A Body Area Network as a Pre-Screening Surrogate to the Polysomnography

by

Sheryl LaFleur

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This dissertation was prepared under the direction of the candidate's dissertation advisor, Dr. Imadeldin Mahgoub, Department of Computer & Electrical Engineering and Computer Science and has been approved by the members of her supervisory committee. It was submitted to the faculty of the College of Engineering and Computer Science and was accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy.

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I would like to gracefully acknowledge the sovereignty of my Lord Jesus Christ.

Genesis 48:15 And he [Jacob] blessed Joseph and said, The God before whom my fathers Abraham and Isaac walked, the God who has shepherded me all my life to this day,.

Living Stream Ministry, Crystallization-Study of Genesis, Volume Six.

Abstract

Author: Sheryl LaFleur

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Out of 60 million Americans suffering from sleep disorder, an estimated 18 million have sleep apnea. According to the U.S. Department of Health & Human Services, sleep apnea is a chronic condition that disrupts a patient's sleep. While the annual cost of treating sleep apnea patients in the United States is approximately $3.18 billion (including screening costs) it is estimated that untreated sleep apnea may cause $3.4 billion in additional medical costs. A polysomnography (PSG) is an all-night sleep study which monitors various physical functions during sleep including electrical activity of the heart, brain wave patterns, eye movement, muscle tone, body movements, and breathing. It is currently, the most accurate and sophisticated test for the diagnosis of sleep-disordered breathing (SDB), but also, the most expensive. The cost of an overnight sleep study is estimated between $900 and $3,000. In addition, the PSG is not mobile and has to be administered outside a patient's home. The Long QT Syndrome (LQTS) is a rhythm disorder that causes erratic (unpredictable) heartbeats. The LQTS has been linked

to patients with the most severe form of sleep apnea. If LQTS is left untreated, sudden cardiac death may occur. Different methods for the classification and detection of sleep apnea have been proposed, we offer the Long QT (LQT) interval that is too often left undiagnosed and untreated as an symptom of sleep apnea. Additionally we are offering the LQT interval as apnea event(s) in the computation of an apnea-hypopnea index (AHI).

We proposed the use of a Body Area Network as a Pre-Screening Surrogate to the Polysomnography (PSG) consisting of, a heart and activity monitor and pulse oximeter. A system that is cost-effective, mobile, non-invasive, and flexible. Initial analysis and validation was performed on a dataset taken from the MIT-BIH arrhythmia database of (10 to 35 data subjects) a typical sleep apnea population for age, gender and heart rate. A clinical evaluation of the proposed scheme was performed alongside overnight sleep studies at the University of Miami (UM) Sleep Center over a period of elven nights. A patient dataset of elven patients that underwent a PSG was selected.

Dedication

I would like to consecrate my journey in the pursuit of my doctoral degree to Christ and the Church. Ephesians 1:22 “And He subjected all things under His feet and gave Him to be Head over all things to the church,” Ephesians 1:23 “Which is His Body, the fullness of the One who fills all in all.” Ephesians 3:21 “To Him be the glory in the church and in Christ Jesus unto all the generations forever and ever. Amen.” Living Stream Ministry, Recovery Version.

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1. Introduction

"Mr. Watson, come here, I want you." these were the first words, spoken by inventor Alexander Graham Bell on March 10, 1876 [84]. Wow, that was only hundred and thirty eight years as of 2014, he only had his assistant, Thomas Watson at the other end of that phone call acknowledging it. Evolution is absolutely not just for living things, but for all things. Today, there need not be another living being on the other end of that phone call to make a reply, just an electronic device. Neither is there need for anymore wires to make that phone call. Also, not just voice can be transmitted over a phone, with today's Smartphone and Tablets PC's, an assortment of services are supported, that comprises, Multimedia Messaging Service (MMS) email, Internet access, short-range wireless communications (infrared, Bluetooth), business applications, gaming, and photography. For, certain these services are applicable to today's health care system.

Today, everyone is demanding universal health care, all-inclusive, health care, pervasive health care, they all have the same meaning and opinions; now is better than later, in real-time of course, and let's not forget affordable. So, let's give it to them in the form of an at home monitoring system day and night; better yet, a body area network (BAN) or Wireless Body Area Networks (WBANs) and it is wearable. Through the advancements and achievements in wireless and mobile communication that is absolutely possible.

The idea of using a BAN as an automated screening of sleep apnea, in a home environment has proven to be beneficial, in [8, 22, and 31]. It presented itself as valuable

screening tool, to evaluate the existence or non-existence of apnea. We focus our work on obstructive sleep apnea, because of its wide effect on the American population and enormous cost on health care.

There are many good reasons and advantages in employing BANs:

- One advantage of using BANs is ease of use - non-invasive sensors can be used to automatically monitor physiological readings, which can be forwarded to nearby devices, such as a cell phone, a wrist watch, a PDA, a laptop, or based on the application needs.
- Another is their effectiveness – the physiological signals from the sensors are processed in the most effective way to obtain reliable and accurate physiological estimations. Also, these sensors power consumption is very low, making their batteries life long lasting.
- One more advantage in the use of BANs is that they are cost effective, as sensors are inexpensive to produce. They also help deflate the cost of health care.

With this emerging technology of BANs, many applications will benefit from it, such as sport medicine monitoring, military, training, interactive gaming, and government surveillance [51].

1.1 Background

The concept of using a wireless Body Area Network of wearable computing devices got its start in 1995; this technology would implement communication of miniaturized body sensor units coupled to a single body central unit. Later at the beginning of 2001, a WBAN/BAN was thought of as systems where communication took place entirely within, on, or in the direct area of the human body [92].

1.1.1 Body Area Network Components and Functionality

A BAN has simple components and functionality such that; each node work as an independent communicator. The components and functionality are as following:

- Tablet PC or Smartphone provide acts like a gateway, sending data to a display and to a network server on the Internet.
- Sensor(s) - measurement could be internally or externally, types may vary physiological sensors, ambient sensors or biokinetics [85, 86]. The numbers of sensors are dependent upon the patients' needs.

In a BAN the physiological sensors, main functions including some of the following:

- Monitoring, processing, sampling and recording patients' vital signs.
- These clinical measurements may consist of
    - Monitoring patients' heart activities, sleep activities and oxygen saturation levels (SpO2).

Sleep is very important to everyone, because it helps reduces the heart rate and the blood pressure by about 10 percent [59]. If a person does not get enough sleep, the nightly dip in one's blood pressure, may not occur. This nighty dip is known to be one of the important factors in promoting good cardiovascular health.

If buy any coincidental some abnormalities are detected sensors can send their data through a gateway (cell phone) to the Internet. Their data transfer is done in real time making them an ideal solution in early detection [87].

One of the newest network projects that have come about in the last few years is the Ambient Networks. Its infrastructure runs on top of all current network physical

infrastructures, thus providing a way for devices to connect to each other, and through each other to the outside world [81]. It is also part of the Wireless World Initiative in [82]. In a nutshell this infrastructure would allow for suitable mobile networking technology in a wireless environment. Thus, allowing someone to be able to wear a Personal Area Network (PAN) on their body. Subsequently, because each device has its own Bluetooth for mobile capability, it is able to use another device's infrastructure.

An example being: Laptop -> (Bluetooth) -> Mobile -> (GPRS) -> Mobile phone network.

1.1.1.1 Overview of Sensor Operation and Characteristics

Figure 1.1 shows the classic interworking of a sensor node communication setup. It has a sensor, radio and memory units. Each sensor unit comprises of a sensor, a filter and an analog-to-digital converter (ADC). Sensor used in most designs converts some form of energy to electrical signals. These signals need to be filtered, a typical band-pass filter is normally chosen for this process.

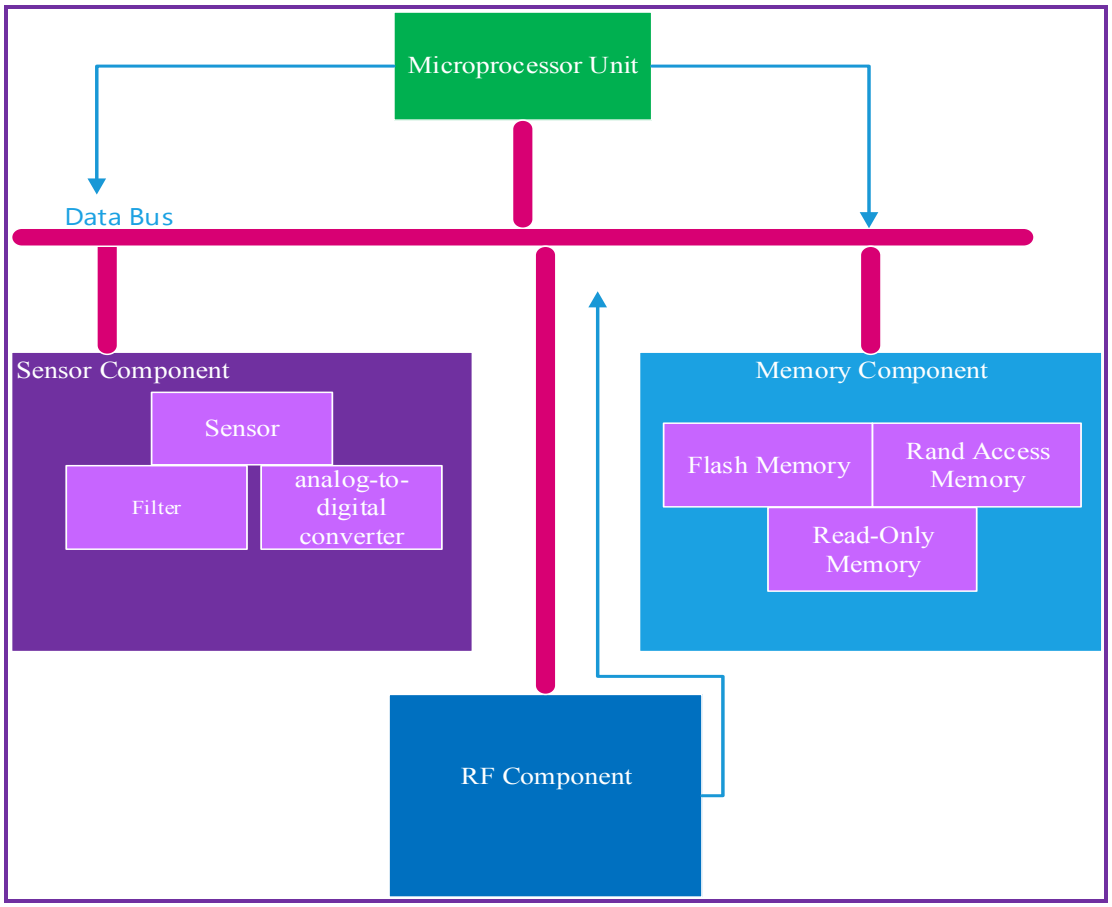


Figure 1.1 Classic Interworking of a Sensor Node Communication Setup

1.1.2 The Usage of Body Area Network

The most recent use of the BAN technology is in the detection and classification of sleep apnea. Its portability help deflate the cost of an overnight study. A general architecture [1] [8] of sensors and detection schemes send recorded data to a smart phone, a home computer, and clinic or physician secure website. Communication between BAN and the medical server is done with either Bluetooth® wireless technology, ZigBee, or IEEE 802.16 [52]. Bluetooth wireless technology [53] has become the standard for exchanging data over short distances from fixed and mobile devices, creating personal area networks (PANs) with high levels of security. We will use it in our scheme.

A few BANs have been developed just in the past few years. A wireless body area network to assist in physical rehabilitation was present in [51]. A wearable health-monitoring device using a BAN that was integrated into clothing (a wearable motherboard Smart Shirt), was develop by research at Georgia Tech in [97].

Just in the past ten years the use of wavelets in the filtering process of medical sensors has gained significant respect because of their accuracy in the detection and removal of unwanted artifact in the ECG signals. Having access to these types of sensors will increase the quality of the physiological readings, improving much better diagnosis of patients' medical conditions. Our developed work in detection and classification of sleep apnea is based on our collection of data form our sensors which will include feature extractions from the ECG signal and feature extraction from the SpO_2 levels. These features will be extracted using the Daubechies 4 wavelets and Daubechies 6 wavelets scaling functions. The Daubechies' scaling functions are a said to be a better filter, because it looks like the ECG signal. Thus a better feature detection is attainable [95, 96]. Our work focus on the ECG signal and the oxygen saturation levels as an indicator of the present of sleep apnea [3].

1.2 Motivation

A polysomnography (PSG) is used to diagnose sleep disorders and sleep disorders breathing (SDB); it is the most accurate and sophisticated test currently being used today. PSG is an all-night sleep study which monitors various physical functions during sleep including electrical activity of the heart, brain wave patterns, eye movement, muscle tone, body movements, and breathing. The most common SDB is known as sleep apnea - a disorder of interrupted breathing during sleep [58, 60]. Out of 60 million Americans, an

estimated 18 million have sleep apnea, which is more common in African Americans, Hispanics, and Pacific Islanders than in Caucasians. Obstructive sleep apnea (OSA) is a more severe form of SDB, and is a common condition in both adults and children, with estimates of up to 1% to 10% of young children being affected. An estimated 80 million children (defined as the population under 18) reside in the United States as of 2011. OSA syndrome is also most common in middle-aged, overweight men and women, prevalence of which has been estimated to be 9 % of women and 24 % of men, but it can occur at any age, from infancy to old age. About 70% of people who have OSA are overweight. While the annual cost of treating sleep apnea patients in the United States is approximately $3.18 billion (including screening costs) it is estimated that untreated sleep apnea may cause $3.4 billion in additional medical costs. If left untreated an undiagnosed OSA can have the following effects: raise heart rate and increase the risk of high blood pressure, heart attack, stroke, arrhythmias (irregular heartbeat), diabetes, and obesity. The cost for an overnight sleep study is estimated to be between $900 and $3,000. Patients with OSA are more likely to have automobile accidents than the general population [59].

Untreated sleep apnea causes the QT interval, to be prolonged causing someone to be at risk of sudden cardiac death. Those people with sudden cardiac arrest can die within minutes unless they receive immediate treatment. One of the first sign of LQTS is sudden cardiac arrest in 10 percent of the people who has this disorder. LQTS in the United States causes about 3,000 to 4,000 sudden deaths in children and young adults each year.

Most research studies have stated the one of the main challenge with BAN is getting their sensors small enough, so they can be placed discretely into clothing, without alternating or encumber the user's daily activities.

Sensors have to be low on complexity, light in weight, power efficient, easy to use and reconfigurable. Also, there is the need for the storage devices to facilitate remote storage and viewing and analysis tools of patient's data. The collection of data is has become can issue, because it resides on multiple sensors [98]. It stated in [99] that some of the sensors sold on today's market do not provide consistent and accurate data reporting.

Fault tolerance, the ability of a system to respond gracefully to an unexpected hardware or software failure is another significant challenge for these BANs. In order to overcome this problem the deployment of a wireless local area network (WLAN) is needed [100].

In most BANs, their ECG sensors use a filtering technique known as moving average filter. It is a type of finite impulse response filter-FIR. Statistically, the moving average is optimal for recovering the fundamental trend of a given time series when the fluctuations about the trend (tendencies in the data) are normally distributed. The normal distribution does not place high probability on extremely large deviations (the degree of difference between the observed value of a variable and some other value) from the trend. This illuminates why such deviations will have an excessively large effect on the trend estimate. Also another disadvantage of this type of filtering method is that the smoothed series (smoothing – used to reduce the noise) can jump abruptly in response to large single-year anomalies in the time series; the smoothed series can therefore appear jagged. FIR filters consumes much more power in a general purpose processor [101, 102], became of their inherent traits, these type of filters alone are unsuitable for our developed work.

Long QT Syndrome is a rare inherited heart condition in which delayed repolarization of the heart occurs and is more often seen in patients with OSA [54, 55]. This syndrome can be potentially life threatening. Together OSA and LQTS are linked to obesity. Furthermore, LQTS is often an under-diagnosed condition during a PSG.

There is absolutely a need for a more cost-effective early diagnosis of patients' medical condition. Most physicians would agree that early detection is the key. But, the cost of treatment at treatment facilities is not manageable by the majority of United States working and middle class people. Taking time off work for an overnight sleep study might cause some people to lose their only source of income. Not to mention, all the inconveniences imposed on some having to hold down multiple jobs to pay for a heath care for a household of two.

1.3 The Long QT Syndrome (LQTS)

LQTS is a rhythm disorder that causes erratic (unpredictable) heartbeats. If someone is suffering from LQTS their heart beats are irregular or fast and even chaotic rhythm. He or She may experience a seizure or fainting spell. If LQTS is left untreated, sudden cardiac death may occur. This syndrome can either be inherited from one or both parents or developed as side effect of taking certain medications.

LQTS is got its name because of the waveforms that are produced by the heart and shown on an electrocardiogram (ECG) print out. The QT interval is the time that it takes the electrical activation and inactivation of the ventricles of the lower heart chambers. The QT interval time measurements (in fractions of a second) are measured between the Q and T waveforms. If the interval is taking longer than it normally should it is called a prolonged QT interval.

If a person is diagnosed with LQTS syndrome, their family members should be tested as well. Including parents, children and siblings of the person who was diagnosed needs to be tested. Testing generally include blood tests, to look for the abnormal gene, an exercise (test treadmill test), and an ECG outlining the heat's electrical activity.

In some instances LQTS may discovered is during physical activities or exercise, and event during an intense bout of anger or pain or even becoming frightened, or startled by a noise.

The QT interval of the ECG represents the duration of ventricular depolarization and subsequent repolarization, and is measured from the beginning of the QRS complex to the end of the T wave.

Similar to the RR interval, the QT interval is dependent on the heart rate. If the heart rate is fast the QT interval will be shorter. It needs to be adjusted to improve the detection of ventricular arrhythmia. Bazett's formula in equation 1 is given and is one of the most common correction method being used, where RR Interval = 60/HR and HR is the heart rate.

$$QT_B \frac{QT}{\sqrt{RR}} \quad (1)$$

The corrected QTc interval can vary from less than or equal to 400 ms or 440 ms. An abnormal QTc in adult males is above 450ms, and in females above 470 ms [65-68]. Figure 1.2 below shows a typical graph of an ECG signal waveform.

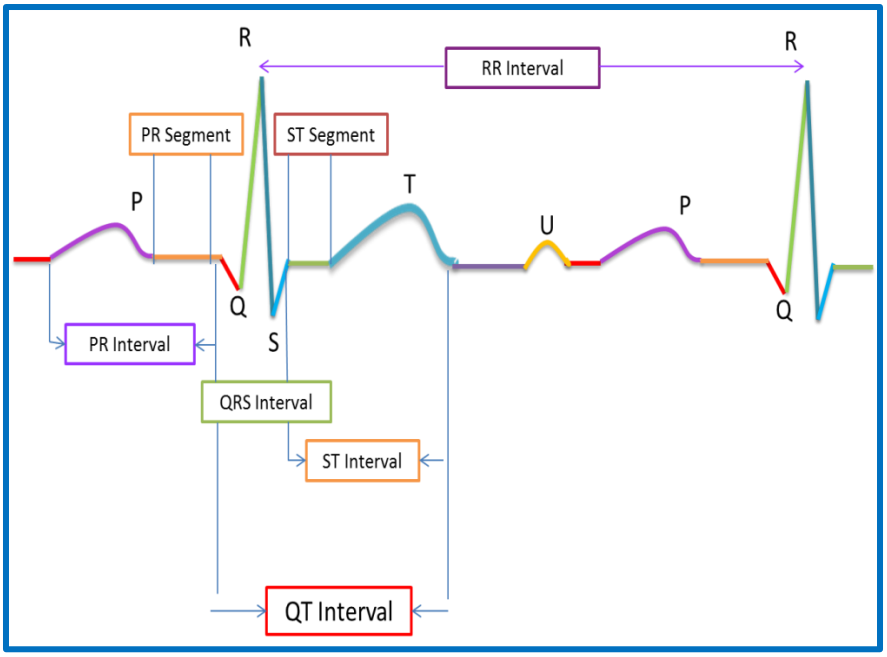


Figure 1.2. The ECG Signal Waveform

The heart muscles have to repolarize (reset) at the end of each beat. This reset activates the heart's electrical circuit to trigger the next heartbeat. The time it takes the heart to reset is called the QT Interval. With patients who experience Long QT the heart takes longer to reset for the next heartbeat. Further, QT variability will be correlated with the minimum oxygen saturation. The abnormalities of the LQT as a marker are most challenging.

1.4 Overview of Sleep Apnea

What is Sleep Apnea? According to the U.S. Department of Health & Human Services, Sleep Apnea is normally a chronic condition that disrupts a patients' sleep. An indication of this is that the patients' breathing pauses or becomes shallow causing the patients to move out of deep sleep and into light sleep. These pauses can occur 30 times or more an hour. Resulting in very poor quality of sleep thus, leading to other more serious disorders in patients [58].

Sleep reduces your heart rate and blood pressure by about 10 percent. [59] If not enough sleep, the nightly dip in blood pressure, which appears to be important for good cardiovascular health, may not occur.

Several studies have revealed if your blood pressure does not dip during sleep, you are more likely to experience the following:

- Strokes,
- Chest pain known as angina,
- An irregular heartbeat,
- Heart attacks

Failure to experience the normal dip in blood pressure during sleep can be related to insufficient sleep time, an untreated sleep disorder, or other factors.

Types of Sleep Apnea

There are four main categories of sleep apnea:

- Central sleep apnea is a less common type of sleep apnea. It happens if the area of your brain that controls your breathing doesn't send the correct signals to your breathing muscles. This will result in you making no effort to breathe for brief periods of time.
- Central sleep apnea can occur in anyone. However, it's more common in people who have certain medical conditions and are using certain medicines.
- Central sleep apnea often occurs with obstructive sleep apnea, but it can occur alone. Snoring doesn't typically happen with central sleep apnea.
- Obstructive Sleep Apnea (OSA) The airway has collapsed or is blocked during sleep. The blockage may cause shallow breathing or breathing pauses. [74] A typical characteristic of snoring pattern is associated with this syndrome and consists of loud snores or brief gasps that alternate with episodes of silence that usually last 20 to 30 seconds.

In this study we focused on the detection and classification of obstructive sleep apnea given that it is the most severe form of SDB and life threatening.

1.4.1 Classification and Measurements of Obstructive Sleep Apnea

An apnea is a period of time during which breathing stops or is markedly reduced. In other words, an apnea occurs when a person stops breathing for 10 seconds or more, which includes complete stoppage of airflow [58, 60, 79, and 80].

Also if you stop breathing completely or take less than 25% of a normal breath for a period that lasts 10 seconds or more, this is an apnea.

Others define an apnea as having occurred if there is at least a 4% drop in oxygen in the blood, a direct end result of the reduction in the transfer of oxygen into the blood when breathing stops. Apneas are usually measured during all stages of sleep over a two-hour period.

Hypopneas usually occur during sleep and can be defined as 69% to 26% of a normal breath. Like apneas, hypopneas also may be defined as a 4% or greater drop in oxygen in the blood.

Calculation of the apnea index is as following:

- An approximation of the severity of apnea is calculated by dividing the number of apneas by the number of hours of sleep, giving an apnea index (AI in apneas per hour); the greater the AI, the more severe the apnea.
- A hypopnea index (HI) can be calculated by dividing the number of hypopneas by the number of hours of sleep.
- The apnea-hypopnea index (AHI) is an index of severity that combines apneas and hypopneas.
- Combining them gives an overall severity of sleep apnea including sleep disruptions and desaturations (a low level of oxygen in the blood).

The severity criteria can be seen from the following:

- Mild:
    - Most of the habitual sleep period is free of respiratory disturbance. The apneic episodes are associated with mild oxygen desaturation or benign cardiac arrhythmias.
- Moderate:
    - Associated with moderate sleepiness or mild insomnia
    - The apneic episodes can be associated with moderate oxygen desaturation or mild cardiac arrhythmias.
- Severe:
    - Associated with severe sleepiness
    - Most of the habitual sleep period is associated with respiratory disturbance, with severe oxygen desaturation or moderate to severe cardiac arrhythmias. There can be evidence of associated cardiac or pulmonary failure.

