SLEEP APNEA MONITORING AND DIAGNOSTIC SYSTEM IMPLEMENTATION PLAN

Team Snooze

Version 1.0

1/25/2018

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Implementation Plan Document

Version 1.0

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A. Introduction

1. Purpose

Our project is to create a sensor system that can collect physiological variables (e.g. EEG, EOG, EMG, EKG, oximetry, PTAF, thermistor, RIP, and body position). Once collected, the sensors would push the data wirelessly to a hub device. The hub device could be the user's cell phone or wireless router. If it is a cell phone, an application, running on the smart phone, collects the data and pushes the data to the cloud for post-processing and scoring.

The collection and storage of data will be encrypted and meet the current HIPPA guidelines for patient privacy. The system should have the ability to be used as the gold standard for the diagnosis of Obstructive Sleep Apnea (OSA) while meeting the standards for FDA approval.

2. Functional Requirements

ID	Functional Requirements	Team Member Responsible	Effort (in %)
1	There should be a system that will measure the respiratory movement and airflow from the patient.	Andrew Asdel	35
2	There should be a system that will measure the movement of the body throughout the study.	Andrew Asdel	15
3	Each sensor should have their own power circuitry to power the sensor and communication systems.	Andrew Asdel	40
4	There should be a sensor system that will measure the heartrate of the patient.	Yale Empie	10
5	There should be a sensor system that will measure the oxygen saturation of the patient.	Yale Empie	10
6	There should be a sensor system that will measure the body heat of the patient.	Yale Empie	30
7	There should be data transmission from each of the sensor systems to the smartphone/hub device.	Yale Empie	40
8	There should be an application that will be ran on a smartphone device that will handle interfacing to the sensor embedded systems. Application will have a user interface.	Tyler Anderson	20
9	The application should take sensor data and transmit to a cloud service provider over the internet for processing and archival.	Tyler Anderson	50
10	There should be a function of the smartphone application that will use the smartphone's microphone to record sounds from the patient during the study.	Tyler Anderson	20
11	Cloud-located software should contain an implementation of a common Obstructive Sleep Apnea diagnosis scoring algorithm.	Jason Van	35
12	Cloud-located software should archive data on the cloud system from nightly studies so that the doctor can view patient sleep study history.	Jason Van	35
13	Data should be formatted in a method (e.g. European Data Format) that can be imported into an application for diagnosis scoring.	Jason Van	20

3. Non-Functional Requirements

ID	Non-Functional Requirements	Team Member Responsible	Effort (in %)
1	Sensor systems must be capable of 8 hours or longer runtime.	Andrew Asdel	5
2	Battery should be rechargeable for repeated use if necessary.	Andrew Asdel	5
3	Meets Type 3 OSA diagnosis level at minimum.	Yale Empie	5
4	Devices should be in the form of a patch or wristband.	Yale Empie	5
5	Meets Standards for FDA approval	Jason Van	10
6	Meets HIPPA guidelines for patient privacy.	Tyler Anderson	10

4. Constraints

a. Sensor systems will be implemented in forms dictated as the technology used allows.
b. Sensors will be able to fit within size and power consumption constraints.
c. Wireless connection to a router, hub, or cell phone must remain reliable and seamless to the end user.
d. Battery Power and Chargeability.
e. Easy-to-use software that runs on a smart phone.

5. System Overview

a. System Overview

This system is intended for those that suffer from chronic Obstructive Sleep Apnea (OSA), a disorder that causes patients to be unable to breathe for periods of time during sleep. Physiological variables will be measured through various sensor systems, tabulated, and scored in order to determine the severity of the patient's OSA diagnosis.

b. System Organization

The system structure is broken down into three categories: hardware sensor systems, smartphone application, and the cloud. The hardware sensor systems measure various physiological variables and transmit those to the smartphone device running the smartphone application. The application is the core of this system as it handles sensor system data collection and transmission of that data to the cloud systems. The cloud system handles storage and archival of all data, and processes the data into easy analysis for each patient session.

