SLEEP APNEA MONITORING AND DIAGNOSTIC SYSTEM SPECIFICATIONS

Team Snooze

Version 1.2

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Yale Empie, Jason Van, Andrew Asdel, Tyler Anderson

Team Reporter Contact: jasonvan@my.unt.edu

Requirements Document

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Contents

A. Project Overview 2

B. Current Problems and Proposed Solutions 2

C. Requirements 3

1. Functional Requirements 3
2. Non-Functional Requirements 4
3. Constraints 4

D. Specifications 5

1. Functional Requirements Specifications 5
2. Non-Functional Requirements Specifications 6

A. Project Overview

Our project is to create a sensor system that can collect physiological variables (eg. 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 OSA while meeting the standards for FDA approval.

B. Current Problems and Proposed Solutions

- Will the open-source program be reliable and secure?
    - Solution: Implement modern encryption standards so that the data cannot be modified by outside sources.
- *Actual Size* of the device(s)?
    - Solution: Implement sensor systems that will be in forms dictated as the technology used, allows. One such example would be a wrist-band "patch" that will contain multiple functions localized to Median antebrachial, Ulnar, and Radial veins in the wrist.

C. Requirements

1. 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 for processing.	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 from nightly studies so that the doctor can view patient sleep study history.	Jason Van	35
13	Data should be formatted in a method that can be imported into an application for diagnosis scoring.	Jason Van	20

2. Non-Functional Requirements

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

3. Constraints

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

D. Specifications

1. Functional Requirements Specifications

ID	Functional Requirement Specification
1	Respiratory movement and airflow shall be measured using audio that is collected by a wireless sensor system, attached to the patient's body in a medically safe way. Audio shall be collected by at least one microphone in proximity of the patient's neck. The audio signal shall be amplified and converted as necessary and interfaced with an Arduino microcontroller.
2	Body movement shall be measured using an inertial measurement sensor (IMU attached to the patient's body in a medically safe way. Motion shall be detected in three axes. The sensor shall be interfaced with an Arduino microcontroller and the sensor data shall be transmitted via Bluetooth to the hub/smartphone device.
3	Each sensor system shall include a rechargeable battery, or batteries, capable of powering the included electronic components. Power regulation circuitry shall be included as necessary.
4	The sensor system that will measure the heartrate of the patient will be combined with the sensor system that will measure the oxygen saturation of the patient. Physically, this will be incorporated into a wrist-band design given the components that are to be used. The heartrate is implemented using a pulse-oximeter sensor such as Maxim Technology's MAX3010x (where 'x' denotes a number). This pulse-oximeter sensor will be attached to an Arduino microcontroller capable of Bluetooth communication.
5	The sensor system that will measure the oxygen saturation of the patient will be combined with the sensor system that will measure the heartrate of the patient. Physically, this will be incorporated into a wrist-band design given the components that are to be used. Oxygen saturation detection is implemented using a pulse-oximeter sensor such as Maxim Technology's MAX3010 x (where 'x' denotes a number). This pulse-oximeter sensor will be attached to an Arduino microcontroller capable of Bluetooth communication.
6	The sensor system that will measure the body heat of the patient will be implemented with a thermistor sensor mounted to the patient's forehead using a medically-safe method. This temperature sensor will be attached to an Arduino microcontroller capable of Bluetooth communication.
7	For all sensor systems, the embedded programming will be implemented in C/C++/INO-format using the Arduino open-source library of functions to both retrieve data from the sensors on each system and to transmit that data to the hub/smartphone device. If a sensor system requires data manipulation from the sensor data feed, that will be done on the microcontroller before being transmitted to the hub/smartphone device.
8	The smartphone application will be created using a cloud service provider (eg. Amazon Web Services). After connecting the sensor systems to the smartphone using Bluetooth, the application will collect the data from the sensors systems. It will take that data and store it in the application's data collection folder in a format that will be readable by the analysis program (located in the cloud). The application will also provide the user with a user interface which will allow the user to start recording data, stop recording data, and calibrating the sensors (eg. IMU) to the user's base state.
9	Using the Bluetooth function of the smartphone, the application will connect to each sensor system. The data will be collected in the applications data collection folder until

	the end of the monitoring session in a format readable by the analysis program (located in the cloud). Once the session has ended due to user input, the data will be delivered to the cloud software for processing and scoring.
10	The application will ask permission to use the smartphone device's internal microphone. Once it has been given permission and the recording session has been started, it will execute a function call to collect the data from the microphone. The information will then be stored in the application's data collection folder until the end of the recording session.
11	The cloud system should automatically send the raw data file to the Sleep Apnea scoring software so that the program can automatically score and format the data into a viewable report. This will allow the doctor to easily read the data.
12	The raw and scored data will be cataloged and archived in a folder dedicated to the patient that is currently being diagnosed for OSA.
13	The raw and scored data should be formatted into a EDF file. The raw data will be saved and then converted into EDF file formatting to allow the program to read in the data. The doctor will then have the capability of viewing the raw or scored data.

2. Non-Functional Requirements Specifications

ID	Non-Functional Requirement Specification
1	The power storage block for each sensor system shall have sufficient capacity to run its respective system for 8 hours or longer.
2	Rechargeable batteries shall be used, allowing for multiple uses.
3	The sensor systems, individually, will collect the required physiological variables that are required at minimum for Type 3 OSA diagnosis.
4	As the cardiac variable (heartrate) and oxygen saturation variable can be read from the same sensor (pulse-oximeter), there will be a wrist-band to house the sensor system components required for collecting those physiological variables.
5	To ensure that the OSA diagnosis system should meet FDA guidelines. By ensuring the HIPPA privacy guidelines are met; then document any and all that's being used so when registering the device every single component being used inside the device is known. Then the device is fully tested and should not cause any damage mentally or physically.
6	To ensure that this OSA diagnosis system meets HIPPA patient privacy guidelines, locally stored data and data transmissions to the cloud will be encrypted.