There is a duration criteria that is associated with OSA:

- Acute: 2 weeks or less.
- Sub-acute: More than 2 weeks but less than 6 months.
- Chronic: 6 months or longer.

1.4.2 Markers Used as Indicators of Sleep Apnea

In earlier studies, classification markers used from the oximetry sensors where the number of dips in oxygen saturation per hour, and frequency based features such as the

spectral peak in the SpO2 spectrum and pulse rate using the power spectral density in the range 30-70 seconds [3, 20, and 52].

Previous studies have used the timing of the QRS complexes and amplitude height as indicators for the classification of OSA.

The QRS complex duration is between 0.06-0.12 seconds, it is even shorter in children; and the amplitude is normally less than 0.5 mV. Most cardiologists agree that, the QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle [63, 64].

The Body mass index (BMI) categories outline in Table 3.3 are used the authentication phase of our research. Previous research studies have indicated that the BMI and the AHI are closely related [110]. We use the BMI in our study not as a determination of OSA, but see if there is a linkage in the presence of a LQTS.

1.4.3 Classification Methods Used for Sleep Apnea

Linear classification is most often used for verification of feature values extraction. Some researcher might use k-nearest neighbor (KNN), Naive-Bayes and Support Vector Machine (SVM), Leave-one-out cross-validation, and other obtain from the Weka tool [72]. The linear discriminant classifier introduced in [56, 71]. The developed scheme will use. A classifier performance using cross- validation of both the ECG and oximetry data is presented in the above studies. Our classifier method like that in the above works will include the ECG data and the SpO2 data.

1.5 Introduction to Wavelets

A wavelet can be thought of as a wave-like oscillation with amplitude that begins at zero, increases, and then decreases back to zero. This can be seen as an oscillation produced from a heart

monitor [76, 78]. Wavelet transforms have three appropriate and useful properties such as those in listed in [73-75]:

1. The original signal can be described in different time scales for example: In the second level scale high energy waves like the QRS complexes can be easily distinguishable from other waves; the other lower scales weak or very weak waves like the T-wave, P-wave, and or the U-wave can be seen. Therefore if multi-step algorithm is applied those very weak as well as the strong waves are easier detectable. It has been said that this might be the most significant characteristics of wavelet transforms that can be implemented to attain more accurate outcomes.

2. Wavelets are known to be better at removing unwanted artifacts and baseline-wandering (isoelectric line (0mV) changes position which might be due to where and how the electrodes are attached to the surface of the skin that appears to be part of the heart electrical activity. These unwanted signals that mass as the real signal can be distinguished according to their specific frequency (low noise).

3. These wavelet transforms are easy implementable because they are a cascade of sequential short unit impulse response of finite impulse response (FIR) filters.

The DWT has a mother wavelet (t) seen in the equation below is shifted and scaled by the powers of two. In the equations 5 j is the scale parameter and k is the shift parameter and they are both integers. Passing the signal through the low-pass filter with its impulse response g[n] produces a convolution show in calculation. Decomposition of the signal takes place simultaneously using a high-pass filter h. High-pass filter produces the detail coefficients h[n] and the low-pass filter gives the approximation coefficients g[n]. The equations used in this section can be seen the work of [109].

The DWT mother wavelet (t) mathematical equation in equation 2:

$$\psi_{j.k} = \frac{1}{\sqrt{2^j}}\psi\left(\frac{t - k2^j}{2^j}\right) \text{ (2)}$$

Signal convolution mathematical definition in equation 3:

$$y[n] = (x * \mathrm{g})[n] = \sum_{k=-\infty}^{\infty} x[k]g[n-k] \text{ (3)}$$

Mathematical representation of the low-pass filters resulting in the approximation coefficients in equation 4

$$y_{low}[n] = \sum_{k=-\infty}^{\infty} x[k]g[2n-k] \text{ (4)}$$

Mathematical representation of the high-pass filters resulting in the detail coefficients in equation 5:

$$y_{high}[n] = \sum_{k=-\infty}^{\infty} x[k]h[2n-k] \text{ (5)}$$

The DWT of an ECG signal ***x*** is calculated by passing it through a series of filters. Samples are passed through a low pass filter with response ***h*** resulting in the convolution of the two. The signal is also decomposed using a high-pass filter ***g***. The outputs giving detail coefficients from the high-pass filter ***g[n]*** and approximation coefficients come from the low-pass filter ***h[n]***. These equations and processes can be seen in Figures 3 and 4, the wavelet coefficients are derived by reversing the order of each scaling function, then reversing the sign of every second one. The mathematical representation is the following in equation 6:

$$b_k = (-1)^k a_{N-1-k} \ eq \text{ (6)}$$

Where **k** is the coefficient index, **b** is coefficient of the wavelet sequence, **a** is coefficient of the scaling sequence and **N** is the wavelet index (4 for D4).

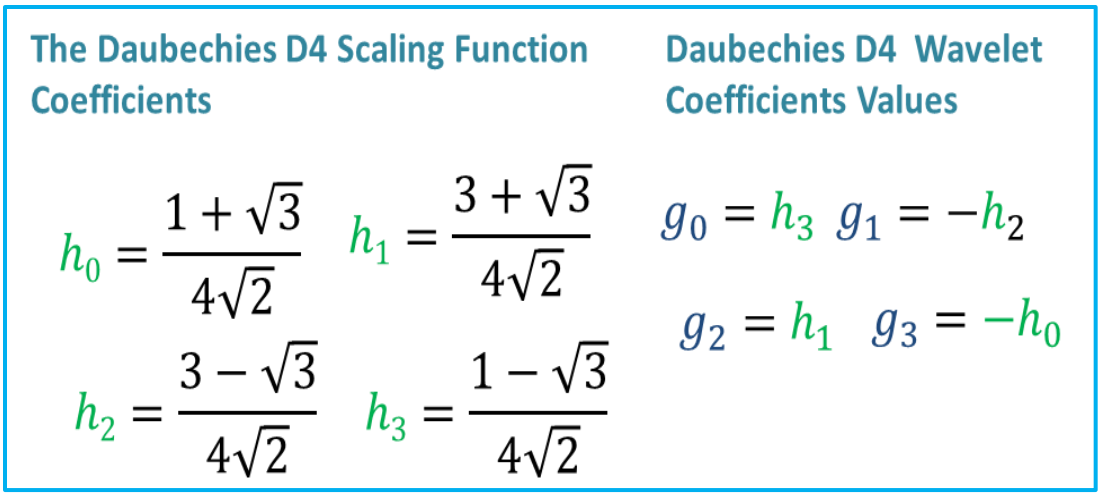


Figure 1.3. Scaling Function Daubechies

Figure 1.3 has the equations that represent the scaling function coefficients and the coefficients values for the Daubechies D4 wavelet transform. Each equation is calculated by taking the inner product of the coefficients and that of the four data values thus, formulating the scaling and wavelet functions equations. Figure 1.4 and 1.5 illustrations the decomposition of the Daubechies D4 and D6 with respect to the ECG signal where h[n] present the low pass filter and the g[n] high pass filter [109]. The outputs of the high-pass filter produce the detail coefficients. It is also stated that the output of the low-pass filter defines the approximation coefficients. These filter can be thought of as quadrature mirror filter. This is true in multi-resolution analysis when using the Daubechies wavelet transforms. It is important to state that the wavelet transform is a bank of multi-resolution filters.

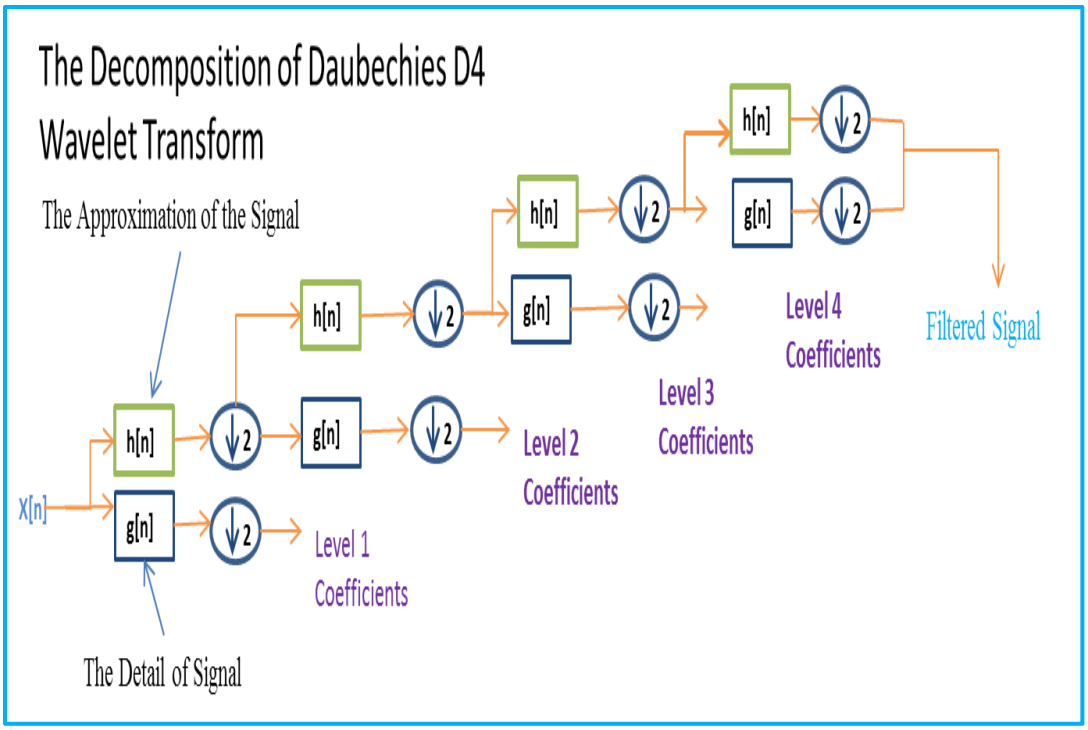


Figure 1.4. Decomposition D4

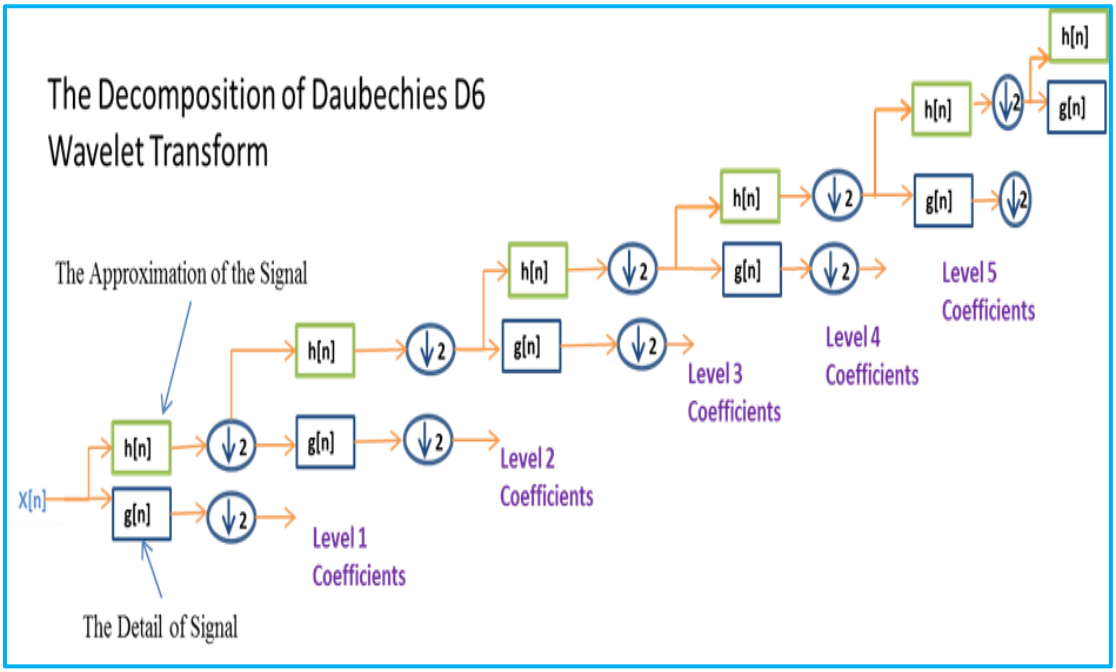


Figure 1.5. Decomposition D6

1.6 Problem Statement

Out of 60 million Americans suffering from sleep disorder, an estimated 18 million have sleep apnea [59]. According to the U.S. Department of Health & Human Services, sleep apnea is a chronic condition that disrupts a patient's sleep. It is also a type of sleep disorder and is referred to as sleep-disordered breathing (SDB). An indication of this chronic condition is that the patient's breathing pauses or becomes shallow. Therefore, these disruptions in breathing cause a patient to move out of deep sleep into light sleep. These pauses can occur 30 times or more an hour. This results in very poor quality of sleep thus, leading to other more serious disorders in patients. Obstructive sleep apnea is the most severe form of sleep apnea, which can be life threatening. While the annual cost of treating sleep apnea patients in the United States is approximately $3.18 billion (including screening costs) it is estimated that untreated sleep apnea may cause $3.4 billion in additional medical costs.

A polysomnography (PSG) is an all-night sleep study which monitors various physical functions during sleep including electrical activity of the heart, brain wave patterns, eye movement, muscle tone, body movements, and breathing. It is currently, the most accurate and sophisticated test for the diagnosis of sleep-disordered breathing (SDB), but also, the most expensive. The cost of an overnight sleep study is estimated between $900 and $3,000. In addition, the PSG is not mobile and has to be administered outside a patient's home.

There is a great need for cost-effective, mobile, non-invasive, and flexible systems for the detection and classification of sleep apnea. This dissertation proposes and validates one such a system.

1.7 Contributions

The main contributions of this dissertation are the design and validation of a body area network-based system that serves as a prescreening surrogate to the PSG. The system consists of real time heart and activity monitor and pulse oximeter, is cost-effective, mobile, non-invasive, and flexible.

We propose an algorithm for the detection of Obstructive Sleep Apnea (OSA), the most severe and life threatening. OSA has been linked to the Long QT Syndrome (LQTS) inspiring our algorithm to use the long QT interval as an indicator of sleep apnea. The proposed algorithm uses Daubechies 4 and Daubechies 6 wavelet transforms for the extraction of the QT intervals.

An initial analysis and validation of the proposed system has been performed using an online database (MIT-BIH arrhythmia database). Initial analysis and validation resulted in a sensitivity of 99.94% and a specificity of 82.04% with a statistical kappa value of 0.691733.

A clinical evaluation of the proposed scheme has been performed alongside overnight sleep studies at the University of Miami (UM) Sleep Center located in the Bascom Palmer Eye Institute over a period of elven nights. A patient dataset of elven has been selected that consists of three split-study patients and nine baseline patients have been solicited during the actual studies. Results obtained are promising and show a statistical kappa value of 0.6634 and a mean absolute error of 0.1701.

Our work contributes a screening technique for LQTS. LQTS is too often undetected and has been known to affect at least one in 7,000 people. It is said to cause about 3,000 to 4,000 [12] sudden deaths, in both adults and school age children in the United States alone.

An exhaustive survey and classification of sleep apnea detection and classification schemes has been developed.

1.8 Organization

Chapter 2 provides investigation of the literature. The proposed scheme is outlined in Chapter 3. Chapter 4 is the clinical evaluation of our proposed system. Conclusion and future work are presented in Chapter 5.

2. Literature Review

2.1 Classification of the Existing Work for OSA Using a BAN

Figure 2.1 shows a breakdown of the existing work in the use of a BAN for home use only and in the use for detection and classification of sleep apnea. Works done for home use only and with no particular diagnosis in mind were also present in the diagram above. We did a further classification of the present work in the detection and classification of sleep apnea and OSA that uses the feature extractions from either the ECG signal only or the SpO_2 levels only, or both the ECG signal and SpO_2 levels. The classification of the literature base on BAN is as following:

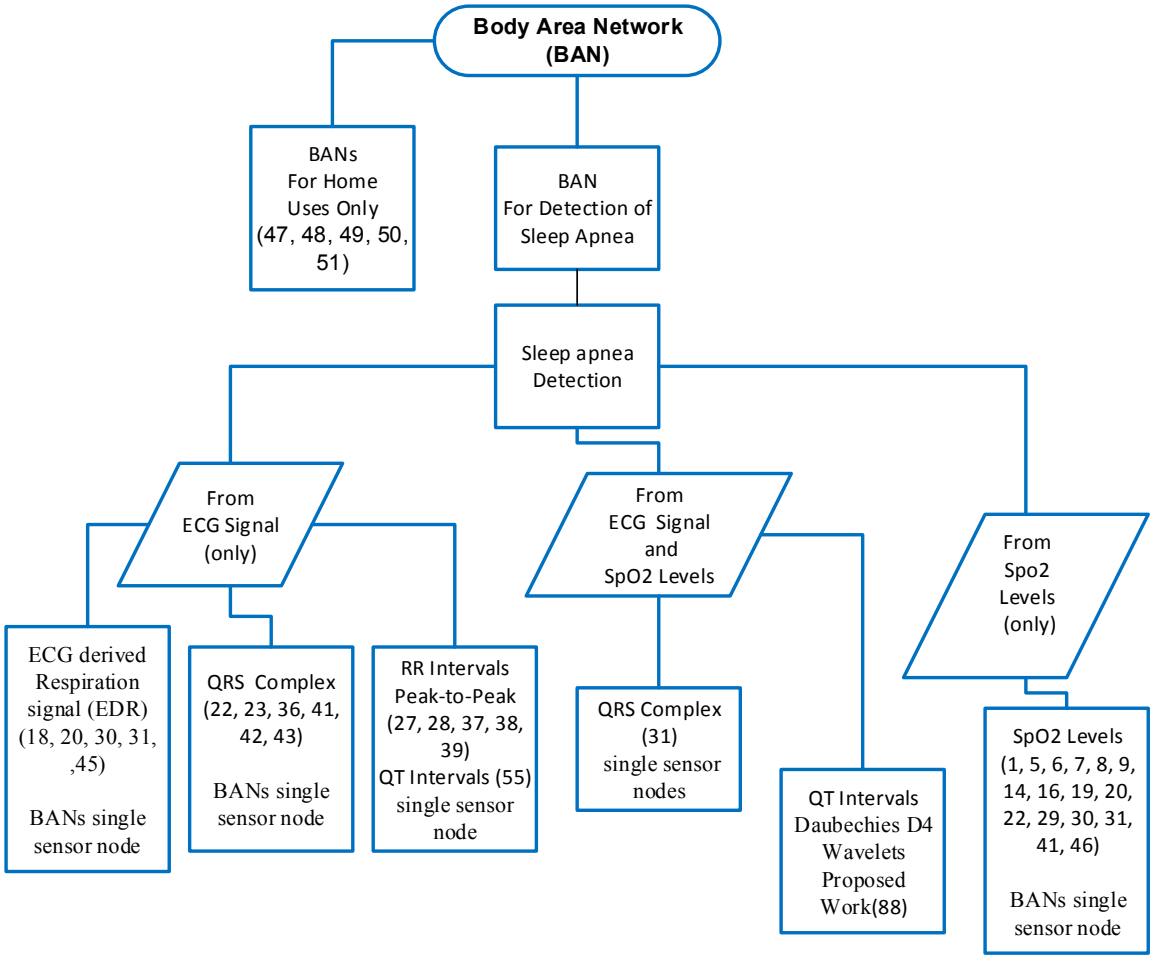


Figure 2.1 Existing Work

- BANs for home use only and with no particular diagnosis [47, 48, 49, 50, and 51].
- BANs for classification of sleep apnea and OSA.
    - ❖ ECG Signal Only.
        - ▪ BANs with a single sensor node.
            - An ECG derived respiration signal [18, 20, 30, 31, and 45].
            - The QRS Complex [23, 34, 35, 36, 41, 42, 43].

- Using the RR Intervals - peak-to-peak detection methods [27, 28, 37, 38, and 39].

❖ Both ECG Signal and the SpO_2 Levels.

- BANs with multi sensor nodes.
  - Using both the ECG Signal and the SpO_2 levels feature extractions work was done [31, 55].
  - Our Developed Work [88].

❖ SpO_2 levels only.

- BANs with a single sensor node
  - Using only the SpO_2 levels only [1, 5, 6, 7, 8, 9, 14, 16, 19, 20, 22, 29, 30, 31, 41, 46, 55]

2.2 Detection of Sleep Apnea from Oxygen Levels

In [1] a real-time a detection and classifier of sleep apnea and hypopnea syndrome (SAHS) presented with pulse oximeter with Bluetooth® technology over a serial line. SpO_2 levels along with the current heart rate sent to the hospital via GPRS/UMTS for a personal digital assistant (PDA).

A comparison study of OSA syndrome in [3] with the use of the Nonin WristOx 3100, a lightweight pulse oximeter designed to be worn comfortably on the patient's wrist. Their study was done alongside a PSG. The Nonin's NVision 5.1 software was used to SpO_2 analyses. The sensor was replaced by the WristOx2™, Model 3150 and the current software is nVISION® 6.3. Our study uses the new sensor (3150) and the current version of the nVISION software as of the time of our study, contact information given in

[4]. The data in our study will be transferred securely to nVISION® data management software via Bluetooth wireless or USB connection and evaluated by the software.

Another comparison study done in [5] the pulse oximetry data recorded from a PSG study and calculated indexes such as the average of the absolute differences of oxygen saturation levels in twelve seconds intervals; desaturation events each hour; and cumulative time take be below the certain thresholds. In this study only the SpO_2 levels were to detect sleep apnea.

The study in [6] using the Holter oximeter monitor against the standard PSG along with the ECG data for the detection of sleep apnea. A Holter-Oximeter in [7, 8, 9 and 14] combined with the ECG from PSG was used in this study to provide continuous. Data was obtained simultaneously during a PSG. The main objective of the study was to see if there method could be used a home screening tool for OSA some of the researcher used their own data and other from the well-known online databases in [10-13]. Our study uses a Bluetooth® wireless technology sensor [4] unlike that of the Holter monitor.

Some studies used signals such at that in [14], a photoplethysmogram (PPG); it can be obtain by using a pulse oximeter. One home base system [29] uses a pulse oximeter for measuring sleep apnea. While others use signals like that in [16] a nasal airflow signal obtain from the database in [11]. Others in [17] use ECG signal to define the oxygen levels. This was based the assumption that OSA has a behavior in which a patient stops breathing; then after a given time the oxygen level in the blood falls; then that patient might wake up and begins to breathe again to improve the oxygen level.

Although in the above studies, the blood oxygen saturation is a major marker according the Report of an American Academy of Sleep Medicine Task Force [2] in

characterizing a sleep apnea and hypopnea events it is not reliable on its own for the cause of the most serve form of sleep apnea OSA. Our work is closely related to that in [1].

In [18] the rate of respiration was derived from the ECG signal along with the autonomic arousals markers used. T-waves were chosen because they are small waves which indicate ventricular repolarization. The rate of respiration was maker used in their detection process for determination of OSA. Discrete harmonic wavelet transform was used to analysis the power within the respiratory frequency.

Sleep Apnea Monitor called SAM by the researchers in [19] is a remote mobile monitoring system. SAM using a voice recording software with the Android-based Sony Xperia neo V (OS 2.3.4) and the Windows-based HTC & T8698 Mozart (OS 7.0) built-in microphone for recording breathing SpO_2 levels, accelerometer for recording movements. Storage is done of SD cards. This system also consist of Global System for Mobile Communications (GSM) modem, android-base phone with a Windows-based phone, MySQL database system, and a website for remote access and analysis of users' records. MATLAB is used to process data from the smartphones using Short-time Fourier transform analysis. Only the breathing patterns and movement patterns the ECG was not used even although this signal is most reliable in the detection of OSA.

