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碩士論文

無線多重生理狀態監控系統-應用於居家睡眠監控

The Development of Wireless Polysomnography System for Sleep Monitoring At Home

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摘要

目前要確立睡眠呼吸中止症的檢查方法要靠「睡眠多項生理監測儀 (polysomnography-PSG)」,但睡眠呼吸中止症的檢查,必須在睡眠檢查中心進行整夜檢查。然而,數量有限的睡眠中心和床位往往導致診斷和治療的漫長等待; 再加上睡眠在陌生的環境,及次數不多的測量,可能影響受測者的睡眠情況,造成無法完整診斷病症。所以,在家檢查睡眠情況會提供一個比在實驗室中設置更切合實際及效率的評估方式。

本論文提出一個以電池供應電源、微小化及便攜式的無線多重生理參數介面,並以JAVA 開發監控及紀錄的軟體,將受測者睡眠時的生理參數存入接收的電腦中,專家可依儲存的資料,判讀及診斷使用者的睡眠情況。於真實的環境中,居家睡眠監控系統必須是個便利的大小、堅固耐用、重量輕且低功率消耗來達到可穿戴便利與持久性的需求。為了證明我們提出系統的可行性,我們於台北榮民總醫院的睡眠中心在健康的受測者上同時錄製標準的 PSG 系統- Alice 5[®] Diagnostic Sleep System 與本論文提出的系統。而兩套系統在時域及睡眠階段上的比較分析,均達到很好的相似程度,故我們提出的系統可以在居家睡眠檢查的長期追蹤研究上實際運用。

關鍵字: 睡眠多項生理監測儀, JAVA, 無線, 居家睡眠監控

The Development of Wireless Polysomnography System for Sleep

Monitoring At Home

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Abstract

The polysomnography (PSG) is considered as the gold standard for the diagnosis

of Obstructive Sleep Apnea (OSA). The examination of OSA requires an overnight

sleep experiment in a laboratory. However, due to the limitation for number of labs

and beds, patients often have to wait for a long time before being diagnosed and

eventually treated. In addition, the unfamiliar environment and restricted action when

operating PSG may disturb the sleep of patients, and then cause an incomplete or

corrupted test. Therefore, a PSG conducted at the patient's home would be more

reliable and more convenient.

In this study, we implemented wireless polysomnography system for sleep

monitoring at home, which involves with a battery-powered, miniature, wireless,

portable, and multipurpose recorder. A java-based PSG recording program in the

personal computer was designed to save several bio-signals and transfer them into

EDF format. And then, these PSG records can be used to determine patient's sleep

stages and diagnose OSA by specialists. This system is portable, lightweight, and low

power-consumption. To demonstrate the feasibility of our proposed PSG system, the

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comparison between the standard PSG-Alice 5® Diagnostic Sleep System and our system was examined. Here, several healthy volunteer patients simultaneously performed PSG experiment with standard PSG-Alice 5® Diagnostic Sleep System and our system under the supervision of specialists at the Sleep Laboratory of Taipei Veteran General Hospital. The results for comparison of time-domain waveform and sleep stage between the above two systems showed that our system was reliable and can be applied in practice. Our system can serve for a long-term tracing and research of personal sleep monitoring at home.

Keywords: Polysomnography (PSG), JAVA, wireless, sleep motoring at home



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Chapter 1 Introduction

1.1 Sleep monitoring

Sleep is a natural state of bodily rest observed in humans and other animals. A sleep disorder is a medical disorder of the sleep patterns of a person or animal. Obstructive sleep apnea (OSA) is the most common category of sleep-disordered breathing. The term "sleep disordered breathing" is commonly used in the US to describe the full range of breathing problems during sleep in which not enough of air reaches the lungs (hypopnea and apnea). Sleep disordered breathing is associated with an increased risk of cardiovascular disease, stroke, high blood pressure, arrhythmias, diabetes, and accidents. [1-4]

Some sleep disorders are serious enough to interfere with normal physical, mental and emotional functioning. It is often ordered for patients with complaints of daytime fatigue or sleepiness that may be caused by interrupted sleep. According to the study in Hong Kong, middle-aged people suffering from sleep apnea syndrome, the rate of male is about 4% and female is about 2%, which in Taiwan is estimated about 45 million people and Japan currently has more than 200 million people suffer from sleep disorder. Once the disease is often not enough sleep, most of them will be daytime sleepiness, inability to concentrate attention, and even individuals can easily lead to accidents and traffic accidents [5], it has direct impact on the patient's quality of life. In recent years sleep disorder in Europe, America, and Japan has become one of the focuses of public safety.

1.2 Previous Work

Sleep disorder is a major public health problem, affecting up to 5% of the world population [6], with levels reaching values as high as 4% for men, 2% for women, and 3% for children [7]. The science of sleep medicine has evolved tremendously as a result of the development of tools that enable us to detect and document the activities of various physiological and pathological events that occur in the central nervous system accompanied by changes, which develop in the cardio respiratory, circulatory and autonomic nervous systems during sleep. Polysomnography is used to diagnose, or rule out, many types of sleep disorders including narcolepsy, restless legs syndrome, REM behavior disorder, parasomnias, and sleep apnea.

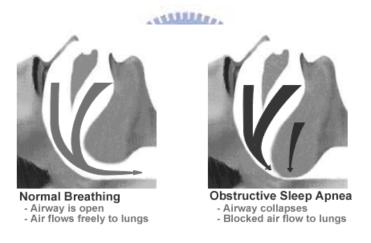


Fig. 1-1: Normal people and OSA patient [44]

Obstructive sleep apnea syndrome (OSAS) evaluation from PSG data was scored by clinical experts by using the standard procedures and criteria [6]. Sleep Apnea is a condition where a person periodically stops breathing during sleep. This causes the person to wake up dozens of times during the night, but in most cases they are unaware of this disruption. The most common type of sleep apnea is Obstructive Sleep Apnea (OSA), which is caused by closure of the airway. The drawing to the right shows the airway of a healthy individual (left) and an OSA patient (right). The

healthy patient is breathing normally with the airway open, but the OSA patient's airway is closed, with the arrows showing the blockage [Fig. 1-1].

The American Association of Sleep Medicine [AASM] published initial practice parameters regarding the use of Portable Monitor (PM) devices in the assessment of OSA in 1994[8]. Many studies have been carried out for OSAS screening attempting to reduce PSG cost and complexity. Different techniques have been proposed, oximetry-based screening being one of the most widely suggested for both the adult and pediatric population. Although these methods have high sensitivity, they tend to have very low specificity [9]. The society classified sleep apnea evaluation studies based on the number of channels or signals that the monitor employed, categorized from level I to level IV. A minimum of 6 hours of recording time was recommended when using any of the configurations. The levels of portable recording equipment and delineated specifications are shown as Table 1.

Table 1: Sleep-apnea evaluation studies (6-hour overnight recording minimum)

	Level I Standard polysomnography	ard Comprehensive portable Modified portable sleep		Level IV Continuous single-or-dual bioparameter recording	
Parameters	Minimum of seven, including EEG(C4-A1 or C3-A2), EOG, chin EMG, ECG, airflow, respiratory effort, oxygen saturation	Minimum of seven, including EEG(C4-A1 or C3-A2), EOG, chin EMG, ECG, airflow, respiratory effort, oxygen saturation	Minimum of four, including ventilation (at least two channels of respiratory movement, or respiratory movement and airflow), ECG, oxygen saturation	Minimum of None	
Body position	Documented of objectively measured	May be objectively measured	May be objectively measured	Not measured	
Leg movement	EMG or motion sensor desirable but optional	EMG or motion sensor desirable but optional	May be recorded	Not recorded	
Personnel	In constant attendance	Not in attendance	Not in attendance	Not in attendance	
Interventions	Possible	Not possible	Not possible	Not possible	
Type of Study	Attended polysomnography	Unattended full polysomnography	Cardiopulmonary study-four of more bioparameter (usually unattended)	Single or dual bioparameter	

Level I monitoring consists of full overnight polysomnography, with a minimum of two channels each for EEG, chin EMG, EOG, as well as respiratory airflow (with thermistor or pressure-flow transducer), respiratory effort (thoracic and abdominal breathing movements), oximetry, and ECG or heart rate monitoring. These studies are fully attended by a technologist and are typically conducted in a sleep center. The level I system is shown as Fig. 1-2.



Fig. 1-2: Alice 5® Diagnostic Sleep System and Pediatric Polysomnography patient [10]

Laboratory-based polysomnography forms the framework upon which the field of sleep disorders medicine has been built over the last 40-50 years. For the standard test the patient comes to a sleep lab in the early evening, and over the next 1-2 hours is introduced to the setting and "wired up" so that multiple channels of data can be recorded when he/she falls asleep. The sleep lab may be in a hospital, a free-standing medical office, or in a hotel. A sleep technician should always be in attendance and is responsible for attaching the electrodes to the patient and monitoring the patient during the study. After the test is completed a 'scorer' analyzes the data by reviewing the study in 30 second 'epochs' [11].

When obstructive sleep apnea (OSA) became recognized as a common sleep

disorder, cardiorespiratory variable were added to polysomnography as a standard feature. The high prevalence of sleep-related breathing disorders has highlighted limitations in patient accessibility to diagnostic and therapeutic services. In addition, and the need for studies has increased, less costly but comparable efficacious alternatives to laboratory-based polysomnography are being sought in response to current economic imperatives. Standard sleep laboratory research protocols often require two consecutive PSG nights because of inter-night variability in sleep attributed to first-night adaptation to a novel sleep environment and recording procedures. Finally, home studies may provide a more realistic appraisal of nighttime pathology than can be obtained in the laboratory setting. Patients can now be evaluated outside of the laboratory by using portable devices that can record a single channel such as oximetry, two or more channels that measure only respiratory variables, or multiple channels that allow for sleep staging as well as measurement of respiratory variables.

Portable studies (level II to IV) are summarized as follows: level II consists of an equivalent number of channels as level I, with the singular difference being that the study is not attended by a technician. Like level I studies allow for the identification and quantification of sleep stages. Using the Sleep Heart Health Study (SHHS) methodology and technology, Iber and colleagues [12] recruited 76 participants from the general community to volunteer for recordings both in the laboratory and at home. Subjects were randomized with respect to recording order and were monitored with the same level II device used for the SHHS cohort (Compumedics; Abbotsford Australia). From this study, Using SHHS methodology, median RDI was similar in the unattended home and attended laboratory setting with differences of small magnitude in some sleep parameters. Differences in RDI between settings resulted in

a rate of disease misclassification that is similar to repeated studies in the same setting.

The level III utilizes at least four channels, including two channels for respiration and one channel for cardiac monitoring. The level III system is shown as Fig. 1-3. Dingli and colleagues [13] assessed the diagnostic accuracy of a type 3 monitoring. The study design consisted of simultaneous recording with the PM and traditional in-laboratory polysomnography, followed by an at-home assessment with the same PM. While the in-laboratory RDI and home RDI recorded from the type 3 monitor demonstrated no difference, the AHI generated from the in-laboratory polysomnography was significantly different.



Fig. 1-3: Patient wearing the Embletta (Level III) [13]

Level VI is made up of only one or two channels, typically including oxygen saturation or airflow. Pittman and colleagues tested a novel type4 monitoring device (Watch PAT; Itamar Medical; Caesarea, Israel, Fig.1-4) against traditional in-laboratory polysomnography [14]. The Watch PAT is wrist-worn device that collects peripheral arterial tonometry and oxygen saturation data, coupled with actigraphy.





Fig. 1-4: Watch PAT; Itamar Medical; Caesarea, Israel[45]

The paper [12] objective of this meta-analysis study was to compare the accuracy of home sleep studies with laboratory polysomnography in the diagnosis of obstructive sleep apnea (OSA). Home sleep studies provide similar diagnostic information to laboratory polysomnography in the evaluation of sleep-disordered breathing but may underestimate sleep apnea severity. The lower cost of home sleep studies makes it a viable screening tool for patients with suspected OSA; however, these lower costs are partially offset by the higher rate of inadequate examinations.

The primary end point examined was the ability of PM devices to confirm or rule out disease. The AASM guidelines [15] did allow for the use of PM devices under certain conditions. These include the lack of available polysomnography for patients with severe clinical symptoms consistent with OSA, the inability of the patient to be studied in the laboratory, or to evaluate response to therapy in a patient who has already undergone traditional in-laboratory polysomnography. A number of limited-channel, in home devices for the diagnosis of OSA have been described [16-22]; however, as a group they have not been recommended in the published practice parameters for in-home unattended studies [15, 23]. The primary reason given is the lack of acceptable validation studies. But when a scheme classifying sleep

apnea diagnostic systems into levels of complexity is used to simplify comparisons [23], it has the effect of obscuring the validity of individual devices with acceptable validation studies.

