Faculdade de Ciências e Tecnologia da Universidade de Coimbra

Departamento de Física

Sleep@Home
Remote Monitoring of Sleep Apnea Syndrome Patients

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Abstract

Obstructive sleep apnea is nowadays as respiratory disorder with serious consequences that affect people's life quality. The percentage of cases in children in pre-school age is around 1-3%.

Polissomnography (PSG) is currently the most common technique for sleep study, during an entire night , where countless vital signs are continuously monitored. The short number of pediatric hospital with this kind of testing, its complexity and elevated costs, lead to the development of new devices.

Sleep@Home is an innovative and non-invasive system, with which children can be monitored from their homes and the signal feed is remotely uploaded to a health unit where the data can consulted. The purpose of this system is not to replace the PSG but rather be a less awkward tracing device fro children. To reach this goal, it is necessary to carry out more clinical tests in order to validate the system.

Key-words (Theme): Obstructive sleep apnea syndrome, oxygen saturation, heart rate, home monitoring, diagnosis support, childhood.

Key-words (Technologies): Oximeter, video camera, respiratory effort bands, sound.

Resumo

A apneia obstrutiva do sono é nos dias de hoje um distúrbio respiratório com consequências graves que afectam a qualidade de vida das pessoas. A percentagem de casos em crianças de idade pré-escolar é de cerca de 1-3%.

A Polissonografia é actualmente a técnica mais utilizada para o estudo do sono, durante uma noite completa num hospital, em que inúmeros sinais vitais da criança estão continuamente a ser monitorizados. O reduzido número de hospitais pediátricos com este tipo de exame, a sua complexidade e custos elevados, promovem o desenvolvimento de novos dispositivos.

O Sleep@Home é um sistema inovador e não invasivo, em que as crianças podem ser monitorizadas a partir de suas casas, e a aquisição dos sinais é transmitida remotamente para a unidade de saúde onde os dados podem ser consultados. O objectivo deste sistema não é substituir a PSG, mas ser utilizado como um dispositivo de rastreio menos estranho para as crianças. Para isso é necessária a realização de mais testes clínicos a fim de validar o sistema.

Palavras-chave (Tema): Síndrome da Apneia Obstrutiva do Sono, saturação de oxigénio, frequência cardíaca, monitorização no domicílio, apoio ao diagnóstico, crianças.

Palavras-chave (Tecnologias): Oxímetro, câmara de vídeo, bandas de esforço respiratório, microfone.

Acknowledgments

This article is the result of one year's work, in a bussiness enterprise environment in which I learned much of what is presented here. Besides this, I've met awe-inspiring people with whom I spent a lot of good moments. I thank all the ISA team.

This article would never be finished if not for the support of some people, who always trusted me and to whom I must state my appreciation.

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To all my friends, without discriminating any of them, for their ways to incentivate me in wanting more and more, for standing by my side on the good and bad moments and for demonstrating the existent strength among all of us. Thank you.

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Acronyms and definitions

	Description
ADSL	Asymmetric Mobile Telecommunications System
AHI	Apnea/Hypopnea Index
BOX	Portable box that concentrates the various signals monitored during an exam
CEI	Centre of Electronics and Instrumentation
CPAP	Continuous Positive Airway Pressure
ECG	Electrocardiography
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography
HSDPA	High-Speed Downlink Packet Access
ISA	Intelligence Sensing Anywhere
N-REM	Non – Rapid Eye Movement
ODI	Oxygen Dessaturation per hour of sleep
OSAS	Obstructive Sleep Apnea Syndrome
PAT	Peripheral Arterial Tone
PCB	Printed Circuit Board
PES	Esophageal Pressure
PS	Primary snoring
PSG	Polissomnography
REM	Rapid Eye Movement
SpO_2	Saturation of Peripheral Oxygen
UARS	Upper Airway Resistance Syndrome
UMTS	Universal Mobile Telecommunications System

1. INTRODUCTION

1.1 Motivation

The sleep related respiratory disorders are common in children. While some of these disorders have no impact on the child's health, such as snoring, others have serious consequences on the child development, such the obstructive sleep apnea syndrome (OSAS).

Actually, the gold standard method to diagnose OSAS is Polissomnography (PSG), for adults or children. However, the examination PSG has certain limitations, including:

a) It is required the presence of technicians during the entire night;
b) Only few number of the sleep laboratories is prepared for children;
c) It is an extremely expensive method;
d) The different environment in the child's room might reduce the sleep quality.

A more attractive alternative to laboratory testing is an innovated technology for home screening. This is easier and more comfortable for the child and their parents.

The Sleep@Home project is a continuation of last year's, where a prototype was developed to become simple and portable. The prototype was tested simultaneously with PSG in a clinical environment.

1.2 Objectives

The huge amount and complexity of the information that a PSG exam monitors lead the need of alternative methods. It would be interesting, on one hand, to have a cut back in amount of existent signals; on the other hand, a tool that

detected events related to apnea or hypopnea, in other words, clinical important events.

This paper intends to explore alternatives that provide improvements in the support system for diagnosis of obstructive sleep apnea syndrome, presented as the end-course final project of the year 2006/2007. This is a continued project.

The first objective of the Project refers to the analisys/review and acquaintance of the most relevant components/channels used in PSG and other portable monitoring systems. The components implemented in prototype A and others that might be integrated are analyzed considering their precision e effectiveness in recording the vital signs detected, allowing the identification of obstructive apnea episodes.

The second objective, as exposed on chapter 4, is the development of a prototype B, in order to improve the system with new components and upgrading it to a medical device that, after carrying through several clinical tests, validations and certifications, would become fit for a market launch.

The remote transmission and database related stage are also being developed alongside with the ISA team.

1.3 Involved Entities

I. ISA - Intelligence Sensing Anywhere (1)

Company of technological base, leader in telemetry and remote systems sectors. ISA is an awarded winner global telemetry company, leader in different segments of market, offering innovative remote management systems with a broad range of applications: gas, oil, chemical products, water and sewers networks, industry, environment and domotics.

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II. CEI - Centre of Electronics and Instrumentation

The Center of Electronics and Instrumentation is a investigate unit of the Department of Physics at the University of Coimbra. The areas of research of the CEI are the Biomedical Instrumentation, the Atomic and Nuclear Instrumentation, Instrumentation for Physics of Plasmas, the Signal Processing and Industrial Telemetry and Control. It is the receptor entity where the main tasks were developed.

Contact: Departamento de Física – Universidade de Coimbra
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III. Coimbra Children's Hospital

This clinical institution has the role of validate and test the Sleep@Home System. Coimbra Children's Hospital area of influence encloses the country´s central region, and it presents itself as a Hospital of reference for the district Hospitals in the central region and for the health centers of the district of Coimbra.

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http://www.chc.min-saude.pt/departamentos/Pediatrico

1.4 Project Team

This project was developed by various elements, including people the Hardware and Software Applications Departments of ISA. In case of students is the final Project course.

Table 1 *– Project Team*

Name	Designation	Contact
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Doctor José Moutinho	Medical Supervisor (CHC)	

1.5 Overview of the report organization

This document is divided in 5 parts:

Chapter 1 – Introduction

In this chapter, the document is contextualized, objectives are focused, the motivation and contains a small introduction of the involved entities in this project.

Chapter 2 – Theoretical Background

In this chapter, it is presented a theoretical presentation of respiratory disorders and more specifically Obstructive Sleep Apnea Syndrome (OSAS).

Chapter 3 – Technical Review

The purpose of this chapter is to present the state of the art of the several existent products and their functionalities.

Chapter 4 – Sleep@Home – Project Developments

Based on the previous, this chapter will seek the most effective and practical system for OSAS diagnosis.

Chapter 5 – Conclusion

This chapter presents the conclusions concerning the objectives set in the beginning of the project and ideas for the future.

2. THEORETICAL BACKGROUND

This chapter is intended to give some theoretical concepts to understand the physiology of sleep disorders.

2.1 Sleep Disorders

Disorders include sleep disorders such as difficulty sleeping or to keep oneself to sleep, disturbed sleep due to respiratory events or external factors (temperature, noise, etc) or sleepwalking.

The interruption and subsequent fragmentation of sleep is the cause of the negative effects associated with various sleep disorders – process vital to healthy function of the body – and as such is responsible for the health problems that may result from them(2).

In 1997 a first manual called *The International Classification of Sleep Disorders* was developed (3) (4), for the American Academy of Sleep Medicine, aiming to provide more accurate diagnoses and improve the forms of treatment for sleep disorders. In 2001 it was revised and about 88 of sleep disturbances were described among which was obstructive sleep apnea syndrome.

2.2 Obstructive Sleep Apnea Syndrome (OSAS)

First mention, of the respiratory disorders in childhood was in 1836. Charles Dicken's in your publication, *The Posthumous Papers of the Pickwick Club*(5), description a boy with 10 years, who spent most of the time to sleep and eat.

Sir William Osier (6), in 1982, explain first medical opinion about OSAS in children, commenting the symptoms on the day and sleep very disturbed at night. Osler described night and daytime symptoms as follows*: "At night the child's sleep is greatly disturbed; the respirations are long and snorting, and there are sometimes prolonged pauses, followed by deep, horsy inspirations. The expression is dull, heavy, and apathetic ... In long-standing cases, the child is very stupid-looking, responds slowly to questions, and may be sullen and crosses. Among other symptoms may be mentioned headache, which is by no means uncommon, general listlessness, and an indisposition for physical or mental exertion."*

In 1976, Guilleminault et al. (7) described a group of 8 children with OSAS, diagnosed for PSG. Futhermore, Guilleminault et al. (8) published a review of 50 children and adolescents with OSAS, concluding that the syndrome it was not uncommon and that the impact intellectual, cardiovascular and neuromuscular of the same should be considered.

The symptoms of OSAS including frequently snoring and snorts, gasps or intermittent pauses (at night), and daytime sleepiness may occur in adolescents. (Table 2)

Table 2 – Features that may suggest a sleep related OSAS (adapted (9))

During Sleep	Symptoms on waking	Daytime
• Snoring • Parents concerned about their child's breathing • Unusual posture during sleep • Listening apneas Cyanosis	• Difficult to awake in the morning • Irritability on waking	• Excessive sleepiness • Hyperactivity and behavioral disturbance • Learning and memory difficulties • Growth delay

The prevalence is estimated to be between 1-3% in the child population with a similar distribution among boys and girls. It is more frequent in children

between 2 and 6 years (preschool-aged), when tonsils and adenoids are largest in relation to the diameter of the upper airway (9).

OSAS is define by repeated episodes of upper airway obstruction, usually associated to a dessaturation of oxygen in the blood. It is characterized by apnea or hypopnea moments, following the breathing restore with micro-awakening, caused by brain stimulating triggered during the obstruction, which leads to a state of less profound sleep.

In childhood, an apnea is described as several periods of times in which there is a breathing interruption and an obstruction of upper airways occurs. The three categories of apnea are central, obstructive and mixed.

Central apnea occurs when the signal of the respiratory center for the muscles involved in the respiratory tract ceases or when the signal is interrupted. The muscles cease all movement as well as respiratory effort, and thus any air flow . The central apnea is common in neonates and infants, since the problems should be, often, the immatureness of their nervous system.

The **obstructive apnea** is the interruption of the air flow by a total airway obstruction, although there is respiratory effort. In Figure 1, is possible see the state of the upper respiratory tract and the (none) passage of the air during an obstructive apnea. If the obstruction is partial, there is still a diminutive passage of the air but with reduced flow, it is a period of **hypopnea**. The obstructive apnea is the most common type of apnea in children (10).

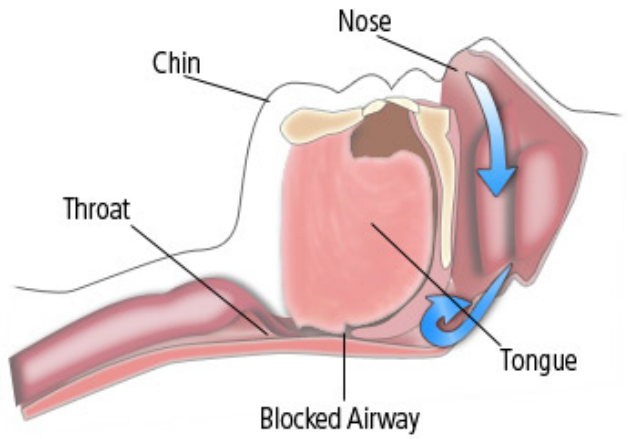


Figure 1 – Collapse the airway in the obstructive sleep apnea. *Source* (11)

The **mixed apnea** is a combination of central and obstructive apnea, involving either the decrease in respiratory control or the obstruction of the airways.

According to standard pediatric criteria (9), the apnea index was defined as the number of obstructive and mixed apneas, of at least two respiratory cycles duration, per hour of total sleep time. Although a hypopnea was defined as a partial obstruction characterized by a 50% or greater decrease of ventilation during at least two breath cycles or 30% associated with insaturation of 4%. Normally, the severity is calculated by the total number of apneas and hypopneas divided by the total sleep time; this is as Apnea/Hypopnea Index (AHI). In children, AHI of 1 – 5 events/hour is moderate, while in the most severe situations AHI is higher an 10 events/hour(12).

2.3 Diagnosis methods of OSAS

The diagnosis aims to not only to identify children who are at risk of presenting complications, to avoid prevention in cases who present no risk and to evaluate children who may suffer from post surgery complications in order to take appropriate precautions.

The methods of diagnosis that have been (scientifically) evaluated include:

a) History and Physical examination;

b) Video and snore documentation;

c) Oximetry;

d) PSG.

Several studies have shown that History and Physical examination can be brief and simple reports that allow a pre-diagnosis of OSAS. For example, OSAS needs to be distinguished from primary snoring (PS), which is defined as snoring without obstructive apnea. History and information given by the parents are not enough to perform a differential diagnosis between OSAS or PS (13).

Actually PSG is considered the standard method (gold standard), while the remaining considered as alternative methods. Sometimes more than one method of diagnosis is needed to identify more accurately the disorder in question.

Nocturnal PSG is the only diagnostic technique shown to quantify the respiratory process factors and abnormalities associated with sleep-disordered breathing. PSG involves recording of multiple physiologic variables including brain and heart signals (Electroencephalography (EEG) and Electrocardiography (ECG)), leg motion and eye motion (Electromyography (EMG) and Electrooculography (EOG)), blood oxygenation, respiration effort, air flow and others sensors. PSG requires monitoring, during the the examination, of specialized technical staff to control the records and to document the occurrence of events, which is most important for diagnosis.

PSG recordings provide the true assessment of sleep architecture and high quality, although it is very expensive and too many sensors attached to the child's body is highly intrusive. Besides, those exams are not very suitable for young children, not only because the trauma of sleeping in a hospital, away from their parents, which obviously affects the sleep quality, but also because children sleep patterns are

substantially different from adult sleep patterns, which are more broadly covered in the literature.

Nocturnal video/snore recording are important results to PSG, but are not enough.

Other studies have evaluated the pulse oximetry in the evaluation of OSAS. There are two advantages of nocturnal oximetry use compared with PSG: cost and convenience. Brouillette et al (14) performed oximetry in a group from the Montreal Children's Hospital with suspected OSAS and compared it with simultaneous full PSG. The study conclusions indicated that oximetry was useful when results were positives. In the other words, comparing nocturnal oximetry with PSG, they found positive predictive values (PPV) of 97% and negative predictive values (NPV) of 47%. Children with negative oximetry results indicate that additional study, such as PSG, is necessary for definitive diagnosis. Normally, these negative results were found in children with medical problems, such asthma, cardiac complications or obesity.