In [20] a system called Apnea MedAssist for monitoring OSA consist of a single lead ECG sensor and an Android based smartphone. Also a low-order Daubechies/D4 wavelet for filtering process was used. An ECG derived respiration signal (EDR), because a pulse oximeter was not used to obtain the SpO_2 levels. This system only

examines the heart's electrical system and categorizes the apnea and non-apnea minute our system analysis both the ECG signal and SpO_2 levels.

In [33] home-based investigation Patients in this study were recruited from a university sleep clinic. A pulse oximeter suitable for home use was compared to the actual SpO2 levels of each patient.

In [22] the physiological sensors consisted of a pulse oximeter, an ECG sensor, and a spirometer (a device used for measuring the volume of air from a person's lungs). Only the single led ECG signal was used in their testing. The PDA transported the patient's information through the Internet to the hospital. Their algorithm is based on the Open Source ECG Analysis Software in [23 and 24] and all validation done with the use of the Apnea-ECG Database (a conceptual study). Our algorithm incorporates this software also; reasons given 1) it is was developed for Heart Rate Variability Analysis and 2) the Alive Heart and Activity Monitor in [26] is what is used in our study. The monitor runs this software for ECG analysis and recording. In addition the software was also designed to run in embedded devices that have low computing capability. We also coupled this software in our study with the algorithm in [25]. The power spectrum of heart rate variability was calculated to determine the timing differences in the RR interval. This is also known as a peak-to-peak analysis. Only the ECG signal in [32] was used in this low-complexity screening algorithm for at home. In this system data could be sent to the Internet via mobile phones or computers. Their study RR interval extraction our study focuses on the QT interval extraction.

A detection of sleep apnea that is suitable for a home environment is presented in [31]. This home base system uses an ECG-derived respiration signal and SpO_2 levels. We

take note that, this study did not use a BAN and the Holter Monitor was used, this is not a smart monitor. Also these researchers did not take into consideration the LQT intervals.

2.3 Detection of Sleep Apnea from ECG Signal

Here we make a comparison of our work to that of others, having a similar nature. We feel it is useful to report a number of studies, if only to conclude that the developed work is highly need. Also to state by employing use of different filtering techniques in the detection process that will always produce different results. It is especially true when consideration as to what area of the ECG curve is being detected and to what purpose.

2.3.1 Detection Based on the QRS Complex and RR Interval Features

Other studies use QRS for complexes which are then used to filter out the RR interval are in [27, 28, 37, 38, and 39]. Some of these home base systems also uses for nasal airflow, thorax, and an abdomen movement like that in [38] and the Holter Monitor was also used in [39] which does not have wireless capability.

In [44] the filtering method used in their detection scheme is based on the agrave trous wavelet decomposition algorithm of the wavelet transformation. It employed a pulse oximeter and respiration rhythm monitored in real time from a pressure signal that can be placed under a pillow.

Almost all of the data using in the verification of the studies examined above was obtain through the databases in [10, 11, 12, 13, and 21]. Our study also used these databases to examine our initial analysis of our algorithm. Additional testing will be done during a genuine PSG.

2.4 Detection of QT Features

A study done in [55] used the effected of sleep stages with a respiratory disturbance index and the variability of the QT interval in determination OSA. This study failed to use the variability of the QT interval as apnea events in the computation of an actual AHI and did not incorporate the use of a BAN. Also this study did not use a smart monitor instead a Holter monitor was used. Furthermore our proposed scheme used the variability of the QT interval as actual apnea events to construct an actual AHI as a standalone or correlated with the SpO2 events. In addition our proposed scheme used the Daubechies D4 and D6 filtering algorithm unlike this study. Our proposed work did not use a respiratory disturbance index in the calculation of an overall AHI in clinical evaluation results and analysis.

In [34] a smart phone base system is present for the QT interval detection. The Alive Heart and Activity Monitor in [26] is also used in our proposed scheme. The QRS complex is used to find the Q-wave onset and T-wave offset. Dyadic wavelet transforms is used as the filtering method [35 and 36]. It function produces decomposition on of the ECG signal, Furthermore this work was not used in the detection of sleep apnea. This aids in the detection of the QRS complex. Our system uses the wavelet algorithm in [25]. A similar algorithm is presented in [40] that is a real time personal computer base. Their detection method was not used in the classification and detection of sleep apnea.

In this work, a smart phone-based automatic QT interval measurement system was developed in [34]. The ECG signal was captured by Alive Technologies ECG wearable sensor, [26] and processed on the smart phone. The processed results are sent using cellular network to the internet server. A dyadic wavelet formation was using in the

detection method were the offline test sensitivity (99.75%) and positive predictivity (99.85%). Our study obtained data from the same online database in [10].

This home base system developed their own version of a QRS detector which determines R-to-R peaks using fuzzy classification of two ECG parameters. Unfortunately, they did not develop an automated detection algorithm like ours. Validation was performed on the MIT-BIH arrhythmia database they claim to have results as such, detection rate over 99% and false detection rate of less than 1% [8].

Work in [96] showed that using the wavelet family Daubechies 6 gives better results than Daubechies 4. The D4 transform has proven in [118] to have better results than D6 in the detection and the removal of unwanted artifacts. Even though D4 was shown to have better results based on their algorithm, it was also stated that D6 is similar to the QRS complex. Our decision to use a hybrid filter was based on these results.

Most details about the original signal are reconstructed in lower scales where however, the influence of noise is higher. The developed system is the first in applying the algorithm in one run so that the whole signal samples are processed all at once taking into account all kind of beats. The developed QRS detector reaches a sensitivity of 99.18%± 2.75 and a positive predictability of 98.00%±4.45.

2.5 BAN Home Monitoring System

A wearable device that can be worn on the hand for measuring SpO_2 levels and heart rate variability was developed in [41]. It uses a time domain method, for detecting the QRS complex based on normal-to-normal intervals. There is no sensor that actually is used to measure an ECG signal. In additional their remote monitoring system only has a

personal computer with TCP/IP server and a Graphic User Inter. Others also use comparable methods with time-frequency wavelet analysis [42 and 43].

In [45] an automatic and continuous sleep monitoring system is developed in for daily home healthcare. This system uses a sensor that is placed under the pillow which measures pressure variations respiratory motion and heartbeat, another sensor monitor the environment such as room temperature and humidity. There is also a third sensor, a smart telecom unit the other two sensors feed their data into. This sensor also sends the data to the Internet. No sensors are placed on the patient and this system has no wireless or Bluetooth® capability. No detection of any sleep disorders are performed by this system.

In [46] a wireless network for wearable sensors and assistance to chronic assisted-living residents patients. This study has motion sensors place in rooms to track human movement; a body network that is a wearable jacket with embedded sensors to record human activities and locations; sensor to record a home's environmental conditions. These sensor record biophysical data such as heart rate and rhythm, also SpO2 levels. This system does not detect for the present of sleep disorders. The data from the sensor are transported to a PDA and a Personal computer with an IEEE 802.15.4 ZigBee based infrastructure.

Other wireless sensor networks that use a PDA and personal computer and a ZigBee based infrastructure and record biophysical data are in [47, 48, 49, 50, and 51].

The ECG monitor chosen for these [6-14, 37 and 39] BANs was the Holter monitor. Our scheme will use the heart monitor in [26]. Its features are: real-time transmission to PC, Smartphone or PDA continuous wireless transmission up to 48 hours, and internal SD memory card. It takes recordings of the heart rate, activity, body position,

and falls. This monitor can be worn comfortably during normal daily activities. The sampling rate is 300 samples/sec. It also has a dynamic range of 5.3mV peak to peak and Bandwidth 0.5Hz – 90Hz.

2.6 Filtering Algorithms

Discrete Wavelet Transform (DWT) analysis was performed to filter out the characteristics of the ECG signal. Multi-resolution Analysis (MRA) was chosen to extract the ECG features for annotation. Multivariate Analysis tool was used for classification of extracted features [69]. The ECG recording was obtained from database in [12, 13]. In the previous work mentioned the filtering process consists of a 2nd order- band pass filter (0.5-40Hz) [57].

3. The Proposed Scheme

3.1 The Body Area Network

We develop a BAN for the detection and classification of sleep apnea and OSA. Classification procedure is based on both the ECG and SpO2 levels. A consideration of one minute epochs will be used in the determination of an apneic or a normal respiration. The software provided by the Nonin's Onyx II Model 9560 with Bluetooth® wireless technology sensor [4] will be used. It also provides a fast and accurate snapshot of the patient's SpO2 and pulse rate [25, 61, and 62]. We made modification to the existing C, C++ code to include D4 DWT filtering algorithm for the QT Interval detection process to remove obvious artifacts from the ECG [25]. Alive Technologies' Heart Monitor uses the detection method in [23]. The performance of other detection algorithm has been validated against the QT Database in [10, 11]. The remainder of this chapter is as following, in section 3.1.1 the system architecture of the BAN is presented and in section 3.1.2 we describe developed detection and classification scheme of the BAN.

3.1.1 System Architecture of the BAN

Our developed BAN is presented in this in this section. The proposed network's system architecture consists of three levels, the Physiological Sensors, the Central Communication Access Point, and Data Routing. A star topology design is configured for the overall system. Within this system we have firstly the Physiological Sensors level. We use the two physiological sensors, Alive Technologies' Alive Heart and Activity Monitor (ECG sensor) [26], and the WristOx2™, Model 3150 Wrist-worn Pulse

Oximeter (SpO_2 sensor) [4]. All sensors at this level have their own Bluetooth component. At the second level is the Central Communication Access Point; it is comprised of a personal computer, a smartphone, or a tablet with Wi-Fi and Bluetooth modules. Finally at the third level we have the Data Routing substructure. This discussed in more details in section 3.1.1.3. In Figure 3.1 gives an illustration of the proposed system architecture.

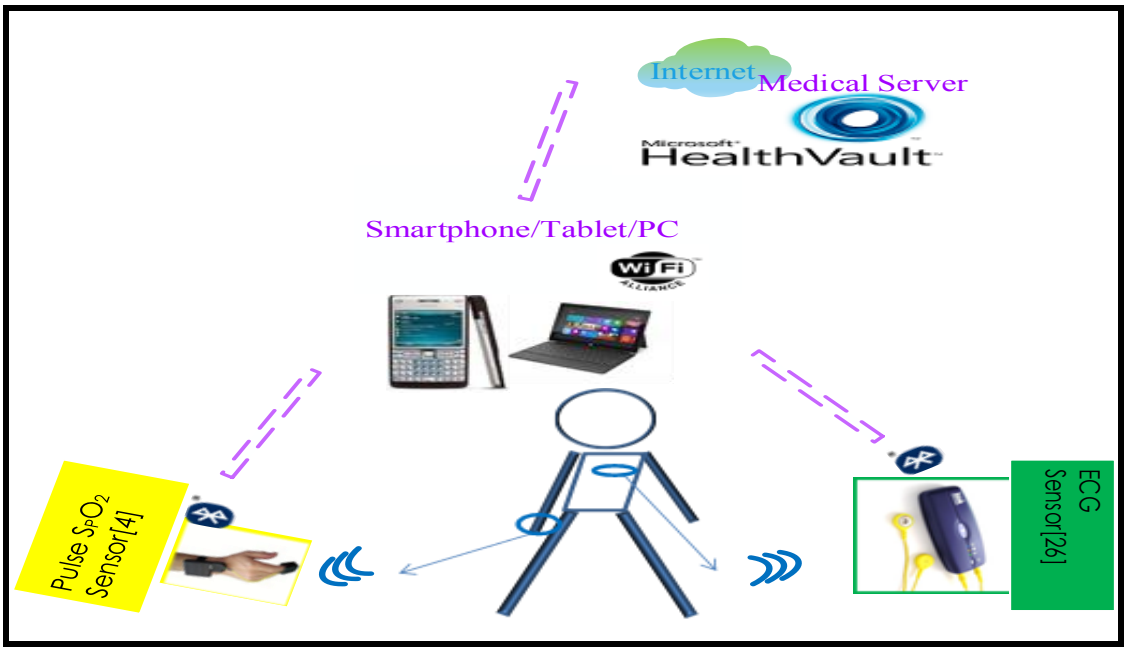


Figure 3.1 Proposed System Architecture

3.1.1.1 Physiological Sensors

The specifications of our ECG sensor and SpO_2 sensor [4, 26] used within our BAN are located in the Appendix. Layer 1 is a star topology design, comprising of physiological sensors; each sensor is Bluetooth enabled. Through their Bluetooth capabilities they are able to communicate with the central hub. The central hub can be either a smartphone, Tablet, or a personal computer. Our sensors have their backup storage units, their memory cards; data will be stored on them as well. Figure 3.1

provides a diagram of the star topology design and Figure 1.1 give a breakdown of the sensors nodes infrastructure.

The sensors are a pulse oximetry sensor and an ECG and heart activity sensor. The pulse oximetry measures the oxygen saturation by means of a non-invasive probe. This probe is a small clip with a sensor that is placed on the patient's finger. It transmits a light signal that travels through the skin and measures the amount of red and infrared light emerging from the skin tissues. The amount of light absorption determines the oxygenated hemoglobin and the total hemoglobin in arterial blood, (the oxygenated blood in the lungs) by taking this measurement the ratio of oxygenated hemoglobin to the total amount of hemoglobin can then be expressed as a ratio. The ECG sensor used in our BAN is also a heart activity monitor. It takes a graphical recording of the heart's electrical activity. A diagnostic study of a patient’s heart can be made from the graph to determine the presence of OSA. This sensor can also be used to monitor the patient’s body positions or falls.

3.1.1.2 Central Communication Access Point

Our access point is layer 2 of our system. It consists of a personal computer using Microsoft ActiveSync® 4.2 synchronization software. Each gateway can send the data received from the sensor to the Internet via Wi-Fi (IEEE 802.11).

3.1.1.3 Data Routing

In layer 3 the sensors’ data is routed to the Internet, either the personal computer running on Windows 7. Figure 3.2 shows the breakdown of the online data storage for the patients’ medical records.

We selected Microsoft HealthVault in [107] as the Medical Server because, it is a web-based system that allows a patient to store and maintain health records as well as fitness information. A patient can authorized whom they wish to have access to their records. Once access is granted a health care provider can then send messages alerting patients when a diagnostic study is completed are when a prescription is ready, and when pertinent information is to be passed along. Furthermore, Microsoft live account allows the patient to have a single user login to access many websites. The HealthVault is used to store the all calculations made and records produced from our BAN.

(1) These records include a full report of the pulse oximeter sensor data; a minute-to-minute report of the SpO_2 levels and the heart rate as they are trending. As shown in Figure 8 the pulse oximeter sensor has a direct connection to the HealthVault through its Bluetooth access point. Nonin's sensor [4] used in our BAN comes with an application that provides direct tracking of the sensor's data. It is part of HealthVault personal health devices directory, and which API's are available to allow accessibility.

(2) The ECG sensor report contains the QT time-intervals, an ECG-derived respiration index and the heart rate. (3) Also, the final results of the Linear Regression Classifier the AHI calculation are uploaded to the HealthVault account.

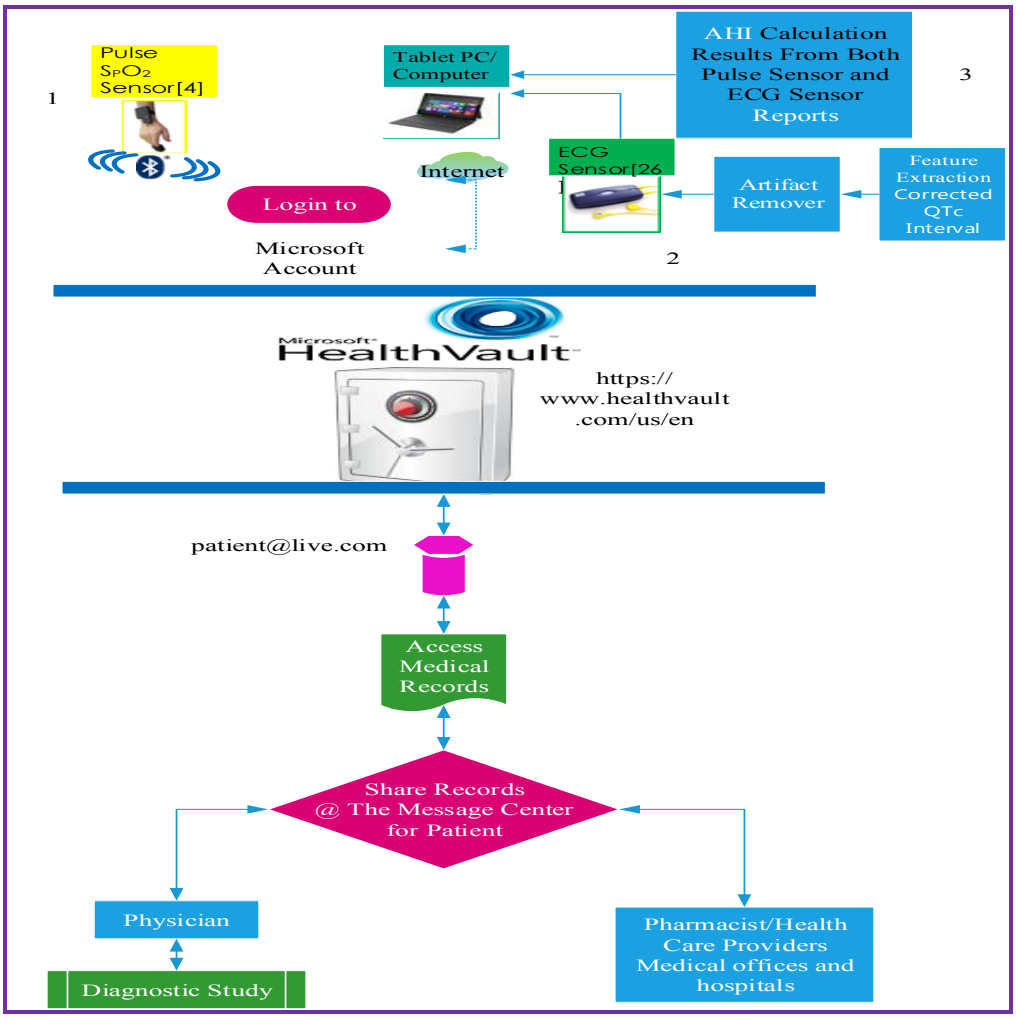


Figure 3.2 Data Routing to the Internet Access Point

After the patient has login to their HealthVault account, they will be able to access webpages that consists of their history from year to date; uploaded document files from themselves are the health care providers; and a personal message center that include a direct address than can be shared. Please see Figure 3.3 for a visual description.

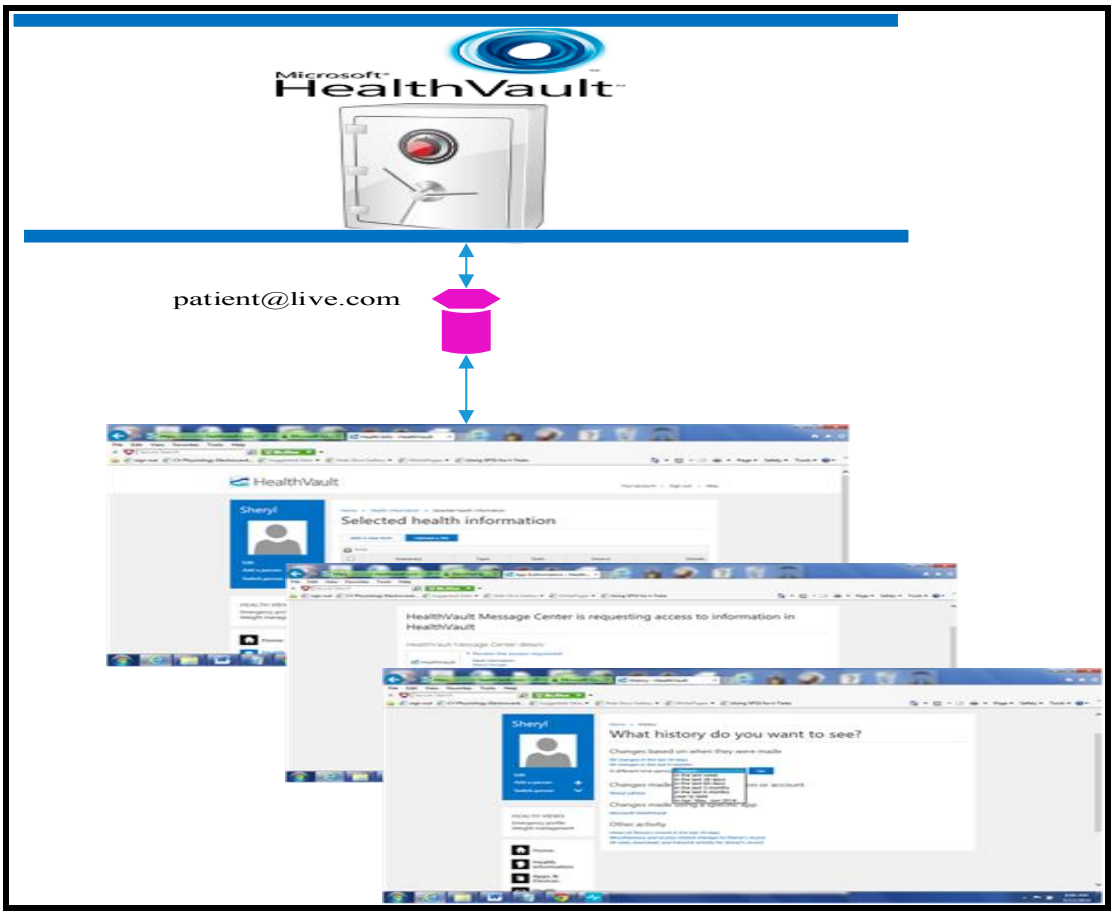


Figure 3.3 Patient's Information Sent to the Health Vault System.

3.1.2 Developed Detection and Classification Scheme of the BAN

Figure 3.4 demonstrates an overview of the developed detection and classification scheme. The scheme is organized three phases. Phase one is the pre-processing of the SpO_2 sensor data and the Daubechies Hybrid Filter implementation of the feature extractions of the ECG signal. In phase two we perform the remover of artifacts form the SpO_2 data. Once that process is completed the feature extraction takes place. Also at this phase the corrected QTc interval is produced and an ECG-derived respiration is calculated. This information from phases one and two are transferred to phase three. In phase we have our Linear Regression Classifier. The LRC is comparable to a black box

pattern recognition system and it computes the AHI from all of the data features that were trafficking through the sensors. The three phases consist of four main modules:

- ECG Signal
- Daubechies Hybrid Filter
- SpO2 Module
- Linear Regression Classifier (LRC)

The LRC is union of the first two modules. All the modules work in processing either the ECG signal or the oximetry signals, thus generating the two outputs the ECG signal and the SpO_2 levels. Then in turn these two outputs produce apnea-hypopnea index -AHI. We have defined these modules in the sections given below.