Please see *Diagrams 1 & 2* below for a graphical representation of how these systems interact:

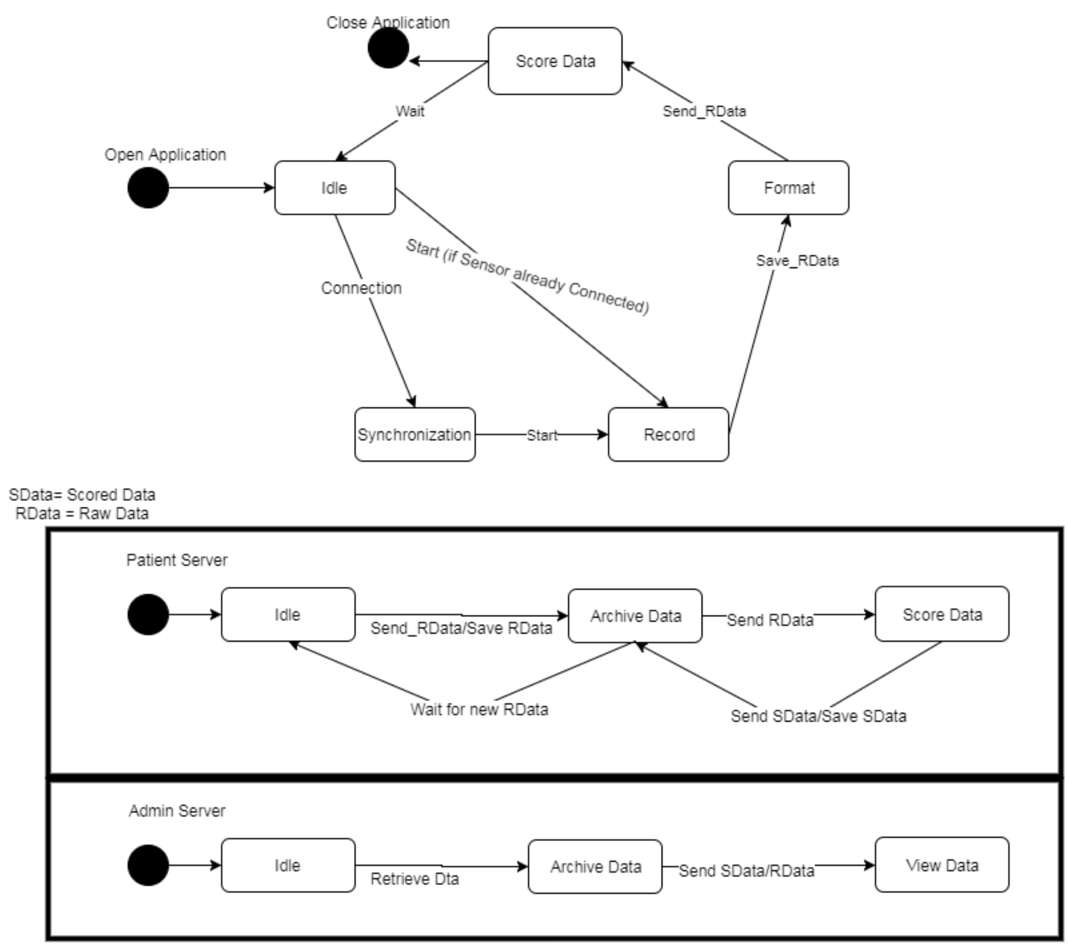

Diagram 1: Application State flow

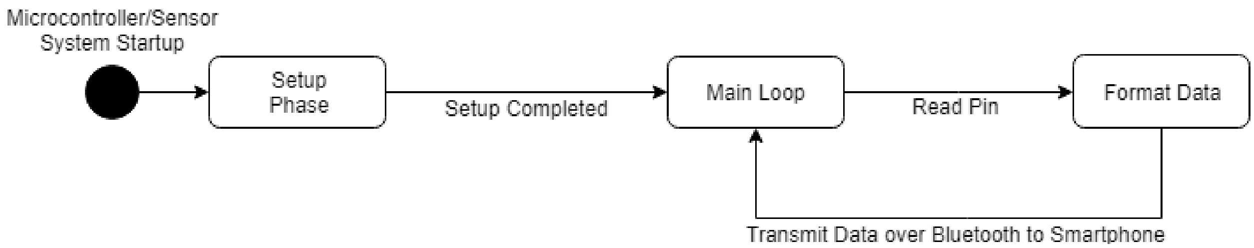

Diagram 2: Hardware State flow

6. Project References

Please see **Appendix 1** for any project references.

7. Glossary

Please see **Appendix 2** for a glossary of terms used in this document.