The negative implications of any respiratory sleep disorder, particularly OSAS, in the quality of life of children demonstrate the importance of their diagnosis for further treatment.

Besides PSG, there are other diagnosis methods as mentioned in the beginning of this section (2.3). Although they do not provide as complete information as the PSG in laboratory, they can be very useful as a means of screening or when in situations where it is not possible to perform the PSG.

Currently, new methods - less invasive than the PSG - and preferably using a small number of signals that facilitate and help the diagnosis of OSAS, have emerged and are the subject of several studies and investigations.

This project, based in the studies published, intends to explore the sensitivity of a classification system for the different types of apneas, as aim to support the OSAS diagnosis.

3. TECHNICAL REVIEW

More and more studies in this century, demonstrated the most importance of sleep apnea diagnose in children. This chapter analyzes some types of sensors/methods in the market.

3.1 Literature Review

The classification of the recording technology used for the diagnosis of sleep-related breathing disorders, proposed for the *American Sleep Disorders Association* (15) about different monitors used in diagnostic for sleep apnea, can be represented in:

Table 3 – Types of sleep-study monitoring devices

Type 1	• Minimum 8 channels • Is considered the gold standard in-laboratory	EEG, EOG, ECG, EMG, airflow, respiratory effort, SpO2, body position
Type 2	• Minimum 7 channels	EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort and SpO_2
Type 3	• Minimum 4 channels	Airflow and two channels of respiratory movement. Usually no EEG is monitored. SpO_2 or airflow.
Type 4	• 1 or 2 channels	

The Polysomnography (PSG), the gold standard technology for diagnosing OSAS, is defined a Type 1 and the portable monitors are classified for three types (2, 3 and 4).

Increased investigation in sleep studies, simultaneously with PSG limitations, triggered the search of alternative methods of diagnosis, not only simpler and economic but also performable in a family environment.

Interest and development of these alternative methods have been growing, mainly at the portable monitoring level. Recently, new devices have been developed capable of monitoring the sleep, the nocturnal breathing and oxygenation of the blood in patients at home. Likewise, more sophisticated equipment was also developed in order to enable the study (at home) equivalent to PSG in the laboratory.

The alternative methods, although they are not a complete means of diagnosis, may be useful in screening or in preliminary studies, in cases where there are not necessary resources to carry out the PSG.

A more attractive alternative to in laboratory testing is to evaluate children in their homes. In your ambience, the sleep is natural and feelings better.

The recent literature review, it is analysed the different portal devices in market and some applications in sleep centers. The number of signal monitored (channels) and the conclusions of sensibility/specificity tests are very important for the study validates and sleep disorders diagnosis.

***Table 4 – SleepScout™*(16)**

SleepScout™
(CleveMed)

7 channels

- Pulse oximetry
- Airflow
- Snore
- Thoracic and Abdominal Effort
- Body Position
- Thermistor or Blood pressure

2 additional channels

- ECG/EMG or EEG/ECG

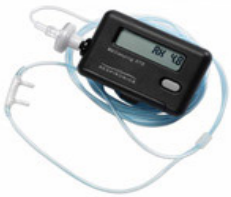
***Table 5 – PSG@Home™*(17) (18)**

PSG@Home™
(CleveMed)

- System upgrade to any system of PSG CleveMed, suitable for home monitoring
- System with 14 channels (EEG, EOG, chest and abdominal respiration effort, pulse oximetry, airflow, snore, body position, ECG, EMG)

***Table 6 - RUSleeping™ RTS Screener for Apneic Events*(19)**

RU*Sleeping*™ RTS Screener for Apneic Events
(Respironics)



1 channel

- Nasal cannula

***Table 7 – Stardust®*(20)**

***Stardust®* - Sleep Recorder**

5 channels

- Airflow sensor
- Effort sensor
- Oximeter
- Body position monitor
- Patient event monitor

***Table 8 - SleepStrip®*(21)**

SleepStrip® Disposable Sleep Apnea Sensor

1 channel

- Oral and nasal airflow sensor

***Table 9 – LifeScreen Apnea®* (22)**

LifeScreen Apnea®
Holter Oximetry Apnoea Assessment®

2 channels

- 3 sensors of ECG
- Oximeter

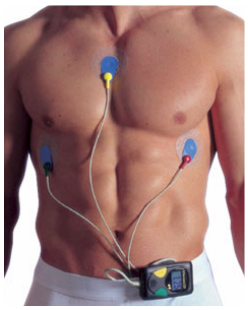


***Table 10 - ApneaLink™*(23)**

ApneaLink™
(ResMed)

3 channels

- Oximeter
- Airflow
- Snore

***Table 11 – NovaSom QSG™* (24)(25)**

NovaSom QSG™ 5 channels - Oximeter (finger oximeter) - Airflow - Respiration effort	

***Table 12 - Embletta™*(26)(27)**

Embletta™ 7 channels - Nasal cannula - Oral thermistor - Abdominal and chest movement - Oximeter - Body position and activity sensor - Snore	

The new technologies present in tables 4-12(for patent information, please consult Appendix I) do not replace the PSG. There is a need to establish development priorities for home screening and simple-diagnosis. It is not necessary to displace children (or adults) to a laboratory for studies of sleep, often distant from home. Is important refer that the nine devices mentioned in this chapter (tables) similar to the Sleep@Home. They were chosen because they provide portable monitoring in patients' home of, reducing the number of children submitted to a study in the sleep laboratory at a clinic or a hospital.

A report by the *American Sleep Disorders Association* and *American Thoracic Society,* demonstrated that home tests for the screening of OSAS should be a Type 3 or lower (Type 2) (15). Type 4 (1 or 2 channels) has a good performance, but was given a low evidence rating.

The several conclusions of the different products studies indicate that only the clinical use of Type 2 portable monitors in either attended or unattended settings and some Type 3 monitors seemed to be potentially acceptable in the attended laboratory setting, but with some limitations.

These conclusions has also provided us (team project) will and strength to do better and to develop a simple, portable and efficient device.

3.2 Signals used for detecting events

This research assessed the performance and high-fidelity of signal monitoring by the different systems in detecting OSAS symptoms.

To start it is very important to distinguish between the terms “signal” and “channel”. In a system of diagnosis of sleep disorders, there are different channels that collect the various signals which will then be analysed. It is possible that a channel collects more than one signal. For example, an oximeter, usually detects the heart rate, the saturation of oxygen, among others, but it is a single channel.

One of the objectives of this project was to understand what are the most important signals for a diagnosis similar to the PSG, so as to reduce the costs and the other less attractive aspects of PSG, but always ensuring a proper screening of OSAS.

3.2.1 Oximeter

In sleep medicine, the pulse oximetry has as important role in the interpretation of PSG, but has lost status as the sole parameter for diagnosis of respiratory sleep disorders. In recent years, it has been discussed about the effectiveness of digital nocturnal oximetry as a tool for screening, to identify patients with respiratory sleep disorders. The need to reduce the cost for diagnostic procedures in sleep disorders has increased, while technological advances have developed portable pulse oximeter , reliable and of low cost (28).

Oximetry is a part of PSG and it is used to measure the **oxygen dessaturation** (SpO_2) and rate. It has been an essential tool in sleep medicine as it detects the rapid fluctuations in arterial oxygen saturation during sleep, which is a characteristic of sleep apnea patients. Thus it allows the early detection of respiratory disorders.

In the majority of oximeters it is possible to detect the **heart rate** (number of heart beats per unit of time).

Through pulse oximetry systems based on absorption of light by the blood on fingertip (same systems that measure oxygen saturation in the blood), we are able to get on a non-invasive **plethysmographic signal**. This signal represents the volume of arterial blood continuously (peripheral arterial tone - PAT) and presents a cyclical pattern due to the sync with the heart rate, to measure the pulse. Volume of arterial blood depends on blood pressure and also the degree of contractility of the arteries. Thus, the volume of blood to light absorption by the system of oximetry reflects on the recording of the plethysmographic signal (29).

The contraction of the muscles and the relaxing the arteries walls are controlled, among other mechanisms, by the autonomous nervous system that determines muscle tone. Depending mainly on the action of the sympathetic nervous

system or the parasympathetic nervous system the arteries will contract (vasoconstriction) or dilate (vasodilatation) respectively (30).

An event of apnea is associated with increased activity of the sympathetic nervous system. This activity, leading to vasoconstriction, is reflected in the plethysmographic signal as a reduction of the fluctuations size whose detection may be useful in identifying apneas.

Many PSG systems and some investigators use this signal for detecting apneas and hypopneas.

The study of the recognition of apnea events in children were based only on a plethysmographic signal as cited in the work of Gil E. et al. (31)(32). These authors have developed a method where the apnea events to detect are those longer than 3 seconds in which the magnitude of the signal is less than 33% of the normal range, referring to the previous cycles to the apnea event.

The method uses an algorithm that compares the decision to plethysmographic signal modified with a limit value. The method was applied to simulated signals and real signals and, in the both cases, the results suggest that the physiological plethysmographic signal contains information that may be useful in various fields of medicine, including on studies of sleep disorders since it provides information on the activity of the sympathetic nervous system (33).

Another author (Schnall et al. (34)) explains in his article that pulsatile finger blood flow patterns can be evidently diagnostic of OSAS and other settings of sleep disorders breathing.

The additional value of this type of diagnosis is the rapid efficiency and, in many cases, quickly followed by treatment Figure 2. In other, words, children do not have to go to long waiting queues for a test of PSG, in the few laboratories adapted to pediatric situations.

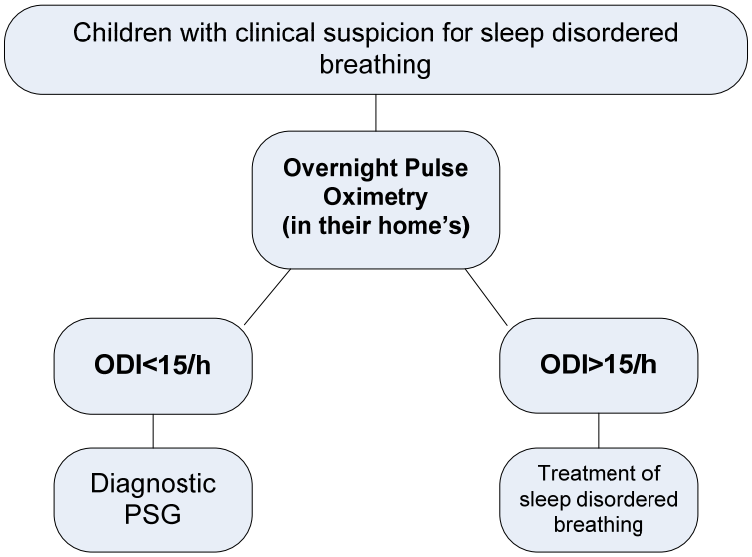


Figure 2 – Diagram of overnight pulse oximetry to screen for sleep disordered.
ODI: Oxygen Dessaturation Index (oxygen dessaturation per hour of sleep) – Adapted (35)

3.2.2 Respiratory parameters

The respiratory measures can be classified as direct, such as pneumotachograph to evaluate direct airflow; or indirect measures, using respiratory effort to estimate changes in airflow in the upper airways.

- ***Direct measures***

The standard method for quantifying and identifying airflow during sleep is the **pneumotachograph**, but it is not usual in detection of apnea of sleep, because it is uncomfortable and can disrupt sleep.(36)

The **nasal cannula** is connected to a specific pressure transducer that is a piezoelectric sensor (crystal). This crystal estimates the changes in air pressure, into the nostrils. During the inspiration, the air pressure is negative regarding atmospheric pressure and during expiration the pressure is positive, usually know as the fluctuations of nasal pressure.(37)

The extent of these changes in pressure can be used as qualitative and quantitative estimate of airflow in the upper airways.

The evaluation of the shape of the curve or airflow, usually sinusoidal, has also been used in assessing breathing.

It is a more sensitive and specific technique than a thermistor record of hypopnea awakenings and related increased in respiratory effort. The nasal cannula is not invasive, tolerated without difficulties and has been regarded as the best technology available for non-invasive monitoring of breathing during sleep, does not require calibrations for use.

The **thermistors** and **thermocouple** transducers are sensitive to changes in air temperature. The electrical resistance of the resistor changes in accordance to changes in air temperature during the respiratory cycle. The higher temperature of breath warms the sensor increasing the resistance and the flow inspiration cools the sensor, causing a decrease in resistance in thermistor or voltage in the thermocouple.

These sensors do not produce a quantitative and real measure of the volume of air that enters or outs the nostrils and mouth, but only an indirect and qualitative measure of the airflow, or whether there is respiration (airflow).

The waveform signal is generated by the nasal cannula detecting the fluctuations in pressure caused by inspiration and expiration. These fluctuations (inspiratory and expiratory) give different signals recorded from a thermocouple or thermistor. These signals are proportional to the flow. There is a theoretical possibility that applies a linearization of the pressure signal from taking its square root, but this has little influence in the shape of signal in most cases.

These sensors are susceptible to detection of obstructive sleep apnea and central sleep apnea but, unlike the nasal cannula, they are not sensitive enough to detect hypopnea as. This technique was widely used in the past due to lack of better techniques. Today, it has been replaced in most clinical laboratories and research by nasal cannula. (36)

- ***Indirect measures***

There are several methods of registering the respiratory effort during sleep such as the record the movements of expansion-retraction of the chest and abdomen, the diaphragmatic muscular activity or variations in esophageal swing pressure.

Measures of respiratory effort are very useful in assessing breathing, especially during periods of increased resistance of the upper airways, where the respiratory effort increases to continue adequate ventilation.

The measure of respiratory effort is essential to differentiate the central sleep apnea and obstructive sleep apnea. In central events there will not be respiratory effort, while during the obstructive event the respiration effort remains.

In some cases, the patients have signals and symptoms that propose obstruction of the upper airway, but the PSG made in sleep laboratory does not present many apneas and hypopneas to give a sleep apnea diagnosis . The esophageal pressure swing or just, **esophageal pressure** (PES) is the monitoring gold standard for determining the quantitative and qualitative respiratory effort and repetitive, gradual increases in negative intrathoracic pressures, during sleep.(38)

This process uses a flexible catheter and a pressure transducer of piezoelectric crystal. The catheter is flexible and of small diameter, with an inflatable balloon at the bottom, known as esophageal balloon. The balloon, inflated with 1 ml of the air, transmits the intrathoracic pressure using the pressure transducer. The quantitative record of esophageal pressure reflects the changes in effort, during the respiratory cycle.

The highest inspiration effort will be the most negative intrathoracic pressure. The balloon is extremely useful in diagnosis of the upper airway resistance syndrome (UARS).(39)

The use of a esophageal balloon requires trained technicians in its use. The catheter is inserted by the nostril after local anesthesia of the nasopharynge and placed in the esophagus. It should be positioned in the center third or bottom of the esophagus, scouting for suitable variations of intrathoracic pressure. However, some patients do not tolerate well the intra-esophageal catheter. In children, this type of surgery is unusual.

Despite increased interest in UARS and the diagnosing of PES, little literature has been published about this subject. (40)

Thoracoabdominal movements are an indirect flow measurement. (41)

Respiratory effort bands consist of a transducer that converts the kinetic energy into electrical potential. The goal of the system (transducer and band) is to register the change of thoracic and abdominal volume and generate an electrical signal transmitted to the polygraph. Therefore, the strapping does not records physical forces but the change in the expansion of chest and abdomen.

