carbon dioxide are, on average, 21% and 0.04% respectively.

A. Oxygen Sensor

We use a SST LOX-O2 Sensor as the oxygen sensor in the mask. This sensor uses fluorescence quenching to detect the changes in oxygen concentration. In particular, it uses an optical probe that contains an indicator dye sensitive to oxygen. This dye is then excited by an LED light source. The fluorescence emission of the dye decays; however, if oxygen is present, an energy transfer occurs and decreases the fluorescence decay, which is known as oxygen “quenching” the fluorescence. The amount of quenching that occurs determines the amount of oxygen present. This sensor has the oxygen detection range of 0-25%. The human breath is about 16% oxygen, therefore, the 0-25% detection range allows this sensor to detect the oxygen concentration in human respiration. The oxygen sensor has a relatively short warm-up time of 15 seconds. A short warm-up time is beneficial for the application, since users of the mask will be able to use it immediately on start up. The sensor has an accuracy of +/-2% within the measured value and a sampling rate of once per second, allowing the measurement of proper trends in respiration.

B. Carbon Dioxide Sensor

The mask uses a MinIR 100% CO₂ Sensor. The MinIR 100% CO₂ sensor uses Non-Dispersive Infrared (NDIR) detection. NDIR detection works by using an infrared lamp and infrared light detector. The infrared lamp directs waves of light through a tube filled with air towards an infrared light detector. As light passes through the tube, the CO₂ molecules absorb their corresponding wavelength of light while letting the rest of the light pass through. This remaining light is then passed through an optical filter that absorbs every wavelength of light, except for the one absorbed by CO₂. An infrared light detector then measures the amount of light not absorbed by CO₂. The difference between the light radiated from the infrared lamp and the light detected by the infrared light detector determines the number of CO₂ molecules in the air inside the tube. The utilized sensor has high measurement accuracy of +/- 70 ppm +/- 5% within the measured value, allowing mask users to observe small variations in CO₂ concentrations. The CO₂ sensor is refreshed at twice per second to allow the mask to exhibit trends in respiration.

C. Accelerometer

Activity data can be matched with respiration data to correlate exertion levels with CO₂ and O₂ respiration levels. The accelerometer is used in 2g mode, where the magnitude of the maximum output is at 2 times gravity, or 19.6 m/s². The 2g activity data is filtered and placed into 11 different thresholds of activity. Numbers between 0 and 10 are assigned to each threshold of activity, with a 0 corresponding to the lowest level of activity and a 10 corresponding to the highest level of activity.

D. Energy Analysis

TABLE I. SENSOR VOLTAGES AND CURRENTS

Component	I _{avg} (mA)	V _{avg} (V)
Oxygen Sensor	10	5
Carbon Dioxide Sensor	1.5	3.3
Accelerometer	0.184	3.3
PSoC	1.7	3.3

TABLE II. SENSOR POWER CONSUMPTION

Component	P _{avg} (mW)
Oxygen Sensor	50
Carbon Dioxide Sensor	4.95
Accelerometer	0.607
PSoC	5.61
Total Power:	61.17

Power is supplied by a 9V battery to allow users to easily replace the battery in between uses, as commonly done before using medical equipment. The 9V from the battery is regulated down to 3.3V and 5V. Both regulators have an output current of 800mA. The 3.3V regulator output powers the PSoC 4 BLE micro-controller, accelerometer, and CO₂ sensor, which require 1.7mA, 0.184mA, and 1.5mA of current respectively. The 5V regulator powers the O₂ sensor, which requires 10mA of current.

The 9V battery has about 4950 mWh. Therefore, each battery should last about 81 hours of continuous run time before it needs to be replaced

E. Integration

The oxygen and carbon dioxide sensors both use a universal asynchronous receiver/transmitter (UART) to communicate with the PSoC 4 microcontroller, while the accelerometer uses I²C, as shown in Fig. 1. Both the carbon dioxide and oxygen sensor output eight bytes of data at a baud rate of 9600.