B. Management Overview

1. Description of Implementation

The physical system will be comprised of 4 sensor inclusive sensor systems, a mobile phone device, and a computer to access the cloud services over the internet. Planned deployment of the system will be done once all parts have been implemented and verified working.

The software system will be comprised of an Android-based mobile application and a combination of Amazon Web Service (AWS) cloud-based services. Planned deployment will occur once these software systems have been fully implemented and verified working.

2. Points of Contact

Priority 0 – Highest 2 – Lowest	User (Group)	Participation	Phone Number
0	Dr. Robin Pottathuparambil	Project Manager	Cell: (940) 369-8807
0	Yale Empie	Project Leader & Reporter Functional Requirements(s) In Charge: • ID#: 4, 5, 6, 7	Cell: (580) 504-7895
1	Andrew Asdel	Team Member Functional Requirements(s) In Charge: • ID#: 1, 2, 3	Cell: (760) 622-8957
1	Tyler Anderson	Team Member Functional Requirements(s) In Charge: • ID#: 8, 9, 10	Cell: (512) 293-3901
1	Jason Van	Team Member Functional Requirements(s) In Charge: • ID#: 11, 12, 13	Cell: (432) 770-1347
2	Edwin Simon, MD	Intellectual Property Rights Holder	Work: (847) 688-1900

3. Major Tasks

a. Hardware Tasks

1) **Respiratory Movement Sensor**
   a) **Person in Charge: Andrew Asdel**
      i) Build Respiratory Movement Sensor System
      ii) Create and Implement Sensor Software Algorithm
      iii) Test Design.
   b) **Resources Required:** Beetle BLE Microcontroller, 3-Axis Accelerometer
   c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.
2) **Airflow Detection Sensor**
   a) **Person in Charge: Andrew Asdel**
      i) Build Airflow Detection Sensor System
      ii) Create and Implement Sensor Software Algorithm
      iii) Test Design.
   b) **Resources Required:** Beetle BLE Microcontroller, 'Small' microphone, audio amplifier
   c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.
3) **Body Movement Sensor**
   a) **Person in Charge: Andrew Asdel**
      i) Build Body Movement Sensor System
      ii) Create and Implement Sensor Software Algorithm
      iii) Test Design.
   b) **Resources Required:** Beetle BLE Microcontroller, 3-Axis Accelerometer
   c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.
4) **Mobile Power Delivery Systems**
   a) **Person in Charge: Andrew Asdel**
      i) Build mobile power delivery systems (battery packs)
      ii) Test Design
   b) **Resources Required:** Battery Cells
   c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc.
5) **Heartrate Sensor**
   a) **Person in Charge: Yale Empie**
      i) Build Heartrate Sensor System
      ii) Create and Implement Sensor Software Algorithm
      iii) Test Design.
   b) **Resources Required:** Sparkfun Particle Sensor MAX30105, Beetle BLE Microcontroller, Portable Battery Pack, Double-Faced Adhesive Pads, Velcro (Hook & Loop) Strips
   c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.

6) **Oxygen Saturation Sensor**
    a) **Person in Charge: Yale Empie**
        i) Build Oxygen Saturation Sensor System
        ii) Create and Implement Sensor Software Algorithm
        iii) Test Design.
    b) **Resources Required:** Sparkfun Particle Sensor MAX30105, Beetle BLE Microcontroller, Portable Battery Pack, Double-Faced Adhesive Pads, Velcro (Hook & Loop) Strips
    c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.
7) **Temperature Sensor**
    a) **Person in Charge: Yale Empie**
        i) Build Temperature Sensor System
        ii) Create and Implement Sensor Software Algorithm
        iii) Test Design.
    b) **Resources Required:** NTC Epoxy Bead Thermistor, Beetle BLE Microcontroller, Double-Faced Adhesive Pads, Velcro (Hook & Loop) Strips
    c) **Training Required:** Basic Electronics Circuit Knowledge. Use of tools such as soldering irons, etc. Acute knowledge of C/C++ programming language.