The rationale is based on the study of the amplitude of the swing movements of the thoracic and the abdominal compartments, and on the comparison of the synchrony between both movements. (42) In case of an obstructive apnea, there is a decrease and an asynchrony of the bands, resulting in a reduction in the amplitude of the sum of the signal from abdominal and thoracic bands. By contrast, during a central apnea, the thoracic and the abdominal compartments move, with which the signs from both bands and their sum are nil.

In Figure 3, shows a mixed apnea in OSAS children.(42) It is possible to analyze the central apnea (in first part) with stoppage of thoracic and abdominal movements and the obstructive apnea with “out-of-phase” thoracic and abdominal movements. The sum of the band movements were approximately zero.

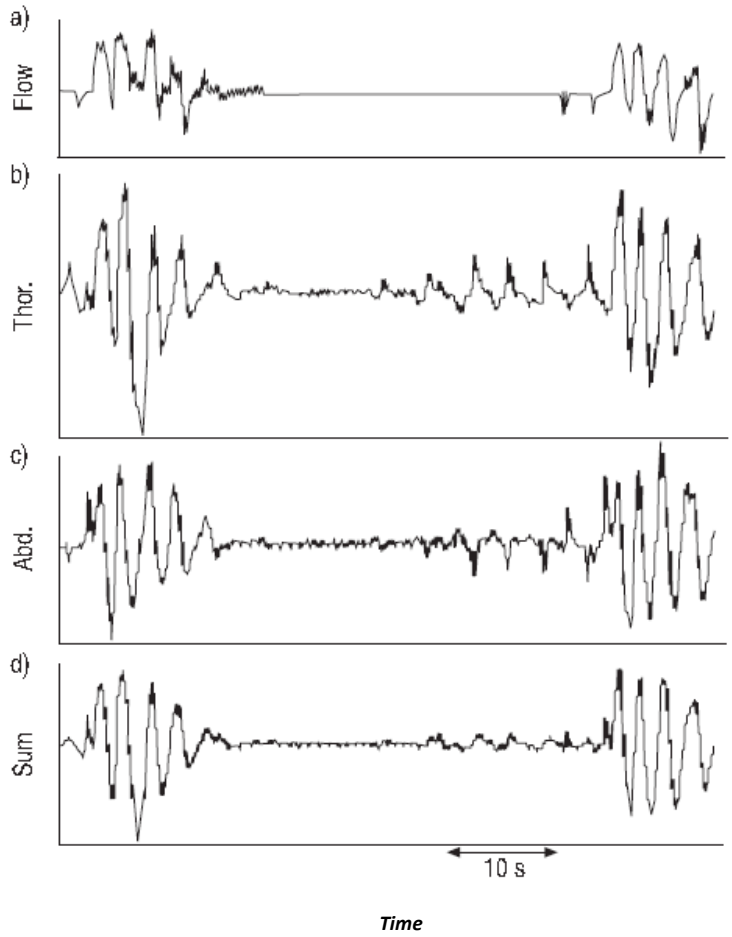


Figure 3 – The mixed apnea in children - *Adapted* (42).
a) Flow – estimated with nasal pressure recording for the PSG; b) Thoracic (Thor.) and abdominal (Abd.) were the signs provided by the respiratory bands movements; c) Sum is the adding of the signs recording by the thoracic and the abdominal bands.

During the PSG, the movement thoracoabdominal paradoxical is frequently found which means a possible obstructive apnea. Under normal conditions, the circumference of the chest during inspiration increases and decreases during expiration. By contrast, abdominal circumference increases during expiration and decreases during inspiration. In obstructive sleep apnea, in some cases, the chest circumference may decrease during inspiration and increase during expiration. This is called a paradoxical breathing and can also happen with no obstructive sleep apnea. (43)

The operation of the transducer can be a silicon tube filled with a liquid substance as conductor, sometimes mercury or a solution whose electrical resistance

varies with the length of the tube filled. The tube is inserted into an elastic strap that accommodated is comfortable around the chest (at the level of armpits) and another band is place around the abdomen just above the iliac crest of the patient.

The belts are simple to use, low cost and serve as a qualitative measure, but not quantitative, of respiratory effort. In very obese patients, the usefulness of these belts is more restricted, mainly by the difficulty of keeping them properly positioned during the examination.

3.2.3 Snore

The snoring is the most common form of manifestation of respiratory sleep disorders, and it is expected to affect 3 – 12% of children. (44)

The snoring attended by respiratory pauses or sudden inspirations can be a symptom of OSAS, UARS (Upper Airway Resistance Syndrome) or indicate a possible trend for these syndromes. Although the majority of children affected by respiratory sleep disorders snore, this condition is not an indicator of the presence of UARS or OSAS. Because of this duality of snoring, the screening of a possible existence of a more serious disturbance is necessary. The American Academy of Pediatrics recommends that all children who snores should be evaluated to discriminate between benign resonate and resonate as pathological symptom. (Figure 4)

Despite the fact that snoring is the most common symptom of OSAS, it is intensity, is not related to the severity of respiratory sleep related disorders.

Many authors consider the respiratory sleep disorders as a continuous spectrum of disorders in which an individual can progress or regress. (45) The degree of severity of an airway obstruction goes from mild obstruction, causing the snoring, to total obstruction, which results in as episode of apnea.

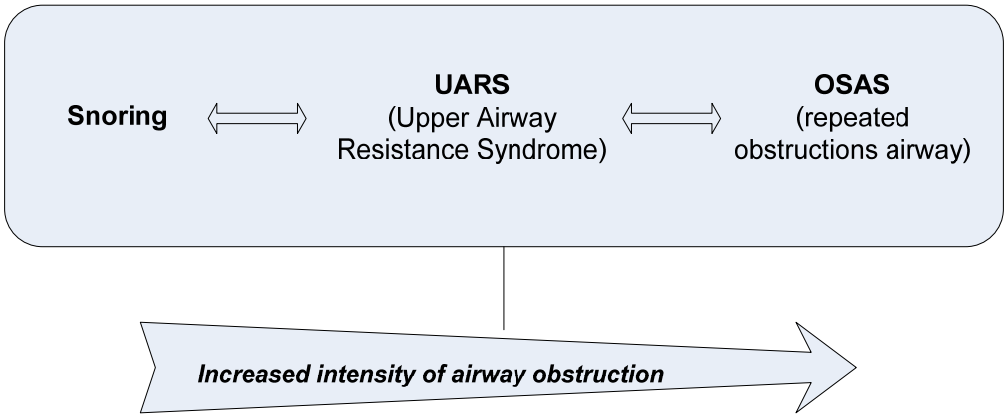


Figure 4 – Respiratory disorders of sleep and degree of severity of airway obstruction. *Adapted* (46)

Although the degree of severity of snoring should be unrelated to the upper airway obstruction severity, this signal when analyzed together with other channel (for example, video signal) may become important to identify the respiratory events observed in the oximeter, video, thoracoabdominal bands or elsewhere. (47) (48)

3.2.4 Body Position (and activity sensor)

The sensors of body position are usually fixed to the children's chest which generates a signal different for each position of the body. The monitoring of position becomes important in the diagnosis and treatment of cases of patients exclusively with respiratory pauses. Nonetheless, this method is also used to detect other causes or sleep disorders apart from respiratory conditions.

Cartwright (49) proves in his investigation that in adults there is a significance decrease in OSAS events, while the supine position[1] is not advisable. In

[1] *The supine position is a position of the body, with lying down the face up. In contrast, the face down, there is the prone position.*

contrast, this conclusion is not confirmed in children. Many authors explain in their studies, the effects of body position in breathing sleep disorders. (50) (51) These studies have reposted that sleep position does not affect the severity of OSAS in children. Inclusively American Academy of Pediatrics suggested that children breathe better when they sleep in the supine position.

Pereira et al. (52) (53) found that there is an increase in the respiratory index, when increased time is spent in the supine position in young children.

3.2.5 Electroencephalography (EEG)

The record of the EEG is the main parameter for the stages of sleep. From the electroencephalography it is possible to identify the specific graphics and recognize the different stages of sleep (stages I to IV of N-REM and REM sleep). (55)

The electrodes are placed according to the international system 10-20. For a study of sleep, are routinely used only the electrodes C3-C4 and O1-O2. The occipital electrodes serve to identify the beginning of sleep, as the high frequency components of the EEG are highly correlated to the level of consciousness of the child or adult patient.

The dominating frequency shifts to higher frequencies and lower amplitude, as the activity increases. The alpha rhythm (α, 8-12Hz) is typical of vigil and observed in regions beyond the brain. Beta (β, 16-20Hz) is a high frequency, as alpha. For lower frequency rhythms, it's necessary to focus on theta (θ, 4-8Hz) and delta (δ, 0.1-4Hz) during sleep.

The observation of breathing events during sleep with only one EEG sensor, will not detect the events of apnea or hypopnea, because the high frequency noise that occurs through REM sleep.

3.2.6 Electrooculography (EOG)

The EOG is a recording of the movement of the eyes, (56) that occur during REM sleep and the slow eye movements that occur during the transition vigil-sleep.

This is a channel, connected to a system of PSG that registers the signal and identify rapid eye movement sleep stage. An electrode is placed about 1 cm below the horizontal plane and slightly sideways, while the other is placed about 1 cm above and also slightly sideways.

This provision allows the identification of horizontal, vertical and oblique eye movements.

3.2.7 Electrocardiogram (ECG)

The ECG serves primarily to detect the frequency and cardiac arrhythmias and, contrary to heart disease diagnosis, does no require any other signal such as morphology. It needs only to demonstrate the QRS complex. (57)

3.2.8 Electromyography (EMG)

The muscle atonia[2] is one of the most characteristic features of REM sleep. PSG and the record of EMG is as criteria for REM sleep recognition and for recognition of awakenings. The electrodes are placed on the skin over the muscle tissue. (58)

[2] *The muscle atonia is a diminution of the skeletal muscle tone marked by a diminished resistance to passive stretching (4)*

Other EMG channels can be used in certain sleep disorders, such as anterior tibial muscle in the previous suspicion of periodic movements of the members and other sleep disorders.

3.3 Importance of fewer channels

As mentioned before, many OSAS patients currently do not have access to a laboratory with PSG. This urgent matter is acknowledged and there is an increasing interest in other approaches to diagnosis, portable monitoring, that have been proposed as an alternative to PSG in the diagnostic assessment of patients with suspected sleep apnea. (59)

Portable monitoring encompasses a wide range of devices that can record as many signals as does attended PSG or only one signal, such as with oximetry. In this project there were three types of portable monitoring investigated:

- Type 2 – comprehensive portable PSG.
- Type 3 – modified portable sleep-apnea testing.
- Type 4 – continuous single or dual bioparameter recording.

Based on the proposal of the American Sleep Disorders Association, see chapter 3.1, type 3 and 4 devices cannot score sleep and, therefore, do not meet some current medical diagnosis.

Usually, EEG, ECG and EMG signals are not recorded by portable monitoring, because they are very complex, require more cables and are most disturbing for children. For this reason, it was decided that the system Sleep@Home would not present any of these signs. But it is important to note, that signals are relevant to the detection of sleep. For example, only through the EEG it can be detected if the patient (child) is sleeping or awake, but for these situations we propose

another type of monitoring, video camera, which allows the detecting of the entire exam and where it is possible to identify some signs of how the child is sleeping.

Developing validated portable monitoring devices is urgently needed.

4. SLEEP@HOME – PROJECT DEVELOPMENT

In this chapter are arguing the choices and decisions based on revision of current literature and the knowledge of other team: students, doctors and sleep technicians.

4.1 Sleep@Home Analysis

Sleep@Home is a result of work done below final project in Biomedical Engineering, beginning in 2006/2007, under a work in various entities, the University of Coimbra, Pediatric Hospital of Coimbra and ISA.

During this period, a prototype A was developed in order to be able to validate the system, having been tested in a hospital environment and outwork. Following the tests, the results were positive and interesting. The hardware and the software have shown good performance, but it is important continue testing the algorithms and the alarms (several statistics results and delta index).

In the end, the mains goals have been met and it was possible to establish a good synchronization of the various components of the system, detect alarms and visualization.

The main objective this year was the certification and validation of Sleep@Home – Prototype B. This validation will be achieved through a fair number of **clinical trials** and **improved level of hardware**, by the *American Sleep Disorders Association*.

As it has been mentioned, this project was developed by a team composed by two elements during a year. The student Ana Sofia Pardalejo was responsible for the analysis and selection of the hardware components for the best results and increased clinical validity. The other student, Rafaela Inácio developed a plan of clinical tests for validation of the system; and its graphical interface was developed by the ISA team. Tests were conducted at the Hospital Centre of Coimbra – Pediatric Hospital (tests in children) and General Hospital (tests in adolescents and adults).

4.2 System Architecture

In **September of 2007**, the prototype A had a basic architecture. At this stage, the system was controlled (Start/Finish) by an interface on a laptop to begin the exam and again to conclude. The oximeter and video camera connected to the video server and the data packets - text files (.txt) - for oximeter and JPEG images format are stored on the video server, for further analysis and consult. (Figure 5)

After an analysis of the system architecture (Prototype A), it was concluded that it was necessary to integrate more components so as to make the Sleep@Home more credible and consistent, thus achieving the minimum requirements for a medical device Type 3 (Airflow and two channels of respiratory movement. Usually no EEG is monitored - *Table 1*). During this year, dedicated entirely to the project, several literary sources and other medical products within the same area of Sleep@Home were searched to analyze the strengths and weaknesses for each proposal. The conclusions aimed for a more comfortable and more complete possible for OSAS screening. (Figure 6)

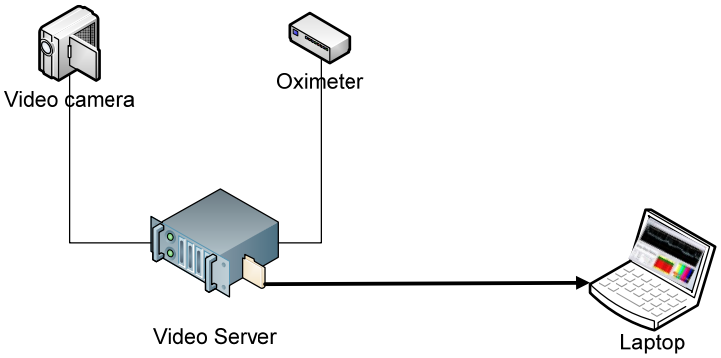


Figure 5 – Architecture of Prototype A

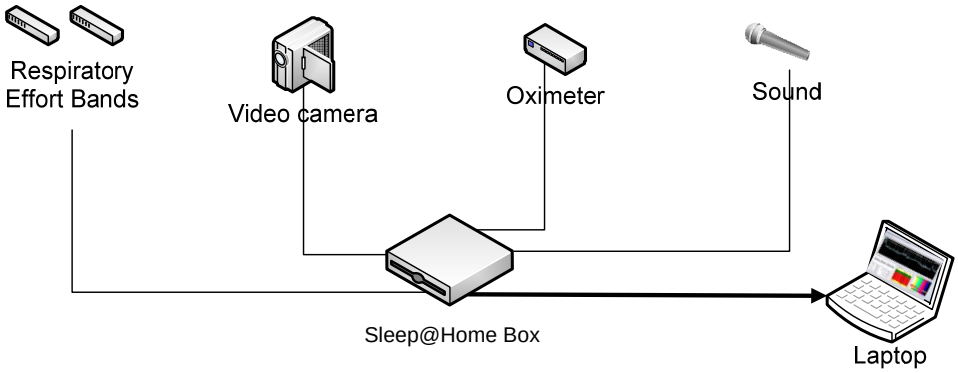


Figure 6 – Architecture of Prototype B

4.2.1 System architecture in modules

The Sleep@Home, as a whole, will have four modules (Figure 7):

- **Acquisition Module** – Will be monitoring the biomedical signals, image and sound; this part of system will be work on the patient's home.
- **Transmission Module** – It makes the connection between the module of acquisition and the Database. The data acquired by the first, when the monitoring is completed, will be sent to the hospital

center via ADSL or UMTS/HSDPA, as available. In the inability to use these means, the equipment will be returned and the data transfer will be made locally in Healthcare Unit. This module contains data compression and security processes.