The accelerometer is a three axis accelerometer with x, y, and z data available. For this implementation, the accelerometer is configured for 8-bit data output, which allows for faster read times. With a sampling rate set at 800 Hz, the axes data is first passed through an internal high pass filter with a cutoff frequency of 2 Hz. By doing so, the offset due to gravitational acceleration is removed from the output and all axes read zero when not moving. The data from all three axes are then passed through a moving filter to average the magnitudes; from there, the activity level can be calculated. The PSoC UART blocks are configured for eight data bits and one stop bit for both the oxygen and carbon dioxide sensors. The sensors are set into polling mode, in

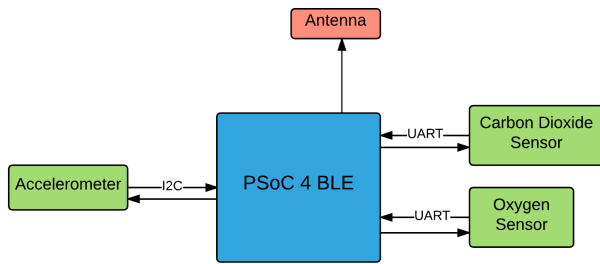


Figure 1. Communications Diagram

which, it will only respond when given a request for data. When the data comes in, it is parsed to separate the five data bytes and then converted into integers to be stored into an array. This array of integers allows the sensor data to be sent over BLE to the phone and easily displayed on the Android application.

F. Mask Design

The OOCOO Mask, as shown in Fig. 2, is comprised of a rubber face mask and a neoprene cover to hold the rubber face mask in place. The rubber face mask contains three holes: one for free air flow, one for the oxygen sensor, and one for the carbon dioxide sensor. The carbon dioxide and oxygen sensors are contained on circular Printed Circuit Boards (PCBs) sized to fit neatly into the mask holes. The carbon dioxide and oxygen sensor PCBs are then sealed into the two mask holes with glue. The battery and main PCB are housed in a 3D printed encasing on the back strap of the neoprene cover.

G. Device Firmware

Motion and the human breath are the two main sources of information. The accelerometer axes data are collected into three separate arrays that are then passed through a moving average filter and placed into 11 different thresholds. Each threshold is assigned a number between 0 and 10, with a 0 corresponding to the lowest level of activity and a 10 corresponding to the highest level of activity. From there, the activity level can be determined in correlation to the threshold number reached. For example, an activity level 3 corresponds to the user walking at a moderate pace, and an activity level 10 is reached when the user sprints. The human breath is observed through oxygen and carbon dioxide sensors. Because data from the UARTs are in ASCII, each character must first be parsed and then converted into integers, so that the mobile application can easily display the oxygen and carbon dioxide levels as percentages. The integers are stored into an array before they are sent over BLE to the mobile application.

The system is governed by a simple state machine, where the operation begins in the start state. It automatically moves into the searching state, where no data is being transmitted. In the searching state, the PSoC initializes the gas sensors and

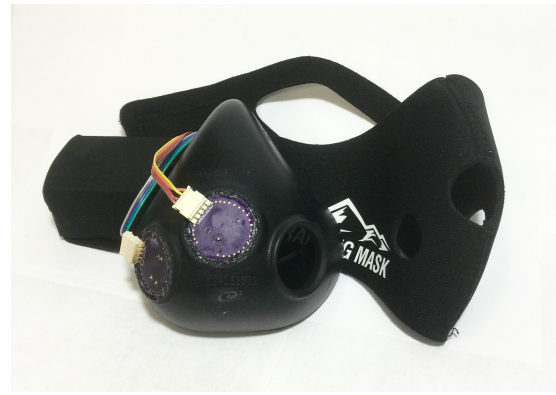


Figure 2. OOCOO Mask Design

accelerometer. The PSoC puts the oxygen and carbon dioxide sensors into polling mode, where the sensors output data only when receiving the request from PSoC. The accelerometer is initialized by the PSoC into 2g fast read mode. In this mode the data from the accelerometer is 8 bits long and the resolution is 2g. This resolution and data length make it so that each bit is 15.6 mG. Once the phone and the PSoC are paired over BLE, the system moves into the active state. The respiration and activity data are both read by the PSoC and displayed on the phone application in the active state. Once the phone application and the PSoC disconnect, the system moves back into the searching state.