However, there are several limitations of PM devices that must be considered as well. These include the inherent lack of an attendant during the study, which may potentially affect data quality. In addition, the most widely used applications of PM technology do not have EEG channels and are unable to assess sleep architecture of staging. This inability does not allow for the computation of the apnea-hypopnea index (AHI) because total sleep time cannot be calculated.

1.3 Motivation

While clinicians have increasingly turned their attention to this syndrome, and referrals to sleep clinics for diagnostic evaluations have increased dramatically, the infrastructure to support them has not [24]. The report stated that simpler and less expensive diagnostic tests as well as simpler prescreening tests prior to full-channel PSG are needed [25].

Time is of the essence: as many as 82% of men and 93% of women with moderate-to-severe sleep apnea have not received a diagnosis, as estimated by data from the Wisconsin Sleep Cohort study [26]. Patients may have sleep apnea for up to 7 years before coming to medical attention and wait up to an additional 8 months before seeing a sleep specialist [27].

Recently recognized adverse consequences of sleep apnea, along with ongoing therapeutic advances, have heightened the urgency for expeditious diagnosis and treatment. The high prevalence of sleep-related breathing disorders has highlighted limitations in patient accessibility to diagnostic and therapeutic services. In addition,

as the need for studies has increased, less costly but comparable efficacious alternatives to laboratory-based polysomnography are being sought in response to current economic imperatives. Finally, home studies may provide a more realistic appraisal of nighttime pathology than can be obtained in the laboratory setting.

Because of these and other considerations, portable systems intended to assess sleep apnea have been developed for use in settings outside the sleep laboratory. Utilizing a conventional wireless ambulatory recorder, we have developed a portable multipurpose recorder which can store several biosignals simultaneously. In this study, the **EEG** (electroencephalogram), EOG (electrocardiogram), **EMG** (Electromyography), EKG (Electrocardiography), Airflow were recorded during the sleep using monitoring/recording software designed by Java. Data are written in a binary file following by the standard EDF (European Data Format), a standard file format designed for exchange and storage of medical time series[28]. The exchange format can import to other software to analysis sleep disorder and score sleep stage by specialist.

1.4 Organization of Thesis

In Chapter 2, it will describe that what are biosignals, sleep stage scoring and algorithms implemented in this thesis, which including moving average and EDF format. In Chapter3, it will introduce how to implement a wireless portable PSG signal acquisition in hardware design. In Chapter 4, it will explain the detail of Software implement in PSG system include firmware in MSP430 and PC-based Monitoring/Recording software; then the whole system will be verified with test pattern and real biosignals, the procedures and results of verification will be described in Chapter 5. Finally it will have conclusion in Chapter 6.



Chapter 2 Material and Method

2.1 System overview

The purpose of this research is to development a portable wireless polysomnography System for Sleep Monitoring At Home. In order to do this, it needs a system to acquire and monitoring/recording biosignals in EDF format, the exchange format can import by other analysis software to scoring sleep stage; so it was divided into two parts to introduce in this chapter. One is how do we to get the data for signal processing in experimental environment and the other is what does this biosignal means in scoring sleep stage. The diagram of overview system was shown as Fig. 2-1.



Fig. 2- 1: Diagram of Wireless polysomnography system overview

2.2 Biosignals

A polysomnogram will typically record a minimum of eleven channels requiring a minimum of 22 wire attachments to the patient. Two channels are for the EEG, one or two measure airflow, one is for chin movements, one or more for leg movements, two for eye movements (EOG), one for heart rate and rhythm, one for oxygen saturation and one each for the belts which measure chest wall movement and upper abdominal wall movement.

Wires for each channel of recorded data lead from the patient and converge into a central box, which in turn is connected to a computer system for recording, storing and displaying the data. During sleep the computer monitor can display multiple channels continuously. In addition, most labs have a small video camera in the room so the technician can observe the patient visually from an adjacent room.

The difference types of Electrical potentials are listed in Table 2[29]. We describe difference biosignal of electrode position and recorded signal.

Table 2: Medical and physiological parameters [29]

Parameter
20uV-200uV
10uV-5000uV
50uV-3500uV
0.5mV-4mV
- Anna

A. Electroencephalogram

Electroencephalography (EEG) is the measurement of electrical activity produced by the brain as recorded from electrodes placed on the scalp. When measuring from the scalps, recorded the EEG signal is about 20-200uV for a typical adult human. And a common system reference electrode is connected to the other input of each different amplifier. These amplifiers amplify the voltage between the active electrode and the reference (typically 1,000–100,000 times, or 60–100 dB of voltage gain). The EEG is typically described in terms of rhythmic activity and transients. The rhythmic activity is divided into bands by frequency. The common band of EEG is shown as Table 3 [46].

Table 3: Common band of EEG [46]

Туре	Frequency (Hz)
Delta	Up to 3Hz
Theta	4-7Hz
Alpha	8-13Hz
Beta	13 - 30Hz

In PSG system, the electroencephalogram (EEG) will generally use three "exploring" electrodes and two "reference" electrodes, unless a seizure disorder is suspected, in which case more electrodes will be applied to document the appearance of seizure activity. The exploring electrodes are usually attached to the scalp near the frontal, central (top) and occipital (back) portions of the brain via a paste that will conduct electrical signals originating from the neurons of the cortex. These electrodes will provide readout of the brain activity that can be "scored" into different stages of sleep (N1, N2, N3 which combined are referred to as NREM sleep and Stage R which is rapid eye movement sleep or REM, and Wakefulness). EEG electrode position is determined by international 10-20 system [30]. The recommended derivations are shown as Fig 2-2 [11] and brain activity in difference sleep stage is shown as Fig2-3[31].

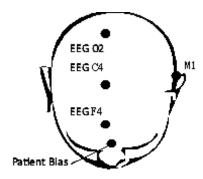


Fig. 2- 2: The recommended derivations of EEG (a) F4-M1; (b) C4-M1; (c) O2-M1 [11]

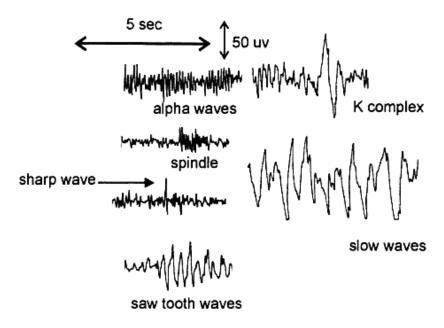


Fig. 2- 3: Brain activities in difference sleep stage [31].

B. Electrooculogram

The electrooculogram (EOG) uses two electrodes; one that is placed 1 cm above the outer canthus of the right eye and one that is placed 1 cm below the outer canthus of the left eye. These electrodes pick up the activity of the eyes in virtue of the electropotential difference between the cornea and the retina (the cornea is positively charged relative to the retina). This determines when REM sleep occurs, of which rapid eye movements are characteristic, and also essentially aids in determining when sleep occurs. The recommended derivations are shown as Fig 2-4[47].

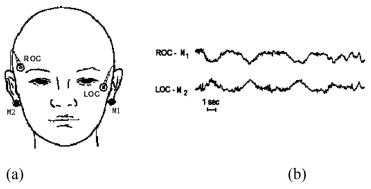


Fig. 2- 4: (a) the recommended derivations of EOG (b) Pattern of eye movement during sleep[47].

C. Electromyogram

The Electromyogram (EMG) typically uses four electrodes to measure muscle tension in the body as well as to monitor for an excessive amount of leg movements during sleep (which may be indicative of Periodic Limb Movement Disorder, PLMD). Two leads are placed on the chin with one above the jaw line and one below. This, like the EOG, helps determine when sleep occurs as well as REM sleep. Sleep generally includes relaxation and so a marked decrease in muscle tension occurs. A further decrease in skeletal muscle tension occurs in REM sleep. A person becomes partially paralyzed to make acting out of dreams impossible, although people that do not have this paralysis can suffer from REM Behavior Disorder. Finally, two more leads are placed on the anterior tibialis of each leg to measure leg movements. The EMG electrodes are placed on the chin to record muscle tension is shown as Fig. 2-5 [47].



Fig. 2-5: The EMG electrodes position and recorded pattern of chin muscle tension [47].

D. Electrocardiogram

Though a typical electrokardiogram (ECG or EKG) would use ten electrodes, only two or three are used for a polysomnogram. They can either be placed under the collar bone on each side of the chest, or one under the collar bone and the other six inches above the waist on either side of the body. These electrodes measure the

electrical activity of the heart as it contracts and expands, recording such features as the "P" wave, "QRS" complex, and "T" wave. These can be analyzed for any abnormalities that might be indicative of underlying heart pathology. The EKG electrodes are placed on the chin to record heartbeat is shown as Fig. 2-6 [47].

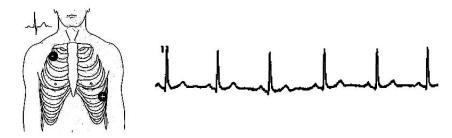


Fig. 2- 6: A single modified ECG Lead II, which use torso electrode placement, is recommended [47].

E. Nasal Airflow

Nasal and oral airflow can be measured using pressure transducers, and/or a thermocouple, fitted in or near the nostrils; the pressure transducer is considered the more sensitive. This allows the clinician/researcher to measure rate of respiration and identify interruptions in breathing. Respiratory effort is also measured in concert with nasal/oral airflow by the use of belts. These belts expand and contract upon breathing effort. The current guidelines recommend the use of a thermal sensor, which is placed in ht e patient's nostril to detect the apnea; the nasal pressure transducer is used for identifying hypopnea. Ideally, both the sensor and transducer should be used. The nasal airflow sensor position and recorded data is shown as Fig. 2-7 [47].

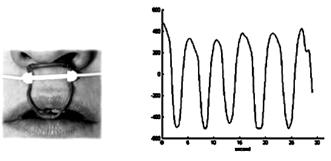


Fig. 2-7: Airflow sensor is placed to record breathing during sleep [47].

F. Others

Pulse oximetry helps determine changes in blood oxygen levels that often occur with sleep apnea and other respiratory problems. The pulse oximetry fits over a finger tip or an ear lobe. Snoring may be recorded with a sound probe over the neck, though more commonly the sleep technician will just note snoring as "mild", "moderate" or "loud" or give a numerical estimate on a scale of 1 to 10. A patient prepared for a polysomnogram patientis and hooked up to several monitors shown as Fig. 2-8. You can see the electrodes next to his eyes for recording eye movement and electrodes on his chin for monitoring muscle tone. The cannula at his nose and over his mouth records airflow. He has two electrodes on his chest for recording heart rate (ECG). One stretchy belt, one on his chest, record breathing effort and Oximetry.

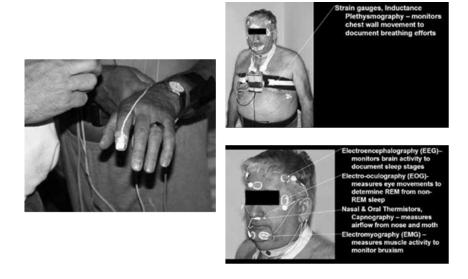


Fig. 2- 8: This patient is wired-up for an overnight sleep study (polysomnogram) [43].

2.3 Methods of Data Analysis

2.3.1 Sleep Stage

According to the "AASM manual for sleep Scoring" [11], considered as the world-wide standard in the medical community, sleep staging relies on three fundamental biopotential: the brain wave activity measured by an EEG, eye movement recorded via an EOG and the muscular tone measured by an EMG. The sleep structure is represented in a dedicated graph, called hypnogram, which represents the course of sleep stages of the patient over night (see Fig. 2-9), and provides the clinician with relevant information for the diagnosis of sleep disorders.

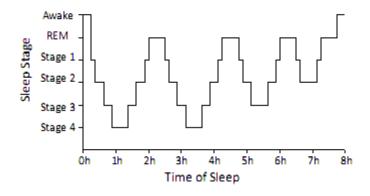


Fig. 2- 9: Sleep stages pattern[41]

In mammals and birds, sleep is divided into two broad types: Rapid Eye Movement (REM) and Non-Rapid Eye Movement (NREM or non-REM) sleep. Each type has a distinct set of associated physiological, neurological, and psychological features. The American Academy of Sleep Medicine (AASM) further divides NREM into three stages: N1, N2, and N3, the last of which is also called delta, or slow-wave, sleep (SWS).[32]

Sleep proceeds in cycles of REM and NREM, the order normally being N1 \rightarrow

 $N2 \rightarrow N3 \rightarrow N2 \rightarrow REM$. There is a greater amount of deep sleep (stage N3) early in the night, while the proportion of REM sleep increases later in the night and just before natural awakening.