b. Software Tasks

1) **Smartphone Application**
   a) **Person in Charge: Tyler Anderson**
      i) Connect application to sensors via Bluetooth (Bluetooth/Bluetooth Low-Energy)
      ii) Data Recording
         (1) Record Sensor Data locally.
         (2) Record Patient Snoring via smartphone's microphone.
      iii) Connect application to the cloud services
      iv) Test design
   b) **Resources Required:** Android Studio, Java Programming Language, C/C++ Programming Languages
   c) **Training Required:** Knowledge of how to operate Android Studio IDE. Acute knowledge of Java, C/C++ programming languages.
2) **Cloud**
   a) **Person in Charge: Jason Van**
      i) Configure cloud services to store data in respective patient folders
      ii) Create and Implement OSA Scoring Algorithm Program
      iii) Conversion of EDF formatted data to PDF viewable document.
      iv) Test Services
      v) Test OSA Scoring Algorithm program
   b) **Resources Required:** AWS S3, Cognito, Lambda, Glacier, and EC2 products. C/C++ Programming languages also required.
   c) **Training Required:** Knowledge of how to use Amazon Web Services systems. Acute knowledge of C/C++ programming languages for OSA Scoring Algorithm program. Knowledge of OSA diagnosis attributes.

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4. Implementation Schedule

1	Respiratory Movement Sensor	Andrew Asdel	Expected Deadline
1.1	Build Respiratory Movement Sensor System (Final Design)		20-Feb-2018
1.2	Create and Implement Sensor Software Algorithm		27-Feb-2018
1.3	Test Design		26-Mar-2018
2	Airflow Detection Sensor	Andrew Asdel	Expected Deadline
2.1	Build Airflow Detection Sensor System (Final Design)		18-Mar-2018
2.2	Create and Implement Sensor Software Algorithm		25-Mar-2018
2.3	Test Design		26-Mar-2018
3	Body Movement Sensor	Andrew Asdel	Expected Deadline
3.1	Build Body Movement Sensor System (Final Design)		20-Feb-2018
3.2	Create and Implement Sensor Software Algorithm		27-Feb-2018
3.3	Test Design		26-Mar-2018
4	Mobile Power Delivery Systems	Andrew Asdel	Expected Deadline
4.1	Build mobile power delivery systems (battery packs)		18-Mar-2018
4.2	Test Design		26-Mar-2018
5	Heartrate Sensor	Yale Empie	Expected Deadline
5.1	Build Heartrate Sensor System (Final Design)		20-Feb-2018
5.2	Create and Implement Sensor Software Algorithm		27-Feb-2018
5.3	Test Design		26-Mar-2018
6	Oxygen Saturation Sensor	Yale Empie	Expected Deadline
6.1	Build Oxygen Saturation Sensor System (Final Design)		6-Mar-2018
6.2	Create and Implement Sensor Software Algorithm		13-Mar-2018
6.3	Test Design		26-Mar-2018
7	Temperature Sensor	Yale Empie	Expected Deadline
7.1	Build Temperature Sensor System (Final Design)		20-Feb-2018
7.2	Create and Implement Sensor Software Algorithm		27-Feb-2018
7.3	Test Design		26-Mar-2018
8	Smartphone Application	Tyler Anderson	Expected Deadline
8.1	Connect application to sensors via Bluetooth (Bluetooth/Bluetooth Low Energy)		8-Feb-2018
8.2	Record Sensor Data locally on device.		15-Feb-2018
8.3	Record Patient Snoring via smartphone's microphone.		15-Feb-2018
8.4	Connect application to the cloud services.		26-Feb-2018
8.5	Test Design		26-Mar-2018
9	Cloud	Jason Van	Expected Deadline
9.1	Configure Cloud Services to store data in respective patient folders.		15-Dec-2017
9.2	Create and implement OSA Scoring Algorithm program.		21-Mar-2018
9.3	Conversion of EDF formatted data to PDF viewable document.		21-Mar-2018
9.4	Test Cloud Services		26-Mar-2018
9.5	Test OSA Scoring Algorithm program		26-Mar-2018

5. Security

The security system of the Snooze project uses Cognito, an Amazon Web Service, that will encrypt the data and securely transfer it to cloud storage. This will allow the project to safely and securely collect data and compile it inside of the cloud.

a. System Security Features

The system encrypts all the data that is collected from the sensors on the mobile device before it is sent off to the cloud-based storage. This is done through the Amazon Web Service, Cognito, to transfer the data from the phone to the cloud. Cognito encrypts the data as it is being delivered from the smartphone application to the Cognito storage. The patient only has permission to send data to the cloud. The patient has no access to the cloud data storage system where the patient sensor data is stored. While the data is in the cloud, the data cannot be tampered/interacted with by anyone else, with the sole exception being the authorized users (i.e. doctor) that will maintain the project. Authorized user will need username/password and a RSA authentication key-fob.

b. System During Implementation

Our codebase is behind a private GitHub account and is not readily available to the general public. Access to this codebase will be given on a person-by-person basis.