- **Database** –The database will store all the data monitored during the examinations of sleep. This module will be work in a hospital, as the nest module.
- **User Interface** – An application will show users stored data in the Database. In this module operates a sub-processing module detects events that suggest sleep apnea situations. From this module, the user can still manage data in the Database .

The data of the peripherals components are concentrated and processed in the Sleep@Home Box. The transmission manages the transfer of data to ensure the safety in the process of storage in Database. From the application, technicians and doctors can observe the night examination period.

The prototype B has components that are extremely important for sleep apnea detection. The future developments will require the creation a new medical device, portable, easy to use and efficient. Therefore, in this chapter, we intend to describe the performance of each of its parts will function. All the technical requirements needed to have the prototype in conditions will be submitted in several validation tests, in clinical environment.

To describe each of the modules of the prototype B and its components, the following points are presented:

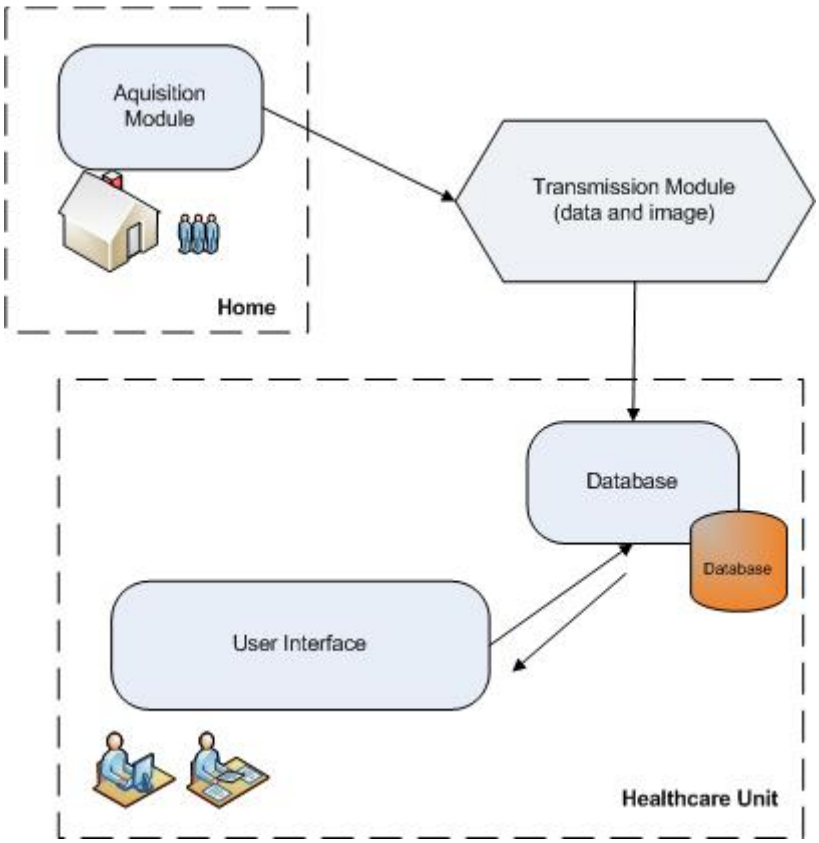


Figure 7 – Modules of the system Sleep@Home.

There are several **Acquisition Modules** (also identified as Sleep@Home Box) distributed by patients homes, where the biomedical parameters are monitored. This monitoring is done through the Box and has the capacity to acquire, store and compress all data locally monitored during the sleep period. After this period, the data is transmitted (**Transmission Module**) and stored remotely in the **Database** installed on the server network. The user has access to the data of signals monitored in the patient's home, through **Interface** with features that process the data automatically in order to detect clinical events with meaning.

▪ ACQUISITION MODULE

Oximeter

A commercially available Smiths Medical PM 31392B1 Micro Power Oximeter Board (Appendix A) was used to collect patient oxygen saturation (%SpO_2) readings for the new system. The oximeter not only monitors continuous the %SpO_2 but also the heart rate and plethysmographic measurements (important clinical signals).

To monitor the oximetry data, an oximeter and a RS232 input are necessary in the Sleep@Home Box. The oximetry routine that runs in the box was developed last year. (Figure 8)

Figure 8 - Medical PM 31392B1 Micro Power Oximeter Board (adapted)

The oximeter sends data packets at a 60Hz frequency, but in each packet and for each parameter (Figure 9) only some values are valid. As such, the routine has been improved in order to detect all valid data in a period of a one second and then it

writes to the txt file according to the template on Figure 9. Thus oximetry can be taken from the data at an equivalent rate of the oximeters used in the Paediatric Hospital.

In the case of oximeters, the Central Hospital operates with a transmission of some information each three seconds. When these exams were taking place, special caution was needed concerning this statistical analysis

YYYY-MM-DD HH:MM:SS:MMM Beep, Pleth, Bargraph, AvgSpO_2, RealSpO_2, HeartRate, Flags RedGain, IRGain

Figure 9 – Template of an oximetry text line.

Parameters (in order): Date, time, signal beep, plethysmography, mathematical average of the SpO_2 signal SpO_2 over a small window of time (, instant SpO_2, heart rate, gain of red and gain of infrared.

The option has been to maintain the same oximeter because their routine was very efficient in event detection by monitoring SpO2, plethysmography signal and heart rate.

The plethysmographic signal was not monitored last year. According to medical opinion, there is a common relation between the occurrence of the arterial vasoconstriction state and the activity of the sympathetic nervous system. This is really important since before REM sleep stage and the end of the apnea event, there is a visible state of vasoconstriction.

The algorithm of detection for this type of alarm, plethysmographic signal, requires a search of mathematical functions in literature. In case of oximetry this project, the PAT signal (the same a plethysmographic signal) of the fingertip returns this signal at a rate of 60Hz, therefore returning to the original routine of the oximeter.

Respiratory effort bands

The respiratory effort bands is the new component of prototype B It increases the performance and offers more detailed confirmation of clinical events.

The integration of this new component is based in researched articles and several medical opinions. In chapter *3.2.2 Respiratory parameters, it has* been mentioned that thoracoabdominal movements are an indirect flow measurement in which reduction of amplitude and inspiratory curve alteration can be detected.

Masa et al. (61), present that the potential advantage of thoracoabdominal bands over nasal cannula is that the registered signal by the bands is not dependent on the patient having to breathe exclusively through the nose. Besides, thoracoabdominal bands are already commonly used in PSG to evaluate whether apnea events are obstructive or central. Therefore, the thoracoabdominal bands could be used in combination with a thermistor or as a complement to other methods that can detect apneas or hypopneas, for example nasal cannula.

The bands chosen are the most commonly used in Healthcare Units. (Figure 9)

Figure 10 – Respiratory Effort Bands (Appendix B)

The connector of the belt (s) connects to the input of PSG recording system. In case of the Sleep@Home (Prototype B), it was necessary to implement a compatible circuit for the monitored signal amplifier.

The circuit was elaborated with the help of NI Multisim10® (Appendix C). This tool offers simulate simulation of the signal monitored by the bands. The main purpose of this simulation is to test the signal before the construction of the circuit in PCB, avoiding unnecessary costs if there are errors in the project. There are very PCB designers, for example, Altium® designer, OrCAD® and others.

Airflow

In clinical practice, a thermistor is the most used method to detect the nasal and oral flow in conventional PSG.

However, the thermistors have long time responses , the airflow can compromise the PSG leading to several false negative and the temperature of the exhaled gas is relatively unaffected by changes in the volume exhaled.

Different methods have tried to identify the respiratory effort-related arousal, without esophageal pressure measurement:

- Alteration in the flow curve obtained by nasal cannula;
- Alteration in the flow curve obtained by continuous positive airway pressure (CPAP);
- Pulse transit time;
- Sum from inductance plethysmography.

After analysis of various products on the market, it was possible to verify that practically all have detection by the airflow.

This interpretation, with reference to the classification of monitoring systems presented by the American Sleep Disorders Association, leads to the following

conclusion: the presence of a sensor for monitoring the oral and nasal flow is important for the medical community, being a factor of greater accuracy and of diagnosis.

Although this component is not to be a part of the prototype B, an acquisition would be of greater value, because it could enhance the product Sleep@Home. In future projects, this is an issue to consider. In project future, been attention for this.

Video camera

In prototype A, the video camera was analogue and the signal was stored in JPEG images format. Choice of this equipment was based on the video surveillance system Look@It (a product by ISA).

To ensure that it's possible to get images in any light conditions; this video camera can get images with good resolution without luminosity, due to its 16 infrared leds, and reaches 30 meters (approximately).

Currently, in the prototype B, it was suggested an implementation of a webcam, because it has a good performance, it's less expensive than one night surveillance camera, as used in the system Look@It and also provides a digital format of the image that will be compatible with a box already implemented; however, this suggestion was discarded because webcam software in the market is constantly updating and cannot be guaranteed the same routine in several studies of sleep, because the Sleep@Home may be obsolete.

The video camera to implement in the prototype can be IP or analogue. Everything will depend on the costs and capital gains with each. The next chapter it will introduce the expenses for components of new prototype.

Sound

The audio signal has low precision therefore not a good method to guarantee that the child has not OSAS, but the sound, synchronized with video, would be very important to help the clinical staff to recognize breathing episodes.

Several authors, including physicians and sleep studies technicians refer sleep as an important diagnosis when associated to another channel, such as a video camera. Therefore, it was considered very important to integrate a snoring microphone (Detects snoring noise during sleep recordings), which is applied to the child's neck. There are also snoring sensors (Small lightweight detects snoring vibrations during diagnostic testing. The sensor is specifically designed to pick up the frequency range of snoring vibrations), available in the market. This type of sensor is widely used in case studies whether with children or adults to detect snores, asphyxia or respiratory efforts, aiding the video images.

Figure 11 – Snoring Microphone

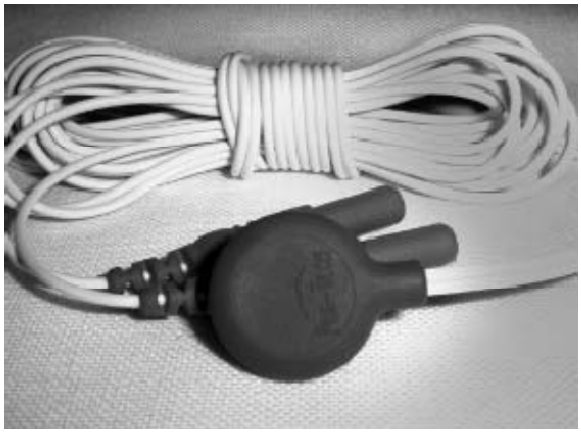


Figure 12 – Snoring Sensor

Box

The Sleep@Home box is a new concept, implemented to improve the performance of the new prototype B. However, it changes the level of programming of all components connected to the box: oximeter and video camera, which already existed in the prototype, and implementation of new routines for the bands of respiratory effort and sound.

It was a great effort to achieve the goal of making the box with small dimensions, conditions for their robust design and easy to transport, compared to the characteristics of the previous video server.

More details about the Sleep@Home are available in the next table.

Table 13 – The Sleep@Home box's main characteristics

BOX of LexSystem (54)	• **LIGHT** (Appendix D) • **NEO** (Appendix E) Both with option: - ADSL Chip: Conexant, ANSI T1.413 Issue 2, ITU-T G.992 (G.dmt) and G.992.2 (G.lite)
MOTHERBOARD of LexSystem (55)	• **CI945C** (APPENDIX F) (only in NEO, 4 –door RS232, max: 4Gb, SATA) • **SI852A** (APPENDIX G) (only 4 input analogue video, 2-door RS232, max: 1 Gb, IDE) • **CV700C** (APPENDIX H) (4-door RS232, max:1Gb, SATA)
HARD DRIVE	• HDD 160Gb 2.5'' (can be achieved, approximately 15 tests in MPEG4 (720x480 30fps) or 62 tests in JPEG (640x480 1 fps))

In box:

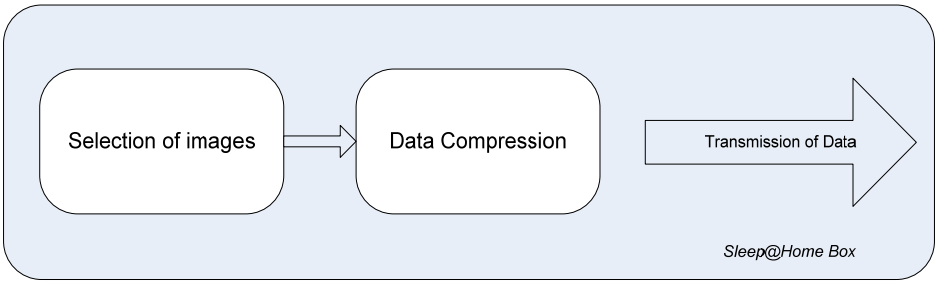


Figure 13 – Architecture logical of Sleep@Home Box

Figure 14 – Sleep@Home Box and oximeter. (Jun 2008)

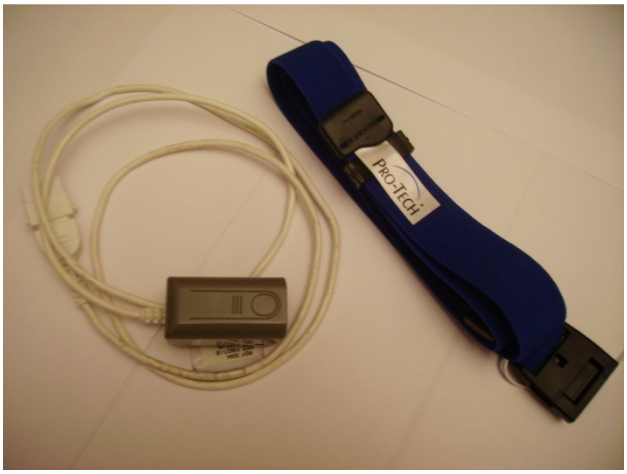


Figure 15-Components of Sleep@Home (Jun 2008)

- **Selection of images**

The objective is to only acquire images of events with clinical interest. Thus, an algorithm was created in order to record an image only in the presence of several factors:

- Low saturation detected by the oximeter (below 92% - this limit is alterable in order to trigger a detection at other percentages);
- Movement detection by the camera;
- Sound detection (snore)

- Curve changes in the respiratory flow
- Curve changes in the respiratory bands (abdominal and thoracic)

  These last two factors have not yet been integrated (as the algorithm has not yet been developed). They are a part of the future development proposal.

As long as one “alarm” from these factors occurs, the camera will start, if not started before.

- **Data Compression**

Image compression algorithms were developed, to shorten the storage space and to enable data upload via UMTS/HSPDA.

The sound is independent from the image, being compressed in mp3 format.

These are all real-time processings.

After the sleep test, there is a final compression of all data.