H. Mobile Application

The mask connects and transfers data to a cellphone through a BLE connection with a Qt Android Mobile Application. This mobile application shows live carbon dioxide, oxygen, and activity data. The mobile application also displays the current battery level percentage of the device.

V. EVALUATION

A. Testing Procedures

To verify the mask design and functionality of the two gas sensors, three tests were completed. The first test that was performed, served to establish a baseline reading for the sensors and acted as the control. The volunteer wore the mask for a session of 20 minutes and was told to remain sitting. Data was recorded every three minutes.

After establishing the resting data, the volunteer then performed a running test. The test was run for 15 minutes: 10 minutes of running on a treadmill plus 5 minutes of rest. Data was recorded every minute to establish the trend. The volunteer's height, weight, age, sex, and average running speed were also collected.

The third test that was performed shows respiration level trends for varying levels of exertion. The volunteer completed 21 minutes of testing: 5 minutes of resting, 5 minutes of walking, 5 minutes of speed-walking, 1 minute of running, and 5 minutes of resting. CO₂ and O₂ levels were recorded every 15 seconds during the running portion, and every minute throughout the rest of the test. The height, weight, age, sex, and treadmill speeds during all exertion levels were collected as well.

All three tests were repeated on multiple users in order to verify the results from the mask.

B. Results and Discussion

The baseline resting test results yielded an average of 18.1% oxygen and 2.35% carbon dioxide in respiration at rest. Fig. 3 displays the observed trends in carbon dioxide and oxygen levels resulting from the running test. The values graphed in Fig. 3 are the change in oxygen and carbon dioxide values from the baseline values observed in the initial test. When users initially put on the mask at time 0 minutes, the O₂ and CO₂ levels rose from the atmospheric levels to the 5 users' resting respiration levels. Once the users began to workout at one minute, their carbon dioxide levels increased, while their oxygen levels decreased. At ten minutes when the users stopped working out and began the resting period, oxygen and carbon dioxide respiration levels returned to the resting levels observed at the start of the testing period. As expected, the specific oxygen and carbon dioxide levels varied from user to user, however, each test yielded the same trends mentioned above.

The exertion level test results yielded similar trends to the running test. However, there was a gradual increase in carbon dioxide and decrease in oxygen as the volunteer progressed from resting, to walking, and then to running. The values displayed in Fig. 4 are the change in oxygen and carbon dioxide values from average resting carbon dioxide and oxygen levels during the 5 minutes of resting at the start of the test. From 0 to 4 minutes, the oxygen and carbon dioxide levels remained relatively flat with minor variations.

At time 5 minutes when the volunteer began to run, the carbon dioxide levels increased and the oxygen levels decreased as expected. Both oxygen and carbon dioxide levels saw minor fluctuations, but remained relatively flat until time 10 minutes. At time 10 minutes when the volunteer began to walk at quicker pace, the carbon dioxide levels again rose and the oxygen levels also saw an overall decrease. However, the oxygen levels experienced a much smaller decrease than the increase the carbon dioxide levels saw.