The stages of sleep were first described in 1937 by Alfred Lee Loomis and coworkers, who separated the different EEG features of sleep into five levels (A to E), which represented the spectrum of wakefulness to deep sleep.[33] In 1953, REM sleep was discovered as distinct, and thus William Dement and Nathaniel Kleitman reclassified sleep into four NREM stages and REM.[34] The staging criteria were standardized in 1968 by Allan Rechtschaffen and Anthony Kales in the "R&K sleep scoring manual."[35] In the R&K standard, NREM sleep was divided into four stages, with slow-wave sleep comprising stages 3 and 4. In stage 3, delta waves made up less than 50% of the total wave patterns, while they made up more than 50% in stage 4. Furthermore, REM sleep was sometimes referred to as stage 5.

In 2004, the AASM commissioned the AASM Visual Scoring Task Force to review the R&K scoring system, which culminated in several changes, the most significant being the combination of stages 3 and 4 into Stage N3. This was published in 2007 as The AASM Manual for the Scoring of Sleep and Associated Events.[11] Arousals and respiratory, cardiac, and movement events were also added [36][37].

2.3.2 Scoring sleep by epochs

Score sleep stages in 30s sequential epochs commencing from the beginning of the study, and assign a stage to each epoch. If 2 of more stages coexist during a single epoch, assign to the stage comprising the largest portion of the epoch. Sl. The rules of sleep stages are listed as Table 4[11].

Table 4: Rules of sleep stage [11]

Stage	EEG	Eye blink	EOG	EMG
W(wakefulness)	A. 8-13Hz over the	0.5-2Hz	0.5-2Hz	Normal or
	occipital region			high tone
N1(NREM1)	${\bf A}.~\alpha$ wave ;low amplitude ;	-	Slow eye	-
	Mixed frequency	Co.	movements	
	activity > 50 % or	The same	(0.25-0.5 Hz)	
	4-7Hz; Vertex sharp	FE		
	waves(50-150 μV)	P		
N2(NREM2)	A. sleep spindles(20-100	F-	-	-
	μV;12-14Hz) or K	Lan		
	complexes (> $100\mu V$;			
	>200ms)(Fz Cz)			
	B . Low amplitude and no			
	SEM			
N3(NREM3 & 4 in	A . 0.5 -2Hz wave $> 20 \%$ in	-	absent	-
R&K,respectively)	a epoch ,and Peak-Peak			
	$>75\mu V$ (frontal			
	region)			
R(REM)	A . 2-6Hz ,low Amplitude	-	Predominantly	Lowest level
	without K complex and		horizontal,	of the
	sleep spindles		and occur in	entire
	B . Saw tooth waves		repetitive	recording
			bursts.	

- **a.Stage W**: is defined by the presence of an alpha rhythm: there are trains of sinusoidal 8-13 Hz activity over the occipital regions and are best seen with eyes closed and attenuated with eye opening. Eye blinks appear as conjugate eye movements consisting of 0.5-2Hz present in wakefulness with eyes open or closed.
- **b.Stage N1:** is defined by presence of slow eye movements (SEM) Conjugate, reasonably regular and sinusoidal eye movements with an initial deflection usually lasting >500ms. The EEG is low amplitude, mixed frequency activity, predominantly of 4-7 Hz. Presence of vertex sharp waves(V waves):are sharply contoured waves with duration <0.5s seen mostly over the central region and are distinguishable from the background activity. Sleep onset is defined as the beginning of the first epoch scored as any other than stage W (In most subjects, this will usually be the first epoch of stage N1).
- **c. Stage N2:** is defined by the appearance of K complexes, which are well-delineated negative sharp waves immediately followed by a positive component standing out from the background EEG, with total duration ≥ 0.5 s, usually maximal in amplitude when recorded using frontal derivations. For an arousal to be associated with a K complex, it should commence no more than 1 s after the termination of the K complex. Sleep Spindle are present in N2; there are trains of distinct waves with frequency pattern of 11-16 Hz (most commonly 12-14 Hz) with a duration ≥ 0.5 s, usually maximal in amplitude in the central derivations.
- **d.Stage N3:** is defined by slow wave activity, which are waves of frequency 0.5-2Hz with a peak-to-peak amplitude > $75\mu\text{V}$, as measured over the frontal regions.

e. Stage REM: Rapid eye movement sleep, or REM sleep, accounts for 20–25% of total sleep time in normal human adults. The criteria for REM sleep include rapid eye movements as well as a rapid low-voltage EEG. Most memorable dreaming occurs in this stage. At least in mammals, a descending muscular atonia is seen. Such paralysis may be necessary to protect organisms from self-damage through physically acting out scenes from the often-vivid dreams that occur during this stage.

2.3.3 Scoring apneas

The amplitude criteria for scoring an apnea are at least a 90% drop of more in the thermal sensor excursion, lasting for at least 10 s. It should be labeled as obstructive if the efforts (respiratory and abdominal continue) are seen; it should be called central if none of these excursions are seen, and mixed, if this effort is resumed toward the end of the period of apnea.

2.3.4 Scoring Hypopnea

The duration of hypopnea should be at least 10 s. The drop in the amplitude of the nasal transducer is > 30%, with a 4% drop in saturation of > 50%, with a 3% drop in the saturation

2.4 European Data format

The European Data Format (EDF) [28] is a simple and flexible format for exchange and storage of multichannel biological and physical signals. It was developed by a few European 'medical' engineers who first met at the 1987 international Sleep Congress in Copenhagen. The EDF logo is derived from the

congress logo which was the green pea from the fairy tale "The princess and the pea" by the Danish writer Hans Christian Andersen. With the support of Professor Annelise Rosenfalck, the engineers initiated the European (EC funded COMAC-BME) project on Sleep-Wake analysis (1989-1992). They wanted to apply their sleep analysis algorithms to each others data and compare the analysis results. So, on a morning in Leiden in April 1990, they agreed upon a very simple common data format. This format became known as the European Data Format. In August 1990, all participating labs had contributed an EDF sleep recording to the project.

EDF was published in 1992 in Electroencephalography and Clinical Neurophysiology 82, pages 391-393. Since then, EDF became the de-facto standard for EEG and PSG recordings in commercial equipment and multicenter research projects. One data file contains one uninterrupted digitized polygraphic recording. A data file consists of a header record followed by data records. The variable-length header record identifies the patient and specifies the technical characteristics of the recorded signals. The data records contain consecutive fixed-duration epochs of the polygraphic recording.

The first 256 bytes of the header record specify the version number of this format, local patient and recording identification, time information about the recording, the number of data records and finally the number of signals (ns) in each data record. Then for each signal another 256 bytes follow in the header record, each specifying the type of signal (e.g. EEG, body temperature, etc.), amplitude calibration and the number of samples in each data record (from which the sampling frequency can be derived since the duration of a data record is also known). In this way, the format

allows for different gains and sampling frequencies for each signal. The header record contains 256 + (ns * 256) bytes. Table 7 shows its detailed format.

The information in the ASCII strings must be left-justified and filled out with spaces. Midnight time is 00:00:00. The duration of each data record is recommended to be a whole number of seconds and its size (number of bytes) is recommended not to exceed 61440. Only if a 1s data record exceeds this size limit, the duration is recommended to be smaller than 1s (e.g. 0.01).

The digital minimum and maximum of each signal should specify the extreme values that can occur in the data records. These often are the extreme output values of the A/D converter. The physical (usually also physiological) minimum and maximum of this signal should correspond to these digital extremes and be expressed in the also specified physical dimension of the signal. These 4 extreme values specify offset and amplification of the signal.

Following the header record, each of the subsequent data records contains 'duration' seconds of 'ns' signals, with each signal being represented by the specified (in the header) number of samples. In order to reduce data size and adapt to commonly used software for acquisition, processing and graphical display of polygraphic signals, each sample value is represented as a 2-byte integer in 2's complement format.

Gains, electrode montages and filters should remain fixed during the recording.

Of course, these may all be digitally modified during replay of the digitized recording.

Below (Table 5) is the detailed digital format of the header record (upper block, ASCII's only) and of each subsequent data record (lower block integers only). Note that each one of the ns signals is characterized separately in the header.

Table 5: Detailed digital format of the EDF header record[28]

Field name	Size	Field rules
Identification code	8 bytes	Byte 1: "0" (ASCII)
Local subject identification	80 bytes	Bytes 2-8:" (ASCII)
Local recording identification	80 bytes	User text input (ASCII)
Start date of recording	8 bytes	dd.mm.yy (ASCII)
Start time of recording	8 bytes	hh.mm.ss (ASCII)
Number of bytes in header record	8 bytes	(ASCII)
Version of data format.	44 bytes	(ASCII)
Number of data records "-1" if unknown	8 bytes	(ASCII)
Duration of a data record, in seconds	8 bytes	e.g.: "1" (ASCII)
Number of channels (N) in data	4 bytes	e.g.: "257" or "128"
record		(ASCII)
Labels of the channels	N x 16 bytes	e.g.: "Fp1", "Fpz", "Fp2", etc (ASCII)
Transducer type	N x 80 bytes	e.g.: "active electrode", "respiration belt" (ASCII)
Physical dimension of channels	N x 8 bytes	e.g.: "uV", "Ohm" (ASCII)
Physical minimum in units of	N x 8 bytes	e.g.: "-32768" (ASCII)
physical dimension	Ž	
Physical maximum in units of	N x 8 bytes	e.g.: "32767" (ASCII)
physical dimension	Ž	, ,
Digital minimum	N x 8 bytes	e.g.: "-32768" (ASCII)
Digital maximum	N x 8 bytes	e.g.: "32767" (ASCII)
Prefiltering	N x 80 bytes	e.g.: "HP:0,16; LP:500"
Sampling rate	N x 8 bytes	e.g. "2048" (ASCII)
Reserved	N x 32 bytes	(ASCII)

Chapter 3 Hardware Frameworks of Portable Biosignal Acquisition System

3.1 System Overview

In our experimental environment, user wore a portable acquisition system developed to continually get multiple bio-signals of human during overnight sleep. This portable acquisition system is a battery-powered and wearable module. It is much easier to set-up, and provides enhanced comfort for users. First, multiple bio-signals was measured by our portable acquisition module continually. After amplifying tiny multiple bio-signals, noise except the frequency band of multiple bio-signals would be removed by filters in our portable acquisition module. And then, filtered multiple bio-signals would be digitized by analog-to-digital converter, and be transited to PC via Bluetooth. The PC-based software was development by JAVA to receive digitalized raw data from our portable acquisition module, to decode raw data, to display raw data in real-time and to save raw data in standard format .The saved records can transmit to hospital via network, and can be analyzed by autoscoring software and validated by clinician. Analysis of autoscoring software and validation of clinician provide simple way for polysomnography test, and allow patients' sleep monitoring at their home. Using our portable PSG system is an easier, more comfortable and close way to its normal sleep habits. The part of hardware in this chapter and the part of software were described in Chapter 4. As followings, the whole system framework was shown in Fig. 3-1.

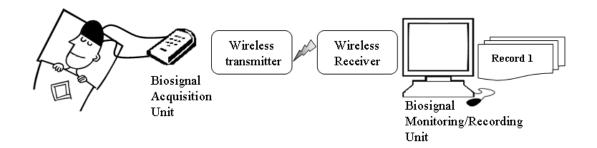


Fig. 3-1: Framework of portable biosignal acquisition system

3.2 Portable biosignal Acquisition Unit

The portable biosignal acquisition unit combines the power, amplifier, band pass filter, ADC, wireless controller, and data encoding into one. It is a light weight, wireless monitor for recording physiological signals. It owns 7-channel bio-signal measurement, includes EEG x2, EOG x2, EMG, ECG, and airflow.

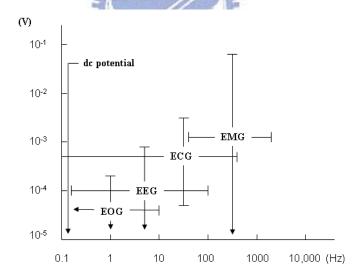


Fig. 3- 2: Voltage and frequency ranges of some common biopotential signals [38]

Fig. 3-2 showed the voltage and frequency ranges of some common biopotential signals; DC potentials include intracellular voltages as well as voltages measured from several points on the body [38]. The portable biosignal acquisition unit mainly

contains four parts: (1) front-end filter circuit, (2) analog to digital converter, and digital controller, (3) power management circuit and (4) wireless transmission. The diagram of the portable biosignal acquisition unit is shown as for various kinds of bio-sensors [Fig. 3-3].