- **Data Transmission**

After final compression, data will be sent through ADSL, UMTS ou local network at the hospital (This procedure is still undergoing tests)

▪ TRANSMISSION MODULE

There has to be a Web Service at the hospital. This Web Service consists in a routine that assures security in the data insertion process into the database, when it’s being remotely transmitted by a http protocol. This is the only link between the

patient's home and the hospital, being a unidirectional communication (from the patient's home to the hospital).

For the remote data transmission, a communication protocol has been created between the box and the Web Service in order to assure that the images are only deleted in the box after data reception confirmation.

- **DATABASE**

The database stores the data sent by the Web Service. It stores all the patients' data as well as all users (physicians and technicians) which can include comments to the several testing and proceed the data analysis.

- **INTERFACE**

The application, developed in Visual C+ on .NET platform, has suffered several changes since the previous application developed in the 2006/2007 project. In this new application, the new components are already considered and presented.

4.3 Sleep@Home - 3 versions proposed

From the first contact with prototype A, in September of 2007, and from meetings with physicians and technicians, new ideas came up and we moved toward a prototype B.

This chapter proposes the Sleep@Home as product able to adapt itself to the various cases of suspicion of obstructive sleep apnea. According to the severity of

the symptoms presented in the clinical history (history and physical examination), the physician can choose from one of three versions:

Table 14 –Sleep@Home Versions

LIGHT VERSION	STANDARD VERSION	ADVANCED VERSION
• Oximeter: - % SpO_2 - Heart rate - PAT	• Oximeter: - % SpO_2 - Heart rate - PAT • Thermistor • Respiratory effort bands	• Oximeter: - % SpO2 - Heart rate - PAT • Thermistor • Respiratory effort bands
• Video Signal	• Video Signal • Sound	• Video Signal • Sound • Alarms • Portable screen • Pajama
Type 4	***Type 3***	***Type 3***

The ***Light version*** presents a Type 4 solution that monitors the less precise cases in sleep disorders. It's a very simple system, with the prototype A features.

The ***Standard version*** is a Type 3 solution, that assures some accuracy in the results, as the selected channels record four bio signs: $\%SpO_2$, heart rate, airflow and abdominal and thoracic respiratory effort bands.

Lastly, there is a more complete version, regarding the monitoring level to which the parents have access, called ***Advanced version***. This version contains a portable screen portable within a limited radius, in which it is possible to visually monitor the child sleeping. Various alarms are triggered when unsual events are detected or rather different sounds (from a normal night sleep), such as asphyxia or agitated awakenings.

The idea for a pajama for this version was analised and considered a desirable requisite, in case the system is wired-based, since these would go through the suture, and therefore not bothering the child during monitoring. After considering Drª Helena Estevão opinion on the matter, it was concluded that a pajama gives the advantage of not presenting to the child the visual idea of the amount of wires in contact with his body. Nevertheless, a gown would suffice as long as it can be easily dressed or undressed without moving or disconnecting any sensor, allowing the exam to continue without the child waking up.

5. CONCLUSION

5.1 Concluded Objectives

Through the course of a year's work, the Project and its objectives suffered changes as the system analysis progressed.

In an early stage, there was a period devoted to contextualize the matter in hands: apnea/OSAS, its causes and consequences, diagnosis methods and very purpose of beginning this project.

A report was created summarizing an analysis to the current literature, the products currently in the market and used in most clinical units,. This document was created with purpose of defining tasks, goals and specifications to the development of a new, more efficient and precise architecture that was less expensive and provided a state of well-being to children by not altering their sleep environment.

The choice of components has shown that the results could have been more rigorous, therefore avoiding the high rate of false negatives registered this (academic) year in the clinical tests on prototype A compared with the PSG (gold standard method. Nonetheless, the presented conclusions refer to the the research and architecture of prototype B, rather than the clinical test results of prototype A.

But the work is not over. It is important to continue testing the hardware, the interface and the algorithms.

Futurely, it is important to establish contact with several technical crews from different hospital units and clinics in order to test the Sleep@Home in their consults, allowing some feedback concerning the system: learning its limitations and qualities, what can be improved and the main assets of the system.

5.2 Future Work

5.2.1 Prototype B Conclusion

Based on prototype B current status, it is expected that it will be soon fit to be tested in a hospital environment.

Concerning the oxymeter, vídeo camera and microphone, there is currently an algorithm able to detect alarms and common episodes of apnea, nevertheless it is still necessary to develop an algorithm capable triggering alarms for all factors: Decrease of SpO_2, movement detected by the video camera, snore, analysis of obstructed airways moments through the curves that represent respiratory effort bands and, if it is implemented, the thermistor, that measures the temperature variations reading the exhaled air (higher temperature) from the inhaled air (lower temperature) or the nasal cannule measuring the decrease of nasal pressure.

As for the respiratory effort bands, it is necessary that the built circuit evolve into a PCB layout circuit.

5.2.2 Accelerometers

While elaborating the specifications document, it was established as a goal the development of accelerometers for the project, based on the use of motion sensors (body sensors) of PSG.

Abrupt movement detection is eventually associated to the sleep apnea disorder (for example, restless legs syndrome).

In the beginning of the academic year, some research was made about the creation of a small device that could be integrated in small boxes (of the size of a wristwatch) that would be attached to the wrist and the ankle. The idea was kept in

standby due to the autonomy of the system; according with Dr Helena Estevão, the child's body position during her rest period is very important, hence the study should be continued.

5.2.3 Hardware development

What makes this Project more expensive and "unsuitable" (price wise) is the need to acquire rather expensive components from specialized companies.

In fact, if the development was performed by the company, it would be possible to greatly reduce the costs when compared with the prices practiced by the companies supplying medical material/accessories.

Soon it should be made about what hardware can be developed internally: oxymeters, respiratory effort bands, microphones and what costs are involved. Maybe this way, Sleep@Home can be more viable and competitive against other systems.

5.2.1 Remote Transmission

One of the most important features of Sleep@Home will be its remote transmission of audio, video and monitorized data from the patient's home to the clinical unit, via UMTS or ADSL. This task will have to be carried through in the future.

5.2.2 Portable screen and pajama

The integration of a screen may serve as an assurement for the parents about the sleep monitoring of the children and later it can integrate an application that instruct on-screen the assembling steps. Whenever a component is malfunctioning, this information will be reported on-screen.

The screen could display real time images in order to better position the camera to the best angle. This would assure the user that everything is working properly and in the best possible conditions

5.2.3 Target population

Since the beginning, Sleep@Home was designed for children because the market doesn't have any product oriented solely for this segment of the population, disregarding often that this is a demanding and very sensitive group and might experience growth difficulties as well as lesser intellectual development due to sleep deprivation. Hence the importance of the specifications made: video camera/microphone and the screen where parents can monitor at a distance their children's sleep.

However, this narrows the market where this system can be commercialized, since that in adults the apnea syndrome and hypopnea is very serious and with irreparable health consequences. Therefore, an early and effective tracing might be the future, in many consults, this way avoiding the long queues for a PSG exam.

5.2.4 Sleep@Home screening disposable

As mentioned through the article, there are several groups of patients that can benefit from an apnea and hypopnea diagnosis in their homes. With the Sleep@Home, a tracing for obstructive sleep apnea syndrome can be done in a simple and effective way, no longer being necessary a trip to the hospital.

A great number of people feel the phobia of spending a night in an hospital environment with a countless number of wires attached to their bodies, continuously

monitoring signals. This leads to the analysis and research for portable devices and wireless technologies.

One of the groups that present an incidence percentage above average is the group of children with Down syndrome, around 20-50%, whereas the normal values for the child population are 1-3%. In the clinical history of those children, snoring, amygdale hypertrophy and agitated sleep are very common thus sleep apnea study might be pertinent. (64)(65)

Nowadays, a lot of studies are carried out in adults diagnosed with fibromyalgia (66), as this group also presents several data in their clinical history that meet the possible symptoms for a obstructive sleep apnea. Fibromyalgia is present in 0,5% of the male population and 3,4% of the female population. According to data gathered in 1995 (67), respiratory sleep disorders affect 76-90% of these patients compared with 10-30% in normal subjects.

5.3 Final Appreciation

During this past year, and during the Sleep@Home, I felt that I was contributing to an innovative and useful system that would improve the life quality of many children and their families. I realized the importance of the multidisciplinary background a biomedical engineer must have and all that can be developed in health care field.

The idea of a child spending a night in a laboratory, with countless sensors attached to her body, is certainly not a pleasant one. Thus the drive to develop a more pleasant solution avoiding runs to the laboratory, despite the fact the system does not replace the PSG.

The opportunity of integrating a business enterprise environment and the learning of several matters concerning new technologies, made me grow on a professional and personally level.

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ATTACHMENTS

APPENDIX A

Data Sheet Smiths Medical Pm 31392b1 Micro Power Oximeter Board

APPENDIX B

Data Sheet CT2™ Effort Sensor, Respironics

APPENDIX C

Circuit elaborated with the help of NI Multisim10®

APPENDIX D

Light System Case

APPENDIX E

Neo Series

APPENDIX F

CI945C Series

APPENDIX G

SI852A

APPENDIX H

CV700C Series

APPENDIX I

"Pesquisa de Patentes relacionadas com o Sleep@Home"

APPENDIX A

smiths

The Smiths Medical PM, Inc.
ADVANTAGE

- Extremely low power consumption
- Micro size
- Cost effective
- Outputs $\%SpO_2$, Pulse Rate, Signal Strength Bargraph, Plethysmogram and Status bits data
- Genuine BCI® reusable & disposable sensors available

Currently offering the lowest typical power draw in the market at 22mW typical power INCLUDING the finger sensor

MICRO POWER OXIMETER BOARD

Low power, micro size, easily integrated

The ***MICRO POWER OXIMETER BOARD*** enables easy OEM integration for fast, reliable SpO_2 and Pulse Rate measurements on any patient from neonate to adult. Serial communication at 4800 Baud provides the host system with $\%SpO_2$, Pulse Rate, Signal Strength Bargraph, Plethysmogram, and Status bits data. This Pulse Oximeter PCB consumes only 22mW of power from a single 3.3V voltage source and has a compact size of 39mm wide by 20mm deep by 5.6mm high. An assortment of compatible Oximeter sensors and patient attachments are available through Smiths Medical PM, Inc. For more information visit www.smiths-medical.com

MICRO POWER OXIMETER BOARD

SPECIFICATIONS:

SpO_2:

Range:	0-99% functional SpO_2 (1% Increments)	
Accuracy:	Adult:	±2 at 70-99% SpO_2 less than 70% is undefined
	Neonate:	+3 at 70-99% SpO_2 less than 70% is undefined
Averaging:	8 pulse beat average and instantaneous	

Pulse Rate:

Range:	30-254 BPM (1 BPM increments)
Accuracy:	±2 BPM or ±2% (whichever is greater)
Averaging:	8 second average

Signal Strength:

0-8 indicates logarithmic strength of patients pulse from 30-254 BPM

Bargraph:

0-15 segments

Plethysmogram:

0-100, auto-gained for highest resolution

Dimensions:

Length: 1.53 inches (39 mm)
Width: 0.8 inches (20 mm)
Height: 0.22 inches (5.6 mm)

Flags:

Pulse Beep
No Finger in Sensor
Sensor Unplugged
Searching for Pulse
Searching Too Long
Lost Pulse

SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE

Software Revision:

X.XX format transmitted upon reset or power up

Serial Communication Logic Levels:

CMOS 3.3V voltage levels (isolated by / from host)

Power Requirements:

6.6mA at 3.3VDC electrically isolated
(22mW typical power)

Serial Communications:

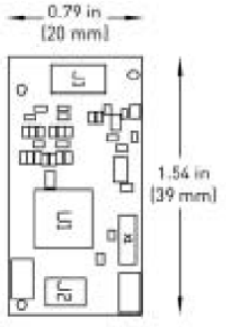
Data is transmitted from the oximeter board to the host at a rate of 60 packages per second. Data is formatted in 5 byte packets. The communication setting is 4800 Baud, One Start Bit, Eight Data Bits, No Parity, One Stop Bit.

The Micro Power Oximeter Board communicates with the host computer through a single, high-speed asynchronous serial channel at 3.3V CMOS levels. Data provided to the host includes %SpO_2 (8 pulse beat average as well as instantaneous), Pulse Rate, Signal Strength Bargraph, plethysmogram and Status Bit data. The host can synchronize the plethysmogram waveform. Using instantaneous SpO_2 values supplied by the board, the host can implement it's own averaging algorithm.

Part Number:

31392B1

Micro Power Oximeter Board
(Actual Size)



For more information, please call Smiths Medical PM, Inc., Patient Monitoring and Ventilation at 262-542-3100 or 800-558-2345 or your Smiths Medical distributor

smiths

Smiths Medical PM, Inc.
Patient Monitoring and Ventilation
N7 W22025 Johnson Drive, Waukesha, Wisconsin 53186 USA
Phone: 262-542-3100 Fax: 262-542-0718 Toll-Free: 800-558-2345
www.smiths-medical.com

APPENDIX B

PRO-TECH®

CT2™ Respiratory Effort Sensor
User Guide

Pro-tech® Services, Inc.
1338 Harbour Pointe Blvd SW
Mukilteo, WA 98275, USA
Tel: 425-322-0300 Fax: 425-322-0301
Toll Free: 000-919-0900
EMail: sales@pro-tech.com
www.pro-tech.com

EC REP Advena Ltd. Hereford HR4 9DQ UK.

CE

OM9364, Rev D

English
CT2™ Respiratory Effort Sensor User Guide

Intended Use & Features
The CT2 Piezo Respiratory Effort Belts are intended for use during sleep disorder studies to detect respiratory effort for recording onto a physiological recorder. The CT2 Piezo Respiratory Effort Belt design combines the piezo sensor element and strap into a single belt with a quick release buckle for easy patient setup and disconnect.

Warning
Sensor must be connected to an electrically isolated input. Patient injury could occur if not connected properly.

Caution Statements
This product is for diagnostic purposes only and is not to be used as an apnea monitor or in a life supporting or life sustaining situation. Federal law restricts this device to sale by or on the order of a physician.

Specifications

Operating Temperature	5°C (40°F) - 40°C (104°F)
Storage Temperature	-20°C (-4°F) - 60°C (140°F)
Operating/Storage Humidity	15 - 95% Non-condensing

Sizing the CT2
The CT2 Respiratory Effort Belts are designed to provide the maximum degree of body coverage within both the pediatric and adult populations. The two belt sizes will fit individuals within the following size ranges.

Adult Size	72 - 200cm (28 - 80 inches)
Pediatric Size	27 - 86cm (10.5 - 34 inches)

If a larger size belt is required add one or more 46cm (18inches) extension straps (sold separately, pn1592).

Sensor Installation
1. Position the belts around the patient's abdomen and thorax and snap the buckle in place as shown in figure 1.
2. The belt should be adjusted to fit snuggly (but not to the point of patient discomfort). Note: For best results patients should be lying down when tightening.
   - To tighten, tilt the buckle and pull the ***front*** strap through the buckle loop until snug. Then position the strap retainer to avoid bunching of the overflow.
   - To loosen, tilt the buckle and pull the ***back*** strap through the buckle loop until a proper fit is achieved.

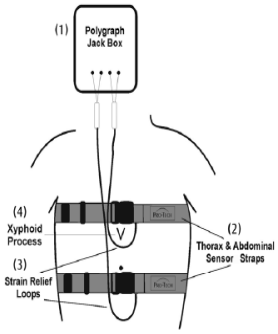


Figure 1

Instrument Connections
Plug the belt's connector(s) into the appropriate input of your recording system.
Note: When disconnecting from the recording system grasp the connector(s) firmly. Do not pull on the wire leads as this can damage the connectors. Damage caused by pulling on the wire leads is not covered under the warranty.