Access to the terminal for setup and retrieval of data from the cloud must be done only by an authorized user(s) as sensitive patient data may be at risk. Data is not held locally, so any machine that has access to the internet is eligible for implementation of this system.

It is our suggestion that access to patient cloud systems are not to be done while using a public, unencrypted form of wireless internet as that is vulnerable to Man-in-the-Middle attacks.

C. Implementation Support

1. Hardware, Software, Facilities, and Materials

a. Hardware

Unit	Quantity
Beetle BLE Microcontroller	4
Portable Battery Packs	4
3-Axis Accelerometer	1
Sparkfun Particle Sensor MAX30105	1
NTC Epoxy Bead Thermistor	1
Double-Faced Adhesive Pads	4
Velcro (Hook & Loop) Strips	4
3.5mm Stereo Equipment • 35mm Stereo Jack • 35mm Stereo to Pigtail Cable	1
24-Gauge Wire	As Much as Required
Texas Instruments LM386 Audio Amplifier	1
Electret Microphone & Amplifier – MAX4466 w/ Adjustable Gain	1
RSA Authentication Key-fob	1

b. Software

Android Studio
Java Programming Language
Amazon Web Services S3
Amazon Web Services Cognito
Amazon Web Services Lambda
Amazon Web Services Glacier
Amazon Web Services EC2
EDFBrowser
Adobe Acrobat PDF Viewer
Web Browser of User’s Choice (Google Chrome preferred)

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c. Facilities

Our system requires that there be a comfortable bed or sleeping area for the patient or tester to use during data-gathering from the active sensor systems. This facility must include electrical outlets for the user's phone to maintain charge overnight while the system is active. Wireless internet access (WIFI) is optional, as the user may use Mobile Internet access through their phone carrier.

The system also requires a private room with internet access for the authorized user to access patient data, as that reduces chances of HIPPA violations. We are expecting these facilities to be provided during testing and implementation. These facilities are not expected to be fulfilled during Senior Project Day Presentation scheduled on April 27th, 2018.

b. Material

No supporting material is needed at this time.

2. Personnel

a. Personnel Requirements and Staffing

Current personnel requirements for this system require 2 people for set-up and maintenance of the system during runtime. One member will be required for set-up of the sensor systems on him/her self. A second member will be required for access to the cloud services containing patient raw and scored data.

b. Training of Implementation Staff

The training required for the implementation and maintenance of our product will require knowledge of:

- Android Studio IDE
  - Java Programming Language
    - Staff will need acute knowledge of this programming language.
- Obstructive Sleep Apnea diagnosis levels
- Amazon Web Services used:
  - S3, Cognito, Lambda, Glacier, EC2
  - AWS Certification preferred
    - https://aws.amazon.com/certification/
- Microcontroller Programming
  - C/C++ Programming Language
    - Staff will need acute knowledge of these programming languages.
- Basic Electronics Circuit Knowledge
  - Knowledge of various basic circuit components (resistors, capacitors, etc.)

D. Implementation Requirements by Site

1. Site Name or identification for Site X

April 27th, 2017 - University of North Texas Senior Design Project Day

a. Site Requirements

- **Hardware Requirements** – The user will need a smartphone device with the Application downloaded onto it so that it can ran to collect sensor data and snoring sounds of the patient.
- **Software Requirements** – The user will need to have free storage space of ~500 megabytes on their smartphone device. The user will also need to have created an account so that their information can be stored in the cloud database.
- **Data Requirements** – The user will need a power source to keep the smartphone operational until the end of the recording session. The user will also need a source of internet (WIFI or Mobile Internet) so that the data can be transferred from the sensors to the cloud database storage. The authorized user (i.e. doctor) will need ~1 gigabyte of data storage available on their computer for EDF Browser application and EDF/PDF files.
- **Facilities Requirements**: Our system requires that there be a comfortable bed or sleeping area for the patient or tester to use during data-gathering from the active sensor systems. This facility must include electrical outlets for the user's phone to maintain charge overnight while the system is active. Wireless internet access (WIFI) is optional, as the user may use Mobile Internet access through their phone carrier. However, one of them must be active. The system also requires a private room with internet access for the authorized user to access patient data, as that reduces chances of HIPPA violations. We are expecting these facilities to be provided during testing and implementation. These facilities are not expected to be fulfilled during Senior Project Day Presentation scheduled on April 27th, 2018.