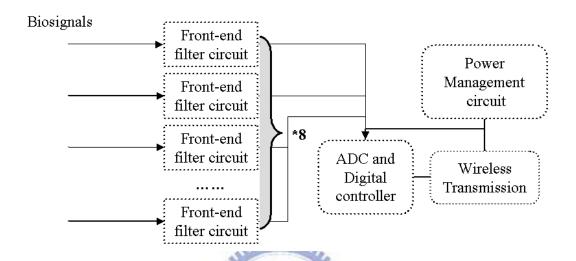


Fig. 3- 3: Diagram of portable biosignal acquisition unit

The physiological potentials were divided to electric physiological potential and nonelectric physiological potential: the electric physiological potentials are well-known as EEG, EOG, EMG, and EKG. They were amplified by bio-amplifier consisted of high-pass and low-pass filters and amplifier. And the non-electric physiological potentials are well-known as air flow, blood pressure, and temperature. They were amplified by bio-amplifier consisted of high-pass filters and amplifier. In our system, we integrated nasal pressure which is a product of Sleep mate. As well as EEG, EOG, EMG and EKG, it was amplified and organized by Micro-processor MSP430. When the signal passed through the high-pass filter, the all unnecessary low-frequency noise would be reduced or eliminated, and when they passed through the low-pass filter, all unnecessary high-frequency noise would be reduced or eliminated. According to AASM recommendations and difference physiological potentials characteristics, the specification for each channel was shown in Table 6.

Table 6: Specification for various kinds of bio-sensors

Input Sensor Signal		Gain (Operation	LFF (Hz)	HFF (Hz)	Sampling rate
	Range	voltage:3V)			(Hz)
EEG	20uV-200uV	4500	.3	45	256
EMG	10uV-5000uV	4500	.3	100	256
EOG	50uV-3500uV	2000	.3	45	256
EKG	0.5mV- 4 mV	100	.3	45	256
Airflow	0-2mV	300	.1	30	256

3.2.1 Multi-Channels Front-End Circuits

The front-end circuit consisted of preamplifier, and band-pass filter. To be useful biologically, all biopotential amplifiers must have high input impedance, high CMRR and low dc offset, so that they can provide minimal loading of the signal being measured. The total gain and frequency band of every channel is listed in Table 6.

a. Preamplifier:

Instrumental Amplifier (IA) is a differential amplifier and which has a high common-mode rejection ratio (CMRR) and high input impendence. A high CMRR is important in applications that the signal of interest is represented by a small voltage fluctuation superimposed on a (possibly large) voltage offset, or when relevant information is contained in the voltage difference between two signals. LT1789-1 owns an ultra low input current and a high common-mode rejection ratio (CMRR) about 96dB.Thus, LP1789-1 is chosen as the Instrumental amplifier to can provide the function of gain and high pass filter by adding a capacitor. The output voltage of the LT1789-1 is referenced to the voltage on the reference terminal. The preamplifier circuit design is shown in

Fig. 3-4.

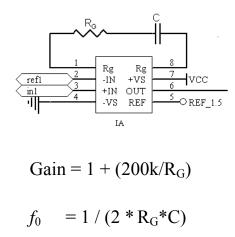
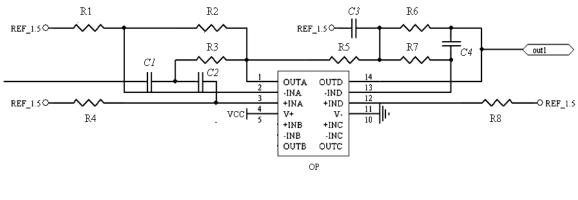


Fig. 3- 4: The R_G decides the gain of preamplifier, and the high pass filter of preamplifier decided by R_G and C.

b.Band-Pass Filter

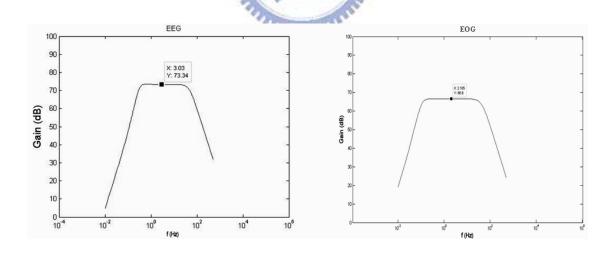
In this thesis, it designs to use operational amplifiers to achieve the function of band-pass filter; the feature of op AMP is suitable for amplifying low-frequency signal. The AD8609 is quad micro-power rail-to-rail input and output amplifiers and low dc offset was chosen to be band pass filter. Fig.3-5 shows High-pass filter and Low-pass filter circuits. The 3dB cutoff frequency of high pass was decided by passive components R3, R4, C1 and C2.



$$f_{H} = \frac{1}{2\pi\sqrt{R_{3}R_{4}C_{1}C_{2}}}$$

Fig. 3- 5: High-pass filter and Low-pass filter circuits

The passive components R7, R8, C3, and C4 decide the 3dB cutoff frequency $f_L = \frac{1}{2\pi\sqrt{R_6R_7C_3C_4}}$. A circuit of band-pass filters and amplifier is designed as shown in Fig. 3- 5 and gain will be determined by passive components R1, R2, R5 and R7. The simulation results of each channel are shown as Fig.3-6.



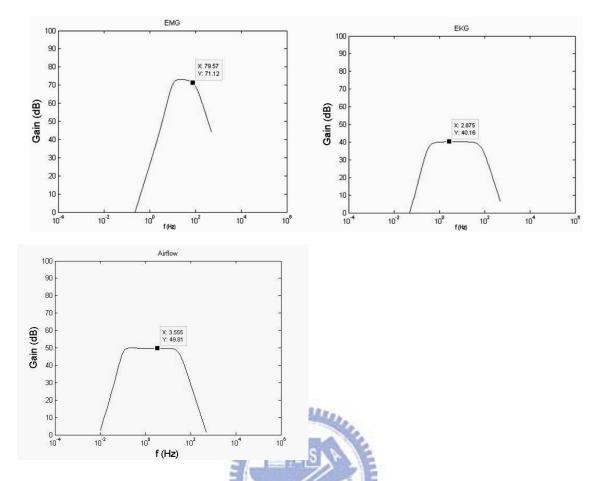


Fig. 3- 6: Simulation results in each channel of amplifier and band-pass filter

3.2.2 Analog to Digital Converter and Digital Controller

For the data acquisition system, it needs a controller to organize the working of ADC and encode the digital data to wireless transmission which received from ADC. The MSP430 is particularly well suited for wireless RF or battery powered applications. The MSP430 incorporates a 16-bit RISC CPU, peripherals, and a flexible clock system that interconnect using a von-Neumann common memory address bus (MAB) and memory data bus (MDB) shown as Fig. 3-7. The clock system is designed specifically for battery-powered applications. Dedicated embedded emulation logic resides on the device itself and is accessed via JTAG using no additional system resources. We configure with built-in 16-bit Timer_A, a fast 12-bit

A/D converter, one universal serial synchronous/asynchronous communication interfaces (USART) and 4M Hz external oscillator to development our design[39].

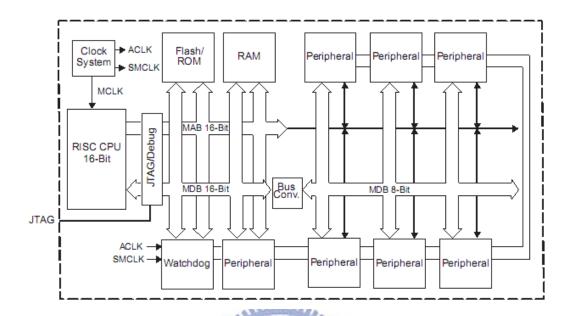


Fig. 3-7: MSP430 Architecture

Timer_A triggers Analog to Digital Converter, and buffers the output data of ADC until buffer full. And then all buffer data will be transmitted via USART. We will describe those modules and software configuration respectively in chapter 4.

3.2.3 Power Management

In our proposed system, the operating voltage VCC was at 3V, and the virtual ground of analog circuit was at 1.5V. LP3985 and AD8628 were used to regulate and buffer battery voltage to 3V and 1.5V. In order to provide stable 1.5V and 3V voltage, Here, The LP3985 is a micro power CMOS voltage regulator that can provide up to 150 mA of output current from a 2.5V to 6V input. And a voltage divider circuit was used to divide 3V voltage into 1.5V, and a voltage buffer constructed from AD8628,

the AD8628 has ultralow offset, drift, and bias current. The importance of this circuit does not come from any change in voltage, but from the input and output impedances of the op-amp. 3V output is used to provide power front end circuit, microcontroller and wireless module. 1.5V output is used to provide front end circuit as a reference voltage. The total power supply circuit is shown as Fig. 3-8.

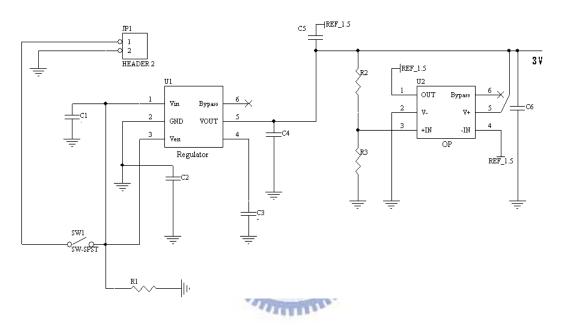


Fig. 3-8: Power supply circuit in data acquisition system

3.2.4 Wireless Transmission

Bluetooth® wireless technology is becoming a popular standard in the communication area, and it is one of the fastest growing fields in the wireless technologies. It is convenient, easy to use and has the bandwidth to meet most of today's demands for mobile and personal communications. For a portable device, wireless communication is an important issue to resolve great inconvenience of using with wire transmission. Bluetooth is a wireless protocol utilizing short-range communication technology to facilitate data transmission over short distances from fixed and/or mobile devices. Bluetooth is defined as a layer protocol architecture

consisting of core protocols, cable replacement protocols, telephony control protocols, and adopted protocols". Mandatory protocols for all Bluetooth stacks are: LMP, L2CAP and SDP. Additionally, these protocols are almost universally supported: HCI and RFCOMM. Bluetooth technology handles the wireless part of the communication Channel; it transmits and receives data wirelessly between these devices. It delivers the received data and receives the data to be transmitted to and from a host system through a host controller interface (HCI). The most popular host controller interface today is either a UART or a USB link; Bluetooth is a standard and communications protocol primarily designed for low power consumption, with a short range (power-class-dependent: 1 meter, 10 meters, 100 meters) based on low-cost transceiver microchips in each device. We choose BM0203 to be Bluetooth module; BM0203 is an integrated Bluetooth module to ease the design gap and uses CSR BuleCore4-External [40] as the major Bluetooth chip. CSR BlueCore4-External is a single chip radio and baseband IC for Bluetooth 2.4GHz systems including enhanced data rates (EDR) to 3Mbps. All hardware and device firmware of BM0203 is fully compliant with the Bluetooth v2.0+EDR specification.

3.3 Hardware System Implementation

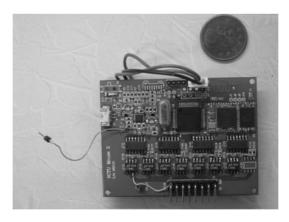




Fig. 3-9: The hardware of Portable biosignal acquisition unit

Fig. 3-9 is the hardware of Portable biosignal acquisition system, there are twelve leads in our portable EEG system, includes six ExG inputs, two airflow inputs, three references, and one virtual ground of the front-end analog circuit. The electrode disposal is shown as Fig. 2-2 to Fig. 2-7. The specification of Portable biosignal acquisition unit was listed in Table 7.

Table 7: The specification of Portable biosignal acquisition unit

Туре	Portable biosignal acquisition unit
Operating Temperature	-40° to +85°C
Size	65 x 50 x 8 mm ³
Weight	33 g(with battery)
	66 g (with battery and box)
Channel Number	8
power	Rechargeable Lithium 3.7V 450mAh
Gain	Depend on difference channel [Table 6]
Bandwidth	Depend on difference channel [Table 6]
Input signal range	Depend on difference channel [Table 6]
ADC Resolution	12bits
Power capacity	16~20hours
Sampling rate	2048Hz up to 200kHz
Communication Interfaces	Bluetooth 2.0

Chapter 4 Software Frameworks of Portable Biosignal Acquisition System

In our proposed PSG system, a microprocessor (TI MSP430) was used to perform bio-signal data acquisition in the bio-signal acquisition module and transmit digitized bio-signals wirelessly to PC via Bluetooth. The software frameworks of the whole system were listed in Fig. 4-1. It includes two major parts: the firmware in MSP 430 and software in PC.

