BME 484/485 Biomedical Engineering Capstone Design I & II
Department of Electrical, Computer and Biomedical Engineering
University of Rhode Island, Kingston, RI 02881

The Effect of Recording Methods on the Frequency Response for an Electronic Stethoscope

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11/2/12

***Abstract*- Current diagnostic testing for sleep apnea requires patients to undergo multiple measurements with wires, electrodes, and other monitoring devices in a sleep laboratory, during an overnight visit. The Jabes Electronic Stethoscope is a hands free method for detecting sleep apnea during a standard clinical visit while the patient is awake. This design project will determine the quantifiable differences in frequency response and the elimination of high or low frequencies due to the probe to skin interface that is in current use. A re-design of the handle will be fabricated with a pressure sensor to determine the ideal pressure which should be applied and to regulate the consistency of the pressure.**

I. Introduction

Sleep disorders affect an estimated 50-70 million US adults and may be linked to hypertension, diabetes, depression, and other health related disorders [2]. Sleep apnea is the interruption of regular breathing when the throat muscles relax which can cause snoring and irregular arousals during the rapid eye movement sleep cycle [3][5]. Nocturnal polysomnography, the diagnostic testing of sleep apnea, requires patients to be hooked up to heart, lung, and brain activity monitors during an overnight testing in a laboratory [6]. Electrodes are attached to the face and scalp to send electrical signals generated by the brain and muscle activity while a belt is worn around the chest and abdomen for breathing measurements [8]. This diagnostic testing can be delayed up to 10 weeks due to wait lists, creating a demand for better access to diagnostic testing [7]. Other comprehensive tests include an electroencephalogram to measure brain wave activity, electromyogram to record muscle activity, electro-oculogram to record eye movements, and electrocardiogram to record heart rate and rhythm [8]. Home sleep tests are a simplified version of the polysomnography in which measurements in heart rate, blood oxygen level, and breathing patterns are monitored; though these portable monitoring systems are not able to detect all cases, requiring further testing [6].

The Jabes Electronic Stethoscope is a hands free method for diagnostic testing of sleep apnea during a standard clinical visit. This proposed system incorporates double-sided tape to attach the stethoscope to the skin at the suprasternal notch. The electronic stethoscope is able to detect signs of sleep apnea in patients who are awake without direct pressure, therefore eliminating human error. The purpose of this design project is to quantitatively compare the frequency response of different methods for recording human breathing and to create a more desirable contact interface between the stethoscope probe.

II. Origin of Problem

The project investigated originates from an industry demand. Determining the difference in frequency response between recording methods is an important study which could have a large impact on society. This specific investigation stems from a similar project which focuses on evaluating patterns in a frequency response to detect sleep apnea. During the original testing, certain variables arose which need to be quantified. One of the major concerns in testing was the effect which double-sided tape had on the frequency response in identical trials. In order to create a standard operating procedure, it must be determined that the tape does not have a negative outcome on the results of a test.

Pressure which is applied to the stethoscope during recording is another large variable which needs to be kept consistent. In simple preliminary recordings, it is clear that there is a different frequency response due to drastic changes in pressure. Building a device which can

quantify pressure applied by the stethoscope will allow for the evaluation of its effects. Results of a recording will be much more reliable if the test is executed consistently with predefined conditions. The testing which will be performed directly impacts a known industry problem and furthers the understanding of these evaluations.

III. Realistic Constraints

This stethoscope must be able to accurately measure the pressure being applied to a patient's throat while not obstructing the airway. An obstruction would be defined as the subject not being able to breathe or the area around the throat is irritated. In order to accomplish this, the current design includes a silicone handle with an embedded pressure sensor that relays to a microprocessor attached along the tubing of the stethoscope. The readout on this portion of the stethoscope will allow the user to apply the correct amount of pressure to the subject's throat. Also, the placement of the microprocessor will allow for the measurements to be taken unobstructed. Other design possibilities looked at include a pressure sensitive balloon attached to a pressure gauge to display the pressure being applied to the stethoscope.

The economic constraint of the stethoscope being designed is that the price range of the product should be less than 500 dollars. Current methods for evaluating and diagnosing sleep apnea are very costly and take a large amount of specialized training in order to operate.

Due to the limited availability of materials in the design process, some materials will need to be reevaluated for both economical and environmental reasons by industry experts. A major ethical concern for the design of the stethoscope is the need for the limiting of pressure being applied to the patient's throat. This is mitigated by the addition of the pressure readout to quantify the amount.

By implementing this method of sleep apnea detection rather than the current methods used, the social constraints of testing for sleep apnea will be lifted dramatically. Currently an overnight stay in a sleep lab is needed to test for sleep apnea [4]. This design will allow patients to have sleep apnea testing determined in a matter of minutes rather than hours. The new design will also increase the portability while simultaneously decreasing the cost of testing equipment. The largest social concern is for which design method physicians see best fit for clinical applications.

There are several important health and safety constraints that need to be addressed in the design of this device. The first is that electronic components need to be encased in a housing to reduce the risk of shock. Also, safety mechanisms must be in place to meet the standards described in the IEC 60601-1 document. This includes the placement of the power source away from contact with the skin as well as mechanisms to prevent discharge of the device to the patient or physician. The second major safety issue is that the amount of pressure applied to the stethoscope is kept to the minimum amount required to take an accurate reading. This is the goal of the pressure sensor. Although the physician could apply as much force as they desired, a major reason for the pressure reading is patient safety. It is hoped that with addition of the pressure readout, that a physician will be able to see and correct the amount of pressure they are applying to the patient. This will help alleviate the amount of discomfort a patient will experience during testing and improve the accuracy of the test.

This device must be able to be manufactured using parts found commonly in industry. This will help to keep the base and maintenance prices to a minimum. In order to accomplish this, we are implementing our design using a Tekscan pressure transducer and PIC

microprocessor. Both of these components can be commonly found throughout industry. The other components that are being used to implement our design can be commonly found in electronics labs throughout academia and industry.

The design being pursued is a multi-use system. As with any standard stethoscope, the only need for cleanliness is to clean the areas that will come in contact with patients. In addition to the cleaning, the digital nature of the design means that the batteries must be replaced periodically.

IV. Engineering Standards

The voltage supplying the circuit is nine volts, which is within a safe range. All wires on both the breadboard and pressure sensor are insulated with the ends caped therefore making them unexposed to human contact. The pressure sensor is encapsulated within an insulated silicon handle. This prevents any current going directly from the circuit to the participant. Sheet metal which is attached as a handle has been filed so that all corners are round. This will prevent the participants from being scratched if there is contact with the skin. The circuit which displays an amount of pressure is placed out of reach from each participant. Distance from the breadboard will ensure participants will be unaffected if the circuit overheats. Simplicity and efficiency were taken into account while writing code for the PIC processor. The program which was created uses the most direct method of calculation to produce a result. All parts used in the pressure sensing circuit are CE and RoHS compliant. A bill of materials is available in *Appendix G* which states the origin and compliance of each component. Circuit diagrams have also been attached in *Appendix F* and *Appendix H* in order to document the layout of the breadboard.