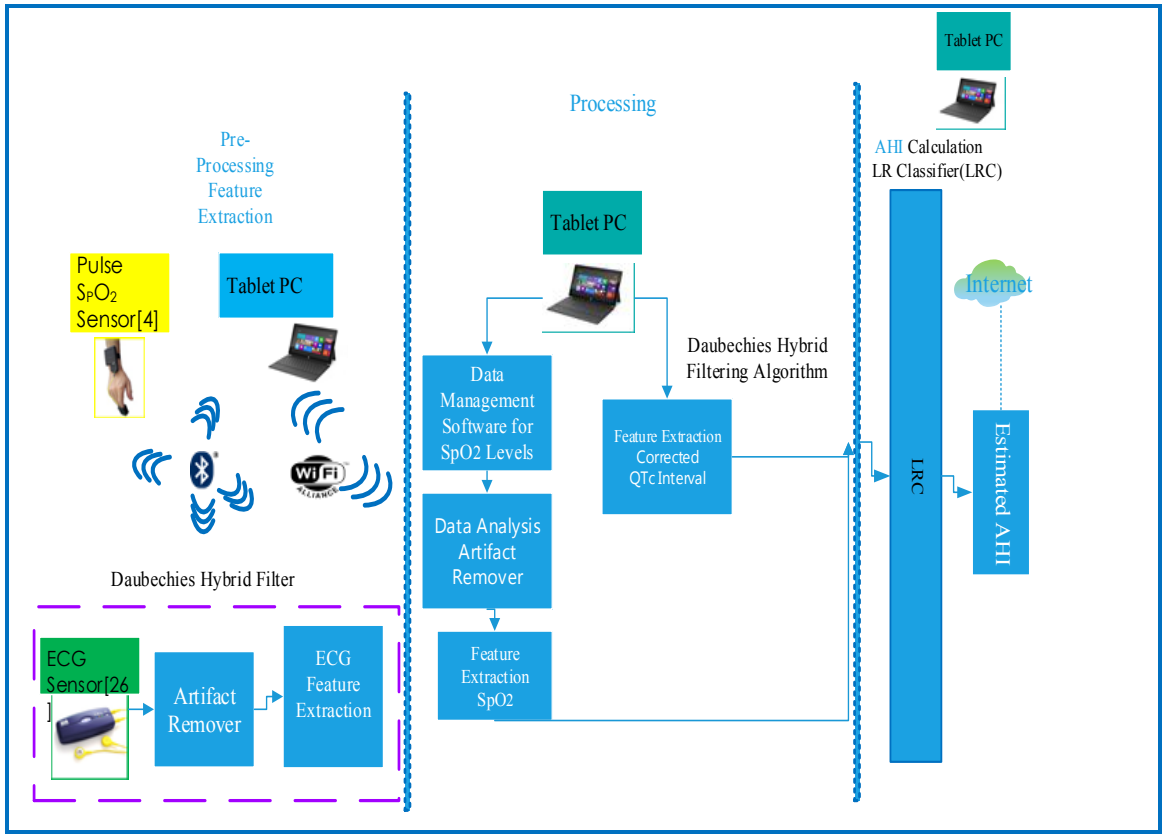


Figure 3.4 Developed Detection and Classification Scheme.

3.1.2.1 ECG Signal Module

The ECG signal is obtained from the heart sensor in [26]. All data is uploaded through the gateway or taken directly from its memory card, then transmitted to the patient's HealthVault account. The gateway is a Smartphone or Tablet PC. Data uploading process is done after the completion of the QT_C feature extraction procedure.

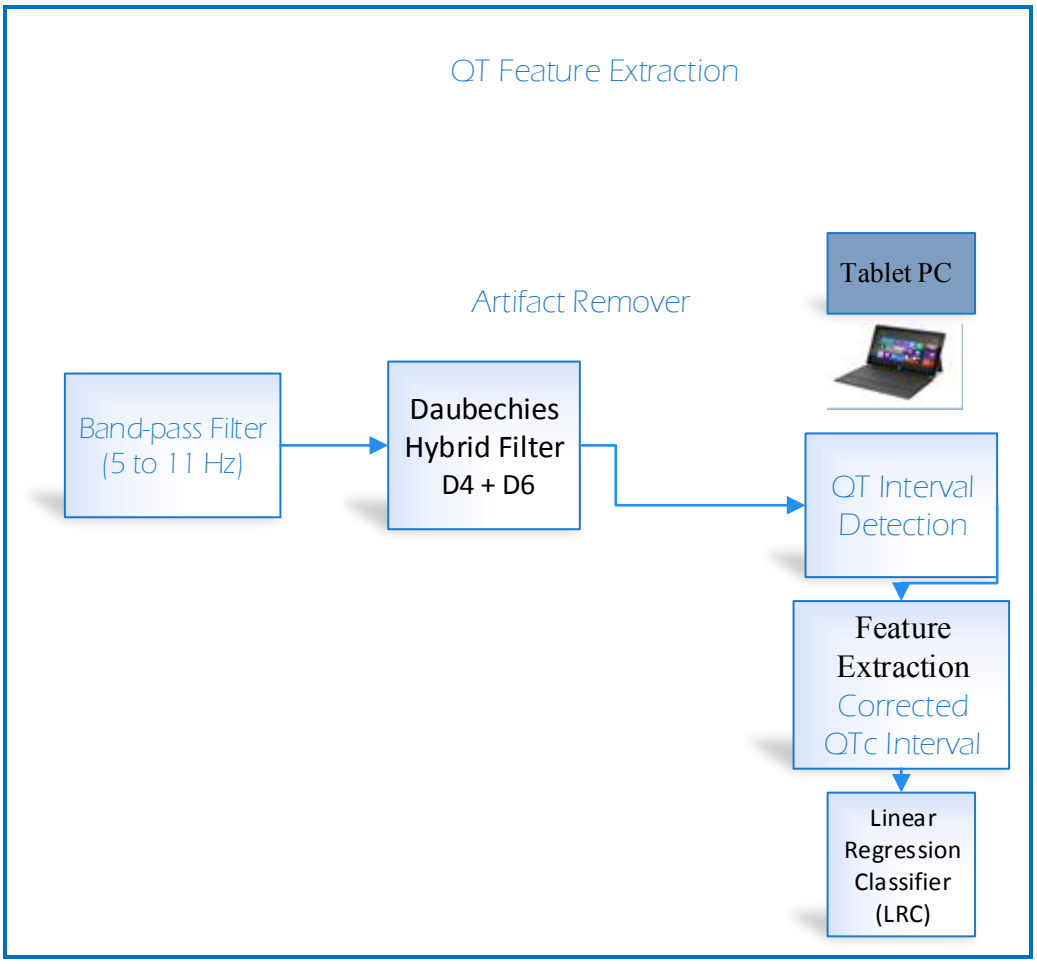


Figure 3.5 Daubechies Hybrid Filter and Artifact Remover.

3.1.2.2 Daubechies Hybrid Filter Module

Daubechies Hybrid Filter – can be demonstrated as following:

Band-pass filter with a pass band from (0.5 to 40 Hz) -> Daubechies Hybrid Filter -> Moving average filter (with an 80 millisecond window)

A band-pass filter, with a pass band from (0.5 to 40 Hz) was used to remove unwanted baseline wander and high frequency interference. We develop this frequency range because of the significant results in [8]. The moving average filter was chosen such that most of the energy from the QRS complex is captured, and that is approximately the size of a QRS complex. Note, that the QT interval is extracted using the location of the QRS complex. Moving average filter is essentially a finite impulse response (FIR) filter and by nature they can become very noisy. This is why we develop a Daubechies Hybrid Filter to remove unwanted baseline wander and high frequency interference, used for noise reduction. This will produce a signal with much better edges (boundaries that are visible). We made significant changes and enhancements to the work in [25] to produce our Daubechies Hybrid Filter. Figure 3.5 help demonstrates this process.

QT and QRS Complex Detection Rules

Here we present a code form of the beat detection steps with an index below:

ECG Signal

A peak is R-peak

A baseline shift occurs if there are no positive and negative slopes

Maximum derivative (dt/dt) – used to find the rate of change at a given time.

Detection Threshold (TH)

Check for beat

if <peak is less than 200 ms>

step over it

Wait for another one

if <peak is detected>

```
  check for baseline shift
  if <shift occurs>
    step over it
Wait for another one
if <peak is greater than or equal to 360 ms>
      take the  (dt/dt)
  if <(dt/dt) less than half of the previous peak> and <the peak is less than TH>
        assume a T-wave
      else
        noise
Wait for another one
if<no peak within 1.5 last peak-to-peak>
 check peak
 if<peak greater than .5 TH>
  check peak
  if<peak greater than 360 ms of the preceding peak>
   QT interval
   Calculate QTc
```

The baseline of a normal ECG can be seen in Figure 3.6. A wave's amplitude naturally measured in reference to the ECG baseline. This baseline is represented by the isoelectric line (no net electrical charge – zero voltage) that immediately precedes the QRS complex. If following the trace of a normal ECG, the baseline is measured as the

part that follows the T wave and precedes the next P wave and the segment between the P wave and the QRS complex that is the PR-segment [108].

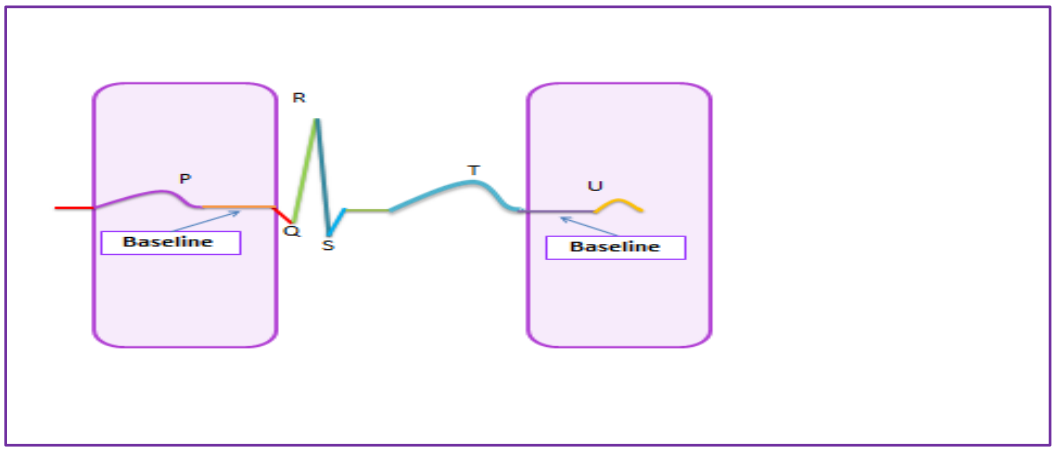


Figure 3.6 The Baseline of a Normal ECG.

3.1.2.3 SpO_2 Module

All obvious artifact must be eliminated, this done by marking all changes of oxygen saturation between consecutive sampling intervals greater than 4% per second as artifact. Furthermore, all SpO2 values of less than 65% or greater than 100% saturation will be marked as artifact. Next produce an estimate of the running 5-minute average of the Spo2 signal. The last step would be to resample both the original Spo2 signal and estimated baseline threshold. The response time of the SpO2 to be based on an exponential averaging every 4 to 8 beats which depends on the actual heart rate. Data Analysis will consist of an independent PSG observer along with the oximetry internal software nVISION pulse oximetry data management software from Nonin Medical [4].

As seen in Figure 3.7 at point 1, the pulse oximeter sensor sends its data to the central hub (Tablet PC/Computer) to generate a plethysmograph of the SpO_2 levels at point 2. On the right hand side of the graph the oxygen levels and as well as the heart rate is presented in numerical form. The graph gives sight into the changes in the Hemoglobin

levels as it might be seen going from normal to abnormal, along with the heart rate. Table 3.1 displays the legend for the plethysmograph extended data view.

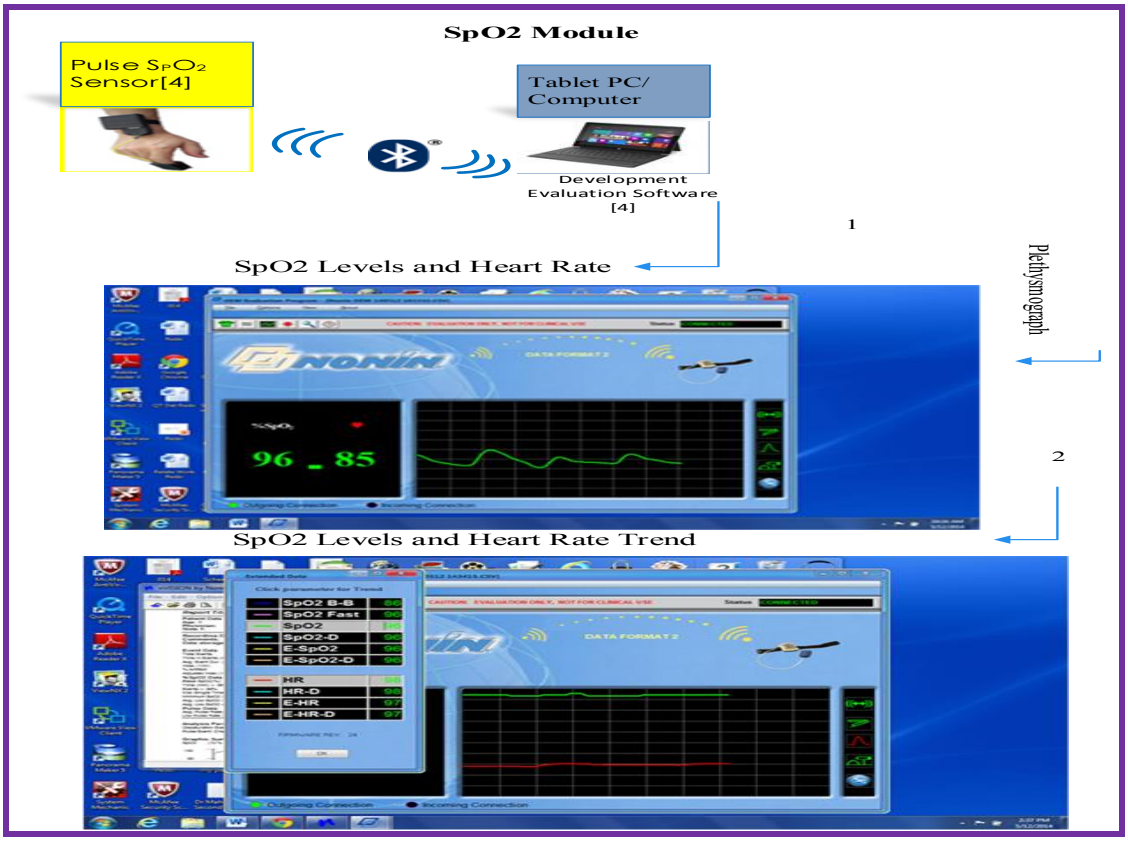


Figure 3.7 Plethysmograph of the SpO2 Levels.

Table 3.1 Noni's Record Format.

Nonin's [4] Record Format	
HR	4-beat Pulse Rate Average
E-HR	8-beat Pulse Rate Extended Average
SpO_2	4-beat SpO_2 Average
E-SpO_2	8-beat $_{SpO2}$ Extended Average
SpO_2 Fast	4-beat Average optimized for fast responding
SpO_2 B-B	Beat to Beat value No Average

The report provides additional information to the physician with a somewhat comprehensive fact sheet of the patient's personal information, which includes the

following listed in Table 3.2. These will assistance with the online tracking and storage of the patient's health records. An example report that contains the patient's personal information is shown in Figure 3.8.

Table 3.2 Patient's Personal Information Record Format

Patient's Personal Information Record Format
Name **Date of birth** **Age** **Height** **Weight** **Gender** **BMI** **Identification Number (ID)** **Physician Name** **Any important or relevant medical notes**

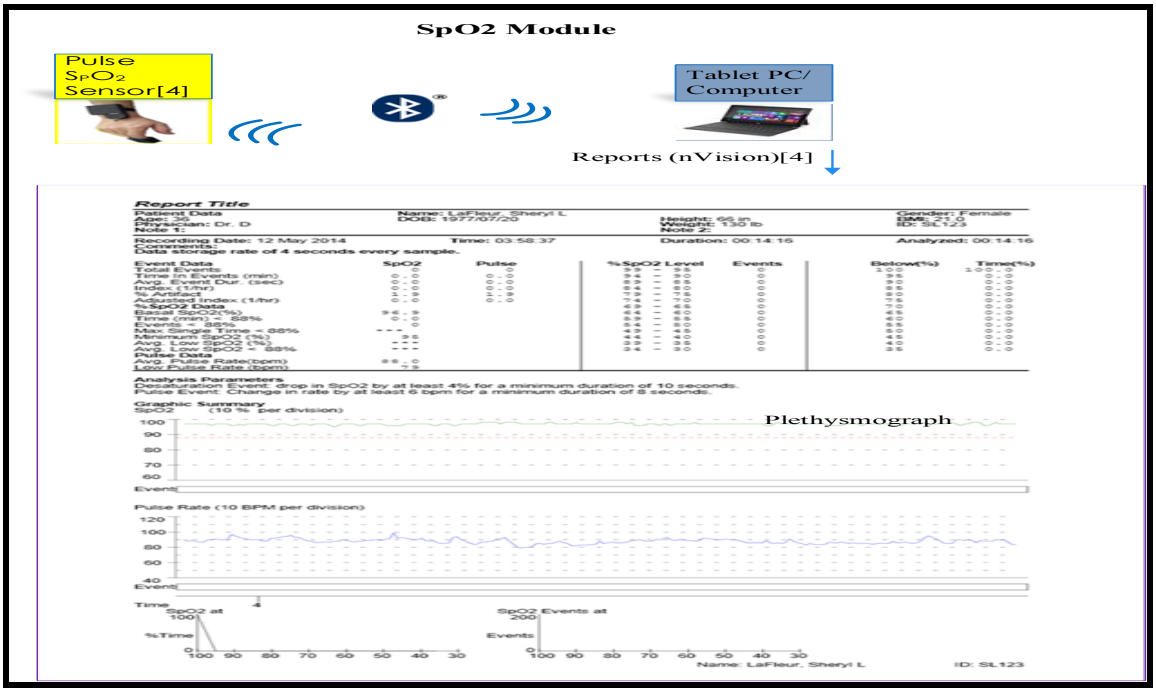


Figure 3.8 Patient's Personal Information Record.

3.1.2.4 Linear Regression Classifier (LRC) Module

We used a linear regression and classifier (LRC), analysis process as a discriminant in the classification of an AHI. Linear discriminant function analysis performs a multivariate test of differences between signals. We developed our respiratory signals (given in breaths per minute) from the work done in [104, 105], major modifications had to be made to accommodate our algorithm. Figure 3.9 shows the LRC process and the breakdown of all the feature extractions (data) from both the pulse oximeter sensor and the ECG sensor that are fed into the LRC.

A pseudo code presentation of the LRC module is given below:

<A Patient's Records>

<Pulse oximeter> && <ECG-Monitor>

<SpO2-Levels>&&<QT-Intervals>&&<Heart Rate>&&<Respiration Rate>

<Perform Linear Regression Analysis>

<Separating data into training and testing sets >

<Perform Linear Regression> && <BMI>

<Estimated AHI>

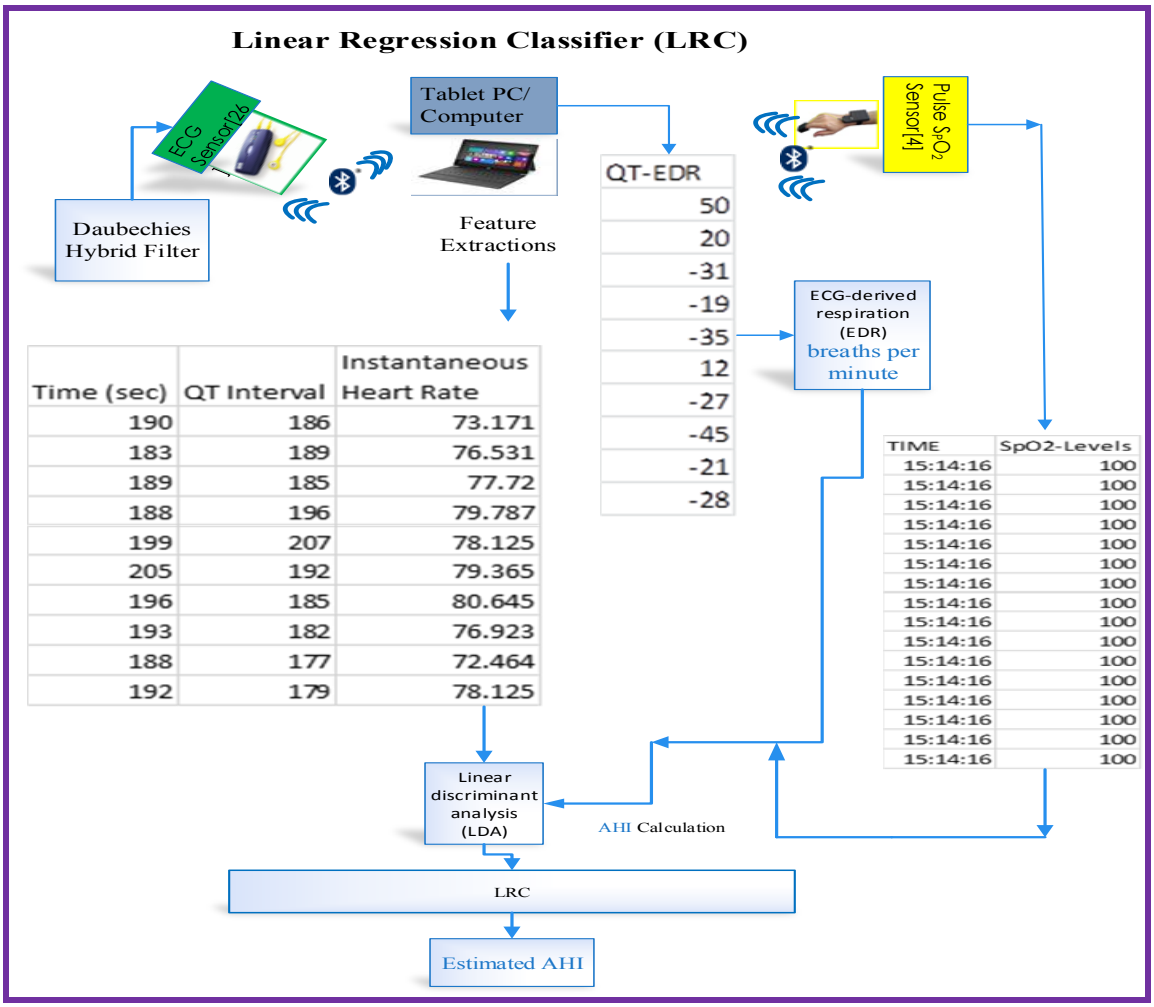


Figure 3.9 Linear Regression Classifier (LRC) Module.

The classifier method is based on linear discriminants and our selected signal representations. Hypoxemia during sleep, sometimes with an oxygen saturation of less than 50%, is a typical feature of the disorder OSA [55]. Apneas and hypopneas will be scored according to standard definitions based on pulse oximeter readings. Hypopneas scoring will be based on the following criteria: Decrease in SpO2 below 92% from a baseline of at least94% or a drop in SpO2 of at least 3% if baseline was less than 90%. AHI is determined by using the following formula: AHI = (Apnea + Hypopnea) / (Actual Sleep Time) [23]. An AHI of 5 to15 is classified as mild obstructive sleep apnea, 15 to 30 is moderate OSA, 30 or more is severe OSA [58], see Table 3.5 the complete layout.

Find $\min_{\alpha,\beta} Q(\alpha, \beta)$, where $Q(\alpha, \beta) = \sum_{i=0}^{n} €_i^2 = \sum_{i=0}^{n} (y_i - \alpha - \beta X_i)^2$ (6)

The model in Equation 6 is of a simple linear regression that provides a graphical representation and illustrations of the statistical classification models that we used in our analysis process. The goal of linear regression is to find the equation of the straight line that provides a best fit for the data points. The best fit is often the least squares method. A more comprehensive explanation of this model and how the objective function is obtained can be found.

$Y = \alpha + \beta X$, where X is the descriptive variable and Y is the dependent variable the slope of the line is β, and α is the intercept (the value of Y when X = 0); where a given data set might consist of n data points {Yi, Xi}, such that i = 1 to n.

3.1.3 The OSA Criteria Procedure

The following markers are used from Tables 3.3, 3.4, and 3.5 in the classification of an epoch event. In Table 3.3 the blood oxygen saturation levels ore given ranging from normal to severe. The heart rate variability is given in Table 3.4 ranging from normal to norm resting. A normal adult has a resting heart rate of 60-80 beats per minutes (bpm). If the range goes below 60 bpm it said to be a bradycardia. When the heart rate is too fast is called tachycardia. It is noted that a low heart rate is sometimes related to sleep apnea [115, 116]. Also, in Table 3.4 the classification of AHI is given. If presence of the LQTS is available it will be used as a marker. As we have stated earlier in section 1.4.2 the BMI is not used as a determination of OSA, but see if there is a linkage to the AHI in the presence of a LQT. The BMI markers in Table 3.3 will be used during the authentication phase. Figure 3.10 shows a graphical presentation of an epoch event.