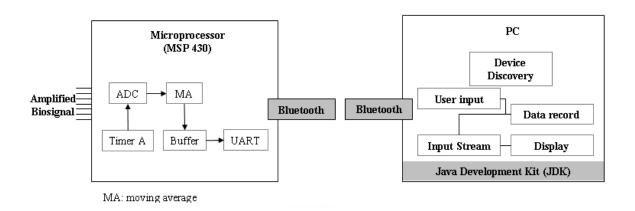


Fig. 4- 1: Diagram of software frameworks

4.1 Firmware in MSP430

In order to avoid WDT reset the system, we close the Watchdog timer at the beginning and then set the system clock, ADC and UART interface, and the parameters of the baud rate is 115200. Timer A, ADC and UART of msp430 are the three main modules what we use. The relation between three modules is "Timer A" triggers "ADC" and the outputs of "ADC" are buffered until buffer full. And then all buffered data will be transmitted via "UART". Flow chart of firmware in MSP430 is

shown as Fig. 4-2.

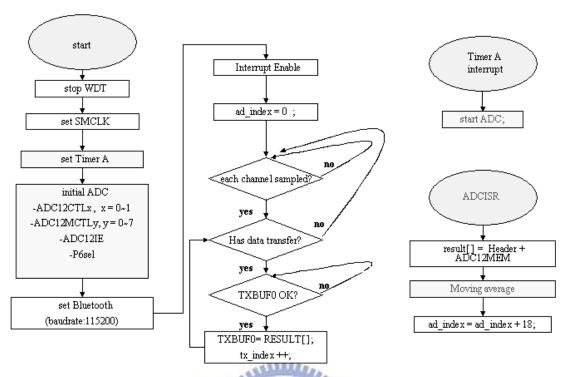


Fig. 4-2: Flow chart of firmware in MSP430

a. Timer A

Timer A is a 16-bit timer/counter with three capture/compare registers. It has four modes of operation as described in Table 7: stop, up, continuous, and up/down. The operating mode is selected with the MCx bits [39]. The TACCR0 CCIFG interrupt flag is set when the timer counts to the TACCR0 value. We use "up mode" to trigger enable Analog Digital Converter. The trigger rate is 256Hz.

Table 8: Timer modes

MCx	Mode	Description
00	Stop	The timer is halted
01	Up	The timer repeatedly counts from zero to the value of TACCR0
10	Continuous	The timer repeatedly counts from zero to 0FFFFh
11	Up/down	The timer repeatedly counts from zero up to the value of TACCR0 and back down to zero

b. Analog to Digital Converter

In this system, by passing the signal through wireless, it needs an analog to digital converter to convert the continuous signal to discrete number. To suit with the filtered and amplified signal from front-end circuit, built in ADC of MSP430 was chosen to be an analog to digital converter.

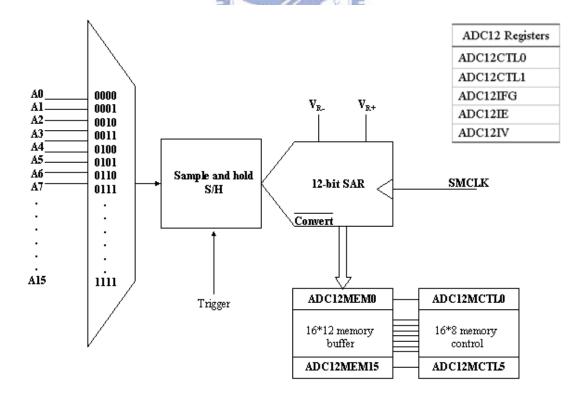


Fig. 4-3: ADC12 Block Diagram

Fig. 4-3 shows ADC12 Block Diagram. The ADC12 module supports fast, 12-bit analog-to-digital conversions. The module implements a 12-bit SAR core, sample select control, reference generator and a 16 word conversion-and-control buffer. The conversion-and-control buffer allows up to 16 independent ADC samples to be converted and stored without any CPU intervention [39]. The ADC12 inputs are multiplexed with the port P6 (A0-A7) pins, which are digital CMOS gates. An analog-to-digital conversion is initiated with a rising edge of sample input signal SHI. The signal SHI will be set by interrupt routine of the timer A at 256Hz. The ADC12 module is configured by three control registers, ADC12CTL0, ADC12CTL1 and ADC12MCLTx. Those registers are set to enable core, select conversion clock, set conversion mode, sample and input channels define. In our system, we used the "multiple channels, single conversion each" mode. In this mode, a sequence of channels is sampled and converted once. Each conversion requires 13 ADC12CLK cycles; include conversion and result restored into ADC12MEMx conversion memory registers. Fig 4-4 shows a diagram for sampling time and conversion time of ADC with trigger by timer A. Here, the total sampling and conversion time less then 15625 clocks. Therefore, the conversion time of ADC is fast enough to fit the requirement of the sampling rate of the whole system. The ADC result of each channel will be 12 bits long in the form of an unsigned integer whose value is:

$$4095*\frac{Ax - Vr}{Vr + - Vr}$$

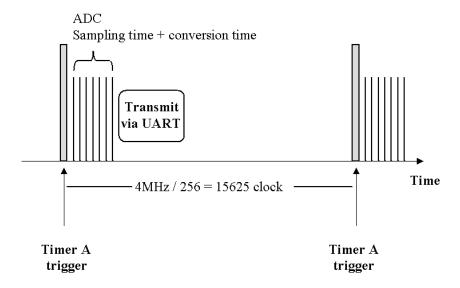


Fig. 4- 4: Diagram of the sampling and conversion with timer A trigger

When conversion results are written to a selected ADC12MEMx, the corresponding flag in the ADC12IFGx register is set. An interrupt request is generated if the corresponding ADC12IEx bit and the GIE bit are set. After ADC12IFGx register set, the interrupt service routine of ADC started. In the interrupt service routine, we buffered ADC12MEMx. Next, a moving average filter was used to remove 60-Hz power line interference, and then filtered signal data was encoded before wireless transmission [Fig. 4-5].



Fig. 4-5: Data format

c. UART

The universal synchronous/asynchronous receive/transmit (USART) peripheral interface supports two serial modes with one hardware module. We use asynchronous UART mode. In UART mode, the USART transmits and receives characters at a bit rate asynchronous to another device[39]. Timing for each

character is based on the selected baud rate of the USART. The transmit function and receive function use the same baud rate frequency. When UTXEx is set, the UART transmitter is enabled. Transmission is initiated by writing data to UxTXBUF. The data is then moved to the transmit shift register on the next BITCLK after the TX shift register is empty (UTXIFG0 =1). We set UBR00=0x22, UBR10=0x00 and UMCTL0=0xDD to fit the requirement of the baud rate: 115200 bps. But it also has some gaps that the effective baud rate is 115274 bps and the transmit errors are shown in Table 8. The results show the maximum per-bit error is about 0.1249 us (1.44%) at 4M Hz clock and the error is acceptable. Each $\frac{1}{256}$ second, there will be 18 bytes transmitted via UART, for sending 18 byte that needs about 6000 system clock [Fig. 4-4], and it has enough time to transmit all data.

Table 9: Transmit time errors (microseconds)

event	desired	effective	error	error%
start bit->D0	8.68	8.75	-0.0694	-0.80
D0->D1	17.36	17.25	+0.111	+1.28
D1->D2	26.04	26.00	+0.0416	+0.48
D2->D3	34.72	34.75	-0.0277	-0.32
D3->D4	43.40	43.50	-0.0972	-1.12
D4->D5	52.08	52.00	+0.0833	+0.96
D5->D6	60.76	60.75	+0.0138	+0.16
D6->D7	69.44	69.50	-0.0555	-0.64
D7->stopbit	78.12	78.25	-0.125	-1.44
end of stop bit	86.81	86.75	+0.0555	+0.64

d. Moving average

The moving average is the most common filter in DSP; the moving average filter operates by averaging a number of points from the input signal to produce each point in the output signal. In equation form, this is written:

 $y[i] = \frac{1}{M} \sum_{i=0}^{M-1} x[i+j]$; we use this method to reduce 60-Hz power line interference.

Fig 4-6 shows signal sampled at 256Hz and filtered with 4-points moving average filter. The simulation result shows the 60Hz noise becomes lower in time domain and frequency domain.

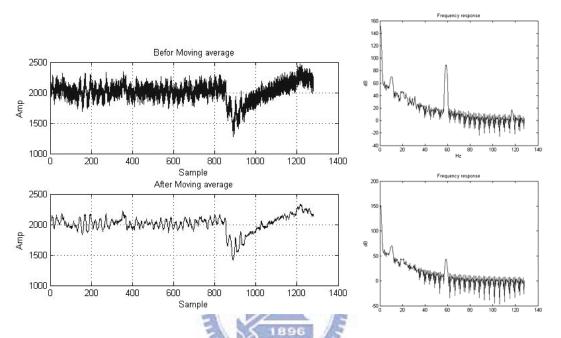


Fig. 4- 6: Simulation result of moving average filter

4.2 Software in Personal Computer

4.2.1 JAVA Environment

The PSG software in PC was developed using JAVA technologies, One characteristic of Java is portability, which means that computer programs written in the Java language can run similarly on any supported hardware/ operating-system platform. One should be able to write a program once, compile it once, and run it anywhere. This is achieved by compiling the Java language code, not to machine code but to Java bytecode – instructions analogous to machine code but intended to be interpreted by a JAVA virtual machine (JVM) written specifically for the host

hardware. End-users commonly use a Java Runtime Environment (JRE) installed on their own machine for standalone Java applications, or in a Web browser for Java applets [Fig.4-7].

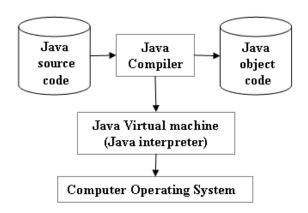


Fig. 4- 7: Java environment

4.2.2 Software interface

We developed a Graphics User Interface (GUI) using Java Development Kit (JDK) 6 to monitor and record bio-signals, the GUI of the PSG system is shows in Fig. 4-8. Here, a function menu is in upper left corner, a system information board is in middle left side, a real-time display of bio-signal waveform is in right side and a form for user information is in bottom of the window. Software of our proposed PSG system is handled by five modules:

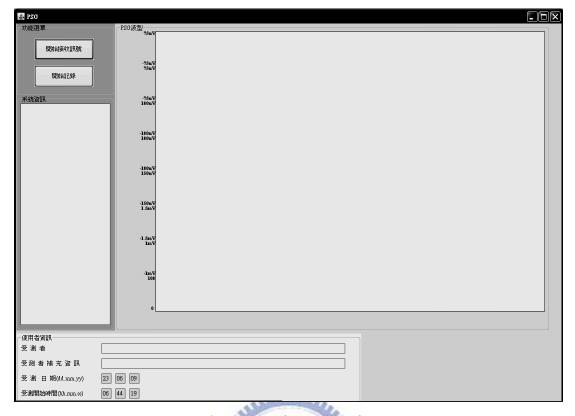


Fig. 4-8: Software interface

A. User input module

According to the EDF file format described in Table 5, in header of EDF, it has two fields need to input: Local subject identification and Local recording identification. We use KeyListener to handle and check user input. The date and time fields are provided by system. The time field is handled by a thread, stop when user push the button "start recording" and continue when user push the button "stop recording".

B. Device discovery module

PC with Bluetooth USB dongle was used as the local device and our probable bi-signal acquisition module was used as the remote device. When user pushed the button of "Begin receiving biosignal", the local device discovery procedure will start to search remote device, the procedure is shown as Fig.4-9. The Discovery Listener interface allows an application to receive device discovery and service discovery

events. This interface provides four methods, two for discovering devices and two for discovering services. The specification of Java™ APIs for Bluetooth was described in JSR 82.