Design alternatives were weighed for the size, shape, and material for the handle of the stethoscope. The size and shape were designed to be ergonomically correct and allow for ease of use. The handle was designed to fit comfortably in the hand and allows for spots where the fingers can grip the handle. These spots allow for accuracy and consistency of the application of pressure. The first material used for the base of the handle was polyvinyl chloride pipe. This material is inexpensive but cumbersome to use. The PVC required constant heating to become malleable enough for creating to correct platform shape and angles. Sheet metal was used in the latest version of the platform. Although sheet metal is more expensive, it allows for easier manipulation of the material to create more accurate bend angles and precise drill holes. Another design alternative came with the pressure sensing mechanism. A pressure sensitive balloon attached to a pressure gauge could have been used and would not require any additional hardware or complex circuitry. The design that was chosen is more complex but incorporates a microprocessor. With the microprocessor, the use of an amplifier and an external circuit was required.

An expedited review was submitted to the International Review Board for the allowance of testing on human subjects, shown in *Appendix A* and *Appendix C*. The IRB sets the standards in human subject research to inform the public about the protection regulations as well as the IRB's role and authority. Collaborative institutional training initiative training for basic human subject protection was completed, shown in *Appendix B.* The waiver for informed consent was completed during the process of applying for a human study.

For project management, one student was chosen to work as the project manager. Andy Spiewak was assigned the project manager. As manager, Andy oversees all aspects of the project including the mechanical and electrical design. He planned for project deadlines and made sure that they are met. The manager gathered and submitted all of the IRB documentation for approval. Andy manages the integration of the hardware and software for the project. He is

responsible for informing the testing process to participants and is the liaison between the participants and Dr. Sun.

V. Methods

Phase I of the design project is to investigate a possible quantitative difference in frequency response due to double-sided tape used as the contact interface for both the stethoscope and microphone. Testing will be completed on multiple participants under four conditions; with tape-no pressure, no tape-low pressure, no tape-medium pressure, and no tape-high pressure. Participants will lie in the supine position with the stethoscope wrapped around their neck. The probe will be adhered at the suprasternal notch around the cricoid cartilage with the microphone resting on top of the probe but below the laryngeal prominence. Testing will be carried out in the "wide load" setting of the stethoscope to incorporate both the low and high frequencies for the heart and lung sounds respectively. Simultaneous recording will be made with the microphone and electronic stethoscope to determine possible difference in the frequency response.

Participants will be randomly recorded for 20 seconds of breathing over 40 seconds without knowledge of the start and stop. This will be done to prevent any abnormal breaths due to the patient's nerves with the commencement of the recording. The signal from the stethoscope and the microphone will be recorded via the Zoom H4N digital recorder, using two separate channels. This data will be stored as a .wave file and is able to be transferred to a computer by a USB cord. The collected data will be analyzed using a fast Fourier transform program in MATLAB. A complete quantitative set of data will allow for comparison of the two different application methods, with varying pressure. Multiple trials will be conducted on 10-20 patients.

Phase II of the project is the designing of a silicone rubber stethoscope handle, containing an embedded pressure sensor, and a mounting platform for probe application with direct pressure. The pressure sensor, Tekscan's FloexiForce A401 sensor, will be placed in a slot within the handle; placement and orientation will be tested. Calibrating the force measurement will be achieved by pressing the probe against a scale. Following calibration, the user will have controlled applied pressure with the feedback from a multimeter. Multiple designs will be drawn up and prototypes will be created for the various versions and materials. Testing of prototypes will identify the best design, and re-designs will be created for more testing. The addition of a pressure sensing handle will allow a more constant pressure to be applied during the test and decreasing the human error of direct hand pressure. A more accurate understanding of how application force affects the frequency output will be attained. Time permitting; the output quantity of pressure will be transferred to an LCD screen through the use of a PIC processor for a more precise measurement of pressure.

VI. Results

The proposed results of this design project were that the double-sided tape being used for the contact interface was creating a bell effect and eliminating the high frequencies which correspond to lung sound. It was proposed that the trials with medium pressure with no tape would produce the best FFT and would not eliminate frequencies. Preliminary recordings were analyzed with a FFT program in MATLAB and graphs were created. The results determined that we needed a larger sample size to determine the outcome of our hypothesis and are shown in *Appendix E.* As a result, we have applied for an IRB study to allow us to get a better sample size and more accurately determine how the pressure and tape affect the readings. In order to apply a

consistent pressure for each person in this study a handle was designed, and is currently being fabricated and tested. This will allow us to quantify the pressure being applied and create a control group to measure the effects of varying the pressure and tape in the study.

VII. Discussion

It is hypothesized that the double-sided tape will create a bell effect because the tape, which is a half inch wide ring is placed directly to the diaphragm of the probe; therefore creating a less than ideal contact to the skin where air can interfere with the recording. The low and high pressure testing is hypothesized to be less accurate than the medium pressure. The low pressure is thought to have a similar problem as that with the double-sided tape. Direct and constant contact between the skin and the probe is necessary for the probe's diaphragm to pick up the breathing sounds. Spaces or gaps in the interfacing will result in a less than ideal contact which increases the signal to noise ratio, creating a less accurate readout with a large presence of noise. The high pressure is thought to distort the signal by preventing or decreasing the vibration of the sound on the probe's diaphragm. The medium pressure will have a constant pressure that creates complete contact between the probe's diaphragm and the skin but does not constrict the diaphragm movement.

It is hypothesized that a silicone handle will allow the constant pressure and contact to the skin that is required for an accurate recording. A design with the pressure sensor and handle centered below the handle and above the stethoscope, respectively, will allow for equal distribution of force. The handle being placed offset of the stethoscope will allow for the user to access the buttons.

At this time no additional supplies are needed, though throughout the design process of the handle some may be required. Later in the time frame of this project, a scale will be necessary for the calibration of the pressure. The timeline for this project is attached separately.

VIII. References

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[2]"Insufficient Sleep Is a Public Health Epidemic." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 17 Mar. 2011. Web. 22 Sept. 2012. <http://www.cdc.gov/features/dssleep/>.

[3] "Key Sleep Disorders." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 01 Mar. 2012. Web. 22 Sept. 2012. <http://www.cdc.gov/sleep/about_sleep/key_disorders.htm>.

[4]Lab 2 manual, BME 361 Biomeasurement Laboratory, Dept. of Electrical, Computer and Biomedical Engineering, University of Rhode Island, <www.ele.uri.edu/Courses/bme360/>, 2011.

[5]National Academy of Sciences. "SLEEP DISORDERS AND SLEEP DEPRIVATION: AN UNMET PUBLIC HEALTH PROBLEM." *The National Academies*. The National Academy of Sciences, Apr. 2006. Web. 22 Sept. 2012. <http://www.iom.edu/~/media/Files/Report%20Files/2006/Sleep-Disorders-and-Sleep-Deprivation-An-Unmet-Public-Health-Problem/Sleepforweb.ashx>.

[6]Staff, Mayo Clinic. "Sleep Apnea: Definition." *Mayo Clinic*. Mayo Foundation for Medical Education and Research, 24 July 2012. Web. 22 Sept. 2012. <http://www.mayoclinic.com/health/sleep-apnea/DS00148>.

[7]Staff, Mayo Clinic. "Sleep Apnea: Tests and Diagnosis." *Mayo Clinic*. Mayo Foundation for Medical Education and Research, 24 July 2012. Web. 22 Sept. 2012. <http://www.mayoclinic.com/health/sleep-apnea/DS00148/DSECTION=tests-and-diagnosis>.

[8] "Tests for Diagnosing Sleep Apnea." *WebMD*.Ed. Kimball Johnson, MD. WebMD, 03 May 0000. Web. 22 Sept. 2012. <http://www.webmd.com/sleep-disorders/sleep-apnea/diagnosing-sleep-apnea>.

IX. Appendices

Appendix A.