b. Site implementation Details

UNT Senior Design Project Presentation Day:

- **Teams:** All team members will be required for set-up and demonstration. Hardware team members, *Yale Empie* & *Andrew Asdel*, will be on hand to ensure that all sensor systems are verified working. Application developer, *Tyler Anderson*, and Cloud Services manager, *Jason Van*, will ensure that data is being transmitted from the smartphone and stored in the cloud.
- **Schedule:** All members will be required to set-up the entire system approximately an hour and a half before the event begins.
- **Procedure:**
    1) Power on and determine if any sensor system in the product is working correctly. This will be done by *Yale Empie* and *Andrew Asdel*.
        - If not, begin troubleshooting measures to ensure working product.
    2) Smartphone application will be engaged by *Tyler Anderson* on the example smartphone.
    3) Calibration and Connection will be engaged on the smartphone application.
    4) Once sensor systems are tested working with the smartphone application, begin data recording.
    5) After sample recording period has passed, initiate upload of that data to the cloud services.
    6) Once cloud services have received the sample recorded data, initiation of data scoring will be done by a simulated authorized user (*Jason Van*).
    7) Verify that sampled data is legitimate and that the scored data is confirmed correctly calculated.
- **Database:** As this system uses cloud-located databases, on-site hardware will only require a web browser to access any database features that are needed in the design.

c. Back-Off Plan

A compatible Android device with an internet connection and active Bluetooth is essential to the operation of the apparatus. The lack of such a device shall result in a "no go" decision. Before beginning the test, it must be verified that all sensors are successfully powered and paired to the Android device, and an internet connection is established. Failure of one or more sensors shall result in a possible 'no go' condition, per the decision of the supervising physician, taking into account how crucial the metric measured by the faulty device is, difficulty involved in repairing the situation, and the inconvenience of postponing the test.

Following a complete test, sensors shall carefully be removed from the patient's body and powered down. Bluetooth may be deactivated at this time and disposable components of the sensors discarded.

E. Appendix

1. Project References

- Hardware References:
    - https://create.arduino.cc/projecthub/Nicholas_N/how-to-use-the-accelerometer-gyroscope-gy-521-6dfc19
    - https://learn.adafruit.com/adafruit-microphone-amplifier-breakout/measuring-sound-levels
    - https://thecavepearlproject.org/2017/04/26/calibrating-oversampled-thermistors-with-an-arduino/
    - http://www.temperatures.com/thermistors.html
    - https://learn.sparkfun.com/tutorials/max30105-particle-and-pulse-ox-sensor-hookup-guide
    - http://www.circuitbasics.com/arduino-thermistor-temperature-sensor-tutorial/
- Software References:
    - https://github.com/Teuniz/EDFlib
    - https://www.teuniz.net/edfbrowser/
    - https://aws.amazon.com/
    - https://aws.amazon.com/iam/details/mfa/
    - https://www.tutorialspoint.com/android/android_bluetooth.htm
    - https://www.tutorialspoint.com/android/android_audio_capture.html

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2. Glossary of Terms

EEG: Electroencephalography

- Test that measures electrical activity in your brain.

EOG: Electrooculography

- Test that measures the voltage between the front and back of the human eye.

EMG: Electromyography

- Test that measures muscle response to a nerve's stimulation of that respective muscle.

EKG: Electrocardiography

- Test that measures the electrical activity of your heart over a period of time

FDA: USA Food and Drug Administration

- USA Federal Agency that is responsible for the protection and promotion of public health through supervision of various industries such as food safety, etc.

IDE: Integrated Development Environment

- Software application that provides comprehensive tools for programmers doing software development.

OSA: Obstructive Sleep Apnea

- Sleep disorder that causes breathing to stop and start during sleep in a non-periodic manner.

Oximetry:

- Test that measures the oxygen saturation in one's bloodstream.

Physiological:

- Characteristic of normal functions of living organisms.

PTAF: Pressure Transducer for Airflow

- Sensor that measures respiratory pressure changes.

RIP: Respiratory Inductance Plethysmography

- Test that measures the movement of the chest and abdominal wall.

RSA: RSA SecurID

- 2-factor authentication for a user on a network resource. System was developed by Security Dynamics.

Thermistor:

- Sensor that measures temperature.