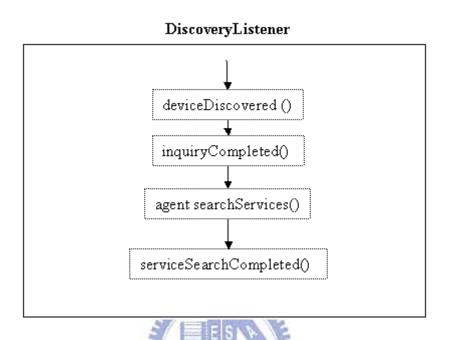


Fig. 4- 9: Procedure of Discovery Listener

C. Input stream module

After discovering the remote device, we used Bluetooth protocol RFCOMM (Radio Frequency Communication) to exchange data between local and remote devices. The RFCOMM is made on top of the L2CAP protocol, providing emulated RS-232 serial ports. We got the Uniform Resource Locator (URL) of remote Bluetooth and opened the connection between Local Device and Remote Device, and exchange data based on RFCOMM protocol. The Java.io package was used to receive data from our portable PSG device. This package has an InputStream and OutputStream. Java InputStream is defined for reading the stream, byte stream and array of byte stream. The data format [Fig. 4-5] of software in PC coincides with firmware in MSP430.The first column of header is "0xFF" and second column is "0x62", the rest is the data of each channel. "FF" is identifier for channel data, "62" is

representative of sample rate and the number of channels. After receiving, data of each channel was rebuilt by equation 4-1:

D. Display module

In bio-signal recording, the scientist and clinician need to know not only the bio-signal waveforms but also their amplitudes. Therefore, we restore the signal and mark the amplitude of bio-signals [Fig. 4-8], the bio-signal waveform is circular drawn using Graphics 2D on a Java JPanel, the panel shows in right side of the windows. The sampling rate of screen display was down sampled to 128 Hz, and each page shows five-second bio-signals.

E. Data record module

When user pushes the button of "start recording", the data is recorded in two format by using java.io package. Form 1 was recorded in text form, as shown in Fig. 4-10.

EEG	CH2	СНЗ	CH4	CH5	СН6	CH7	Timesatama
C4-M1	O2-M1	EOGL	EOGR	EMG	EKG	Airflow	Timestamp

Fig. 4- 10: Record data in Text format

Form 2 is EDF file format [Table 5], which there are four fields of the header of EDF, and these 4 extreme values specify offset and amplification of the signal, the parameter of amplitude and offset is (phy_max - phy_min) / (dig_max - dig_min), as listed in Table 9. In data record, each sample value is represented as a 2-byte integer in 2's complement and little endian format. Depended on the feature of EDF file format; we buffered incoming data until a second data was collected. Next, we write to EDF file when every second data was collected .When user pushes "stop recording" button, the "Number of data records" field of header will be updated.

Flowchart of program is shown as Fig. 4-11, and EDF browse successfully read out the saved EDF file, as shown in Fig 4-12.

Table 10: The parameter of EDF header

	Physical	Physical	Digital	Digital
	minimum	maximum	minimum	maximum
EEG	-333	333	-2048	2047
EOG	-702	701	-2048	2047
EMG	-330	329	-2048	2047
EKG	-13393	13392	-2048	2047
Airflow	-4854	4854	-2048	2047

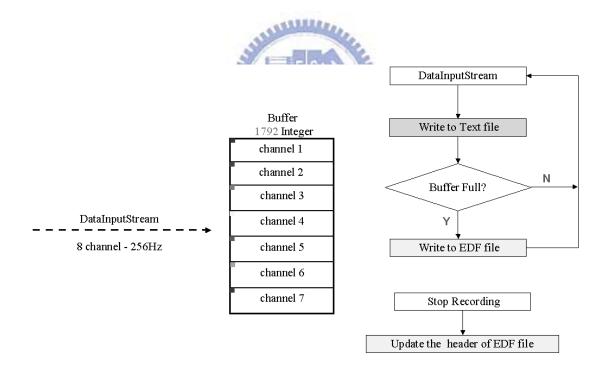


Fig. 4-11: Recording procedure of Text file and EDF

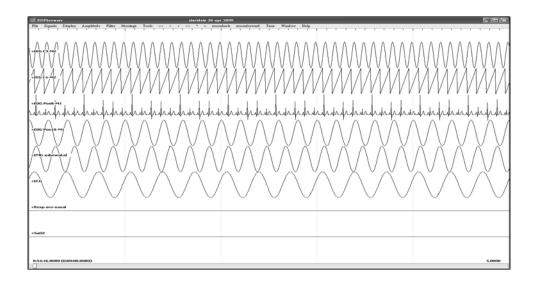


Fig. 4- 12: Simulation data in EDF format and browse by EDF browser [42]



Chapter 5 Experiment Results

To assess the feasibility of our proposed PSG system in this study, we used two settings to verify the whole system. One is simulated signal test and the other is preliminary test on healthy volunteer patients under the supervision of specialist at Sleep laboratory of Taipei Veteran General Hospital.

The results of simulated signal test was presented in Chapter 5.1; In Chapter 5.2 we compared bio-signals acquired with the proposed PSG system with those coming from an off-the-shelf cabled system in the framework of standard sleep staging. The reference system is a complete polysomnography system deigned by Philips Respironics. According to the comparison of difference between the above two system in time domain, our proposed system can perform well and can be applied in practice.

A more quantitative comparison is performed by looking at the duration of each sleep stage and the percentages of each sleep stage over night. Relative errors on stage duration show very good results for sleep (Stage 1), Stage W and REM stage.

5.1 System verification

5.1.1 Verification of Simulation Signals

The feasibility of the proposed PSG system was tested in this section. In order to verify the validity and evaluate the performance of our PSG system for various kinds of bio-signals, first sin waves with difference Frequency (1Hz \cdot 5Hz \cdot 15Hz and 20Hz) and 100 μ V vibration amplitude generated by a function generator was used for simulated signal test. Fig. 5-1 showed simulated signals obtained by our proposed system. Here, simulated signal first was measured by our PSG system, digitized, and

then transmitted to PC via Bluetooth. A Java program was designed for receiving signals transmitted from our PSG system, as shown in Fig. 5-1. Fig. 5-2 showed comparison of FFT between simulated signals obtained by our PSG system and reference signals generated by MATLAB. Here, sin waves generated by MATLAB were used as reference signals. Both simulated signals and reference signals were in 1, 5, 15, and 20 Hz respectively. Results showed that the frequency properties of simulated signals obtained by our PSG system were accurate, and matched that of reference signals.

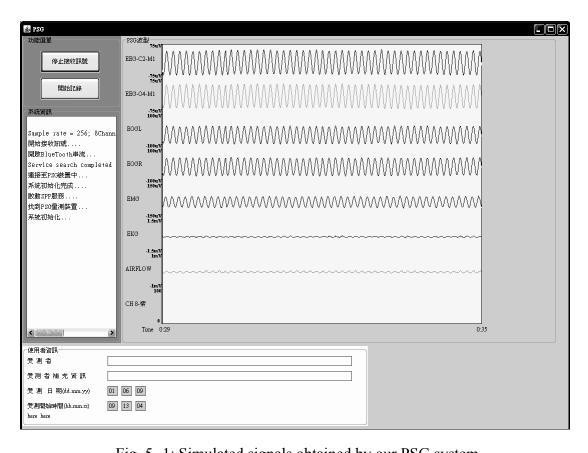


Fig. 5- 1: Simulated signals obtained by our PSG system

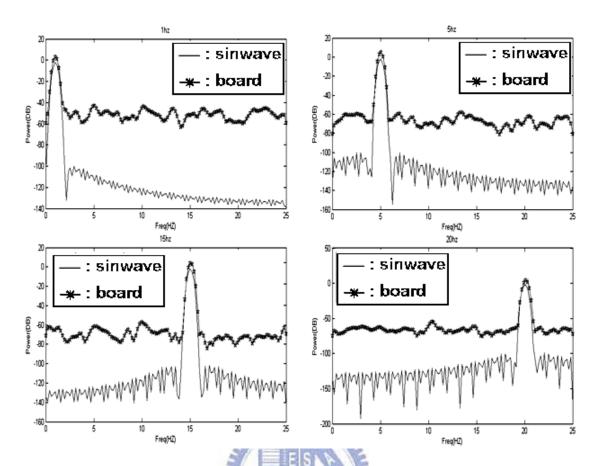


Fig. 5- 2: Comparison of FFT between simulated signals obtained by our PSG system and reference signals generated by MATLAB for 1, 5, 15, and 20 Hz sin waves.

5.1.2 Verification of bio-signals -Calibration

Calibration should be performed both at the beginning and the end of the study under the following categories. Physiological/ biological calibration has to be performed as follows: ask the patient to keep the eyes open, look straight ahead for 30 second, close the eyes, look straight ahead for 30s, look to the left and right, repeat up and down, hold head still, blink eyes slowly five times, grit teeth, clench jaw or smile, inhale and exhale, hold breath for 10s. Mechanical calibration should also be performed. In this experiment, the bio-signals gathered from our proposed system, the sampling rate was set to 256 Hz. Standard Ag/AgC1 electrodes were placed on the patient to allow monitoring of bio-signals in calibration as illustrated on Fig. 5-3. The

following signals were measured: Two channel EEG, central C2/A1 and occipital O4/A1. Two EOG channels measured eye movement in both lateral and frontal directions, one channel EMG measured the muscular tension on the chin, the reference electrode (A1 \ A2) was placed on the mastoid opposite to the brain side investigated. One channel EKG measured heart rate. Fig. 5-4 shows the variation of bio-signal in calibration test.

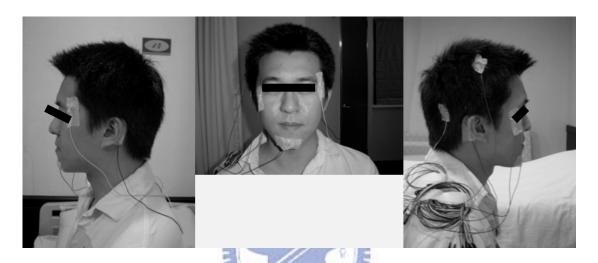


Fig. 5-3: Electrodes disposal for sleep staging investigation

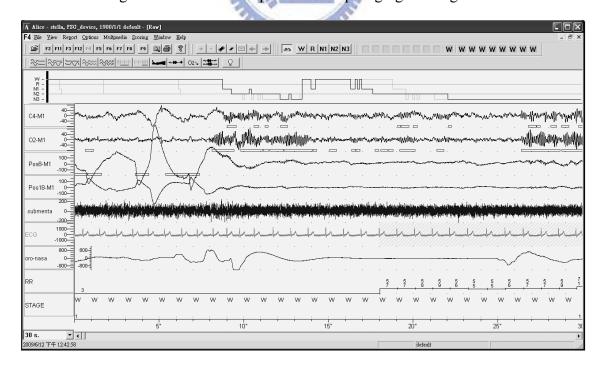


Fig. 5- 4: Variation of bio-signals in Calibration test-recorded by our proposed system

5.2 Comparison between our proposed system and reference system

5.2.1 Experiment environment



Fig. 5- 5: Sleep laboratory of Taipei Veteran General Hospital

To assess the feasibility of using our proposed system for sleep monitoring purposes, we performed a preliminary test on healthy volunteer patients under the supervision of specialist at Sleep laboratory of Taipei Veteran General Hospital, as shown in Fig. 5-5. A Sleep Laboratory is a place where sleep can be accurately recorded through observation and testing. It usually consists of individual rooms which are observed from a control room, there should be a facility for video with lights switched off and an infrared video camera. They are equipped with all the necessary comforts for a good nights sleep and provide an environment free from disruptions such as light, sound and other disruptions.

From the control room, subjects are observed and recordings taken of brain activity that will lead to correct recordings of sleep patterns and other conditions. Sleep studies sought to understand what is happening during the entire sleep cycle. It involves attaching electrodes the body and recording electrical signals from the brain and muscle activity that is digitally recorded. Recordings are taken by attaching electrodes to the head and body. These are easily removed and most people manage to sleep with them attached. The EEG, EMG, EOG, Leg EMG, Airflow parameters, Effort parameters, Oxygen saturation, Body position and ECG will be recorded. In this experiment is to compare bio-signals acquired by the proposed PSG system with those coming from an off-the-shelf cabled system in the framework of standard sleep staging. The two systems shall be set up in parallel on the patient and the same signals will be recorded over night. The reference system is a complete polysomnography system designed by Philips Respironics: The Alice 5 Diagnostic Sleep System [10]. This system was used by the sleep laboratory of the hospital and was considered as the "Gold standard" for this clinical validation. Both above two systems measure the same signals, using the same setting electrodes. The above two systems were electrically isolated (floating) such that they do not interfere with each other and recorded bio-signals simultaneously. Fig. 5-5 showed diagram of bio-signals processing for system verification. We recorded EEG (O2-M1, C4-M1), EOG, EMG, EKG and airflow at the same time. The Alice 5 Diagnostic Sleep System sampling rate is 200Hz and our proposed system sampling rate is 256Hz. After recording, the records of the two systems were adjusted to the same sampling rate, and restored the original signals. Comparison of time domain signal and sleep stage was used to verify whole system. Fig. 5-6 showed diagram of bio-signals processing for system verification. Fig. 5-7 showed electrodes disposal of two systems. Fig. 5-8 showed experimental environment.