University of Rhode Island

Institutional Review Board (IRB)

Instructions and Checklists for IRB Application Submission

This application form is to seek initial IRB approval for a research study.

There are three levels of IRB review (Full Board, Expedited and Exempt), determined by the nature of the project, level of potential risk to human subjects, and the subject population. It is the principal investigator's responsibility to request the type of review he or she believes is appropriate for the study, but the IRB will make the final decision. Regardless of the type of review, all applications use the same submission form.
As required, read the linked URI IRB policies and proceduresmanual, where you will find guidance as to which level of review to request
Following are three separate checklists and instructions for submission for each of the three levels of IRB review: Exempt, Expedited and Full Board. One checklist must be completed and submitted with your IRB application form, located immediately following the checklists.
Be certain to answer all questions thoroughly and attach all necessary documentation to avoid delays in the review of your IRB application.
All documents must be submitted electronically as attachments to the project package on IRBNet. The IRB cannot review any project unless the

documents are submitted as a single package. For instructions on using IRBNet, please see Instructions for IRBNet Online Submissions.
Graduate students must submit an original hard copy of their Thesis/Dissertation Proposal Approval Sheet to the Office of Research Compliance after submitting IRBNet package electronically. A PDF version of the form should also be included with the IRBNet package.
If you have any questions, please contact the Office of Research Compliance at (401)874-4328 or compliance@ds.uri.edu.

University of Rhode Island - Institutional Review Board
Instructions and Checklists for IRB Application Submission
EXEMPT REVIEW – Submit one original or copy of each document

If you are unsure which level of review to request, review the URI IRB policies and procedures manual for guidance, using this link:www.uri.edu/research/tro/offices/compliance

If your research is restricted to the analysis of secondary data, fill out and submit a Secondary Data Analysis Form located on the Compliance website. Do not submit an IRB Application Form unless you are instructed to do so by the Office of Research Compliance.

In making the request for exempt review, complete and submit this Checklist with your application, attaching all required documents to your IRBNet package:

☐Y ☐N/A	Submit a letter by the principal investigator indicating why the exemption should be granted, citing which of the six published reasons for exemption applies. When the research will be conducted by a student, the letter should either be written by or endorsed by the student's major advisor and/or chairperson of the department in which the student is enrolled.
☐Y ☐N/A	Submit one copy of the research proposal (if student, include the original Thesis/Dissertation Approval Sheet).
☐Y ☐N/A	Submit one completed IRB Application Form using the latest version from our website. *The application form is revised regularly. Please check our website for the current version.*
☐Y ☐N/A	Ensure that all parties named on the Assurance (final page of the Application) sign the package **electronically** via IRBNet. Directions for registering with IRBNet and signing a package can be obtainedhere. .
☐Y	If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead, submitted as a PDF) is

☐N/A	required. If the cooperating agency has an IRB, a copy of that agency's IRB approval is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution. Use of secondary data that is not publicly available needs a prior IRB approval number or a letter from a person in authority granting permission to use the data.
☐Y ☐N/A	Submit one copy of all recruitment materials you plan to use, such as flyers, emails, notices, instructions, etc.
☐Y ☐N/A	Submit one copy of all written materials to be used with study participants, such as surveys, questionnaires, sample interview questions or interview guides. If applicable, include online consent document or scripts that are part of consent process.
☐Y ☐N/A	Submit one copy of each informed consent document and/or assent document written using language no higher than the eighth-grade reading level.
☐Y ☐N/A	If you are using secondary data that is not publicly available, include a prior IRB approval number or a letter granting permission to use the data.
☐Y ☐N/A	Provide documentation of CITI Program Training in the Protection of Human Subjects for all key personnel. Comparable training certification from another credible source will be considered by Office of Research Compliance staff.

University of Rhode Island - Institutional Review Board
Instructions and Checklists for IRB Application Submission
EXPEDITED REVIEW – Submit one original or copy of each document

If you are unsure which level of review to request, review the URI IRB policies and procedures manual for guidance, using this link:www.uri.edu/research/tro/offices/compliance

In making the request for expedited review, complete and submit this Checklist with your application, attaching all required documents to your IRBNet package:

☒Y ☐N/A	Submit one completed research proposal (ex. thesis, dissertation, or sponsored research grant proposal) less any appended material not necessary to an understanding of the project. Student proposals must include the original Thesis/Dissertation Approval

	Sheet.
☒Y ☐N/A	Submit one completed IRB Application Form using the latest version from our website. *The application form is revised regularly. Please check our website for the current version.*
☒Y ☐N/A	Ensure that all parties named on the Assurance (final page of the Application) sign the package **electronically** via IRBNet. Directions for registering with IRBNet and signing a package can be obtainedhere.
☒Y ☐N/A	Submit one copy of any survey, questionnaire, sample interview questions, and flyers or advertisements.
☒Y ☐N/A	Submit one copy of all informed consent documents to be used written using language no higher than the eighth-grade reading level. If applicable, include online consent request or scripts that are to be used as part of consent process.
☐Y ☒N/A	If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead, submitted as a PDF) is required. If the cooperating agency has an IRB, a copy of that agency's IRB approval is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution. Use of secondary data that is not publicly available needs a prior IRB approval number or a letter from a person in authority granting permission to use the data.
☒Y ☐N/A	Documentation of CITI Program Training in the Protection of Human Subjects for all key personnel. Comparable training certification from another credible source will be considered by Office of Research Compliance staff.

University of Rhode Island - Institutional Review Board
Instructions and Checklists for IRB Application Submission

If you are unsure which level of review to request, review the URI IRB policies and procedures manual for guidance, using this link:www.uri.edu/research/tro/offices/compliance

FULL COMMITTEE REVIEW

- If neither of the streamlined reviews is possible, the proposal must be reviewed by the convened Institutional Review Board, which meets monthly.
- If it is determined that a student's research proposal will require Full Board review, that student's major professor or a member of the student's research committee must accompany the student to the IRB meeting.
- Material for full committee review must be submitted at least two weeks prior to the monthly meeting (see IRB meeting schedule at http://www.uri.edu/research/compliance/newirb.htm).
- Please make your submission electronically via IRBNet.

For full board review, complete and submit this Checklist with your application, attaching all required documents to your IRBNet package:

☐Y ☐N/A	Submit a completed research proposals (ex. thesis, dissertation, or sponsored research grant proposal) less any appended material not necessary to an understanding of the project, (if student, include the original Thesis/Dissertation Approval Sheet).
☐Y ☐N/A	Submit a completed IRB Proposal Application Form using the latest version from our website. *The application form is revised regularly. Please check our website for the current version.*
☐Y ☐N/A	Ensure that all parties named on the Assurance (final page of the Application) sign the package **electronically** via IRBNet. Directions for registering with IRBNet and signing a package can be obtained here.
☐Y ☐N/A	Submit copies of any survey, questionnaire, sample interview questions, and flyers or advertisements.
☐Y ☐N/A	Submit informed consent(s) used, written using language no higher than the eighth-grade reading level. If applicable, include online consent request or scripts that are to be used as part of consent process.
☐Y ☐N/A	If the research involves a cooperating agency, institution, school district, etc., a letter of agreement to participate in the research (on letterhead, submitted as a PDF) is required. Research that is to be conducted in foreign countries requires a letter of agreement from an appropriate official or cooperating institution. If the

	cooperating agency has an IRB, a copy of that agency's IRB approval is required. Provide a copy of each document.
☐Y ☐N/A	Provide documentation of CITI Program Training in the Protection of Human Subjects for all key personnel. Comparable training certification from another credible source will be considered by Office of Research Compliance staff.