Instrument Settings
Sensitivity - Approximately 50-75 µV/mm. Adjustment of the sensitivity up or down is typically required. Response is dependent on such variables as sensor application and patient effort.

Low Frequency Filter/Time constant - .16 Hz or lower **/** 1 second or longer. Shorter time constants will significantly attenuate waveforms.

High Frequency Filter - 5 -15 Hz

Cleaning
The belt may be safely soaked in a warm *(Do not use hot water)* hospital grade laundry detergent for cleaning and then air dried. Avoid contact of the cleaning solution with the connector(s).

Warranty
Pro-Tech Services, Inc. warrants this product to be free of defects in materials and workmanship for a period of one year from the date of purchase. Should any product prove defective in workmanship, materials or performance during the warranty, the sole liability of Pro-Tech Services, Inc. is limited to repair or, at its option, replacement of the product with no charge for parts or labor. Under no circumstances shall Pro-Tech Services, Inc. be liable for any loss or damage, direct, consequential, or incidental, including property damage or personal injury arising from the use of, or the inability to use this product. This warranty is rendered void and Pro-Tech Services, Inc. cannot be held liable for conditions resulting from: damage, marginal performance or malfunctions caused by: misuse, abuse, neglect, improper line voltage, power fluctuations, or any adverse environmental conditions, tampering, unauthorized modifications, adjustments or repairs to the product or its accessories. This warranty is in lieu of all other warranties, expressed or implied, and is extended only to the original purchaser. Features and specifications are subject to change without notice.

Francais
CT2™ Capteur d'Effort Respiratoire Piezo Guide de l'utilisateur

Utilisation prévue & fonctions
Les ceintures d'effort respiratoire piezo CT2 sont prévues pour détecter l'effort respiratoire lors des études de troubles du sommeil, pour raccordement à un enregistreur physiologique. La ceinture d'effort respiratoire piezo CT2 combine l'élément capteur piezo et sa bande de fixation dans une ceinture simple équipée d'une boucle à ouverture rapide facilitant le branchement et le débranchement.

Avertissement
Les capteurs doivent être raccordés à une alimentation élec-triquement isolée. Risque de blessure du patient en cas de branchement incorrect.

Attention
Ce produit est destiné à un usage strictement diagnostique. Il ne convient nullement de l'utiliser à des fins de monitorage d'apnée, ou de soutien ou entretien de la vie. Ce produit contient du latex naturel qui peut causer des réactions allergiques. La législation fédérale des États-Unis limite la vente de ce dispositif à un médecin ou à sa prescription.

Caractéristiques

Température d'exploitation	5°C (40°F) - 40°C (104°F)
Température de stockage	-20°C (-4°F) - 60°C (140°F)
Taux d'humidité d'exploitation/stockage	15 - 95% sans condensation

Sélection de la taille de la CT2
Les ceintures d'effort respiratoire CT2 sont conçues pour offrir une couverture optimale du corps en pédiatrie comme pour les patients adultes. Les deux tailles de ceintures sont adaptées aux individus correspondant aux tailles suivantes:

Taille adultes	72 - 200 cm (28 - 80 pouces)
Taille pédiatrie	27 - 86 cm (10,5 - 34 pouces)

Si une plus grande taille de ceinture est nécessaire, il est possible d'ajouter une ou plusieurs 46cm (18 pouces) sangles d'extension (vendues séparément, pn1592).

Installation du capteur
1. Placez les ceintures autour de l'abdomen et du thorax du patient et refermez la boucle, comme illustré à la figure 1.
2. La ceinture devra être ajustée de façon à serrer très légèrement le patient (sans causer d'inconfort). Remarque: pour une plus grande efficacité, les patients devront être couchés lors du serrage de la ceinture.
   - Pour resserrer, basculez la boucle et tirez la sangle ***avant*** à travers la boucle jusqu'à ce que la ceinture soit correctement serrée, puis mettez en place le passant de fixation de la sangle, pour maintenir en place la longueur non-utilisée.
   - Pour desserrer, basculez la boucle et tirez la sangle ***arrière*** à travers la boucle jusqu'à obtention d'un serrage adéquat.

« Voir l'illustration »
(1) Boite de connexions du polygraphe
(2) Attache du capteur de thorax/ Attache du capteur abdominal
(3) Boucles de soulagement d'effort
(4) Processus de Xyphoid

Branchement de l'instrument
Branchez les connecteurs de la ceinture dans la prise appropriée de votre système d'enregistrement.

Remarque: Attrapez fermement les connecteurs pour débrancher l'appareil du système d'enregistrement. Ne tirez pas sur les fils, sous peine d'endommager les connecteurs. Tout endommagement occasionné en tirant sur les fils ne sera pas couvert par la garantie.

Réglages du dispositif
Sensibilité – Environ 50-75 µV/mm. Il est typiquement nécessaire de régler la sensibilité vers le haut ou le bas. La réponse dépend de variables comme l'application du détecteur et l'effort du patient.

Filtre basse fréquence/ Constante de temps - .16 Hz ou moins **/** 1 seconde ou

plus. Des constantes de temps plus faibles atténuent considérablement la forme des ondes.

Filtre haute fréquence - 5 – 15 Hz

Nettoyage

La ceinture peut être immergée en toute sécurité dans un détergent hospitalier *(ne pas utiliser d'eau chaude)* pour la nettoyer, puis séchée à l'air. Évitez tout contact des connecteurs avec la solution de nettoyage.

Garantie

Pro-Tech Services, Inc. garantit ce produit contre tous vices de matériaux ou de fabrication pendant une période d'une année à compter de la date d'achat. Au cas où un vice de fabrication, matériau ou performance deviendrait apparent durant ladite période de garantie, la responsabilité de Pro-Tech Services, Inc. serait strictement limitée à la réparation ou, à son gré, au remplacement du produit sans frais de pièces ni main-d'œuvre. Pro-Tech Services, Inc. ne pourra en aucun cas être tenue responsable de pertes ou dommages, fussent-ils directs, indirects ou accessoires, y compris tous dommages matériels ou personnels imputables à l'usage, ou à l'incapacité d'usage de ce produit. La présente garantie sera réputée nulle et de nul effet et Pro-Tech ne pourra nullement être tenue responsable dans les circonstances résultant de dommages, faibles performances ou mauvais fonctionnements imputables à tous abus, modifications, reglages ou reparations du produit ou de ses accessoires. La présente garantie est offerte au lieu et place de toutes autres garanties, expresses ou tacites, et est limitée à l'acheteur original du produit. Les fonctions et caractéristiques du produit sont sujettes à modification sans préavis.

Deutsch
CT2™ Piezo-Atmungsbewegungssensor Gebrauchsanweisung

Anwendungsgebiet und Funktionsmerkmale

Die CT2 Piezo-Atemaufwandsgürtel sind zur Verwendung bei Schlafstörungsstudien vorgesehen und dienen zur Ermittlung des Atemflusses und dessen Aufzeichnung mit einem physiologischen Aufnahmegerät. Der CT2 Piezo-Atemaufwandsgürtel ist so ausgelegt, dass das Piezo-Sensorelement und der Gurt in einem Gürtel mit rasch lösbarer Schnalle kombiniert sind, was ein leichtes Anbringen und Abnehmen beim Patienten ermöglicht.

Warnhinweis

Sensor müssen an einen galvanisch isolierten Eingang angeschlossen werden. Wenn sie nicht vorschriftsmäßig angeschlossen werden, könnte dies zu Gesundheitsschäden bei Patienten führen.

Vorsicht

Dieses Produkt ist nur für Diagnosezwecke vorgesehen und darf nicht als Apnoe-Überwachungsgerät oder in einer lebenserhaltenden Situation benutzt werden. Lt. Bundesgesetz (USA) darf dieses Gerät nur von einem Arzt oder auf seine Anordnung hin verkauft werden.

Technische Daten

Betriebstemperatur	5°C (40°F) - 40°C (104°F)
Lagertemperatur	-20°C (-4°F) - 60°C (140°F)
Betriebs-/Lagerluftfeuchtigkeit	15 - 95% nicht kondensierend

Auswahl der geeigneten Größe des CT2

Die CT2 Atemaufwandsgürtel sind so ausgelegt, dass sie einen Höchstgrad an Körperabdeckung sowohl in der pädiatrischen als auch der erwachsenen Population abdecken. Die zwei Gurtelgrößen passen für Personen in den folgenden Größenbereichen:

Erwachsenengröße	72 - 200 cm (28 – 80 zoll)
Kindergröße	27 - 86 cm (10,5 – 34 zoll)

Sollte ein größerer Gürtel erforderlich sein, können ein oder mehr 46cm (18 zoll) Verlängerungsgurte hinzugenommen werden (separat erhältlich unter Bestellnummer 1592).

Sensorinstallation

1. Die Gürtel um Abdomen und Thorax des Patienten anlegen und Gürtelschnalle wie in Abb. 1 gezeigt einrasten lassen.

2. Der Gürtel sollte fest, aber nicht zu fest anliegen (nicht so fest, dass es dem Patienten unangenehm ist). Hinweis: Die besten Ergebnisse sind zu erreichen, wenn der Patient beim Anziehen des Gürtels liegt.

- Um den Gürtel fester anzuziehen, die Gürtelschnale neigen und den ***vorderen*** Gurt durch die Schnallenschleife ziehen, bis der Gürtel fest sitzt. Dann den Gurthalter so positionieren, dass sich die überschüssige Gurtlänge nicht faltet.
- Um den Gürtel zu lockern, die Gürtelschnalle neigen und den ***hinteren*** Gurt durch die Schnallenschleife ziehen, bis die gewünschte Passform erreicht ist.

„Siehe Abbildung"

(1) Polygraph Anschlußplatte
(2) Sensorband auf Brust/ Sensorband auf Bauch
(3) Entspannungsschlaufen
(4) Prozeß Xyphoid

Geräteanschlüsse

Stecken Sie den/die Anschluss/Anschlüsse des Gürtels in die entsprechende Eingangsbuchse Ihres Aufnahmesystems.

Hinweis: Wenn Sie die Verbindung mit dem Aufnahmesystem wieder lösen, fassen Sie den Anschluss bzw. die Anschlüsse fest an. Ziehen Sie nicht an den Kabeln, da dies die Anschlüsse beschädigen kann. Durch Ziehen an den Kabeln entstandene Schäden sind nicht durch die Garantie abgedeckt.

Geräteeinstellungen

Empfindlichkeit - Ca. 50-75 µV/mm. In der Regel ist eine Anpassung der Empfindlichkeit nach oben oder unten erforderlich. Die Reaktion richtet sich nach variablen wie Sensoranbringung und Atemanstrengung des Patienten.

Niederfrequenzfilter/Zeitkonstante - 10 Hz oder darunter / 1 Sekunde oder länger. Bei kürzerer Zeitkonstante kommt es zur signifikanten Schwächung der Wellenformen.

Hochfrequenzfilter - 5 - 15 Hz

Reinigung

Der Gürtel kann gefahrlos in einem warmen *(KEIN HEISSES WASSER VERWENDEN)* Krankenhaus-Reinigungsmittel eingeweicht und anschließend an der Luft getrocknet werden. Es ist zu vermeiden, dass die Reinigungslösung in Kontakt mit dem Anschluss bzw. den Anschlüssen kommt.

Garantie

Pro-Tech Services, Inc. gewährleistet für einen Zeitraum von einem Jahr ab Kaufdatum, dass dieses Gerät frei von Material- und Verarbeitungsschäden. Falls der Sensor vor Ablauf dieser Frist ausfällt, ist die Haftung von Pro-Tech Services, Inc. nach jeweils eigenem Ermessen auf die Instandsetzung oder den Ersatz des Geräts ohne Berechnung von Kosten für Ersatzteile oder Arbeitsleistung beschränkt. Pro-Tech Services, Inc. haftet unter keinen Umständen für jegliche unmittelbaren oder mittelbaren Verluste, Schäden, Folge- oder Nebenschäden, Sach- oder Personenschaden infolge der Verwendung oder der Unfähigkeit zur Verwendung dieses Geräts. Diese Garantieerklärung gilt als rechtsverbindlich, und Pro-Tech Services, Inc. kann nicht für Missbrauch, unsachgemäßen Gebrauch, Fahrlässigkeit, unzweckmäßige elektrische Spannung, Stromschwankungen, jegliche widrigen Umfeldbedingungen, Verfälschungen, unberechtigte Veränderungen, Justierungen oder Reparaturen des Gerats und seiner Zubehörteile haftbar gemacht werden. Diese Garantieerklärung ersetzt alle anderen ausdrücklichen oder stillschweigenden Garantien und kann nur vom ursprünglichen Käufer geltend gemacht werden. Änderungen der Funktionen und technischen Daten des Gerats ohne vorherige Ankündigung vorbehalten.

Italiano
CT2™ Sensore Piezo per lo Sforzo Respiratorio Guida all'Uso

Caratteristiche e uso previsto

Le cinture piezometriche per sforzi respiratori CT2 sono destinate all'impiego negli esami dei disturbi del sonno per rilevare gli atti respiratori da registrare su un registratore fisiologico. Il prodotto integra l'elemento sensore piezometrico e la cinghia in una cintura singola con fibbia a rapido disinnesto, per una facile applicazione e sconnessione sul paziente.

Avvertenza

Sensore dovono essere collegati ad un ingresso elettricamente isolato.
Il collegamento errato può causare infortuni al paziente.

Dichiarazioni cautelative

Questo prodotto va usato esclusivamente a scopo diagnostico e non come monitor per l'apnea né per l'assistenza o il supporto delle funzioni vitali. Questo prodotto contiene lattice di gomma naturale, una sostanza in grado di provocare reazioni allergiche. La legge federale (USA) limita la vendita di questo dispositivo a medici o dietro prescrizione medica.