Table 3.3 BMI Categories.

BMI Categories:	
Underweight	<18.5
Normal weight	18.5–24.9
Overweight	25–29.9
Obesity	BMI of 30 or greater

All information obtain in Table 3.3 was provide from the U.S. Department of Health & Human Services branch the Centers for Disease Control and Prevention [112].

Table 3.4 Heart Rate Variability.

Classification of OSA	
None/Minimal	AHI < 5 per hour
Mild:	AHI ≥ 5, but < 15 per hour
Moderate	AHI ≥ 15, but < 30 per hour
Severe	AHI ≥ 30 per hour
	Heart Rate Variability
Normal Resting	60 to 100 bpm
Irregular	Irregular 40 bpm

Table 3.5 Normal Respiratory Rate Ranges.

Normal A Ranges	
It is widely known that, children have faster respiratory rates than adults, and women tend to breathe more often than men. The normal ranges for different age groups are listed below:	Criteria: Normal Respiratory Rate at rest (bpm = breaths per minute)
Newborn: 30-60 breaths per minute **Infant (1 to 12 months): 30-60 breaths per minute** **Toddler (1-2 years): 24-40 breaths per minute** **Preschooler (3-5 years): 22-34 breaths per minute** **School-age child (6-12 years): 18-30 breaths per minute** **Adolescent (13-17 years): 12-16 breaths per minute** **Adult: 12-18 breaths per minute**	Age <1 month: 30-60 bpm Age 1 to 6 months: 30-50 bpm Age 6 to 12 months: 24-46 bpm Age 1 to 4 years: 20-30 bpm Age 4 to 6 years: 20-25 Age 6 to 12 years: 16-20 bpm Age >12 years and adult: 12-16 bpm

Table 3.3 has the normal ranges of the respiratory rate [111]. The respiration rate is the number of breath a personal take with a minute. It is formally known as the number of movements indicative of inhalation and exhalation per some of time. In a sleep study it is measure by the number of time the chest rise or falls per minute.

How to compute the AHI is illustrated is provide in section 3.1.2.4 A definition was given in section 1.4.1 as being period of time during which breathing stops or is markedly reduced. A hypopnea occurs during abnormally slow or shallow breathing. Our goal is the count these events during, during an overnight sleep study, base our proposed scheme. Figure 3.10 illustrates a graphical view of our developed OSA criteria procedure for calculating an AHI. We will count the number of hypopnea-apnea events that will occur during each hour of sleep. The AHI determination is formulated from the feature extractions taken from our physiological sensors. We established the criteria as following. A pseudo code representation is displayed below:

```
int LCR()
{

        int minute
                hours = 0
                AHI = 0          //The apnea-hypopnea index
                SPOindex = 0      //SpO2 Levels index
                QTcCount = 0      //The present of the Long QT index
                RespRateindex = 0 //Respiratory Rate index
                HR_PRindex = 0    //Heart Rate/Pulse Rate Variability index
                BMI = 0;          //The Body mass index

        do{//Do While Hours is not equal to 8 hours
         for (minute = 0; minute <= 60; minute++){
                Get <Gender>
                if (Gender == F)
                {
                 mark GenderCode = Female
                }
                else (Gender == M)
                {
                 mark GendrCode = Male
                }
                Get <BMI>
                 if (BMI < 18.5)
                        {
                         mark BMI = Underweight
                        }
                else if (BMI >= 18.5 and BMI <= 24.9)
                        {
                         mark BMI = Normal weigh
                        }
                else (BMI > 30)
                        {
                         mark BMI = Obesity
                        }
                Check <SpO2>
                 if (SpO2  >= 96 % )
                        {
                         mark SPOLevel = Normal
                        }//mark++ oxygen saturation index
                else if (SpO2 >= 80 and SpO2 <= 89)
                        {
                         mark SPOLevel = Mild
                        } //Mild
                else (SpO2 < 80)
```

```
                    {
                     mark  mark SPOLevel = Severe; SPOindex = SPOindex + 1
                    }
                Check <QTc>
                    if (QTc >= 470 and Gender == F)
                    {
                     QTcCount = QTcCount + 1
                    }
                    else (QTc <= 450 and Gender == M)
                    {
                     QTcCount = QTcCount + 1
                    }

                Check <Respiratory Rate> //measured in breaths per minute
                    if (Respiratory Rate >= 12 and Respiratory Rate <= 18)
                     {
                     mark RespRate = Normal
                    }
                    else (Respiratory Rate < 12)
                    {
                  mark RespRateindex = Abnormal; RespRateindex = RespRateindex + 1
                    }
                Check <HeartRate_PulseRate> //beats per minute
                if (HeartRate_PulseRate >= 60 and HeartRate_PulseRate <= 100)
                  {
                  mark HearPulse = Normal
                  }
                else if (HeartRate_PulseRate >= 40 and HeartRate_PulseRate <=  59)
                 {
                 mark HeartPulse = Normal Resting
                 }
                else (HeartRate_PulseRate > 100)
                 {
                 mark HeartPulse = Abnormal;  HR_PRindex = HR_PRindex + 1
                }
        }//end if
Get <All indexes>
        <compute AHI>
        AHI = SPOindex + QTcCount + RespRateindex + HR_PRindex
        Determine <OSA> //calculated per hour
         Classify <OSA>
          if (AHI < 5)
                {
                 mark OSA = None Minimal
                }
         else if (AHI ≥ 5 and  <= 15)
```

```
                {
                 mark OSA = Mild
                }
        else if (AHI ≥ 15 and  <= 30)
          {
                mark OSA = Moderate
                }
        else (AHI > 30)
          {
                mark OSA = Severe
          }
        return (AHI)
                                                    //Upload the AHI to the Microsoft
HealthVault
    hours = hours + 1;
        }while (hour <= 8);
}//end LRC
```

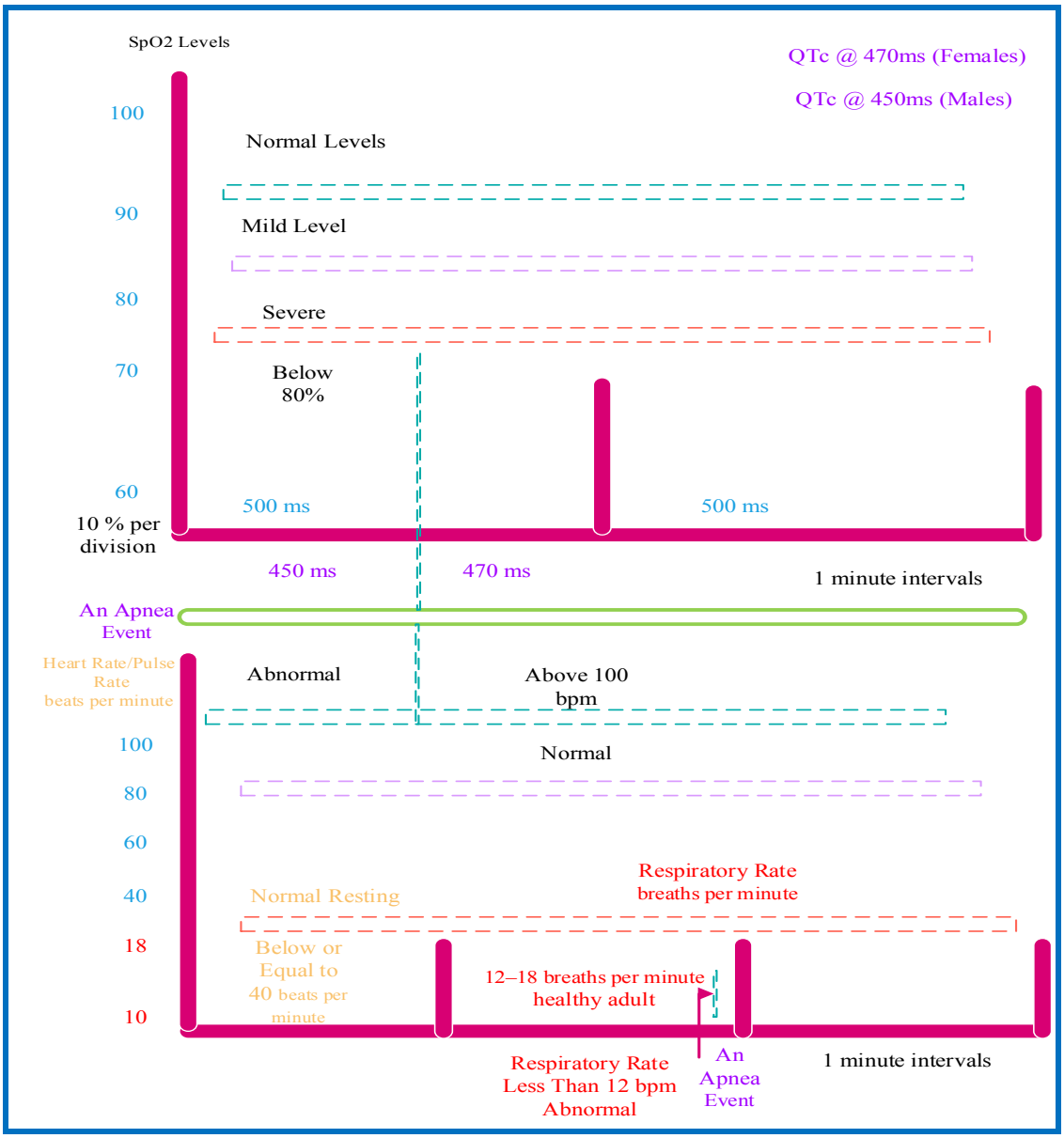


Figure 3.10 The Illustration of the OSA Criteria Procedure and AHI.

3.2 Initial Results and Analysis Using Online Signal Database

3.2.1 Selection of Data

The algorithm ability to detect sleep apnea was evaluated using the data in [10, 11], the Physionet website. This database consists of overnight, single channel ECG recordings (sampled at 100Hz) obtained from 70 patients. There are 35 data recordings designated as training data of one minute annotations (denoting apneic or normal

breathing during each minute) are presented with these records. The other remaining records are test data set. Both the test set and the training set have recordings from twenty patients with moderate to severe obstructive sleep apnea, with ten records as a control set, and five diagnosed as borderline.

The sensitivity and specificity measures were used to compare the annotation files that were outputs for each ECG recording. Sensitivity and specificity measures the performance of a binary classification test. A true positive rate is the sensitivity of actual positives which are correctly identified as having the condition. So, the proportion of negatives which are correctly identified is specificity; the percentage of people who are correctly identified as not having the condition.

A true positive rate is the sensitivity of actual positives which are correctly identified as having the condition. So, the proportion of negatives which are correctly identified is specificity; the percentage of people who are correctly identified as not having the condition. The measurements of Bayes' theorem are defined as following in Figure 3.11. Our initial results from the Bayes' theorem show a *sensitivity of 93*% and *specificity of 90%.*

$$sensitivity = \frac{\text{number of true positives}}{\text{number of true positives} + \text{number of false negatives}}$$

$$sensitivity = \frac{\text{number of true positives}}{\text{total number annotated QT intervals}}$$

$$sensitivity = \text{probability of a positive QT interval detection}$$

$$specificity = \frac{\text{number of true negatives}}{\text{number of true negatives} + \text{number of false negatives}}$$

$$specificity = \frac{\text{number of true negatives}}{\text{total number annotated QT intervals}}$$

$$specificity = \text{probability of a negative QT interval detection given that one exist}$$

Figure 3.11 Bayes' Theorem of Statistical Sensitivity and Specificity Formulas.

3.2.2 The ECG-Derived Respiratory Rate

An automatic template-matching method was applied first to the match the QT intervals from our detection algorithm to produce an annotation file. Then this file is used to derive the EDR signal. Ranges are given in Table 3.3.

A signal processing technique was developed in [12], for measuring the direction of the cardiac electrical axis to form a QRS ECG-derived respiratory signal. This algorithm was designed to correspond to the rapid contraction of the ventricles as blood is expelled from the heart. The algorithm showed poor samples of the respiratory activity. This was mainly due to the low sampling rate paired with the rapid changes in the ECG data during a QRS complex occurrence. Due to these results we chose to use this algorithm from [11] for an EDR-derived respiratory signal.

Again and clearly stating we have developed our algorithm based on the knowledge that wavelets are known to be better at removing unwanted artifacts and baseline-wandering. These unwanted signals that mass as the real signal can be distinguished according to their specific frequency (low noise) with the use of our hybrid filter. Also the Daubechies' scaling functions are said to be a better filter, because it looks like the ECG signal.

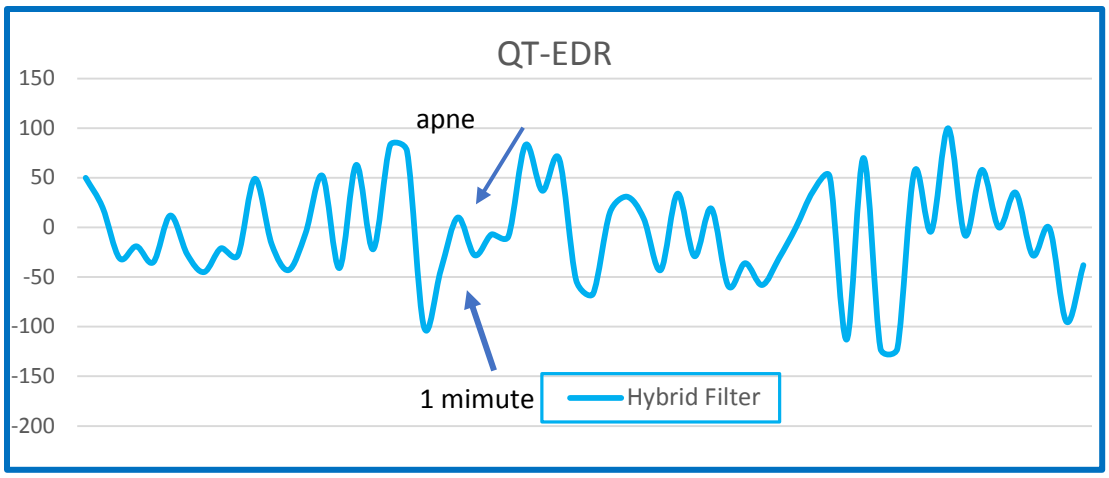


Figure 3.12 The EDR.

Figure 3.12 illustrates the appearance of obstructive sleep apnea within our EDR signal with respect to our hybrid filter. The amplitude of the EDR derived respiratory signal is being altered due to the large baseline shift. Thus, indicating respiratory activity. Within one-minute intervals the amplitude of the signal has low peaks as shown in Figure 5.Our derived respiratory signals produced an apnea index of 12 events per hour. An apnea is defined as cessation of breathing for at least 10 seconds.

3.2.3 Hybrid Filter

After extensive testing of the D4 and D6 separately and could only obtain a Sensitivity of less than 80% and a predictive validity of 78%. After proposing a hybrid filter of the Daubechies D4 and D6 we saw sensitivity of 99.74% and a predictive validity of 99.80% [88].

The D4 transform has proven in [118] to have better results than D6 in the detection and the removal of unwanted artifacts. Even though D4 was shown to have better results based on their algorithm, it was also stated that D6 is similar to the QRS complex. Work in [96] showed that using the wavelet family Daubechies 6 gives better results than Daubechies 4. Our decision to use a hybrid filter was based on these results.

We present the use of a low order Daubechies hybrid filtering, consisting of the Daubechies 4 (D4) and Daubechies 6 (D6). In our previous work we developed the use of a single filter consisting of D4 transform [88]. Our Daubechies hybrid filter was incorporated into the Alive Heart and Activity Monitor's existing software.

A band-pass filter, with a pass band from (0.5 to 40 Hz) was used to remove unwanted baseline wander and high frequency interference. We develop this frequency range because of the significant results in [3, 5]. The moving average filter was chosen by observation such that most of the energy from the QRS complex is captured, with a fixed window size. Thus extending the P-QRS interval (such that each cardiac beat extends 350 ms prior to and after the QRS onset) to accommodate for the corrected QT and long QT interval. When considering a normal heart rate of 60 bpm. A corrected QT interval for example that is $\leq$ 420 ms would be 420 ms, based on Bazett's formula in Equation 1. A detection algorithm based on curve length transform was employed to ensure the end of the T-wave was properly detected. Moving average filter is essentially a finite impulse response (FIR) filter and by nature they can become very noisy. This is why we develop a Daubechies Hybrid Filter to remove unwanted baseline wander and high frequency interference. This will produce a signal with much better edges (boundaries that are visible). We employed the algorithm in [30] with significant enhancements to produce our Daubechies Hybrid Filter. The original software was based on D4 and we extended it to include the D6 wavelet to form a hybrid filter.

3.2.4 The Heart Rate Variability

Some of today's researchers believe that the heart rate variability (HRV) lends itself as a most valuable marker than just the heart rate. The HRV is the measurement of

the time variance between each heartbeat. The HRV is measured in beats per minute. Figure 3.13 presents the frequencies of the heart rate variability as it is trending below 60 beats per minute to about 120 beats per minute. This figure also shows the HRV as it is swings from a normal rate to an abnormal (irregular) rate. The figure is a representation of the comparison study of our detection algorithm to that of the manually annotated data in [23]. Note: We use Microsoft Excel's Frequency algorithm to show the comparison of our algorithm's instantaneous heart rate detection to that of the online databases in [10, 11, and 21]. An average of 62.76 and a standard deviation of 4.43 were found from the comparison study. In statistical analysis a low standard deviation indicates that the data points tend to be very close to the mean (also called expected value or the average); a high standard deviation indicates that the data points are spread out over a large range of values [119].

The heart rate variability ranges from normal to irregular. A normal adult has a resting heart rate of 60-80 beats per minutes (bpm). If the range goes below 60 bpm it is said to be a bradycardia. When the heart rate is too fast this condition is called tachycardia. It is noted that a low heart rate is sometimes related to sleep apnea [20, 21]. Evaluating the heart rate variability to produce a hypopnea index –AHI, we counted the number of times the instantaneous heart rate dipped below 60 bpm and divided by the total sleep time. Also, we took a running average how many times our EDR dropped below 40 breaths per minute based on the total sleep time. Our AHI is a combination of the instantaneous heart rate and our EDR. We saw an average of 10 events per hour.

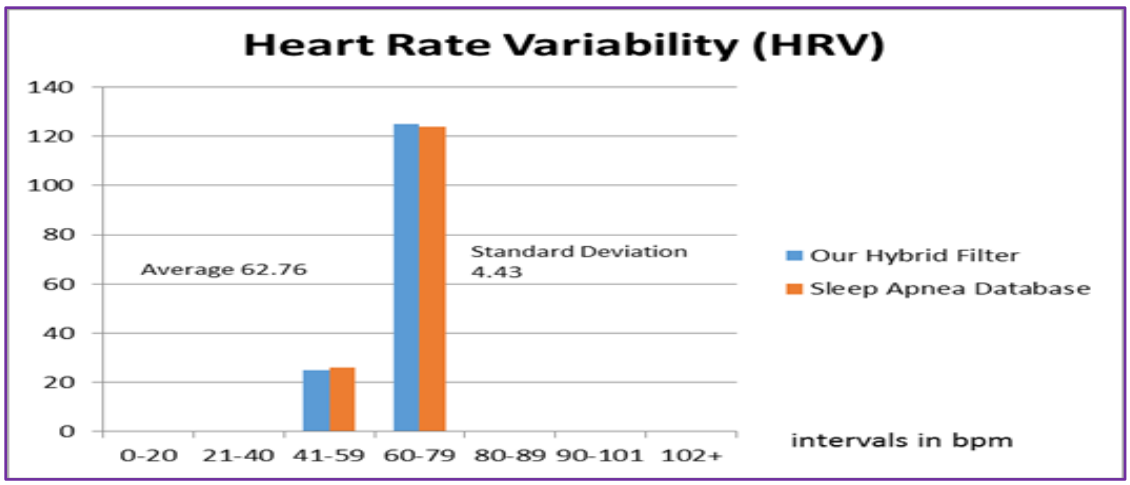


Figure 3.13 HRV with Respect to the Hybrid Filter.

3.2.5 Initial-Analysis

Here we present the results of the feature extraction classifier algorithm based on a linear regression classification methodology. The ECG features we used were a EDR and the instantaneous heart rate (ihr) [22] for determination of the AHI. Here we see that our method did not predict any severe case, but mild: (AHI $\geq$ 5, but < 15 per hour of OSA) and moderate: (AHI $\geq$ 15, but < 30 per hour). This may be due to not associating the oxygen saturation levels. The developed method predicted on average an apnea-hypopnea index -AHI of $\leq$ 21.

After using the Weka data mining software tool we present the overall performance of our system [72]. A linear regression probabilistic statistical classification model was chosen as a best fit for analyzing ECG data, because of its ability to predict a binary response from a binary predictor. A decision was made to use a few of the algorithms and take the average as to show impartial and just results. The results are as following:

- Kappa statistic 0.691733
- Mean absolute error 0.03505
- Root mean squared error 0.132683

Cohen's kappa coefficient is a statistical measure of agreement t for qualitative (categorical) items [120]. If there is a complete agreement than a kappa value of (K = 1) is found. A kappa value of (K = 0) indicates lack of agreement. An overall performance of our work shows a Kappa value of .69 without correlation of the oxygen saturation levels. Thus concluding from these results this algorithm is suitable in the detection and classification of OSA from a EDR signal in the presence of a D4 and D6 hybrid filter. Furthermore a sensitivity of 99.94% and a specificity of 82.04% are presented.

We presented the analysis and the results of our proposed scheme for the detection and classification of obstructive sleep apnea. Our algorithm is based on a low-order Daubechies D4 and D6 hybrid filter. Feature extractions are taken from the QT intervals of the Electrocardiography (ECG) waveform. These features include a ECG derived respiratory rate (EDR) and the instantaneous heart rate. A determination of the existence of sleep apnea is based on the variability of these features. We use HVR and EDR as markers in formulating an AHI in prediction of the existence of OSA; these markers proved to be suitable and reliable. In conclusion our developed scheme performed well in the detection of mild to moderate sleep apnea without the correlation of the SpO2 levels

4. Clinical Evaluation of Proposed System

In this section we present the clinical evaluation of the Pre-Screening Surrogate to the Polysomnography. The evaluation was done alongside overnight sleep studies at the University of Miami (UM) Sleep Center over a period of elven nights. In Figures 4.1 and 4.2 we show how the polysomnographic technologists are placing the surrogate sensors (a body network) on their patients. A sensor for detecting and obtaining the patients' electrocardiogram (EKG) signal on the black band that held the patients' sensors unit. A patient's unit is a box where the PSG sensors are plugged. Another sensor, a pulse oximeter was placed on the patients' wrist and its sensor on the patient's fingertips.

4.1 Patient Database

A patient dataset of elven was selected that consisted of three split-study patients and nine baseline patients were solicited during the actual studies. A split-study is where the polysomnographic technologist spends half the night measuring their patient sleep. If the patient is experiencing OSA, then the second half of their night study is spent using a Continuous Positive Airway Pressure (CPAP). It is a treatment that uses mild air pressure to keep the airways open. CPAP typically is used by people who have breathing problems, such as sleep apnea. Unfortunately only one of the split patients' data could be used for the detection of the presence of the Long QT interval. The other two CPAP patients' data could not be used, for reasons given in Section 4.3. A baseline PSG is a study that could be one to two nights, depending on the results on the first night (the results of the AHI); if the second night is need, than the patient will undergo a spilt night.

A split study is used to establish a CPAP pressure setting. Furthermore, each patient was given an explanation of our study. They were also informed that there were no extra benefits or any additional cost to them other than they were helping to develop a more cost- effective pre-screening at home method. They accepted hoping that one day this method can act as pre-screening surrogate to their polysomnography. Consent forms were signed by each patient before the Surrogate's sensors were placed on the persons.