University of Rhode Island

Institutional Review Board (IRB)

IRB Application Form

IRB ID No._____(Internal Use Only)

Part 1. Project Identification

1.1 Review Requested – Choose One: (See URI IRB Policy and Procedures for guidance)

a☐ Full Board b.☒Expedited Review c. ☐Exempt Review - Category #_____

1.2 Project Title (Project title must match grant title. If different, also provide grant title):

The Effect of Recording Methods on the Frequency Response for an Electronic Stethoscope

1.3 Project Duration:

Start Date: 9/7/12	**End Date:** 1/28/12

1.4 Principal Investigator (PI)

EVERY SUBMISSION REQUIRES A PI. THE PI CANNOT BE A STUDENT.

PI NAME MUST BE THE SAME ON THIS FORM AND IRBNet SUBMISSION

Name: Ying Sun	
Mailing Address: 4 East Alumne Avenue, Kingston, RI 02881	**Phone Number:** 401-874-2515
Email: sun@ele.uri.edu	**Fax:** 401-782-6422
University Department: Department of Electrical, Computer, and Biomedical Engineering	**College:** University of Rhode Island College of Engineering
Occupational Position at URI: x Faculty Staff Other: _____	

1.5 Co-Investigator (Students cannot be co-investigators):

Name:	
Mailing Address:	**Phone Number:**
Email:	**Fax:**
University Department:	**College:**

Occupational Position at URI: Faculty Staff Other: _____	

1.6 Student Investigator

Name Brittany Alphonse	
Local Mailing Address 2337 Kingstown Road, Kingston RI 02881	**Phone Number:** 774-275-0410
Permanent Mailing Address (if different) 104 Bumble Bee Circle, Shrewsbury MA 01545	**Fax:** N/A
Email: balphonse@my.uri.edu	
University Department: Electrical, Biomedical, and Computer Engineering	**College:** University of Rhode Island
Dissertation/Thesis Proposal: Yes ☐ **No** ☒ **IF YES, please submit thesis or dissertation proposal with this IRB Application Form**	

1.7 Key Personnel - Other people engaged in the study who have access to identifiable information about subjects (i.e. enroll participants, conduct consent process, collect or review identifiable information, or conduct intervention activities):

Name	Position	Role on study
Andrew Spiewak	Student investigator	Manager
Erik Walder	Student investigator	Software Engineer

1.8 Training in Responsible Conduct of Research With Human Subjects

Have all study investigators and other key personnel completed training in the responsible conduct of research with human subjects within the past three years?

YES ☒

NO ☐

If NO, it is the principal investigator's responsibility to ensure that all key personnel complete responsible conduct of research with human subjects training and to provide documentation to the Office of Research Compliance in order to receive IRB approval. Use the following link to access URI's training program, the CITI Program:**https://www.citiprogram.org/default.asp**

CITI CERTIFICATES MUST BE SUBMITTED WITH YOUR IRBNET SUBMISSION

1.9 Funding

A. Will this be an externally funded project?

YES ☐

NO ☒

If yes, please answer the following:

Funding source:

Is the funding source PHS?

C. URI Log Number:

1.10 Collaborating Institutions and Investigators

A. Does the research involve a collaborating agency, institution, school district or other organization (entity)?

YES ☐

NO ☒

IF YES, please complete the following:

A1. List all collaborating entities.

A2. Does each collaborating entity have a Federalwide Assurance?

YES ☐

NO ☐

A3. If yes, please provide the Federalwide Assurance Number(s) of each collaborating entity:

A4. For each collaborating entity, a copy of a letter of agreement to participate in the research (on letterhead) is required. If the collaborating entity has an IRB, a copy of that entity's IRB approval is required. Please include all necessary documentation with the submission of this IRB APPLICATION form.

B. Does the project involve one or more independent investigators who are not formally affiliated with the URI or another institution with a Federalwide Assurance (FWA)?

YES ☐

NO ☒

If YES, the independent investigator(s) must sign a formal written agreement of commitment to follow the human subject protection policies of URI.

Part 2. Summary of Activities

You may copy and paste information from your proposal or consent, if appropriate, in response to any of these questions.

2.1 Briefly describe the research study design, providing a short overview using layman's terms: The research study will involve evaluating the frequency response for an electronic stethoscope under different pressure conditions. There are three quantified amounts of pressure which will be applied to the stethoscope which will be located below the Adam's Apple of each test subject. The goal is to record the breathing of each subject and export the sound file in order to evaluate any differences.

2.2 Describe the tasks research subjects will be asked to perform. Attach surveys, instruments, interview questions, focus group questions, etc. Describe the frequency and duration of procedures, tests, and experiments.

Testing will be completed on multiple participants under four conditions; with tape-no pressure, no tape-low pressure, no tape-medium pressure, and no tape-high pressure. Participants will lie in the supine position with the stethoscope wrapped around their neck. The probe will be adhered at the suprasternal notch around the cricoid cartilage with the microphone resting on top of the probe but below the laryngeal prominence. Testing will be carried out in the "wide load" setting of the stethoscope to incorporate both the low and high frequencies for the heart and lung sounds respectively. Simultaneous recording will be made with the microphone and electronic stethoscope to determine possible difference in the frequency response.

Participants will be randomly recorded for 20 seconds of breathing over 40 seconds without knowledge of the start and stop. This will be done to prevent any abnormal breaths due to the patient's nerves with the commencement of the recording.

2.3 Provide a full description of risks and measures to minimize risks. Include risk of psychosocial harm (emotional distress, embarrassment), economic harm (e.g., loss of employment or insurability, loss of professional standing or reputation, loss of standing within a community), and legal jeopardy. Describe what will be done to minimize those risks.

The only risk of harm would be pressure applied at the suprasternal notch. This has been addressed by calibrating our pressure sensor during preliminary tests in order to ensure safety. There is a numerical value of pressure which we have deemed as unsafe, and the value of high pressure has been set well below a harmful amount. Physical contact my cause temporary redness depending on skin sensitivity.

2.4 Describe any potential for direct benefit to individual subjects, as well as the benefit to society based on scientific knowledge to be gained; these should be clearly distinguished. Monetary payment or other compensation is not considered a benefit.

There is a great deal to be gained from this testing. Results will give insight into current research involving sleep apnea. The quality and methods of current industry standards can be changed for the better. Individuals with sleep apnea could undergo a shorter and more accurate test for the condition without requiring patients to participate in an overnight sleep test.

2.5 Does the research involve (Check all that apply):

- ☐ **Use of private records (e.g. medical, educational financial)**
- ☐ **Possible invasion of privacy of subject or subject's family**
- ☐ **Deception**
- ☐ **Deprivation of physiological requirements such as sleep or food**
- ☐ **Surveys requesting disclosure of sensitive information or illegal activities**
- ☐ **Diet and exercise interventions**
- ☐ **Presentations of materials that might cause stress to a particular population**
- ☐ **Infectious or hazardous materials**
- ☐ **Risks to job security or financial stability**
- ☐ **Invasive medical procedures other than blood draws**
- ☐ **Blood draws**
- ☐ **Investigational New Drug**
- ☒ **Investigational New Device**

Other (please describe)

Part 3. Characteristics of the Subject Population and Location of Study

3.1 Expected total maximum number of subjects:

20**Must be an exact number – cannot be a range.**

Note: You may not exceed the number of subjects approved by the IRB. If you wish to enroll more subjects, you must first submit a request to the Office of Research Compliance.