Specifiche

Temperatura di funzionamento	5°C (40°F) - 40°C (104°F)
Temperatura di conservazione	-20°C (-4°F) - 60°C (140°F)
Tasso di umidità di funzionamento/ conservazione	15 - 95% senza condensa

Dimensioni del CT2

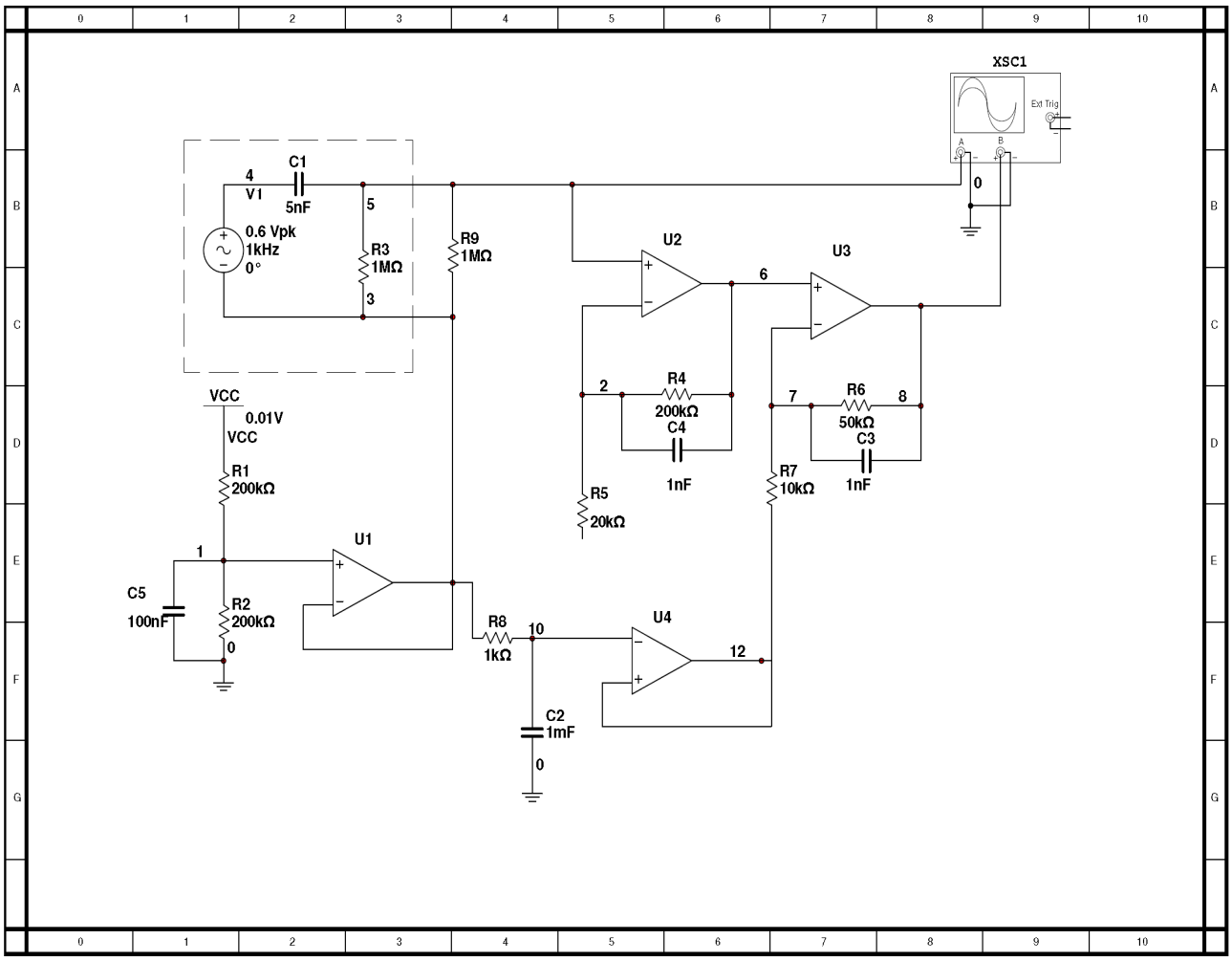
Le cinture per sforzi respiratori CT2 sono progettate per fornire il massimo grado di copertura corporea nei pazienti sia pediatrici sia adulti. La cintura è disponibile in due dimensioni adatte per le seguenti tipologie di paziente:

Adulto	72 - 200 cm (28 - 80 pollici)
Pediatrico	27 - 86 cm (10.5 - 34 pollici)

Se occorre una cintura più grande, aggiungere una o più cinghie 46cm (18pollici) di estensione (vendute separatamente, pn1592).

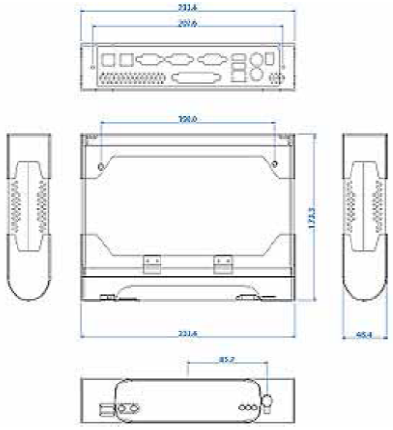
APPENDIX C

Circuit elaborated with the help of NI Multisim10®



APPENDIX D

Lex SYSTEM Embedded System.



LIGHT

Low Cost System Case
Fanless up to 800Mhz CPU Model SBC Board

Description: :

Light Case was featured with Simple, Compact, Small, Stylish.
It can be applied as Thin Client, NetWork Device, Set-Top Box, VPN, VOIP and POS system. Major Material is Aluminum for good heat solution.
Light System Case provides 1 x 2.5" Slim HDD Space.
For VIA EDEN 400/533Mhz CPU, Light System can provide Fan-Less Solution.

Technical Data :

Dimension	48.5 H x 234 W x 175 D mm
Material	Aluminum + Plastic (Out-Side Cover)
Color	Blue / Silver
Weight	1 Kgs (Include M/B)
Storage Space	2.5" HDD x 1
LED Light	Power / Network / HDD
Front Connector	2 x USB, Mic-in, Lin-out

M/B information: (Please reference M/B specification) :

SBC Board Model	Description
CV860A	1~3 Lan
CV862A	Pin Head connector
CV860B	Lan, TV-out
CV860C	4 Com Ports

CV863A	2 PCMCIA Slot / 4 Lan
CV866C	4 Com Ports, LVDS
SV823A	4-16 Video in
MV823A	2 IEEE1394 / Video in & TV-out, LVDS (option)
MV823S	1 Lan, TV-out

Option (Function inside the case):

Wireless Lan	Chip : ATMEL , USB Interface , 802.11b Standard , Driver :Win98,ME,2K,XP,Linux, 128bit WEP Encryption Support
56K Modem(ST)	Chip : ST , USB Interface , Driver : Win98,ME,2K,XP,Linux
56K Modem(CX)	Chip : Conexant , USB Interface , Driver : Win98,ME,2K,XP.
ISDN	Chip : Cologne, ISDN Standard ETSI Euro ISDN, Driver : Win98,ME,2K,XP,Linux
ADSL	Chip : Conexant , ANSI T1.413 Issue 2, ITU-T G.992(Gdmt) and G.992.2(Glite) Annex A,B . Driver : Win98,ME,2K,XP,Linux , No WinCE


CV860A


CV860B


CV860C


SV823A


MV823A


MV823S

APPENDIX E

Embedded System

NEO Series

NEO Series

NEO Chassis without top-cover

Application :
Thin Client, Network device, Set-Top Box, VPN, VOIP, DVR and POS system

M/B information: (Please refer to M/B specification)

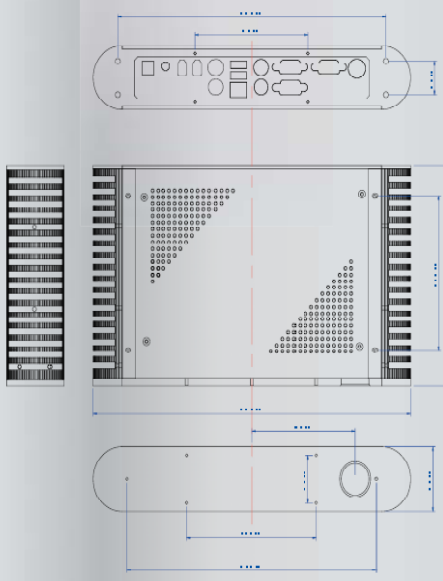
M/B Model	Description
CI945A	Core 2 Duo solution / 4 LAN / PCI / Mini PCI / PCMCIA / SATA
CV700A	3 LAN
CV700C	4 COM Ports
CV763A	2 PCMCIA Slot / 4 LAN
MV700A	Twin view/ Video in, LVDS(option)
CI852A	4 LAN
CI852C	4 COM ports / PCI 104
SI852A	4~16 Video in
MI853AW	2 IEEE1394 / PCI / DVI / TV-Out / Wide range DC-IN

Technical Data :

. Dimension	50 H x 275 W x 172 D mm
. Material	Aluminum
. Color	Black
. Weight	2 Kgs (Inc. M/B)
. Storage Space	1 x 2.5" HDD

Option (CV763A are excluded)

Wireless Lan	Chip: ATMEL , USB Interface , 802.11g Standard , Driver: Win98,ME,2K,XP,Linux, 128bit WEP Encryption Support
56K Modem(CX)	Chip: Conexant , USB Interface , Driver: Win98,ME,2K,XP,Linux
ISDN	Chip: Cologne, SDN Standard ETSI Euro ISDN, Driver: Win98,ME,2K,XP,Linux
ADSL	Chip: Conexant , ANSI T1.413 Issue 2, ITU-T G.992(G.dmt) and G.992.2(G.lite) Annex A,B Driver: Win98,ME,2K,XP,Linux



Wireless Lan

Lex SYSTEM®

APPENDIX F

Embedded Solution CI945C Series

New Product
POS application

CI945C Series

Application

POS, KIOSK, Information desk, Automation control

Features

CORE 2 DUO, SATA, LVDS, 4 COM, Mini PCI, PCI, Touch Screen, WDT/DIO

POS

Specifications

CPU type	Intel Core 2 Duo / Core Duo
. Front Side Bus	533/667 MHz
. MB Chipset	Intel 945GME/GM + ICH7M (82801GBM)
. Graphics	Intel Gen 3.5 Integrated Graphics Engine Dynamic Video Memory Technology(DVMT 3.0) Higher performance MPEG-2 decoding
. LVDS	Supports data format of 18 bits/36 bits
. Memory	DDR2 SODIMM(max. 4GB)
. IDE	Ultra ATA 100/66/33, 1x 40 pin 2.54mm, 1x44 pin 2.0mm Support Compact Flash card type II for ATA interface
. SATA	Two SATA ports with independent DMA operation supported on ports 0 and 2
. Audio	Intel High Definition Audio Specification Rev.1.0 Compliant
. LAN	2 x Realtek RLT8101E 10/ 100 Mbps or Intel 82573L 10/100/1000 Mbps Supports PCI Express™ 1.0a Intel 82573L or Realtek RLT8101E LAN Chip
. IO function	4 x RS232 Supports IrDA 1.0/ASKIR protocol Supports PS2 keyboard and mouse
. USB	9 x USB 2.0
. Touch Screen	USB interface Touch screen controller Supported 4- , 5- , 8- wire Analog Resistive touch screen. USB 1.1full speed sample rate max. (300points/s)
. DIO & WDT	Hardware digital Input & Output, 4xDI / 4xDO Hardware Watch Dog Timer, 0~255 sec programmable
. Expand interface	1 x Mini PCI for only PCI rev: 2.2 interface 1 x PCI gold finger for only PCI rev: 2.2 interface
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system -12V support (optional)
. Dimension	200 x 150 mm

. Operation Temperature: 0 ~ 60° C
. Operation Humidity: 5~95% @ 60°C, non-condensing

Available Chassis

Neo, Twister, Tino

Ordering Information

. CI945C	TBD

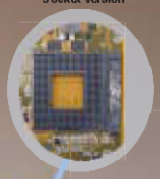
POS
KIOSK
Information desk
Automation control

Lex SYSTEM®

APPENDIX G

Embedded Solution SI852A Series DVR application

Socket Version



SI852A Series

Application

Video Surveillance for building monitoring, Access control & mobile PC.

Features

Intel P-M/C-M | Twin View | 4~16 Video-in | WDT/DIO | LVDS | TV-OUT

Specifications

. CPU type	Intel Pentium M/ Celeron M 1GHz- Dothan processor
. Front Side Bus	400/533 MHz
. MB Chipset	Intel 82852GM/ 82852GME(Socket) + ICH4
. Graphics	Integrated with Intel 82852GM/GME Shared system memory up to 64MB
. LVDS	Support data format of 18 bits/36 bits
. Memory	1 x DDR SDRAM (max. 1GB)
. IDE	Ultra ATA 100/66/33, 1x 40 pin 2.54mm, 1x44 pin 2.0mm Support Compact Flash card type II for ATA interface
. Audio	AC-Link for Audio CODEC, AC'97 2.1
. TV-Out	Analog S-Video for SDTV, for all NTSC & PAL
. LAN	1 x Realtek 10/100 Mbps (optional Realtek/Intel Gigabit) Intel 82541PI or Realtek RLT8100C/RLT8110SB LAN Chip
. IO function	1x RS232, 1x RS232/422/485 Supports IrDA 1.0/ASKIR protocol Supports PS/2 keyboard and mouse
. Video-In	4 ports with Conexant Fusion 878A video codec
. USB	6 x USB 2.0
. DIO & WDT	Hardware digital Input & Output, 8xDI / 8xDO Hardware Watch Dog Timer, 0~255 sec programmable
. Expand interface	1 x Mini PCI
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system
. Dimension	200 x 150 mm

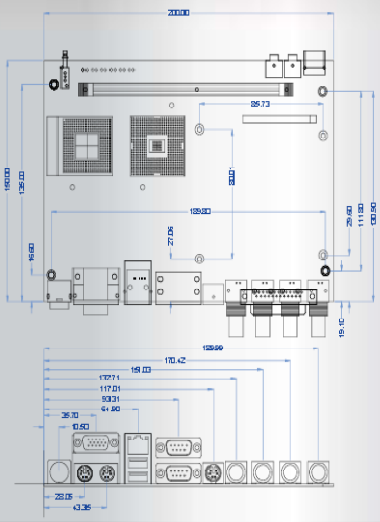
. Operation Temperature: CF Card : 0~60°C ; 2.5"HDD : 0~45°C

. Operation Humidity: 5~95 % @ 60 °C, non-condensing

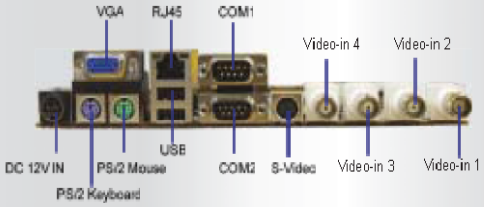
Ordering Information

. SI852A-4SR10	1 chip (Conexant BT878A) with 4 video-in channels
. SI852A-4UR10/4URXX (socket)	4 chip (Conexant BT878A) with 4 video-in channels
. SI852A-4HR10/4HRXX (socket)	4 chip (Conexant BT878A) with 16 video-in channels

Dimension



Back Panel



Testing environment

Model name : SI852A-4UR10
CPU : Intel Celeron M 1GHz
Chipset : Intel 82852GM and Intel 82801DB ICH
OS : WIN XP
Testing Program 3D Mark 2001 SE

Fanless solution with CF card

Chassis Temperature	Light	Neo	Twister	Tino
0°C	Pass	Pass	Pass	Pass
40°C	Pass	Pass	Pass	Pass
45°C	Pass	Pass	Pass	Pass
60°C	Pass	Pass	Pass	Pass

Fanless solution with 2.5" HDD

Chassis Temperature	Light	Neo	Twister	Tino
0°C	Pass	Pass	Pass	Pass
40°C	Pass	Pass	Pass	Pass
45°C	Pass	Pass	Pass	Pass

Testing environment

Model name : SI852A-4URXX
CPU : Intel Pentium M 2.13GHz
Chipset : Intel 82852GME and Intel 82801DB ICH
OS : WIN XP
Testing Program 3D Mark 2001 SE

Fanless solution with CF card

Chassis Temperature	Twister	Tino
0°C	Pass	Pass
40°C	Pass	Pass
45°C	Pass	Pass
60°C	Pass	Pass