All ten of the patients' data were included with the results and analysis of our BAN. Within Section 4.3 titled Challenges and Oversights a brief explanation is outlined and as to why only eight of the elven patients' data were relevant to the study. They were given identification numbers ranging from P1 to P11, respectively.

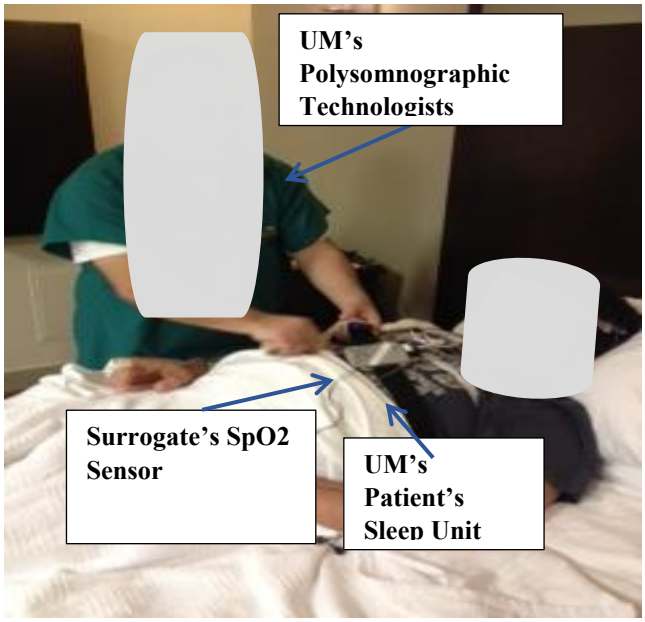


Figure 4.1 Polysomnographic Technologists Placing the Surrogate's Sensors.

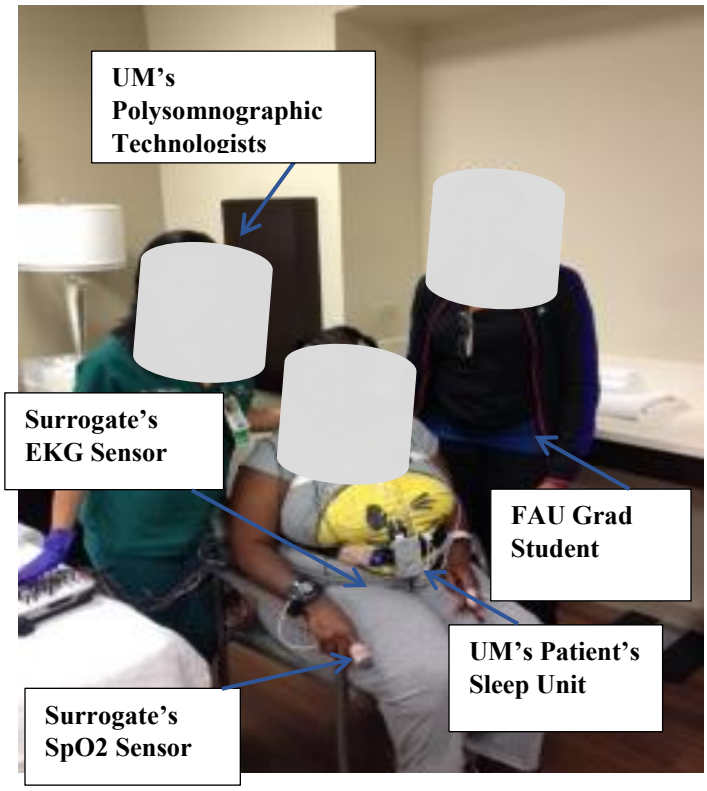


Figure 4.2 Polysomnographic Technologists Successfully Placing the Sensors.

4.2 Results and Analysis

In this section we present the actual result of the proposed scheme function along the PSG study done at the University of Miami Sleep Center. We outline the results and analysis of the QT detection algorithm as well as the computation of an overall AHI for each patient within our database. We conclude with the overall performance of our proposed scheme.

Table 4.1 Patients' General Information Form UM Sleep Center.

Patient General Information			
	Age, years	Gender	BMI
P4	57	male	40
P5	32	male	36.5
P6	64	female	26.34
P7	62	female	24
P8	50	female	36.3
P9	46	female	36.5
P10	41	male	32.3
P11	51	female	36.88

Shown in Table 4.1 is the general information of the entire patient in our study whose data that was actually used in our results and analysis process to validate our proposed scheme. This table is used in the determination of the AHI.

4.2.1 Split-Study Patients

During the first two nights of the clinical testing three split-study patients were asked to have the extra sensor placed alongside their PSG sensors. It was discovered next morning for these patients that the heart monitor sensor experienced major interference from the CPAP machine. Also the SpO2 sensor did perform adequately to collect enough data to produce meaningful results. Although these occurrences did happen we were still able to use one of the patients' data; the patient with the identification number P7 in our LQT analysis.

4.2.1.1 Split-Study QT Detection Algorithm Results and Analysis

No data was recorded in the P2' s (a split study patient) sleep study by the Surrogate's sensor due to the interference with the patients' unit and the CPAP. This was due to the fact that the EKG sensor was not strapped down.

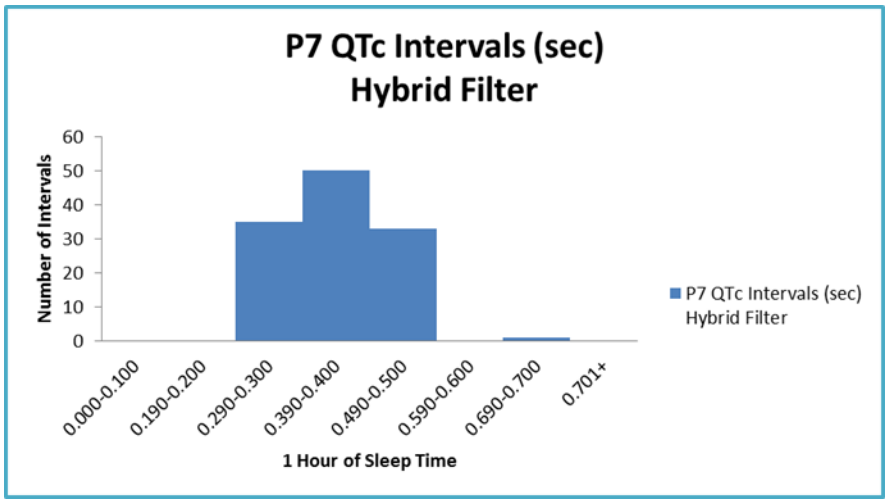


Figure 4.3 Split-Patient QT Analysis.

Figure 4.3 gives a detailed outline of the P7's QT interval trends. We were able to observe form this figure that this patient does show intervals lasting between 0.60 seconds to 0.7 seconds, a sign of a LQT. P7 is a female patient and her QTc should be < .47ms, clearly the figure is showing intervals greater that the normal QTc range in females.

4.2.1.2 Split-Patient Heart Rate Variability Analysis

In Figure 4.4, P7's HVR is showing signs of tachycardia a fast or irregular heart rhythm, usually more than 100 beats per minute and as many as 400 beats per minute. The graph below demonstrates signs of a heart rate of less than 60 beats per minute (BPM) in adults known as bradycardia.

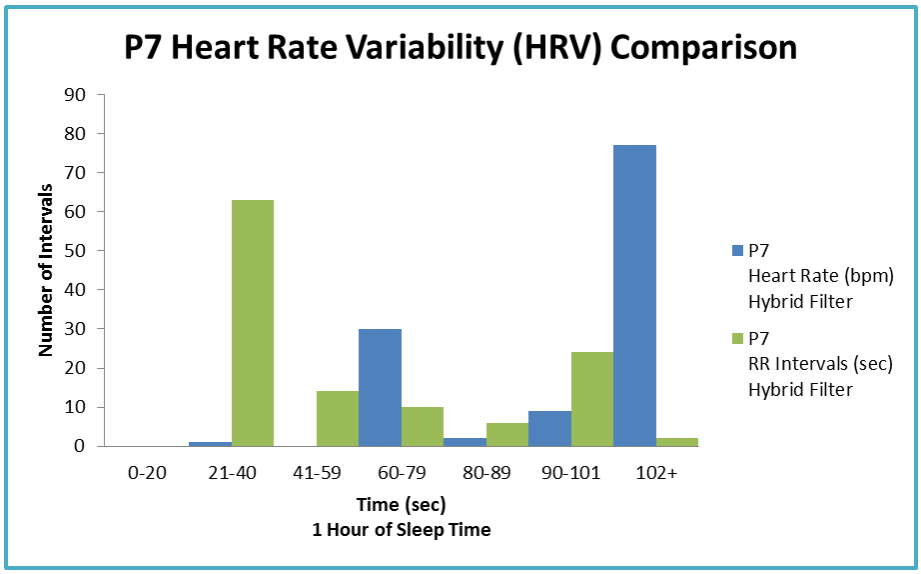


Figure 4.4 P7 HRV Analysis.

4.2.1.3 Split-Study SpO2 Results and Analysis

Likewise no data was recorded by the Surrogate's sensor due to the fact that the patient's finger was not securely attached inside the sensor and the patient was wearing their CPAP.

4.2.2 Baseline Study Patients

Only seven of the nine baseline patients' data could be used within our actual analysis of the performance of our BAN as a surrogate to the polysomnography, for the reasons stated in Section 5.

4.2.2.1 Baseline Study Heart Rate Variability Analysis

The HRV is one of the most valuable markers than just the heart rate itself. It aids in the diagnosis of a patient's overall wellbeing. In Figures 4.5 through 4.11 we have the results of the analysis done on all the baseline patients within our study. Patients P4, P9 and P11 show signs of tachycardia, whereas P9 also appears to have bradycardia.

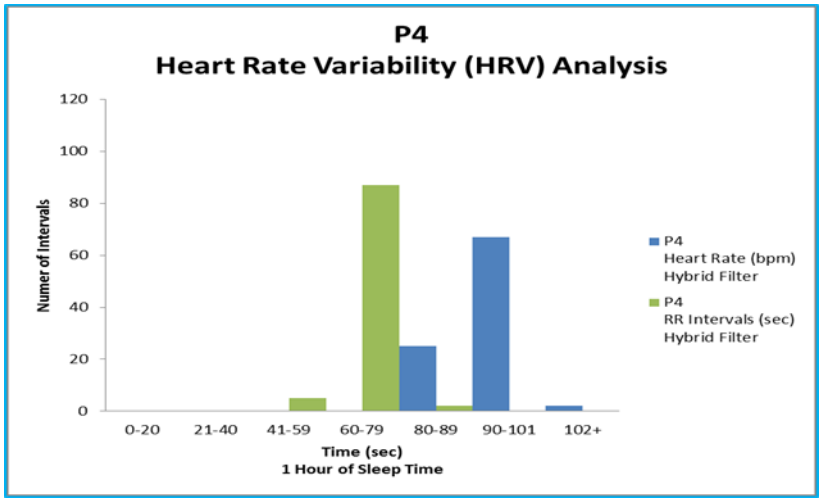


Figure 4.5 .P4 HRV Analysis.

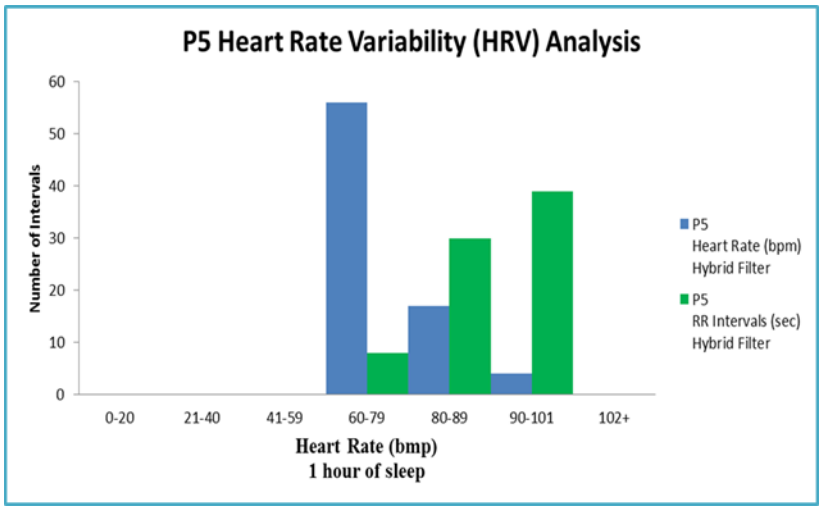


Figure 4.6 P5 HRV Analysis.

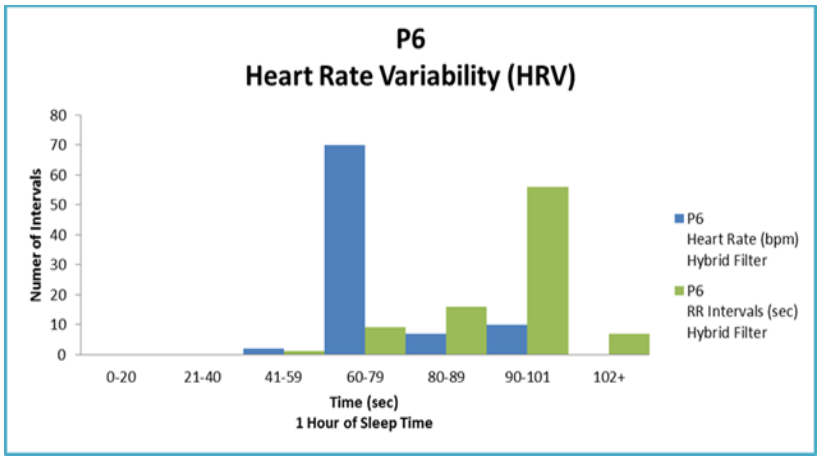


Figure 4.7 P6 HRV Analysis.

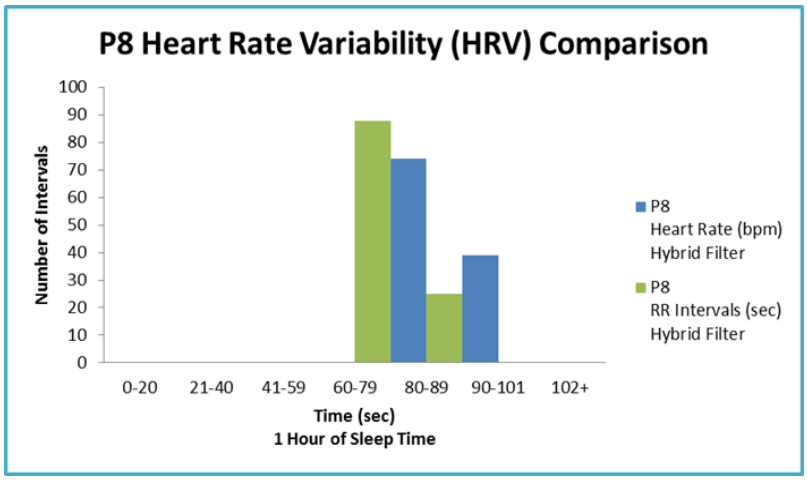


Figure 4.8 P8 HRV Analysis.

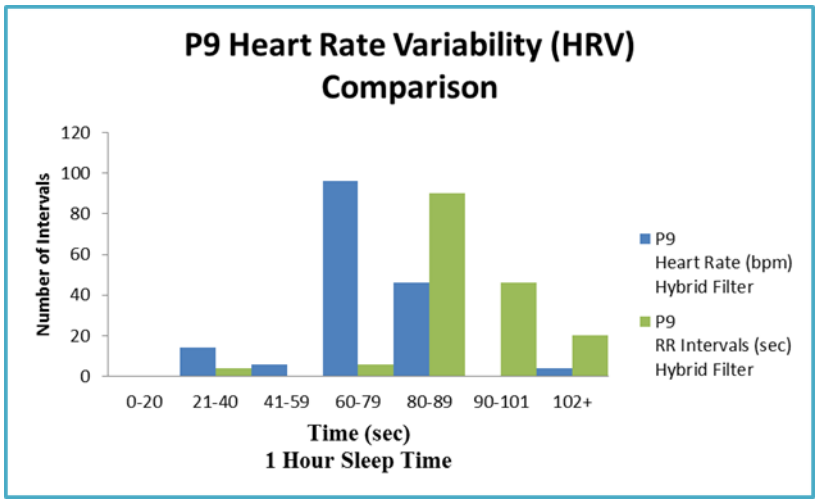


Figure 4.9 P9 HRV Analysis.

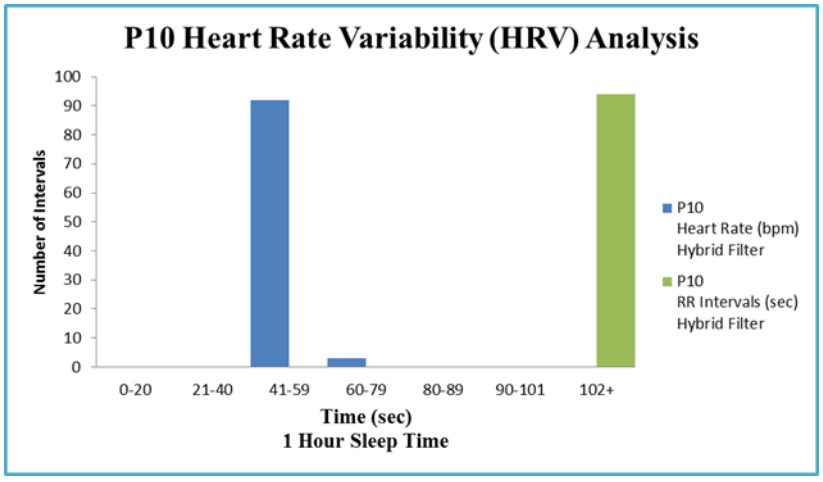


Figure 4.10 . P10 HRV Analysis.

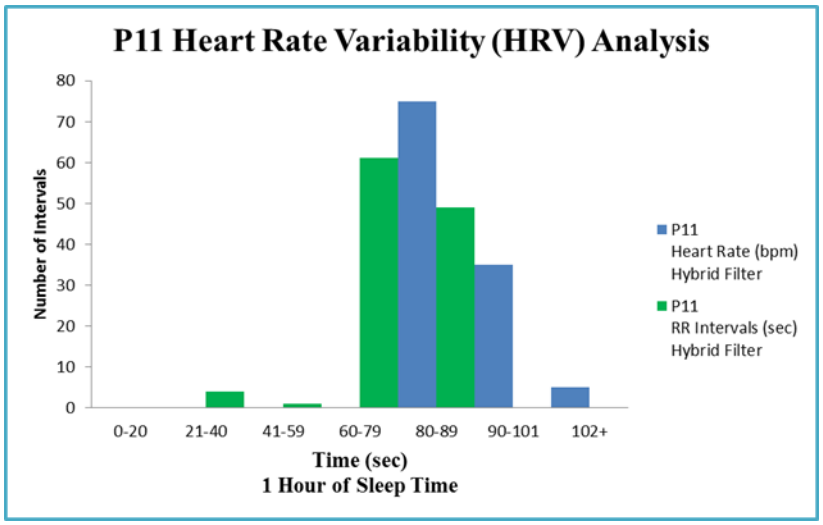


Figure 4.11 P11 HRV Analysis

4.2.2.2 Baseline Study QT Detection Algorithm Results and Analysis

The QT detection analysis and result are given and displayed in Figures 4.12 through 4.18. These figures give us a broad view of the accuracy of our proposed scheme in the detection of the LQT. Our result for Patient P8 shows her at that she is likely to be at a borderline level of having LQT. Patient P10 was one of the male patients in the study and his QT analysis show that he is most likely to have the LQT syndrome. Figures 4.14 and 4.16 respectively show both P6 and P9 QT intervals falling within abnormal ranges. None of the other either patients in the study showed any signs of having the syndrome.

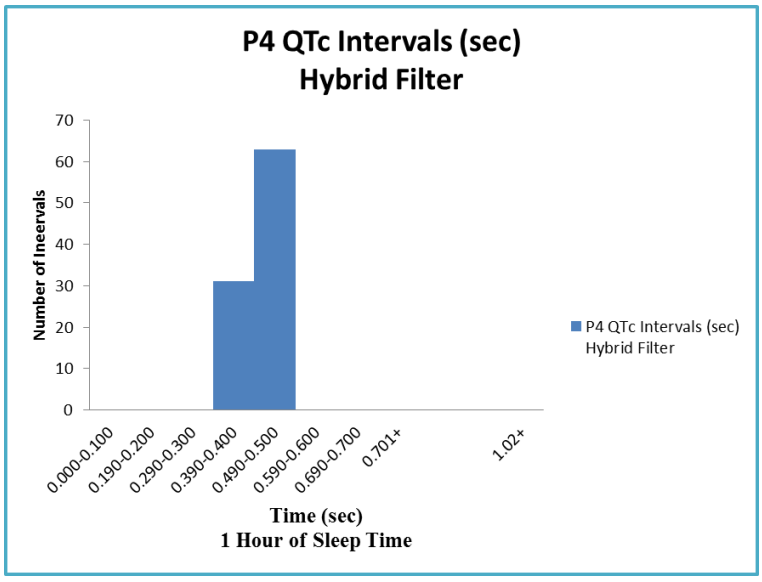


Figure 4.12 . P4 QT Analysis.

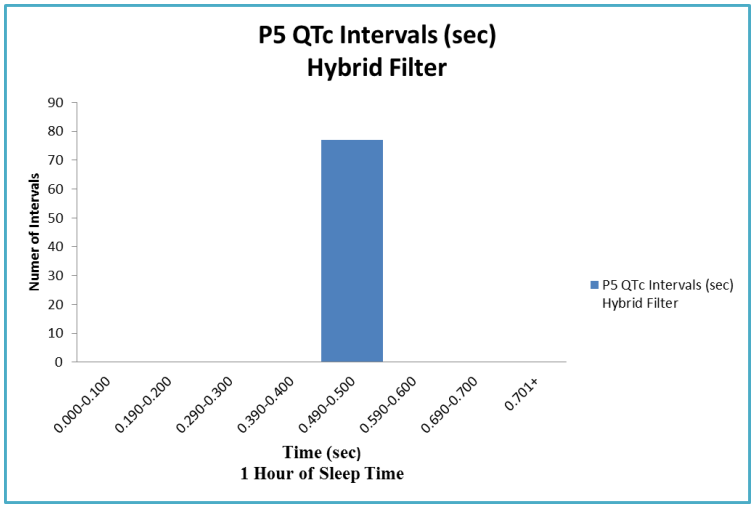


Figure 4.13 P5 QT Analysis.

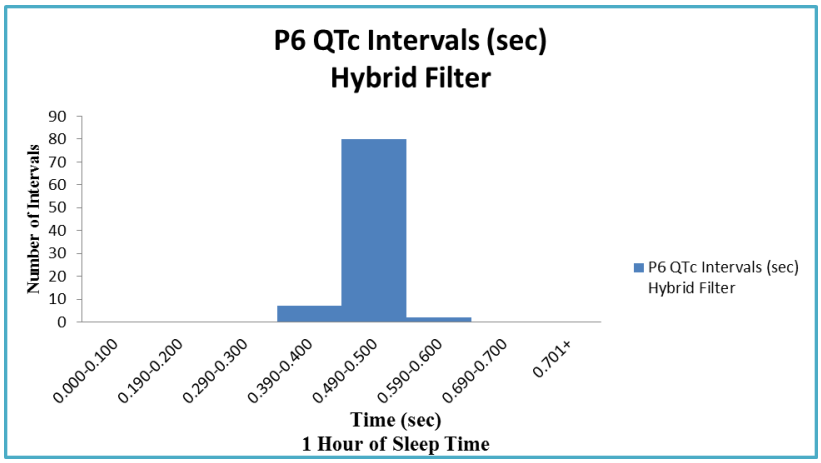


Figure 4.14 P6 QT Analysis.