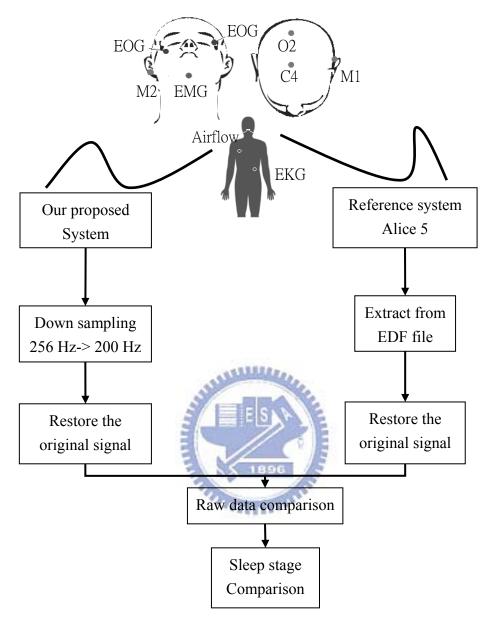


Fig. 5- 6: Diagram of bio-signals processing for system verification



Fig. 5-7: Electrodes disposal of two systems

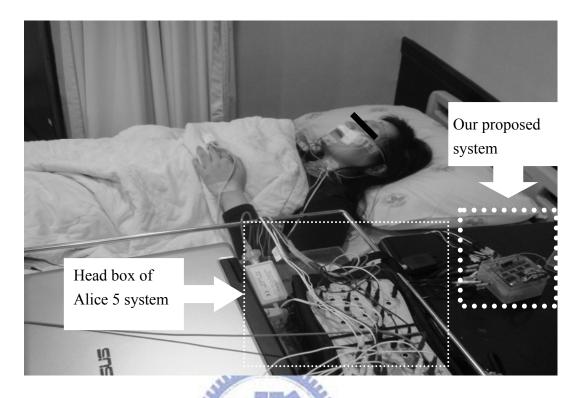


Fig. 5- 8: Subject wire up two systems: left is Alice 5 Diagnostic Sleep System and right is our proposed system.

5.2.2 Alice®-family

Respironics, Inc. is the recipient of this year's Frost & Sullivan 2005 Customer-Ranked Leader in Sleep Diagnostic Equipment Quality and Customer Service Award. The award recognizes Respironics as the leading sleep diagnostic equipment manufacturer in both product quality and customer service for its production and support of the Alice®-family of polysomnographic (PSG) sleep systems.

The latest Alice ® system, Alice ® 5, displays and prints physiological adult and infant patient information for clinicians and/or physicians. The system helps to

simplify the integration of sleep lab devices through a high-tech consolidation requiring a maximum of two cables. Alice ® 5 features expanded channel capability to 55 total channels, high quality ECG with six channels, pulse transit time (PTT), and real time impedance display.

Alice ® 5 collects data from sensors placed on a patient and delivers the information to a computer running the Alice ® Sleepware[™] application. Alice ® Sleepware[™] is a Windows ® -based software program designed to monitor, display, process and download polysomnographic data. The data is then presented graphically on a computer screen for diagnostic review, similar to traditional paper-based polygraph records [10]. Fig. 5-9 shows Alice ® Sleepware[™] can import EDF data for diagnostic review by specialist.

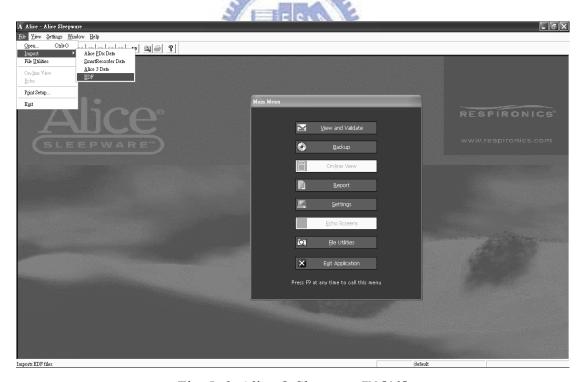


Fig. 5-9: Alice ® SleepwareTM [10]

5.2.3 On-line bio-signal monitoring/recording

When the subject wore our PSG system, a PC-based software would start link our PSG system. After completing the communication link between the PC-based software and our PSG system via Bluetooth, physiological signals were received by this PC-based software. Physiological signals would displayed and recorded if user pushed the save button. Next, the received data would be transferred into EDF format file format so that other software can read by technical staff for further interpretation. Fig. 5-10 showed raw physiological signal data received by PC-based software and real-time display /record in the subject's sleep period.

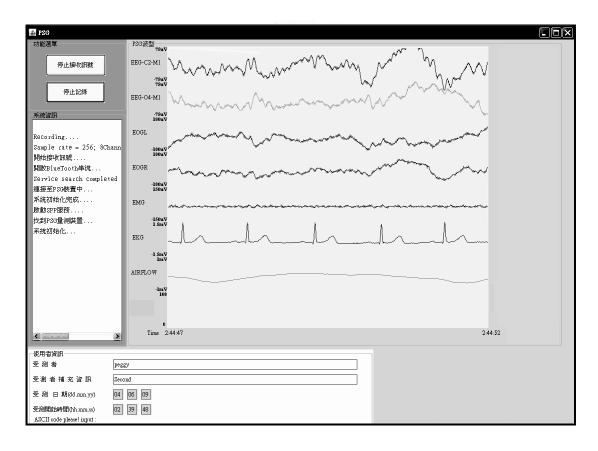


Fig. 5- 10: PC-based recording/monitoring user interface

5.2.4 Experiment output

A total of three subjects wore the two subjects system at the same time, and their physiological signals were simultaneously measured during sleep. After the test, we imported the EDF file to Alice Sleepware and the clinician was asked to scoring sleep stage. Fig. 5-11 to Fig. 5-15 showed the variation of subject's bio-signals during difference sleep stage. According to the 2007 AASM standards, there were listed five different stages of sleep, following by Stage W (Wakefulness), Stage N1 (NREM1), Stage N2 (NREM2), Stage N3 (NREM3) and Stage R (REM). After completing the sleep experiment, a 'scorer' would analyze these data by reviewing 30-second epochs to make up a hypnogram for overnight sleep and to summarize sleep structure. The top of Alice Sleepware showed sleep stage, and 30-second physiological signals were shown in the main window. These physiological signals listed from top to bottom respectively were EOG-left, EOG-right, EEG(C4-M1), EEG(O2-M1), EMG, Airflow and ECG.

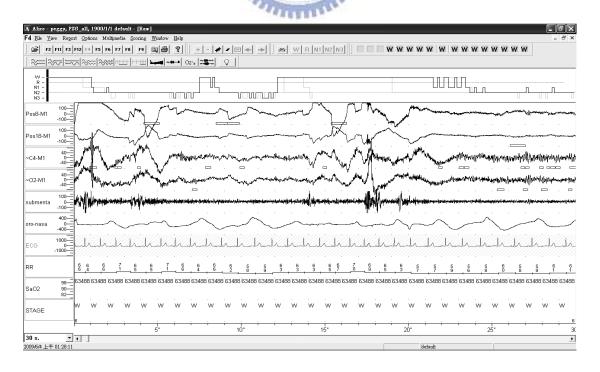


Fig. 5-11: Stage W: note the eye movements with high chin tone, 30-s epoch

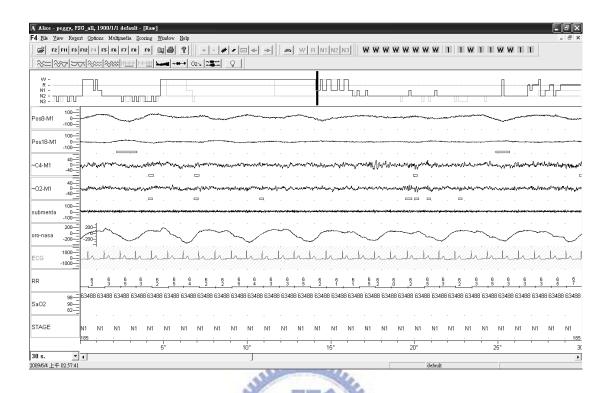


Fig. 5- 12: Stage N1: SEMs are seen with gradual drop out of alpha,30-s epoch

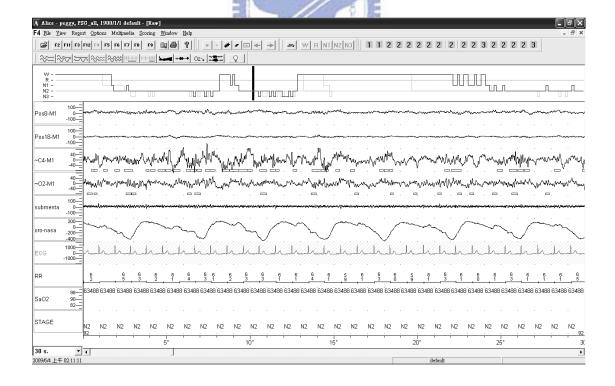


Fig. 5- 13: Stage N2:K complexes and sleep spindles seen, 30-s epoch

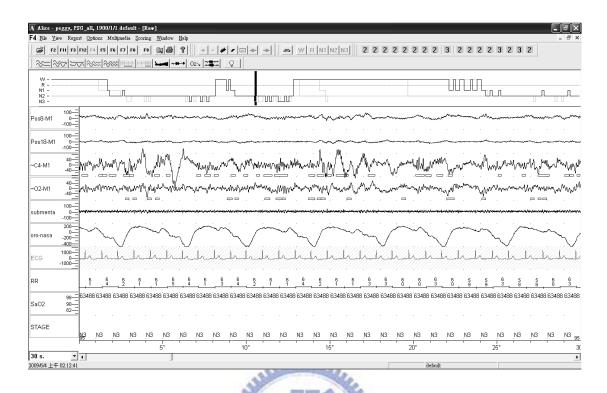


Fig. 5- 14: Stage N3: Delta slow waves are seen, 30-s epoch

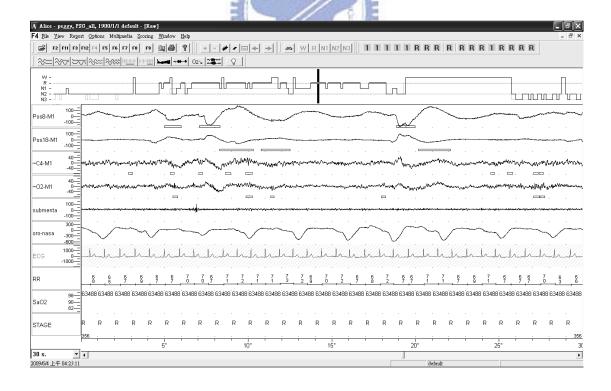


Fig. 5-15: Stage R: Note saw tooth waves with REMS

In statistics, correlation (often measured as a correlation coefficient, ρ) indicates the strength and direction of a linear relationship between two random variables. In general statistical usage, correlation or co-relation refers to the departure of two random variables from independence. In this broad sense there are several coefficients, measuring the degree of correlation, adapted to the nature of the data.

The measure of linear association between i and j shows in equation 5-1.

$$R(i,j) = \frac{C(i,j)}{\sqrt{C(i,i)C(j,j)}} \tag{5-1}$$

$$\mathrm{cov}(x_1,\!x_2) = E[(x_1\!-\!\mu_1)(x_2\!-\!\mu_2)]$$

where E is the mathematical expectation and $\mu_i = Ex_i$.

[R, P]=corrcoef (...) also returns P, a matrix of p-values for testing the hypothesis of no correlation. Each p-value is the probability of getting a correlation as large as the observed value by random chance, when the true correlation is zero. If P (i, j) is Small, say less than 0.05, then the correlation R (i, j) is significant, Fig. 5-16 shows Correlation examples.

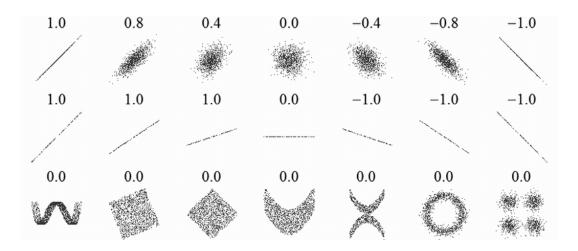


Fig. 5- 16: Correlation examples

In order to verify the validity of bio-signals obtained by our PSG system, we random selected 30-second raw physiological signals obtained by our PSG system and Alice 5 Diagnostic Sleep system, and compared to each other. The two sets of physiological signals looked very similar, and owned the same obvious features. Therefore, a more quantitative comparison was then performed by using cross correlation and correlation coefficients function in MATLAB to obtain the linear correlation of the two sets of physiological signals. Fig. 5-17 to Fig. 5-23 showed the comparison of 30-second raw physiological signal data in time domain and their correlation in every 1 second. From the above results, we found that physiological signals obtained by our PSG system and the reference system in the time domain were highly similar. Therefore, our PSG system can be viewed to own a high level of reliability.