3.2 Expected age range of subjects:

3.3 Briefly describe the subject population. Specify number, sex, ethnicity, race and age. Justify exclusion of any group, especially by criteria based on gender, ethnicity, race or age.
Subject population is expected to be college age males and females. No exclusion on sex, ethnicity, race and age.

3.4 Vulnerable populations to be recruited for this project (Check all that apply):

☐ Children (17 or under)	☒ URI Students	☐ Decisionally impaired
☐ Prisoners	☐ URI employees	☐ Frail elderly
☐ Pregnant Women	☐ Employees of Researcher	☐ Other:_____

3.5 Describe the location(s) where subject recruitment will take place (e.g. university, agency, hospital, shopping mall)?

University of Rhode Island

(Private settings require an authorization letter.)

Part 4. Recruitment and Informed Consent Process

4.1 Describe the recruitment process, being sure to explain who will approach potential subjects and how the privacy of potential subjects will be protected. Describe any incentives or inducements that will be offered. List all recruitment materials to be used (e.g. advertisements, bulletin board notices, emails, letters, phone scripts, or URLs) and attach copies to this form:

Students will be recruited via a generic email to the engineering database. There will be no incentives. Privacy will be protected through the use of a secure computer for data storage.

4.2 Principal investigators are responsible to see that reasonable steps are taken to ensure that subjects are fully informed and understand the study. Considering that consent involves a process of communication in addition to use of a consent form, describe how you plan to consent your subjects.

The process will be verbally explained to each subject. They will then be given a consent form which contains all the details of testing.

4.3 If any potential participants could have limited decision-making capacity, language barriers or hearing difficulty, describe how capacity to consent will be assessed.

If a participant is able to verbally interact and understands the language of the consent form, they will be allowed to participate.

4.4 If your study population includes a substantial number of people who speak a foreign language, a consent form should be provided in translation. Please provide the name/credentials of the person who will do the translations.

No translations will be needed. Our participant population will not include a substantial amount of people who speak a foreign language.

If translated by the PI, a second fluent translator should also review the translation.

4.5 Parent/Guardian Consent and Assent – If enrolling children, describe how parent(s) or guardian(s) will provide consent and how child will provide assent.

All participants will be above the age of 18.

4.6 Waiver or alteration of consent: The IRB may approve waiver or alteration of one or more of the elements of consent in some minimal risk studies. Do you plan to request one of the following:

[X] **Waiver of signed consent form**

Alteration of consent (i.e. deception)

Waiver of any other elements of informed consent , or entire consent

If so, please explain why the study is considered to be of minimal risk and why the waiver would be necessary to conduct the research:

There is minimal risk because the study will include a normal pressure application to an external layer of skin. A waiver is necessary due to the physical contact made with each test subject.

****The consent form(s) to be used for this study must be included with the submission of this IRB APPLICATION form. Use the following link to access recommended consent form templates: www.uri.edu/research/tro/offices/compliance**

Part 5. Privacy and Confidentiality

5.1 Describe any links between data collected and subject identity. Examples of links include names, addresses, telephone numbers, etc.

Each test subject is given a number. Names will only be used in our data base for organizational purposes.

5.2 Describe the provisions made to maintain anonymity and/or confidentiality of data collected, including assignment of identification numbers, coding systems, etc.

Each subject is assigned an identification number. No names of subjects will be used in any data presentation.

5.3 Where, how long, and in what format (such as paper, digital or electronic media, video, audio, or photographic) will data be kept? Include details about where data will be stored (address), how it will be secured and who will have access to the data. For example, storage and security methods can include such methods as locked cabinets, password protection, encryption, firewalls, etc.

Data will be originally stored on an H4N recording device. It will then be saved as a .wav file and uploaded to a secure computer file. It will be analyzed using the MATLAB computer program.

5.4 Is Investigator requesting authorization for use and disclosure of Protected Health Information (PHI) from a covered entity? (Ex. Hospital, pharmacy, physician office)

YES ☐

NO ☒

5.5 Is Investigator requesting waiver of authorization for use and disclosure of PHI?

YES ☐-- Fill out and submit **Waiver of Authorization**

NO ☒

5.6 Describe how the results of this research will be publicly disseminated (e.g. thesis, dissertation, publication, presentation that is not internal):

The results of this research will be presented at the Northeast BioEngineering conference on April 5th, 2013.

Part 6. Conflict of Interest

A conflict of interest may exist whenever financial considerations or publication rights have the potential to compromise or have the appearance of compromising one's professional judgment and independence in the design, conduct or publication of research.

The IRB considers the investigator's financial interests when evaluating the protection of human subjects. If a financial interest is reported, the IRB will assess the investigator's objectivity in:

- Communicating risks
- Selecting subjects
- Promoting informed consent
- Gathering, analyzing and reporting data

6.1 In the space below, identify whether you (including your spouse or dependent child) or any key person affiliated with the project has any financial interest, financial relationship, governance or administrative affiliation with any entity that is providing funds for or which has rights to intellectual property resulting from this study.

There is no financial interest involved with this research.

6.2 Does this study evaluate a drug, a device, a test for disease, or a product?

YES ☒

NO ☐

IF YES, please answer the following two questions:

A. Do you (or any member of your immediate family) own stock, shares, or have other investments in the product or company owning, manufacturing, or developing the drug, device, test, or product exceeding $10,000 or 5% ownership during the conduct of the research or within one year of the termination of the research study?

YES ☐ - Complete the *Conflict of Interest Disclosure Form*

NO ☒

B. Do you receive any remuneration from the manufacturer, developer or owner of the device, drug, test, or product being evaluated?

YES ☐ - Complete the *Conflict of Interest Disclosure Form*

NO ☒

6.3 Are you serving as a paid consultant or speaker on behalf of the sponsor of your research?

YES ☐ - Complete the *Conflict of Interest Disclosure Form*

NO ☒

Part 7. Assurance Statement

Required Electronic Signatures on IRBNet to complete your assurance:

- **Principal Investigator**
- **Co-investigator(s) if applicable**
- **Student investigator(s) if applicable (sign as team member)**
- **Department Chair or Dean**

Submission of the fully signed IRBNet package will serve as your assurance that the following statements are true:

I CERTIFY as follows concerning the above named research proposal:

I have read and am familiar with the University of Rhode Island's "Policies and Procedures Manual for Human Subject Protection."

The rights and welfare of the subjects will be adequately protected.

Risks or discomfort (if any) to subject(s) have been clearly indicated and it has been shown how they are outweighed by potential benefits to the subject or by the importance of the knowledge to be gained.

The informed consent of subjects will be obtained by appropriate methods that meet the requirements of the University's general assurance procedures.

Any proposed changes in research activity will be reported to the IRB. Those changes may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazard to the subjects. Any changes relating to Part 6, Conflict of Interest, will be reported immediately to the Office of Research Compliance.

Any unanticipated problems involving risks to human subjects or others will be reported to the IRB immediately.

The Principal Investigator certifies that he/she has reviewed this IRB Application and ensured that all materials follow the instructions and checklists (see Pages 1-4) developed by the University of Rhode Island Institutional Review Board. The Principal Investigator acknowledges responsibility for the work of student investigators that he/she supervises.

Appendix B.