The levels remained relatively constant with minor fluctuations until time 15 minutes. When the volunteer began to run at time 15 minutes, there was a larger increase in carbon dioxide and a larger decrease in oxygen from their initial values. At time 16 minutes when the volunteer began the final resting period, carbon dioxide levels decreased to below their initial resting levels, and the oxygen levels increased to above their initial resting levels. It is expected for carbon dioxide and oxygen levels to further increase and decrease, respectively, as the volunteers increase their exertion levels. However, since the OOCOO Mask is developed to display respiratory trends in correlation to activity levels, rather than analyze them, the details and analysis of the correlation between respiration and activity levels go beyond the scope of this paper.

Possible sources of error in the results are imperfect mask seal and user biasing. The rubber mask seal works very well for some face shapes, while it may leak very slightly for other face shapes. However, the imperfect mask seal only results in small amounts of leakage and does not affect testing results.

User biasing is accounted for by performing the same test on multiple users.

The initial tests were performed on OOCOO designer team members, where it was found that members often attempted to adjust their breathing patterns to produce the results they wanted. Tests were then performed on users who had no knowledge of the functionality of the mask to verify trends were not caused by user biasing. These tests yielded the same trends as the initial tests on OOCOO Mask team members. Therefore, user biasing does not create a large enough error to affect testing results.

TABLE III. RUNNING TEST DATA

Time (min)	O2 (%)	CO2 (%)
0	18.10	2.47
1	16.81	3.10
2	17.09	3.19
3	17.21	3.27
4	17.29	3.09
5	17.32	3.00
6	17.37	3.05
7	17.52	2.90
8	17.46	2.88
9	17.19	2.95
10	17.47	2.87
11	17.67	2.82
12	17.87	2.53
13	18.26	2.08
14	17.94	2.32
15	18.08	2.20

TABLE IV. EXERTION LEVEL TEST DATA

Time (min)	O2 (%)	CO2 (%)
0	18.10	2.47
1	16.81	3.10
2	17.09	3.19
3	17.21	3.27
4	17.29	3.09
5	17.32	3.00
6	17.37	3.05
7	17.52	2.90
8	17.46	2.88
9	17.19	2.95
10	17.47	2.87
11	17.67	2.82
12	17.87	2.53
13	18.26	2.08
14	17.94	2.32
15	18.08	2.20
15.25	17.25	3.18
15.5	17.20	3.38
15.75	17.12	3.42
16	17.44	3.63
17	18.18	3.44
18	18.57	3.01
19	18.64	2.67
20	18.54	2.55

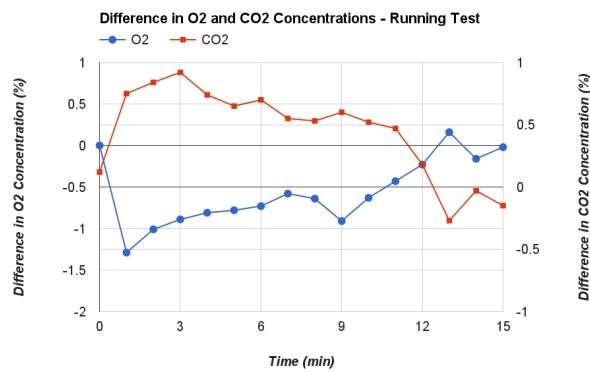


Figure 3. Results from Running Testing

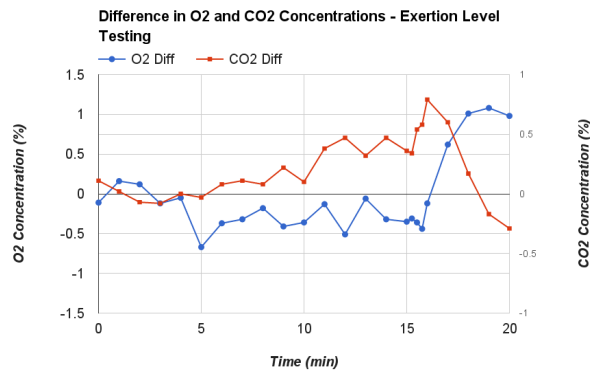


Figure 4. Results from Exertion Level Testing

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