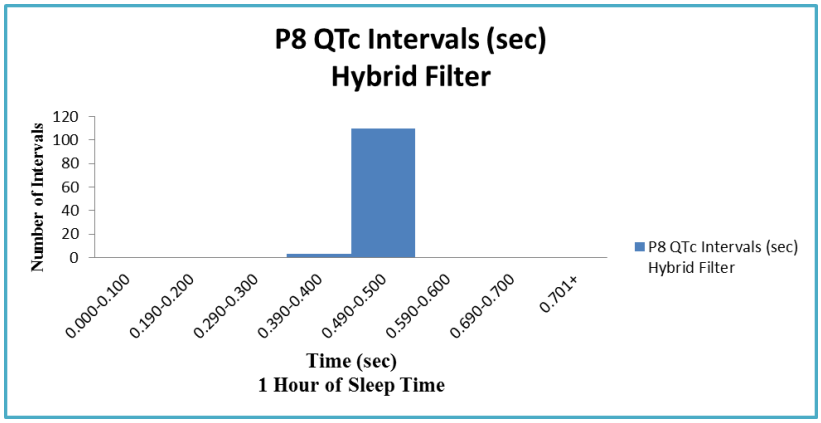


Figure 4.15 P8 QT Analysis.

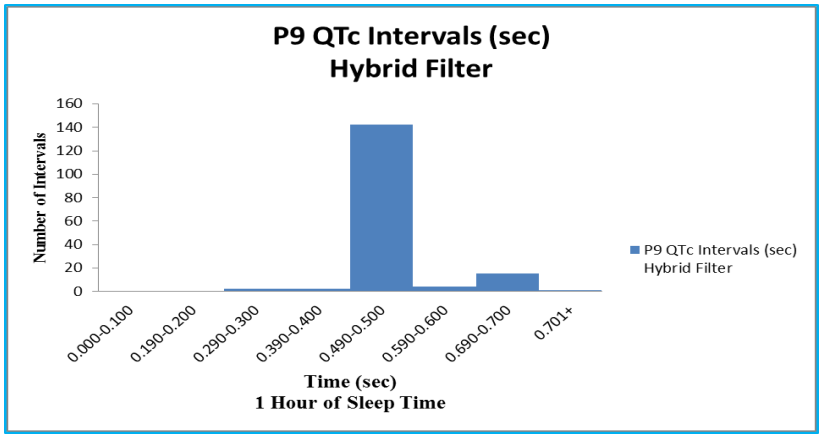


Figure 4.16 P9 QT Analysis.

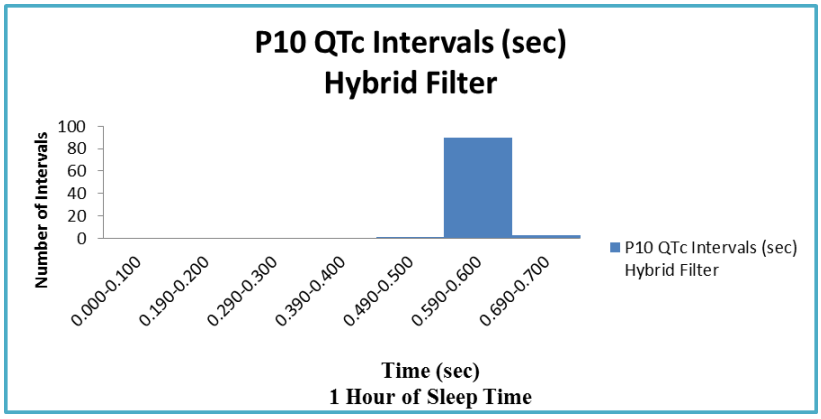


Figure 4.17 P10 QT Analysis.

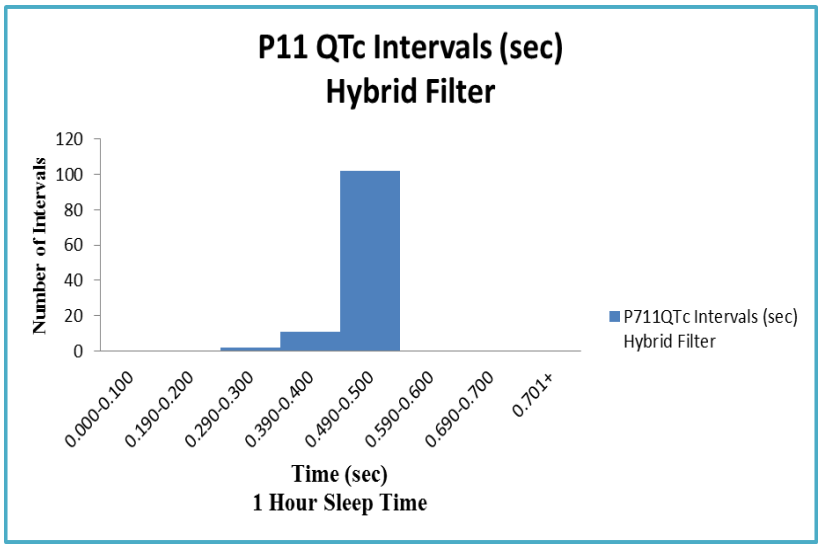


Figure 4.18 P11 QT Analysis.

4.2.2.3 Baseline Study SpO2 Results and Computation of an AHI

Table 4.2 below has the calculations of an AHI based on our proposed scheme SpO2 levels and the LQT interval and to the SpO2 events to calculate an AHI. The PSG AHIs are shown in red. Note that calculation of the AHI was based only six of the actual patients that participated in our study. A comparison of the AHI could not be made for patient P7 because she was a CPAP patient. A CPAP patient has already be found to have moderate to severe sleep apnea. Our proposed scheme did not compute indexes above a mild sleep apnea. These results could be due to the unforeseen circumstances and

challenges stated in Section 4.3. We would like to make a note that the computation of the combined AHI (LQT + SpO2 levels), the total sleep time for each patient was taken from the ECG monitor's actual recording time. This was done under the consideration of the proposed scheme to use a different indicator of sleep apnea with respect to the LQT intervals.

Table 4.2 Apnea-Hypopnea Index Obtained From The Proposed Scheme SpO2 Levels & LQT Intervals.

	Number Events SpO2 Levels	Apnoea–Hypopnoea Index (AHI) SpO2 Only Computed by Proposed Scheme	Number of Events Seen SpO2 Levels + LQT	Apnoea–Hypopnoea Index (AHI) SpO2 + LQT Intervals Computed by Proposed Scheme	Apnoea–Hypopnoea Index (AHI) Computed by UM Sleep Center	Total Time of (ECG Signal) Sleep Recorded by Proposed Scheme Time (hours)	Total Time of Sleep Recorded by Actual Sleep Study Time (hours)	Patients' General Information		
								Age, years	Gender	BMI
P4	30	5	30	5	5	6:26	7:00	57	male	40
P5	17	2	17	2	4	6:54	6:00	32	male	36.5
P6	30	5	32	5	1	6:08	6:00	64	female	26.34
P8	50	8	50	8	11	6:38	6:00	50	female	36.3
P9	19	3	39	7	2	7:06	6:57	46	female	36.5
P10	33	5	126	19	15	6:36	7:02	41	male	32.3
P11	86	12	86	15	42	5:45	7:00	51	female	37.8
	AHI = (Number of Events/Total Sleep Time (min)) * 60				Normal: 0-4					
	Total Sleep Time = (Hours * 60) + mins				Mild Sleep Apnea: 5-14					
					Moderate Sleep Apnea: 15-29					
					Severe Sleep Apnea: 30 or more					

4.2.2.4 The ECG-Derived Respiratory Rate

The Figures 4.19- 4.22, below present a visual support of the respiratory rate measured in breaths per minute of patients P6 (Female), P8 (Female), P9 (Female) and P10 (Male). An ECG-Derived Respiration technique, that was obtain from the online PhysioNet [11] development toolkit, was use to obtain these signals. P6 and P8 both are showing a decreased in their respiratory rate lasting about 3 minutes. However P9 is demonstrating fluctuations in their rate respiratory for a duration of almost four minutes. Whereas P10'a fluctuations are last for just about 3 minutes. Apnea appears in all of the patients' EDR that were presented.

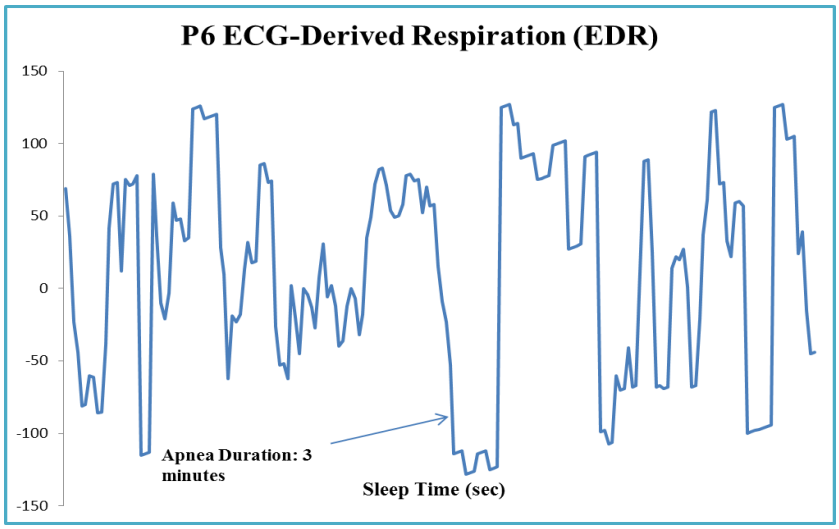


Figure 4.19 P6 ECG-EDR.

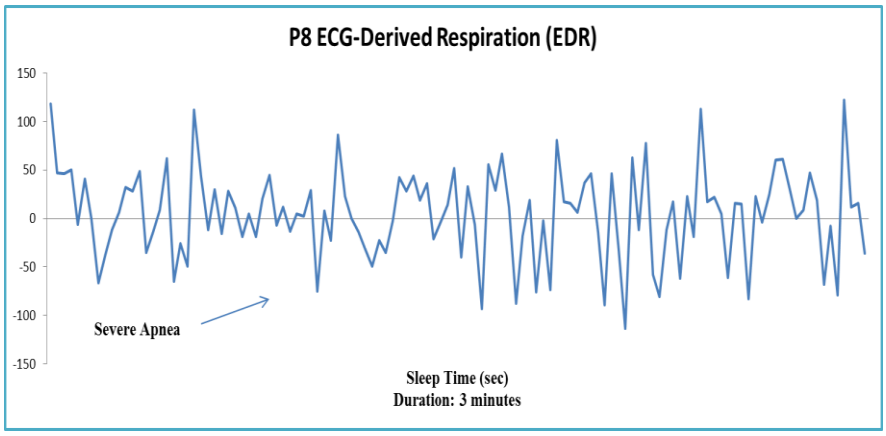


Figure 4.20 P8 ECG-EDR.

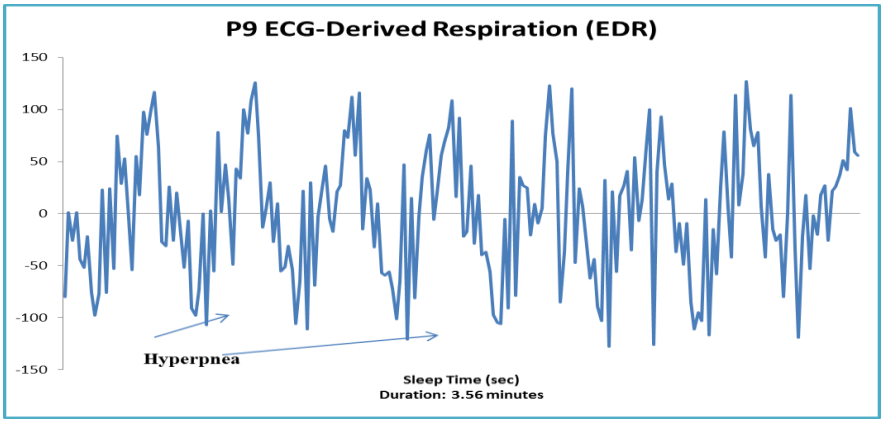


Figure 4.21 P9 ECG-EDR.

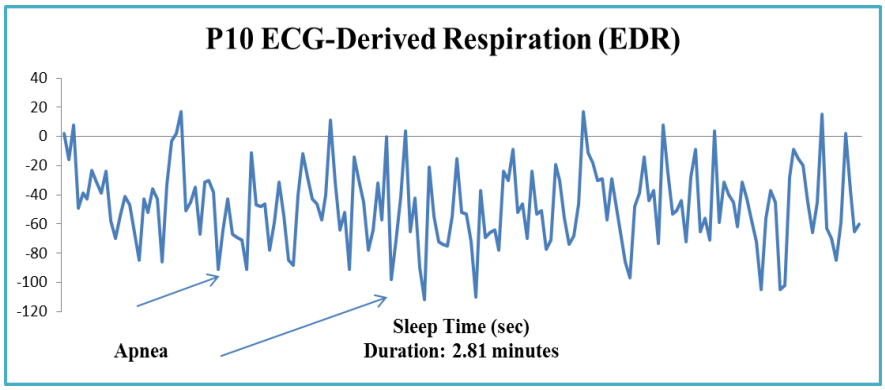


Figure 4.22 P10 ECG-EDR.

4.3 Challenges and Oversights

During the first two nights of the clinical study, there were a lot of things that was not thoroughly thought out, such as where to place the Surrogate's sensor to get good recordings. University of Miami's polysomnographic technologists place the EKG sensor next to the patients' unit, but not strapped down. This in turned caused the sensor to be turned off by the patient during the night. One of the split-night patients was in such debilitating state the EKG sensor just unable to obtain an accurate reading. During the third night one in turned determined that the EKG sensor needed to be strapped down on the black band that held the patients' unit in place. On night where a patient's unit band was not in a position next to the heart it was placed on the white sensor band that recording the patient's chest movements. This caused not interference with the sensor's able to record its data. In conclude only eight of the eleven the patients' data was found to be useful for our study. In addition patients' with ID numbers P1, P2, and P3.

4.4 Overall Analysis and Results of an Apnea-hypopnea Index

The overall objective of this study was to see if suitable AHI could be obtained from the use of potential home-based body area network Surrogate, which consist only

two sensors. One of the sensors is used for recording a patient's EKG activities. In addition the second sensor is used to measure the SpO2 levels.

It was noted that this type of study is not conducive for patients that are undergoing a split-study PSG. The CPAP interference is too great of nuisance to the EKG sensor. Also on a much more different note this study showed that it might not be able lend itself to patients who are in debilitating state. This was seen in the first two patients of the ten day clinical evaluation study.

4.4.1 Overall Analysis and Results of an Apnea in The Presence of LQTS

We have stated previously the following in Section 1.5 titled Problem Statement: The LQT can be a potentially life threatening disorder that has been linked to patients with the most severe form of sleep apnea, OSA. One major problem in diagnosing patients with OSA is that their LQT disorder is too often under-diagnosed during a PSG. If left undiagnosed and untreated OSA can have the following effects: raise heart rate and increase the risk of high blood pressure, heart attack, stroke, arrhythmias (irregular heartbeat), and diabetes. Furthermore, together OSA and LQTS are linked to obesity. Also the main object of this study is to find an at home method a detecting sleep disorders such as OSA in the presence of LQTS. In other words will a patient show signs of having LQTS is they are experience mild to moderate apnea. Our study have concluded that even in the likelihood that a patient only has mild to moderate form of apnea he or she may show early onset of have LQTS.

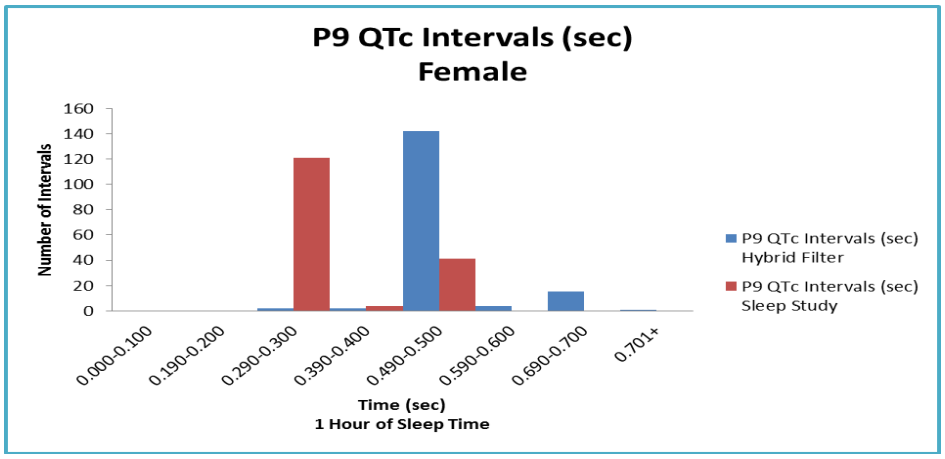


Figure 4.23 P9 with Signs of LQTS in the Presence of Apnea.

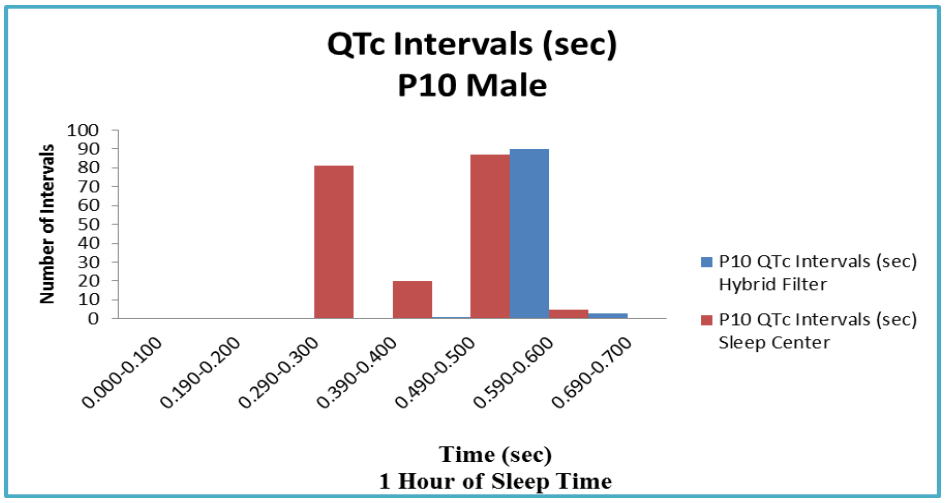


Figure 4.24 P10 with Signs of LQTS in the Presence of Apnea.

Figures 4.23 - 4.26 for patients (P6, P8, P9, and P10) demonstrate our result in validating our conclusion it is a comparison between our proposed scheme hybrid filter algorithm to that of patients' PSG actual sleep data. Patients P6, P8, P9 and P10 give a visual view to our motivation and solution to our problem statement. Furthermore support our results that our BAN is a reasonable to provide physicians with a cost-effective, pervasive, flexible, and real time monitoring access system into their patients' current state of health.

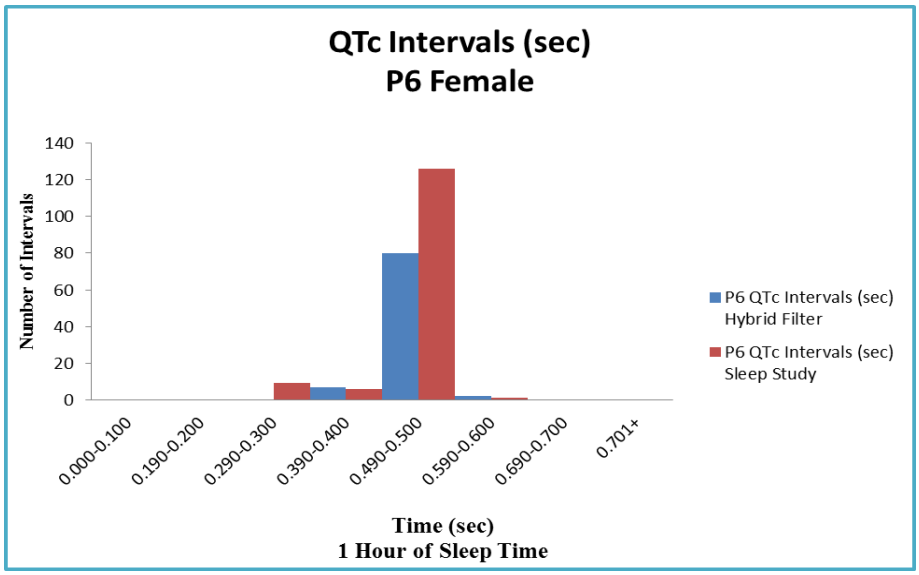


Figure 4.25 P6 with Signs of LQTS in the Presence of Apnea.

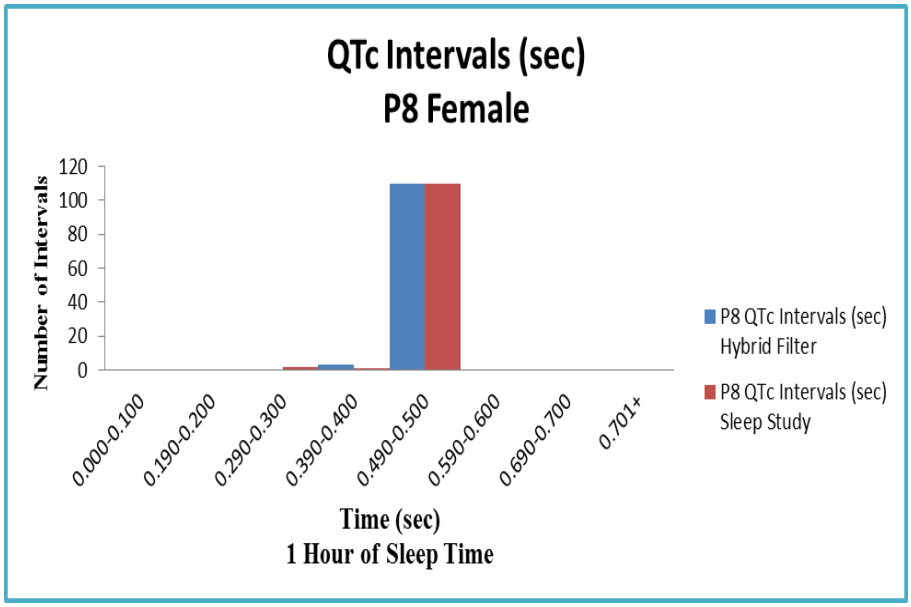


Figure 4.26 P8 with Signs of LQTS in LQTS the Presence of Apnea.

To further support the evidence of the LQT in patients P6, P8, P9, Figures 4.27 - 4.30 gives a graphical view of the patients' heart rate fluctuates in the company of the QTc intervals. We pay special attention to those rates trend from 60 bpm to 90 bpm. They show the HVR as the QT intervals are varying.

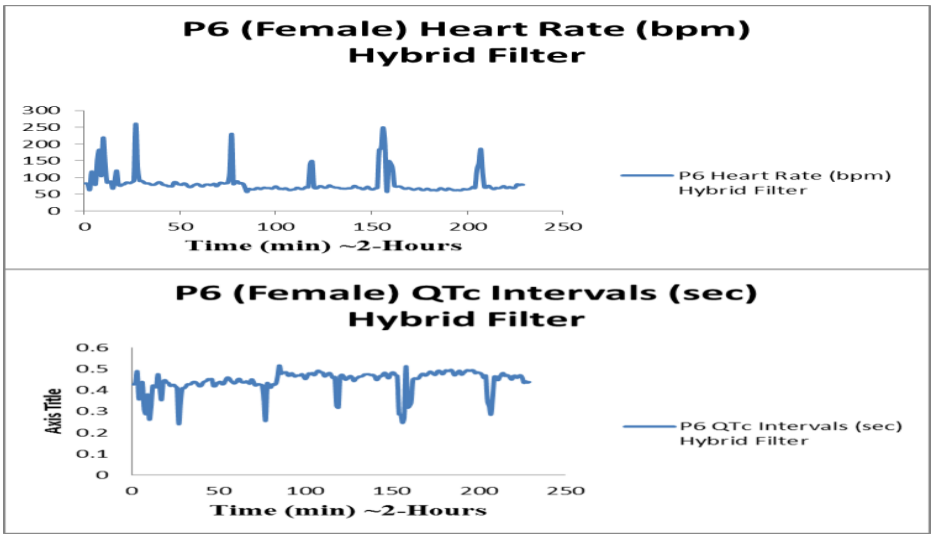


Figure 4.27 . P6 Variations in the Heart Rate.