CITI Collaborative Institutional Training Initiative

Human Subject Research Curriculum Completion Report
Printed on 10/24/2012

Learner: Erik Walder (username: e.wald4)
Institution: University of Rhode Island
Contact Information 95 Sarasota Ave.
Narragansett, RI 02882 USA
Department: Biomedical Engineering
Phone: 9784917269
Email: erik_walder@my.uri.edu

Group 1 (Basic Course):

Stage 1. Basic Course Passed on 10/23/12 (Ref # 9011548)

Elective Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	10/19/12	3/3 (100%)
History and Ethical Principles - SBR	10/19/12	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	10/19/12	5/5 (100%)
Informed Consent - SBR	10/19/12	5/5 (100%)
Privacy and Confidentiality - SBR	10/23/12	4/5 (80%)
Research With Protected Populations - Vulnerable Subjects: An Overview	10/23/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	10/23/12	5/5 (100%)
University of Rhode Island	10/23/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

CITI Collaborative Institutional Training Initiative

Human Subject Research Curriculum Completion Report
Printed on 9/21/2012

Learner: Brittany Alphonse (username: balphonse)
Institution: University of Rhode Island
Contact Information 104 Bumble Bee Circle
Shrewsbury, Massachusetts 01545
Department: Biomedical Engineering
Phone: 774-275-0410
Email: balphonse@my.uri.edu

Group 1 (Basic Course):

Stage 1. Basic Course Passed on 09/21/12 (Ref # 8813321)

Elective Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	09/21/12	3/3 (100%)
History and Ethical Principles - SBR	09/21/12	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	09/21/12	5/5 (100%)
Informed Consent - SBR	09/21/12	5/5 (100%)
Privacy and Confidentiality - SBR	09/21/12	5/5 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	09/21/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	09/21/12	4/5 (80%)
University of Rhode Island	09/21/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

CITI Collaborative Institutional Training Initiative

Human Subject Research Curriculum Completion Report
Printed on 10/24/2012

Learner: Andrew Spiewak (username: andrew_spiewak)
Institution: University of Rhode Island
Contact Information
2 Banfill Lane
Southborough, MA 01772 USA
Department: Biomedical Engineering
Phone: 508-596-9051
Email: andrew.jspiewak@gmail.com

Group 1 (Basic Course):

Stage 1. Basic Course Passed on 09/21/12 (Ref # 8813811)

Elective Modules	Date Completed	Score
Belmont Report and CITI Course Introduction	09/21/12	3/3 (100%)
History and Ethical Principles - SBR	09/21/12	5/5 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process	09/21/12	5/5 (100%)
Informed Consent - SBR	09/21/12	5/5 (100%)
Privacy and Confidentiality - SBR	09/21/12	5/5 (100%)
Research With Protected Populations - Vulnerable Subjects: An Overview	09/21/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	09/21/12	2/5 (40%)
University of Rhode Island	09/21/12	no quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI participating institution. Falsified information and unauthorized use of the CITI course site is unethical, and may be considered scientific misconduct by your institution.

Paul Braunschweiger Ph.D.
Professor, University of Miami
Director Office of Research Education
CITI Course Coordinator

Return

Appendix C.

URI Students,

As a part of our senior capstone project we are completing a study on the effect of different recording methods on the frequency response of a digital stethoscope. We are in need of volunteers to have their breathing recorded and analyzed. This will take approximately ten minutes and free pizza will be provided for volunteers.

If you are interested in participating please reply to Brittany Alphonse at balphonse@my.uri.edu for more information about the time and location of the study. Specifics of the testing procedure will be explained upon arrival.

The University of Rhode Island
Department of Electrical, Biomedical, and Computer Engineering
4 East Alumne Avenue, Kinston, RI 02881

The Effect of Recording methods on the Frequency Response for an Electronic Stethoscope
CONSENT FORM FOR RESEARCH

You have been invited to take part in a research project described below. The researcher will explain the project to you in detail. You should feel free to ask questions. If you have more questions later, Dr. Ying Sun, the person mainly responsible for this study, 401-874-2515, will discuss them with you. You must be at least 18 years old to be in this research project.

Description of the project:

The nature of the study is to determine the effectiveness of the methods of recording breathing sounds used currently with the Jabes Electronic Stethoscope. The purpose of this study is to see the effect that the pressure on a stethoscope has on the quality of the sound heard.

What will be done:

If you decide to take part in this study here is what will happen: An electronic stethoscope will be placed on your neck, just below the Adams Apple. Four separate recordings, each lasting forty seconds will be taken. During the forty seconds your breathing will be randomly recorded for twenty seconds. The first recording will require the stethoscope to be taped to your neck with medical tape. The next three will have no tape but pressure applied to the stethoscope by the researcher. Each recording will have a little more pressure than the last. The maximum pressure applied will never reach a dangerous level. The entire process will last approximately ten minutes. The recordings using pressure are considered the experimental part of the study.

Risks or discomfort:

There may be some discomfort from the stethoscope pushing on your throat during the recording. Redness at the sight of application may occur but is temporary. If the discomfort is too much simply inform Dr. Ying Sun and the experiment will be stopped. There are no other risks from this study.

Benefits of this study:

Although there will be no direct benefit to you for taking part in this study, the researcher may learn more about the differences in the quality of sound that can be heard in a stethoscope depending on how it is attached to the body.

Confidentiality:

Your part in this study is confidential. Each name will be assigned a number and kept in a database on file in the laboratory on a secure computer. Only the researchers and the faculty investigator will have access to these files. The research and analysis of the data will include only the number and not the name of the individual. None of the information will identify you by name.

In case there is any injury to the subject:

If this study causes you any injury, you should write or call Dr. Ying Sun at the University of Rhode Island at (401)(*874-2515*). For any immediate treatment, participants may visit the Heath Services in the Potter Building. You may also call the office of the Vice President for Research, 70 Lower College Road, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

Decision to quit at any time:

The decision to take part in this study is up to you. You do not have to participate. If you decide to take part in the study, you may quit at any time. Whatever you decide will in no way affect your grade or status as a student. If you wish to quit, simply inform Dr. Ying Sun, 401-874-2515, of your decision.

Rights and Complaints:

If you are not satisfied with the way this study is performed, you may discuss your complaints with Dr. Ying Sun or with {name and phone of individual}, anonymously, if you choose. In addition, if you have questions about your rights as a research participant, you may contact the office of the Vice President for Research, 70 Lower College Road, Suite 2, University of Rhode Island, Kingston, Rhode Island, telephone: (401) 874-4328.

You have read the Consent Form. Your questions have been answered. Your signature on this form means that you understand the information and you agree to participate in this study.

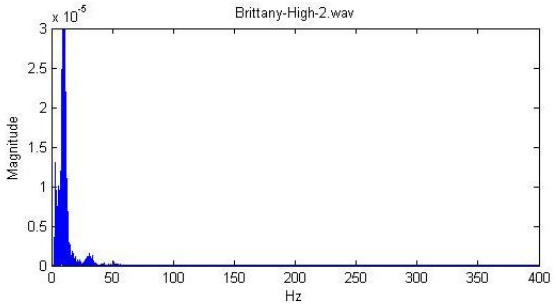
_____	_____
Signature of Participant	Signature of Researcher
_____	_____
Typed/printed Name	Typed/printed name
_____	_____
Date	Date

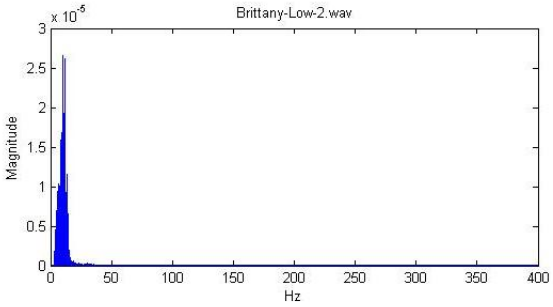
Please sign both consent forms, keeping one for yourself

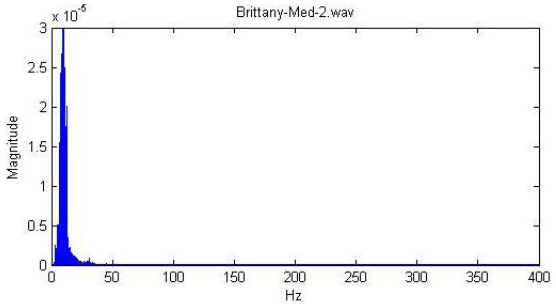
Appendix D.