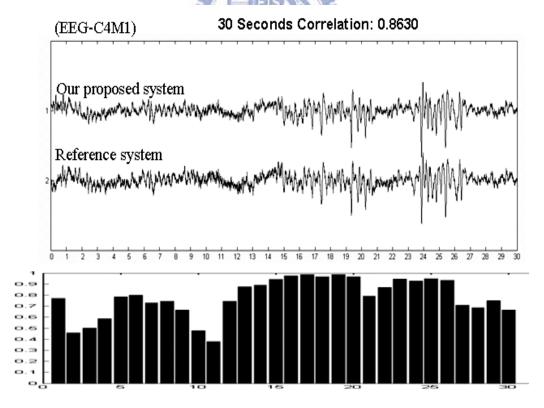


Fig. 5- 17: Comparison of 30-second raw data (EEG C4-M1), and their correlation in every 1 second

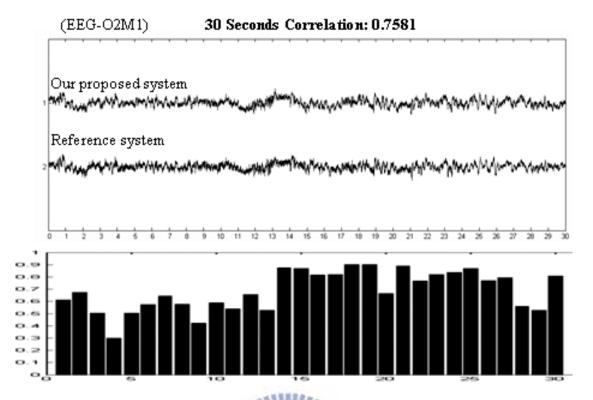


Fig. 5- 18: Comparison of 30-second raw data (EEG O2-M1), and their correlation in every 1 second

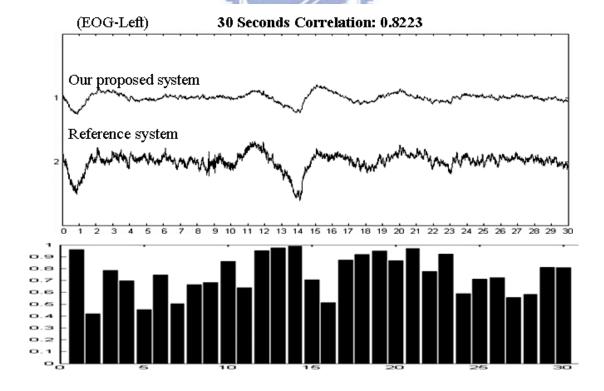


Fig. 5- 19: Comparison of 30-second raw data (EOG-Left), and their correlation in every 1 second

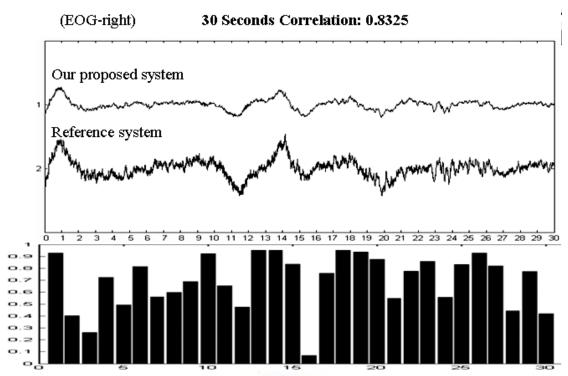


Fig. 5- 20: Comparison of 30-second raw data (EOG-Right), and their correlation in every 1 second

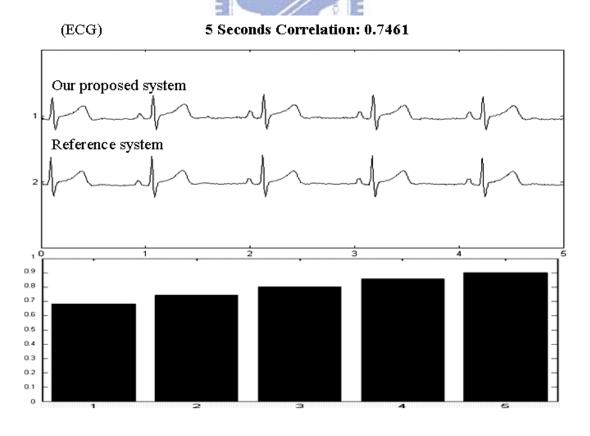


Fig. 5-21: Comparison of raw data (ECG), and their correlation in every 1 second

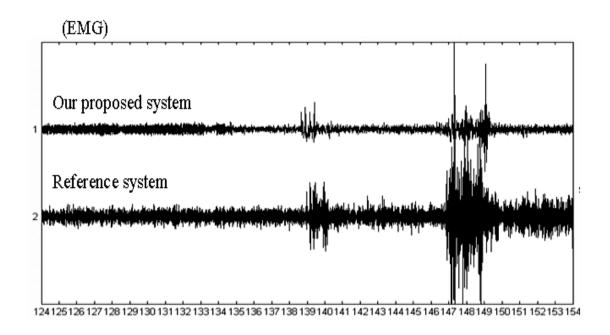


Fig. 5-22: Comparison of raw data (EMG-Right)

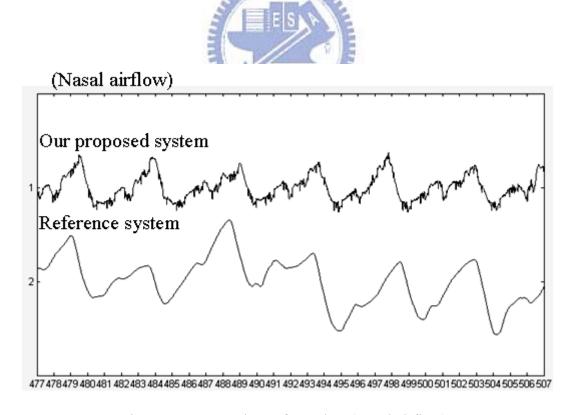


Fig. 5-23: Comparison of raw data (Nasal airflow)

The hypnogram built on the two sets of records were shown from Fig. 5-24 to Fig. 5-26. We found that the night patterns evaluated by the expert clinician for the two sets of data were similar. Comprehensive view of subjects 1 and 3 at the beginning of recorded time were different, but this did not affect the trend of the whole sleep architecture. The major difference in interpretation between the reference system and our PSG system occurred in the case of subject2. This is because of that the electrode lead fell off at 5 o'clock. For the case of subject 3, the sleep stage interpretation of our PSG system was the most similar to that of the reference system.

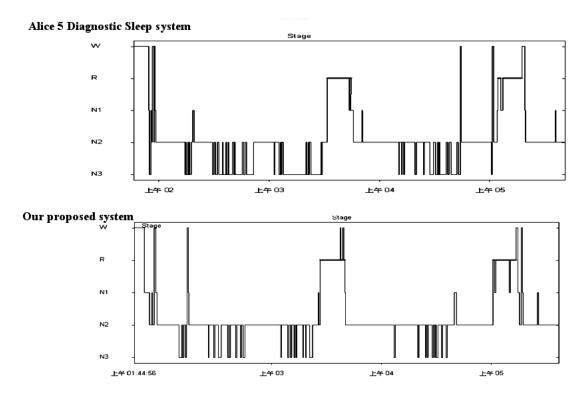
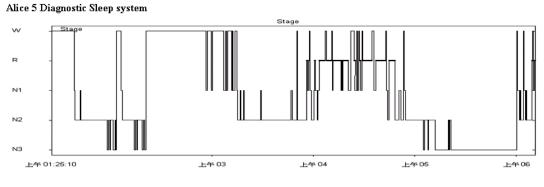


Fig. 5- 24: Hypnograms of the two sets of records (subject 1)



Our proposed system

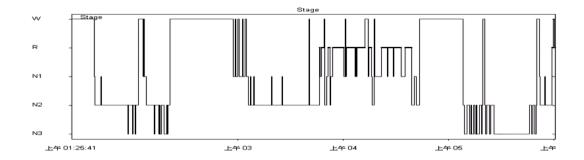


Fig. 5- 25: Hypnograms of the two sets of records (subject 2)

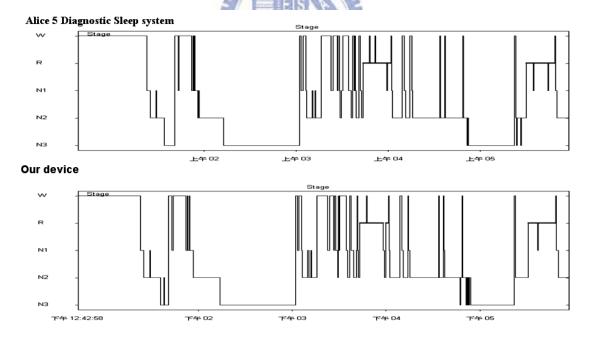


Fig. 5- 26: Hypnograms of the two sets of records (subject 3)

We rejected the segment of subject 1 and subject 2 records obtained by the reference system, which was prior to the beginning of this experiment, and the

segment of subject 2 records obtained by our PSG system, which was after the occurrence of falling off electrode lead. Then, we observed the time duration of each sleep stage which cumulated sleep hours for three subjects (Table 9), and the percentages of each sleep stage over night in two systems (Fig. 5-27). In the view of above, we found that the duration of Stage W, Stage N1 and Stage REM in two systems had similar interpretation, but had a gap between Stage N2 and Stage N3. According to the explanation of clinical expert, the proportions of the combining duration of Stage N2 and Stage N3 to the whole duration for two systems were the same. Thus, here Stage N2 may be interpreted as Stage N3 if some segments of physiology signals were extremely similar. And this caused the difference of interpretation between the two systems for Stage N2 and Stage N3.

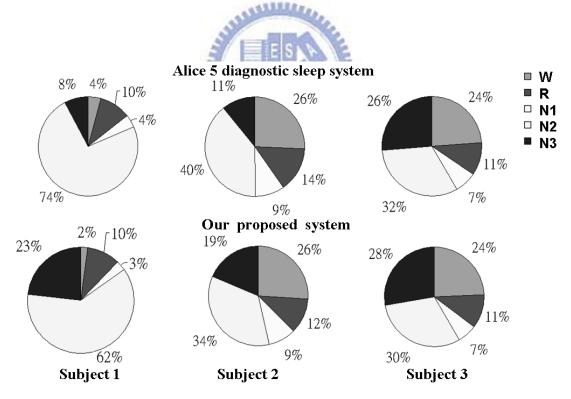


Fig. 5-27: Percentages of each sleep stage over night

Table 11: Relative errors on times spent in each sleep stage

Sleep stage	Ref.	Our	Rel. Err.
		proposed	
		system	
Awakening	156.5	150.5	3%
REM	90	93.5	3%
Stage N1	52.5	56.5	7%
Stage N2	337.5	372.5	9%
Stage N3	194.5	128	51%



Chapter 6 Conclusions

This study presented the design and implement of a battery-powered and ambulatory biopotential acquisition unit and a friendly monitoring / recording interface for sleep monitoring at home. Compare to the standard PSG-Alice 5® Diagnostic Sleep System, our proposed system performed similar performance and quality.

The PSG recording program in the personal computer was developed in JAVA, and can run on any Java virtual machine (JVM) regardless of computer architecture. By combining with Bluetooth® wireless technology, our design can be easily used anywhere at home and will not be restricted in a specific activity area. Moreover, compare to other portable PSG system, our proposed PSG system contains two-channel EEG, and therefore can offer more information to fit the requirement of accurate analysis and diagnosis. In our PSG system, the portable biopotential acquisition unit can continually work for about 16 to 20 hours with a 3.7V lithium battery without loss data. Therefore, it well supports a full-night sleep monitoring.

In conclusion, the aim of our proposed PSG system is not to replace standard 16-channel PSG system, but to collect important physiological information (EEG x 2, EOG x2, EMG x 1, ECG x1, and airflow) for sleep analysis at home. By using our PSG system, the cost of attended in-laboratory PSG experiment for OSA diagnosis can be effectively reduced. Furthermore, our system offers comfort and convenience of sleeping in patient's own bed, and therefore may record more natural information that reflects the patient's sleeping behavior.

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