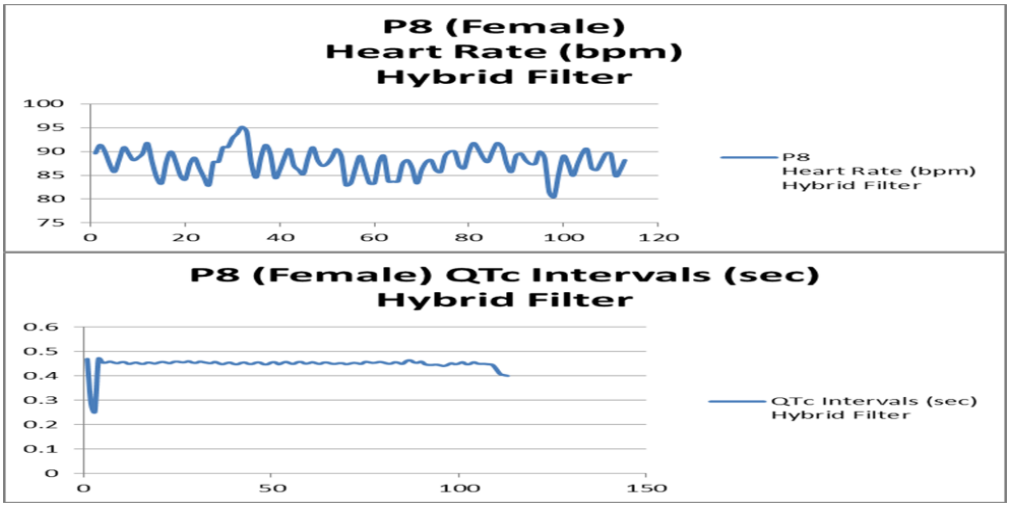


Figure 4.28 P8 Variations in the Heart Rate.

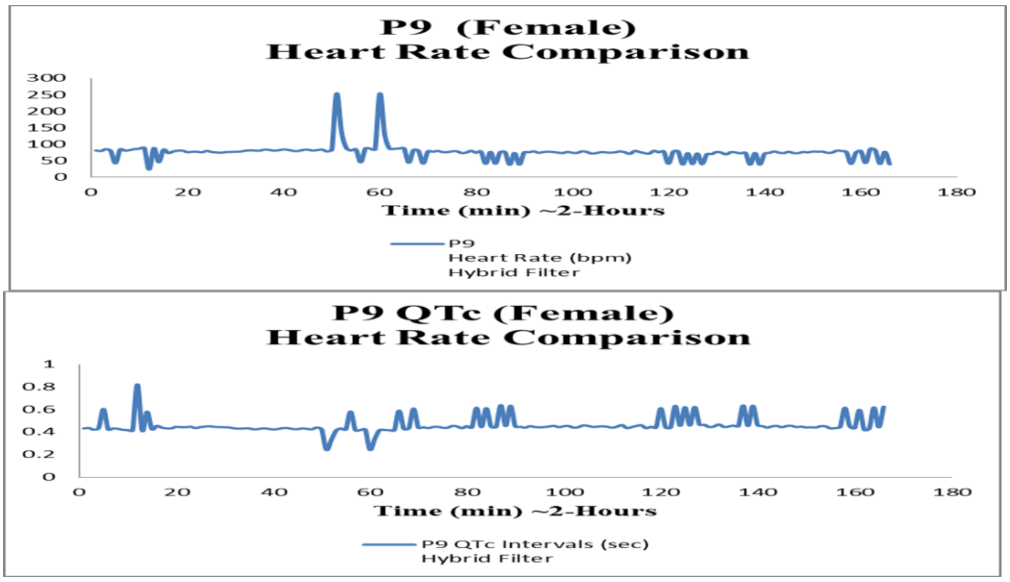


Figure 4.29 P9 Variations in the Heart Rate

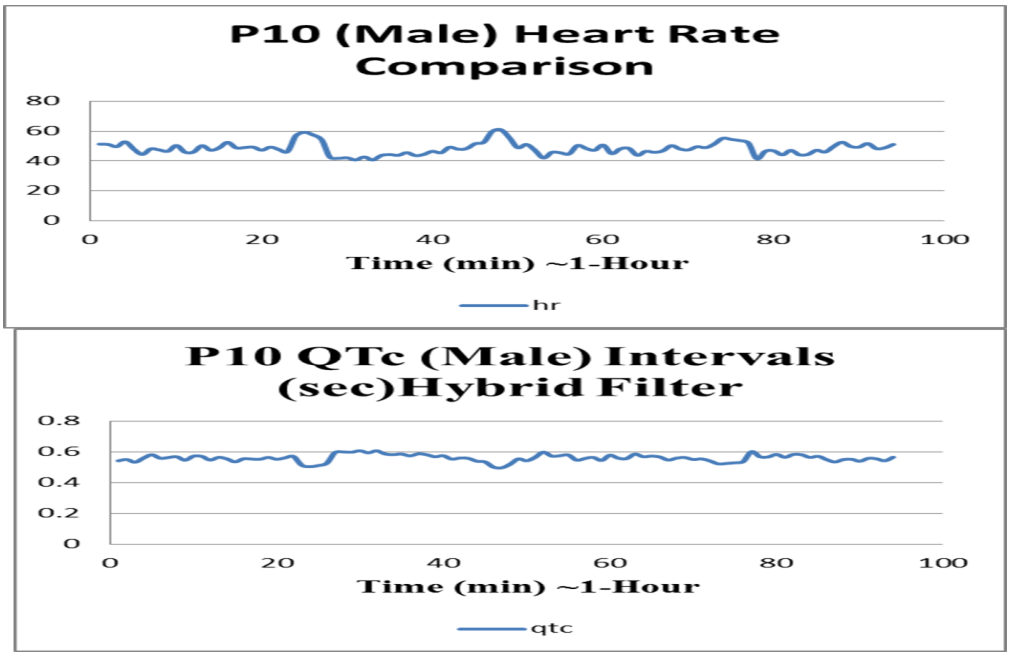


Figure 4.30 P6 Variations in the Heart Rate.

5. Conclusion and Future Work

Out of 60 million Americans, an estimated 18 million have sleep apnea, which is more common in African Americans, Hispanics, and Pacific Islanders than in Caucasians. Obstructive sleep apnea (OSA) is a more severe form of SDB, and is a common condition in both adults and children. OSA syndrome is also most common in middle-aged, overweight men and women, prevalence of which has been estimated to be 9 % of women and 24 % of men, but it can occur at any age, from infancy to old age. About 70% of people who have OSA are overweight. While the annual cost of treating sleep apnea patients in the United States is approximately $3.18 billion (including screening costs) it is estimated that untreated sleep apnea may cause $3.4 billion in additional medical costs. If left untreated an undiagnosed OSA can have the following effects: raise heart rate and increase the risk of high blood pressure, heart attack, stroke, arrhythmias (irregular heartbeat), diabetes, and obesity.

A polysomnography (PSG) is the gold standard in diagnosing sleep disorders and sleep disorders breathing (SDB); it is the most accurate and sophisticated test currently being used today. The cost for a PSG is estimated to be between $900 and $3,000. Patients with OSA are more likely to have automobile accidents than the general population [59].

Different methods for the classification and detection of sleep apnea have been proposed, but the Long QT interval is too often left undiagnosed and untreated as an indicator of sleep apnea. Researchers have stated earlier that there are several advantages

to BANs, such as their ease of use, they are cost effective, and their sensors are non-invasive.

The disadvantages of BANs are often seen within their sensors' filter design. Designing an effective filtering algorithm for ECG sensors for the detection and removal of ECG features can be a difficult and challenging problem. We offer a Hybrid filtering algorithm based on the Daubechies 4 and Daubechies 6 wavelet transforms for the extraction of ECG features. To investigate such an indicator, the Long QT Syndrome (LQTS) for the detection and classification of sleep apnea, we proposed the use of a Body Area Network as a Pre-Screening Surrogate to the Polysomnography (PSG) consisting of, a heart and activity monitor and pulse oximeter. A system that is cost-effective, mobile, non-invasive, and flexible.

We use an online database for the initial analysis and validation of the proposed system. A dataset taken from the MIT-BIH arrhythmia database of (10 to 35 data subjects) which is typical of a sleep apnea population for age, gender and heart rate. Initial analysis and validation resulted in a sensitivity of 99.94% and a specificity of 82.04% with a statistical kappa value of 0.69. Oxygen saturation levels (SpO2) have not been used in the initial analysis.

A clinical evaluation of the proposed scheme was performed alongside overnight sleep studies at the University of Miami (UM) Sleep Center located in the Bascom Palmer Eye Institute over a period of elven nights. A patient dataset of elven was selected that consists of three split-study patients and nine baseline patients that were solicited during the actual studies. The split-study patients' data was not used in the computation

of an apnea-hypopnea index (AHI), but used only in the investigation of the LQTS as a marker for the detection and classification of sleep apnea.

Each patients' ECG signals were collected from the ECG-sensor and sent to either the Table PC or the Laptop-PC via Bluetooth connection each night of the of our clinical evaluation period. Each patient's data was transferred into their individual Microsoft HealthVault folders. The ECG sensor has sampling rate of 300 samples/sec. It also has a dynamic range of 5.3mV peak to peak and Bandwidth 0.5Hz – 90Hz. After the above process each patient's ECG signal underwent our QT extraction process that is our proposed D4 and D6 hybrid filter algorithm to obtain a corrected QT intervals-QTc. The heart rate data was also collected from the ECG-sensor. A frequency analysis was done to determine how many of the QTc intervals (for a period of 1 to 2hours total sleep time) fail outside of the normal range. A QTc is prolonged if > 440ms in men or > 460ms in women. P6, P9, and P10 were found to have QTc intervals outside of the normal ranges and P8 appeared to be at borderline.

All of the patients' SpO2 levels were transferred from the SpO2 sensor to the Table PC or the Laptop-PC via Bluetooth connection, this process took place for each night of the PSG. The nVision (which is part of the SpO2 sensor toolkit), analysis software was used to find the total decreased in oxygen saturation events that occurred during each patient's PSG and it was reported from our SpO2 sensor. Please see Appendix B for an example of the report.

A computation of the AHI given in Table 7 is computed from the totals events of oxygen desaturation levels given from the SpO2 nVision report for each patient. The Nonin WristOx2 3150 Wrist-Worn Pulse Oximeter with Bluetooth sensor has enhanced

memory - 1,080 hours of non-volatile memory at a four-second sampling rate with additional high resolution variable sampling options of one or two seconds The Table 7 illustrations the proposed scheme using only the SpO2 levels that computed an AHI in the range of normal-to-mild sleep apnea. From this method patient P4, P5 and P9 were found to be in the normal range. Whereas patients P6, P8, and P11 in the mild range. The PSG found P6 and P9 to be in the normal range of sleep apnea and P4 and P5 to be mild. P8 and P10 were at a moderate level and P11 at a server level found by the PSG.

The Table 7 in additional demonstrations if we applied our proposed LQT interval scheme we have a slightly better technique of being in the mild to moderate range of sleep apnea. This scheme entails determination of the total number of QTc intervals that fall outside of the patients' normal range for a period of 1 to 2 hours sleep duration were the patient was not known to ask to go the bathroom, and then add that to the total number of events given for the SpO2 levels for the determination of an AHI. This was based on that sleep apnea can appear within an hour of sleep [125]. This method shows P5 at a mild level of sleep apnea, while P4, P6, and P8 through P11 have moderate level of sleep apnea. Again no server form of sleep apnea was found in the proposed scheme.

In conclusion in both methods of calculating an AHI the proposed scheme did not reported any severe form of sleep apnea. However it was able to report the LQT is a rational/fair indicator of sleep apnea with patients who appeared to have normal-to-mild sleep apnea.

The effects of sleep apnea on the QT interval were evaluated in 11 patients, 4 females and 3 males, who underwent either a baseline PSG or a CPAP PSG, to determent any signs of LQTS. The corrected QT interval (QTc) was computed based on the RR

interval for one hour of actual sleep time. This was the measurement of time use in computation the AHI. We considered their HRV and their EDR and their BMI and to adjust for a possibility of a hypopnea. As expected, the QT interval prolonged during sleep apnea (680 +/- .133 sec) compared to those patient whose QT intervals were found to be within normal ranges.

The SpO2 levels were evaluated separately as events to compute an AHI. Results obtained showed a statistical kappa value of 0.6634. Then LQTS intervals were used as events and combined with the SpO2 levels events to compute an AHI. Our proposed AHI computation resulted in a Pearson's correlation coefficient of 0.6552 from our Linear Regression Model. Thus, concluding from these results the proposed scheme is suitable in the pre-screening of mild sleep apnea. Furthermore a sensitivity of 88.11% and a specificity of 80.55% are presented.

Our goal was to discover if the proposed scheme could discover the LQTS in patients who underwent a PSG study. The proposed scheme was able to find 4 out of the 8 patients. These patients ECG were used to derive a respiratory signal to test for complete cessation of breathing for 10 seconds or longer. The derived ECG respiratory signal was not used in the calculation of the patients' AHI, but served only as an observation method. We are able to found from our proposed method 3 out of the 8 patients had complete cessation of breathing lasting more than 10 seconds long. It is safe to conclude that the proposed BAN is a reasonable surrogate to the polysomnography (PSG).

During the analysis process we observed that one out of the four patients who had mild-to-moderate sleep apnea showed signs of LQTS had a normal weight was P7 the

CPAP patient with a BMI of 24. P6 had a BMI in the range of overweight, BMI of 26.34. P8 has a BMI of 36.3 and P9 a BMI of 36.5 placing them within the range of obesity.

Table 5.1 Apnea-Hypopnea Index Obtained From The Proposed Scheme LQT Intervals.

	Apnoea–Hypopnoea Index (AHI) LQT Intervals (only) Computed by Proposed Scheme	Apnoea–Hypopnoea Index (AHI) Computed by UM Sleep Center	Total Time of (ECG Signal) Sleep Recorded by Proposed Scheme Time (hours)	Total Time of Sleep Recorded by Actual Sleep Study Time (hours)	Patients' General Information		
					Age, years	Gender	BMI
P4	0	5	6:26	7:00	57	male	40
P5	0	4	6:54	6:00	32	male	37
P6	0	1	6:08	6:00	64	female	26
P8	0	11	6:38	6:00	50	female	36
P9	3	2	7:06	6:57	46	female	37
P10	14	15	6:36	7:02	41	male	32
P11	0	42	5:45	7:00	51	female	38
	AHI = (Number of Events/Total Sleep Time (min)) * 60				Normal: 0-4		
	Total Sleep Time = (Hours * 60) + mins				Mild Sleep Apnea: 5-14		
					Moderate Sleep Apnea: 15-29		
					Severe Sleep Apnea: 30 or more		

Additional evaluation and conclusion as done to determine is the LQT intervals could be used as a standalone events in the computation of an AHI. The results in Table 5.1 above are shown. It clearly shows that the LQT intervals (events) alone can only give sleep apnea ranges normal and mild. No moderate or severe results were computed. Therefore LQT intervals as standalone events appear to be unsuitable for the computation of an AHI.

5.1 Future Work

According the Centers for Disease Control and Prevention, the average life expectancy for a driver is less than 61 year. It has been estimated that almost three out of 10 truck drivers currently suffer from mild-to-severe sleep apnea. Furthermore there is a fear that these drivers are at greater risk of being involved in a severe crash [122]. We would like to lend our study in hopes to find an underling cause to their apnea, due to that

portable detection will be suitable for this group of people who spends most of their time being mobile.

In addition we will also like to extend our work to expecting women .At least 1 to 10 percent of women of childbearing age experience occurrence of sleep apnea during their pregnancy. Their unborn may be at risk to having gestational diabetes, preeclampsia, preterm delivery and low birth weight [123]. Again we would like to extend our work to this group of people, seeing that it may be a more fitting for an at home pre-screening given their condition.

One major area of detection and classification of sleep apnea is determination of sleep stages. We would like to extend our clinical evaluation of our proposed scheme to include the determination into what sleep stage(s) are patients most likely to experience the LQTS as an indicator of sleep apnea. The period that we are proposing is either doing the time of diagnosis and afterward. Also those patients you are experiencing night terrors or nightmares.

Further work will also include a fully automated version of our proposed scheme with respect to smart phones, Table PC's, and Laptop/PC's, customizing according to their respective operating systems.

Appendixes

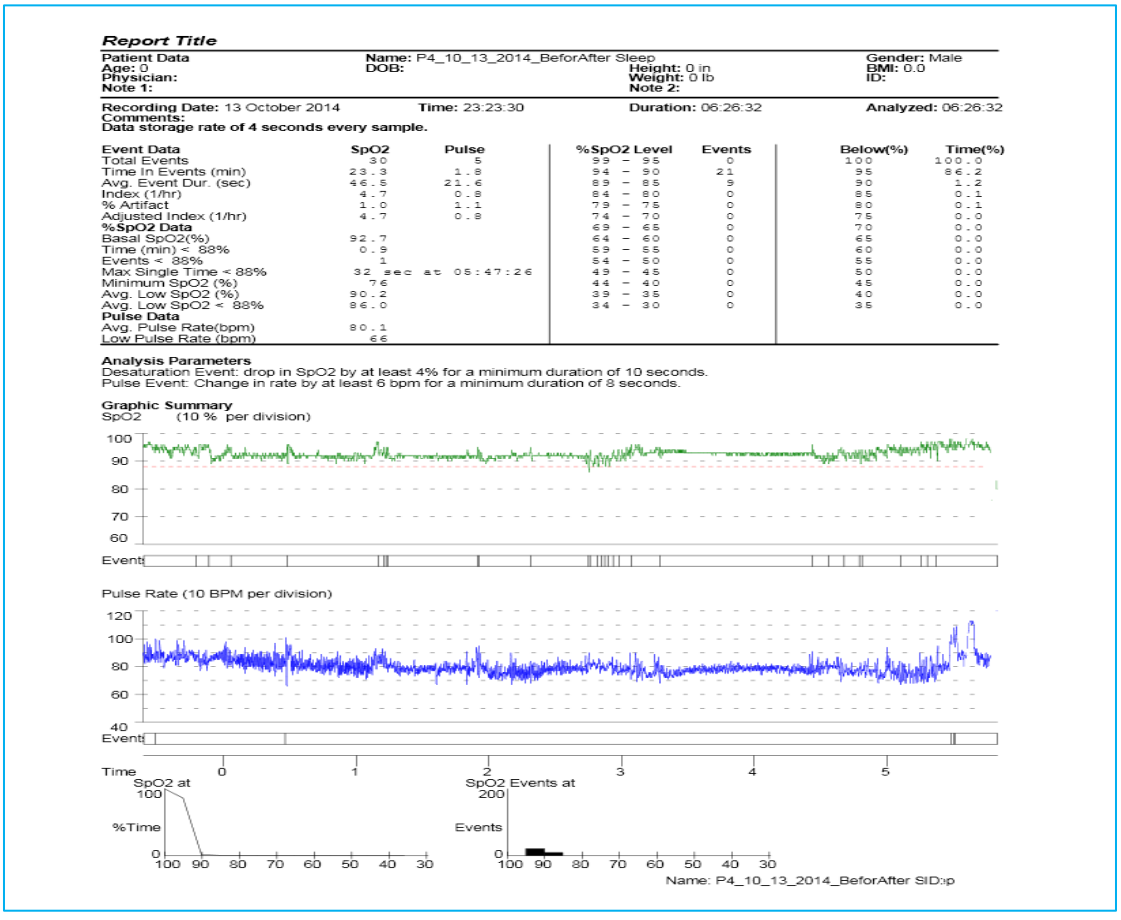
5.2 Appendix A. Sensors Specifications

Oximeter Sensor Specifications	
Oxygen Saturation Display Range	0 to 100 % SpO2
Pulse Rate Display Range	18 to 321 beats per minute (BPM)
Displays**:**	
Numeric	3-digit LCD
Pulse Strength	Pulse Strength Bar Graph
Measurement Wavelengths and Output Power	
Red	660 nanometers @ 0.8 mW max. avg.
Infrared	910 nanometers @ 1.2 mW max. avg.

Alive Wireless Heart Monitor Specifications	
General Features	
ECG	Single channel, two electrodes
Accelerometer	3 axes (monitoring activity, body position and falls)
Patient events	Event button
LEDs	Bluetooth, Battery, Heart Beat
Internal Storage Type	Secure Digital (SD) Card up to 1GB
Internal Storage Capacity	21 days using a 1GB SD Card
ECG Features	
Channels	Single channel
Recording Resolution	8 bit
Dynamic Range	5.3mV Peak to Peak
Bandwidth	0.5Hz – 90Hz
Accelerometer	
Axis	3 axes
Recording Resolution	8 bit
Recording Sampling Rate	75 samples/sec
Dynamic Range	+/-2.7g
Bandwidth	0 – 16Hz
Physical Features	
Dimensions	90mm (length) x 40mm (width) x 16mm (depth)

Weight	55g with battery
Power Source	
Source	3.7 volt removable and rechargeable lithium-ion battery
Operating	48 hrs - continuous wireless transmission
Low Battery Indication	< 2 hours remaining
Bluetooth Features	
Compliance	Version 2.1 compliant
Classification	Class 1 (up to 100 meter range)
Profile	Serial Port Profile (SPP)
Operation	Slave Point-to-Point
Antenna Type	Internal

5.3 Appendix B. Example of SpO2 Report



Report Title

Patient Data
Age: 0
Physician:
Note 1:

Name: P4_10_13_2014_BeforAfter Sleep
DOB:

Height: 0 in
Weight: 0 lb
Note 2:

Gender: Male
BMI: 0.0
ID:

Recording Date: 13 October 2014 **Time:** 23:23:30 **Duration:** 06:26:32 **Analyzed:** 06:26:32
Comments:
Data storage rate of 4 seconds every sample.

Event Data	SpO2	Pulse
Total Events	30	5
Time In Events (min)	23.3	1.8
Avg. Event Dur. (sec)	46.5	21.6
Index (1/hr)	4.7	0.8
% Artifact	1.0	1.1
Adjusted Index (1/hr)	4.7	0.8
%SpO2 Data		
Basal SpO2(%)	92.7	
Time (min) < 88%	0.9	
Events < 88%	1	
Max Single Time < 88%	32 sec at 05:47:26	
Minimum SpO2 (%)	76	
Avg. Low SpO2 (%)	90.2	
Avg. Low SpO2 < 88%	86.0	
Pulse Data		
Avg. Pulse Rate(bpm)	80.1	
Low Pulse Rate (bpm)	66	

%SpO2 Level	Events	Below(%)	Time(%)
99 - 95	0	100	100.0
94 - 90	21	95	86.2
89 - 85	9	90	1.2
84 - 80	0	85	0.1
79 - 75	0	80	0.1
74 - 70	0	75	0.0
69 - 65	0	70	0.0
64 - 60	0	65	0.0
59 - 55	0	60	0.0
54 - 50	0	55	0.0
49 - 45	0	50	0.0
44 - 40	0	45	0.0
39 - 35	0	40	0.0
34 - 30	0	35	0.0

Analysis Parameters
Desaturation Event: drop in SpO2 by at least 4% for a minimum duration of 10 seconds.
Pulse Event: Change in rate by at least 6 bpm for a minimum duration of 8 seconds.

Graphic Summary
SpO2 (10 % per division)

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