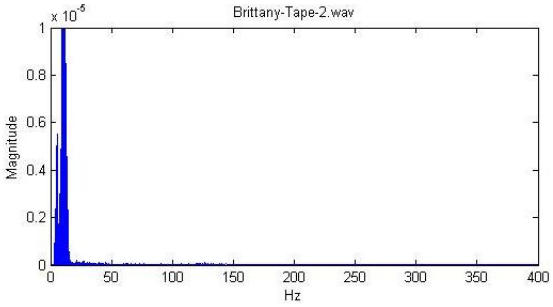
```
function fft_2()

dirlist = dir('*.wav');
deltaT = 0.0002;
Fs = 1/deltaT;

% Adopted from http://www.mathworks.com/support/tech-notes/1700/1702.html

% This check is not really necessary, just a bit cleaned of an error
% message.
if isempty(dirlist)
    message = 'Error: No .wav files found.'
else
    for i = 1:length(dirlist)
        raw_data = wavread(dirlist(i).name);
        data = raw_data(:, 1);

        % Get FFT, cut it in half to remove upper portion (redundant).
        fftx = fft(data);
        fft_len = floor(length(fftx)/2);
        fftx = fftx(1:fft_len);

        % Get magnitude of the FFT as (|x|/length(x))^2 (see above link).
        mx = abs(fftx);
        mx = mx/length(data);
        mx = mx.^2;

        % Double the energy to return to the ammount of energy in the
        % signal before we dropped the upper half of the FFT.
        if rem(fft_len, 2)
            mx(2:end) = mx(2:end)*2;
        else
            mx(2:end-1) = mx(2:end-1)*2;
        end

        % Create a frequency vector.
        f =(0:fft_len-1)*(Fs/fft_len);

        figure(1),
        subplot(2, 2, i)

        plot(f, mx), title(dirlist(i).name)
        if i<4
           axis([0 400 0 3*10^-5])
        else
           axis([0 400 0 1*10^-5])
        end
        ylabel('Magnitude'), xlabel('Hz')
    end
end
```

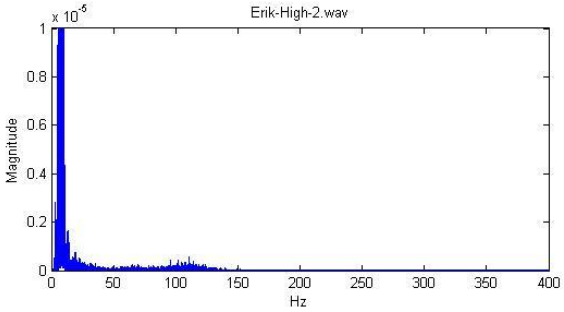
Appendix E.

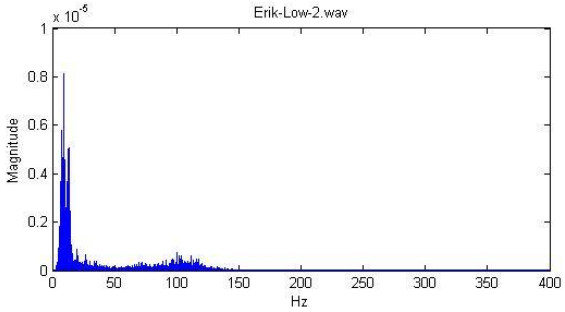

Brittany-High-2.wav
x 10^-5
Magnitude
Hz

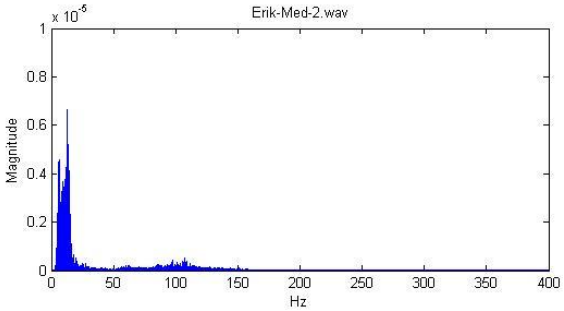

Brittany-Low-2.wav
x 10^-5
Magnitude
Hz


Brittany-Med-2.wav
x 10^-5
Magnitude
Hz


Brittany-Tape-2.wav
x 10^-5
Magnitude
Hz


Erik-High-2.wav
x 10^-5
Magnitude
Hz


Erik-Low-2.wav
x 10^-5
Magnitude
Hz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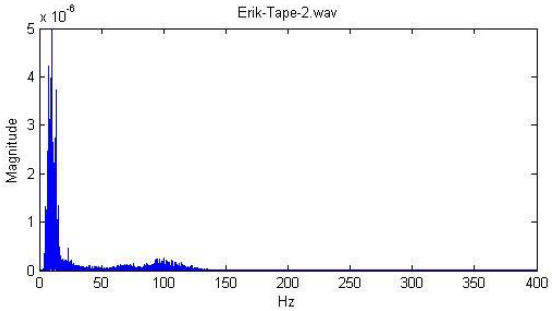
x 10^-5
Magnitude
Hz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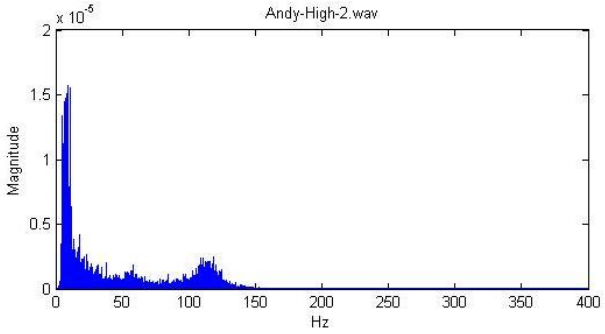
x 10^-6
Magnitude
Hz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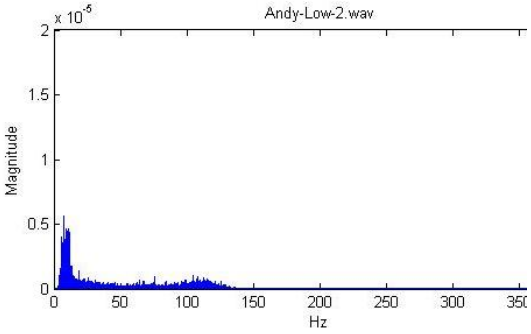
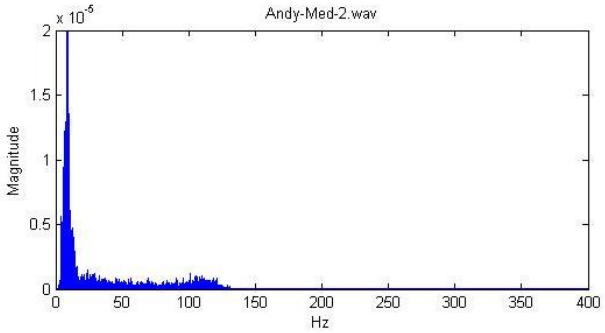
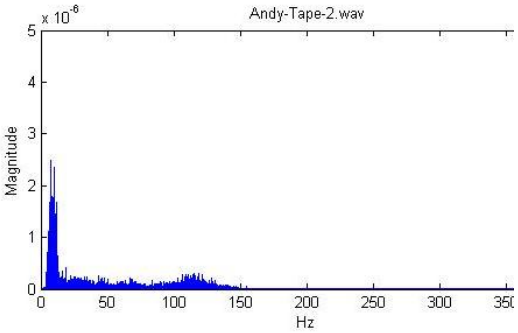
x 10^-5
Magnitude
Hz


Andy-Low-2.wav
x 10^-5
Magnitude
Hz


Andy-Med-2.wav
x 10^-5
Magnitude
Hz


Andy-Tape-2.wav
x 10^-6
Magnitude
Hz

Appendix F.

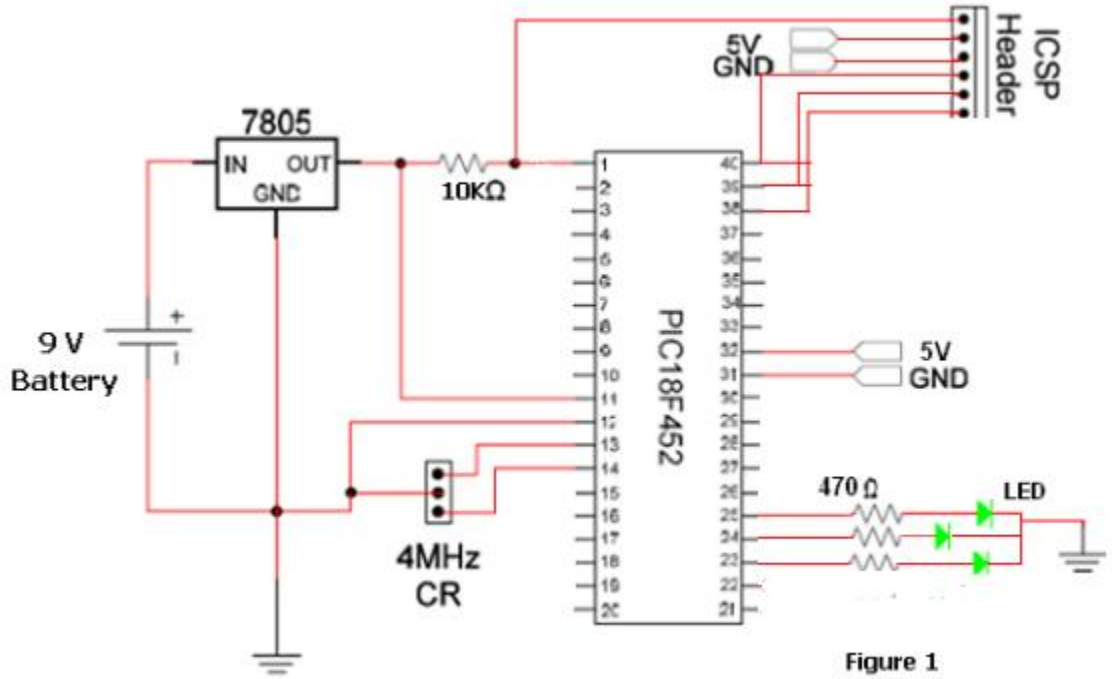
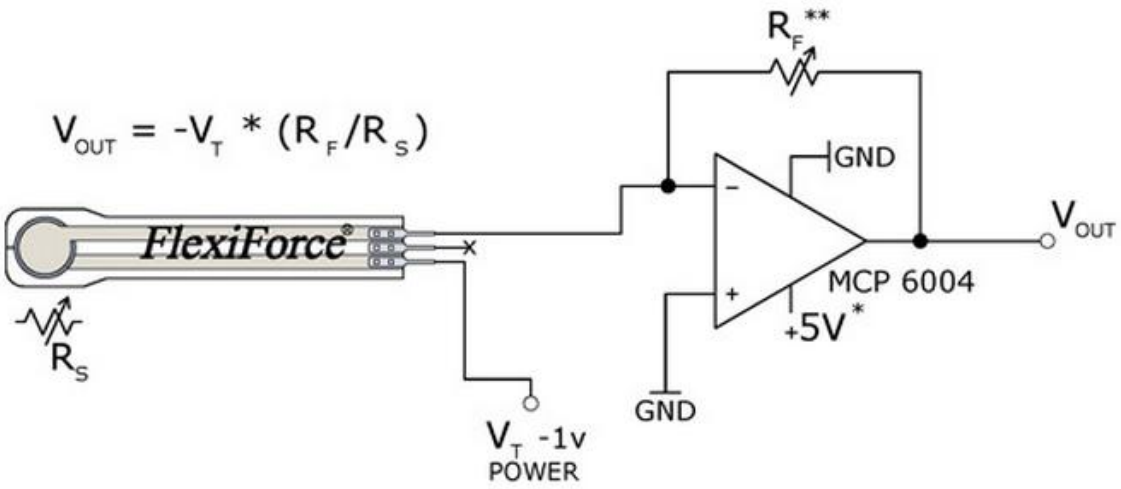


Figure 1

[4]

Appendix G.



- * Supply Voltages should be constant
- ** Reference Resistance R_F is 1kΩ to 100kΩ
- Sensor Resistance R_S at no load is >5MΩ
- Max recommended current is 2.5mA

[4]

Appendix H.

Company	Part	Part Number	Description	Quantity
DigiKey	PIC18F452	PIC18F452-I/P-ND	Lead free / RoHS Compliant	1
DigiKey	LM324N	LM324NFS-ND	Lead free / RoHS Compliant	1
DigiKey	100K resistor	CF18JT100KCT-ND	Lead free / RoHS Compliant	1
Mouser Electronics	5V Regulator	LM7805CT	RoHS Compliant	1
DigiKey	4MHz Oscillator	X911-ND	Lead free / RoHS Compliant	1
SparkFun Electronics	LED	COM-09650	RoHS Compliant	3
Smooth-On	silicone	Mold Star ©15		1
McMaster-Carr	multipurpose aluminum sheet metal	89015K18	Lead free / RoHS Compliant	1
McMaster-Carr	Aluminum threaded Hex Standoff	91780A537	Lead free / RoHS Compliant	2
DigiKey	9V battery	P647-ND	Lead free / RoHS Compliant	1
McMaster-Carr	Philips flat head countersunk screw stainless steel	91500A122	Lead free / RoHS Compliant	4
Philips	Jabes Electronic Stethoscope		CE 0120 Certified ISO 9001:2000 Certified ISO 13485 Certified FDA Certified	3
DigiKey	470 resistor	P470CACT-ND	Lead free / RoHS Compliant	1
DigiKey	breadboard	922318-ND	Lead free / RoHS Compliant	1
Zoom	H4N Digital recorder		Lead free	
DigiKey	20AWG solid core wire	A3053R-100-ND	Lead free / RoHS Compliant	1
DigiKey	oscilloscope	BK2542B-GEN-ND	Lead free by exemption / RoHS compliant by exemption	1