Fanless solution with 2.5" HDD

Chassis Temperature	Twister	Tino
0°C	Pass	Pass
40°C	Pass	Pass

Lex SYSTEM

APPENDIX H

Embedded Solution CV700C Series POS application

POS

CV700C Series

Application
POS/ KIOSK/ Industrial Control Solutions

Features

VIA Eden/C7 | 4 COM | SATA

Specifications

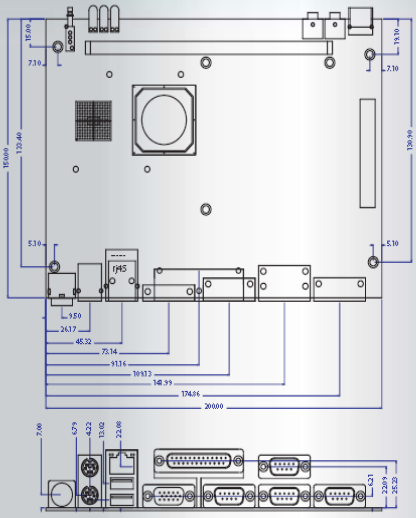
. CPU type	VIA Eden(V4)/ C7 nano BGA2 400 pin, L1/L2 128K on die
. Front Side Bus	400/533 MHz
. MB Chipset	VIA CN700 + VIA VT8237R Plus
. Graphics	Integrated with VIA CN700
	Shared system memory up to 64MB
	MPEG-2 hardware VLD
. TV-OUT (option)	NTSC(M, J) or PAL(B,D,G,H,I,M,N,Nc)
. Memory	1 x DDR II SDRAM 533/400 (max. 1GB)
. IDE	Ultra DMA-133/100/66 transfer protocols
	1x 40 pin 2.54mm, 1x44 pin 2.0mm
	Support Compact Flash card type II for ATA interface
. Audio	AC-Link for Audio CODEC, AC'97 2.1
. LAN	1 x Realtek 10/100 Mbps (optional Realtek/Intel Gigabit)
	Intel 82541PI or Realtek RLT8100C/RLT8110SB LAN Chip
. IO function	3 x RS232, 1xRS232/422/485
	Supports Hardware Monitor Controller
	Supports IrDA 1.0/ASKIR protocol
	Supports PS2 keyboard and mouse
. USB	7 x USB 2.0
. SATA	One channel connector
	SATA drive transfer rate is capable up to 150MB/s
. Expand interface	1x Mini PCI for only PCI rev: 2.2 interface
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system
. Dimension	200 x 150 mm

. Operation Temperature: 0 ~ 60 °C
. Operation Humidity: 5~95% @ 60 °C, non-condensing

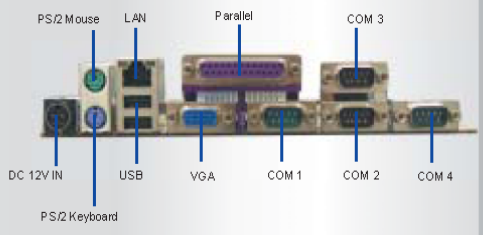
Ordering Information

. CV700C-1R50E	1 LAN, 500MHz, VIA Eden(V4) processor
. CV700C-1R10C	1 LAN, 1GHz, VIA C7 processor

Dimension



Back Panel



Testing environment

Model name : **CV700C1R10C**
CPU : VIA V4 C7 1000MHz
Chipset : VIA CN700 & VIA VT8237R PLUS
OS : WIN XP
Testing Program : 3D Mark 2001 SE

Fanless solution with CF card

Channel / Temperature	Light	Neo	Twister
0°C	Pass	Pass	Pass
25°C	Pass	Pass	Pass
40°C	Pass	Pass	Pass
60°C	FAN	Pass	Pass

Fanless solution with 2.5" HDD

Channel / Temperature	Light	Neo	Twister
0°C	Pass	Pass	Pass
25°C	Pass	Pass	Pass
40°C	FAN	Pass	Pass

Lex SYSTEM®

APPENDIX I

Pesquisa de patentes relacionadas com o Sleep@Home[3]

"Infant blood oxygen monitor and SIDS warning devices"
Nº Patente: 6047201
Data Publicação Patente: Abril 4, 2000
Descrição: O aparelho é composto por um oxímetro colocado no pé dos bebés com vista à detecção da saturação arterial de oxigénio e da frequência cardíaca. O dispositivo comunica com um pequeno monitor via rádio onde são mostradas as leituras relativas à frequência cardíaca e saturação de oxigénio. O monitor soa um alarme se estes valores forem inferiores aos predeterminados.
URL: http://www.google.com/patents?id=vUYEAAAAEBAJ&printsec=drawing&zoom=4&dq=sleep+apnea+device%2B+oximeter%2Bcamera#PPA1,M1, 22 de Agosto de 2008

"Apparatus and method for diagnosing sleep apnea"
Nº Patente: 7169110
Data Patente: Jan 30, 2007
Descrição: Aparelho para diagnosticar a apneia do sono detectando a cessação temporária da respiração durante o sono. Baseia-se nos princípios da oximetria de pulso.
URL: http://www.google.com/patents?id=PMN-AAAAEBAJ&printsec=abstract&zoom=4, 22 de Agosto de 2008

"Method for providing a remote diagnostic"
Application number: 10/951,713
Data Patente: Abril 6, 2006
Descrição: Permite a monitorização remota do doente em casa. Funciona com uma câmara e um oxímetro de pulso, no entanto pode integrar outros sinais como o ECG, pletismografia ou sensores acelerómetricos para a detecção da postura e movimento.
URL: http://www.google.com/patents?id=U5GbAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep+apnea+device%2B+oximeter%2Bcamera%2Bportable, 22 de Agosto de 2008

[3] *This work has made in collaboration with Vânia Almeida.*

"Sleep apnea screening and/or detecting apparatus and method"
Nº Patente: 5797852
Data Patente: Agosto 25, 1998
Descrição: Aparelho portátil para uso na cama do paciente. Usado para detecção de apneias com base em sons respiratórios capturados por dois microfones.
URL: http://www.google.com/patents?id=sm4mAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory#PPA15,M1, **22 de Agosto de 2008**

"Apparatus for detecting sleep apnea using electrocardiogram signals"
Nº Patente: 7025729
Data Patente: Abril 11, 2006
Descrição: Sistema permite o diagnóstico de apneia de sono com base num sinal de electrocardiograma (análise intervalos RR) e com derivação do sinal respiratório.
URL: http://www.google.com/patents?id=c3V3AAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory, 22 de Agosto de 2008

"Portable integrated physiological monitoring system"
Nº Patente: 6083156
Data Patente: Julho 4, 2000
Descrição: Com vista ao uso em ambulatório integra diversos sensores, EEC, ECG, oxímetro de pulso, estetoscópio, sensores de temperatura, sensores de fluxo respiratório. Todos os sensores estão ligados a um computador portátil.
URL: http://www.google.com/patents?id=TogDAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory, 22 de Agosto de 2008

"Ambulatory patient health monitoring techniques utilizing interactive visual communications"
Nº Patente: 5544649
Data Patente: Agosto 13, 1996
Descrição: Sistema de monitorização em casa que consiste num sistema que integra vários equipamentos e uma câmara que permite a monitorização diária. Embora mais relacionado com o AAL pode ser utilizado em aplicações específicas como o de diagnóstico de doentes com síndrome de apneia do sono.
URL: http://www.google.com/patents?id=pnkoAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory#PPA1,M1, 22 de Agosto de 2008

"Sudden infant death syndrome monitor"
Nº Patente: 5505199
Data Patente: Abril 9, 1996
Descrição: Detecção de distúrbios durante o sono em bebés. O sistema é composto por uma câmara de vídeo, sensores de movimento (sem contacto com o bebé) e um oxímetro.
URL: http://www.google.com/patents?id=mBkiAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bhome%2Bmonitoring%2Boximeter%2Bcamera#PPA1,M1, 22 de Agosto de 2008

Faculdade de Ciências e Tecnologia da Universidade de Coimbra

Departamento de Física

Sleep@Home
Remote Monitoring of Sleep Apnea Syndrome Patients

Ana Sofia Almeida Pardalejo

Dissertation presented to the University of Coimbra to complete the necessary requirements to obtain the degree of Master of Biomedical Engineering.

Coimbra, September 2008

Abstract

Obstructive sleep apnea is nowadays as respiratory disorder with serious consequences that affect people's life quality. The percentage of cases in children in pre-school age is around 1-3%.

Polissomnography (PSG) is currently the most common technique for sleep study, during an entire night , where countless vital signs are continuously monitored. The short number of pediatric hospital with this kind of testing, its complexity and elevated costs, lead to the development of new devices.

Sleep@Home is an innovative and non-invasive system, with which children can be monitored from their homes and the signal feed is remotely uploaded to a health unit where the data can consulted. The purpose of this system is not to replace the PSG but rather be a less awkward tracing device fro children. To reach this goal, it is necessary to carry out more clinical tests in order to validate the system.

Key-words (Theme): Obstructive sleep apnea syndrome, oxygen saturation, heart rate, home monitoring, diagnosis support, childhood.

Key-words (Technologies): Oximeter, video camera, respiratory effort bands, sound.

Resumo

A apneia obstrutiva do sono é nos dias de hoje um distúrbio respiratório com consequências graves que afectam a qualidade de vida das pessoas. A percentagem de casos em crianças de idade pré-escolar é de cerca de 1-3%.

A Polissonografia é actualmente a técnica mais utilizada para o estudo do sono, durante uma noite completa num hospital, em que inúmeros sinais vitais da criança estão continuamente a ser monitorizados. O reduzido número de hospitais pediátricos com este tipo de exame, a sua complexidade e custos elevados, promovem o desenvolvimento de novos dispositivos.

O Sleep@Home é um sistema inovador e não invasivo, em que as crianças podem ser monitorizadas a partir de suas casas, e a aquisição dos sinais é transmitida remotamente para a unidade de saúde onde os dados podem ser consultados. O objectivo deste sistema não é substituir a PSG, mas ser utilizado como um dispositivo de rastreio menos estranho para as crianças. Para isso é necessária a realização de mais testes clínicos a fim de validar o sistema.

Palavras-chave (Tema): Síndrome da Apneia Obstrutiva do Sono, saturação de oxigénio, frequência cardíaca, monitorização no domicílio, apoio ao diagnóstico, crianças.

Palavras-chave (Tecnologias): Oxímetro, câmara de vídeo, bandas de esforço respiratório, microfone.

Acknowledgments

This article is the result of one year's work, in a bussiness enterprise environment in which I learned much of what is presented here. Besides this, I've met awe-inspiring people with whom I spent a lot of good moments. I thank all the ISA team.

This article would never be finished if not for the support of some people, who always trusted me and to whom I must state my appreciation.

To Prof. José Basílio Simões for helping me to find this project.

To Eng. Paulo Santos, who directly supervised this work and with whom I learned many of the aspects of Hardware.

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To Prof. Miguel Morgado, for his trust in our class and the skills of each student.

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To Dr Helena Estevão and Dr José Moutinho, for helping me understand sleep apnea beyond any book or article.

To all my friends, without discriminating any of them, for their ways to incentivate me in wanting more and more, for standing by my side on the good and bad moments and for demonstrating the existent strength among all of us. Thank you.

Specially, because they are special, to my parents and brother, for all that I am today. For all they have done so I could be here and that I will always thanks. Thank you.

Last but not least, to all the friends that contributed for this work, with each word, each work hour and in each smile. That made me believe it was possible. Thank you.

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Acronyms and definitions

	Description
ADSL	Asymmetric Mobile Telecommunications System
AHI	Apnea/Hypopnea Index
BOX	Portable box that concentrates the various signals monitored during an exam
CEI	Centre of Electronics and Instrumentation
CPAP	Continuous Positive Airway Pressure
ECG	Electrocardiography
EEG	Electroencephalography
EMG	Electromyography
EOG	Electrooculography
HSDPA	High-Speed Downlink Packet Access
ISA	Intelligence Sensing Anywhere
N-REM	Non – Rapid Eye Movement
ODI	Oxygen Dessaturation per hour of sleep
OSAS	Obstructive Sleep Apnea Syndrome
PAT	Peripheral Arterial Tone
PCB	Printed Circuit Board
PES	Esophageal Pressure
PS	Primary snoring
PSG	Polissomnography
REM	Rapid Eye Movement
SpO_2	Saturation of Peripheral Oxygen
UARS	Upper Airway Resistance Syndrome
UMTS	Universal Mobile Telecommunications System

1. INTRODUCTION

1.1 Motivation

The sleep related respiratory disorders are common in children. While some of these disorders have no impact on the child's health, such as snoring, others have serious consequences on the child development, such the obstructive sleep apnea syndrome (OSAS).

Actually, the gold standard method to diagnose OSAS is Polissomnography (PSG), for adults or children. However, the examination PSG has certain limitations, including:

a) It is required the presence of technicians during the entire night;
b) Only few number of the sleep laboratories is prepared for children;
c) It is an extremely expensive method;
d) The different environment in the child's room might reduce the sleep quality.

A more attractive alternative to laboratory testing is an innovated technology for home screening. This is easier and more comfortable for the child and their parents.

The Sleep@Home project is a continuation of last year's, where a prototype was developed to become simple and portable. The prototype was tested simultaneously with PSG in a clinical environment.

1.2 Objectives

The huge amount and complexity of the information that a PSG exam monitors lead the need of alternative methods. It would be interesting, on one hand, to have a cut back in amount of existent signals; on the other hand, a tool that

detected events related to apnea or hypopnea, in other words, clinical important events.

This paper intends to explore alternatives that provide improvements in the support system for diagnosis of obstructive sleep apnea syndrome, presented as the end-course final project of the year 2006/2007. This is a continued project.

The first objective of the Project refers to the analisys/review and acquaintance of the most relevant components/channels used in PSG and other portable monitoring systems. The components implemented in prototype A and others that might be integrated are analyzed considering their precision e effectiveness in recording the vital signs detected, allowing the identification of obstructive apnea episodes.

The second objective, as exposed on chapter 4, is the development of a prototype B, in order to improve the system with new components and upgrading it to a medical device that, after carrying through several clinical tests, validations and certifications, would become fit for a market launch.

The remote transmission and database related stage are also being developed alongside with the ISA team.

1.3 Involved Entities

I. ISA - Intelligence Sensing Anywhere (1)

Company of technological base, leader in telemetry and remote systems sectors. ISA is an awarded winner global telemetry company, leader in different segments of market, offering innovative remote management systems with a broad range of applications: gas, oil, chemical products, water and sewers networks, industry, environment and domotics.

Contact: ISA – Intelligence Sensing Anywhere
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Portugal

Website / E-mail: *info@isalabs.com*
http://www.isalabs.com
http://www.isasensing.com

II. CEI - Centre of Electronics and Instrumentation

The Center of Electronics and Instrumentation is a investigate unit of the Department of Physics at the University of Coimbra. The areas of research of the CEI are the Biomedical Instrumentation, the Atomic and Nuclear Instrumentation, Instrumentation for Physics of Plasmas, the Signal Processing and Industrial Telemetry and Control. It is the receptor entity where the main tasks were developed.

Contact: Departamento de Física – Universidade de Coimbra
Rua Larga
3004 – 516 Coimbra
Portugal

Website / E-mail: *http://lei.fis.uc.pt*

III. Coimbra Children's Hospital

This clinical institution has the role of validate and test the Sleep@Home System. Coimbra Children's Hospital area of influence encloses the country´s central region, and it presents itself as a Hospital of reference for the district Hospitals in the central region and for the health centers of the district of Coimbra.

Contact: Hospital Pediátrico de Coimbra
Avenida Bissaya Barreto
3000 - 076 Coimbra
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Website / E-mail: *correio.hpc@chc.min-saude.pt*
http://www.chc.min-saude.pt/departamentos/Pediatrico

1.4 Project Team

This project was developed by various elements, including people the Hardware and Software Applications Departments of ISA. In case of students is the final Project course.

Table 1 *– Project Team*

Name	Designation	Contact
Ana Sofia Pardalejo	Student	sofiapardalejo@gmail.com
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Doctor José Moutinho	Medical Supervisor (CHC)	

1.5 Overview of the report organization

This document is divided in 5 parts:

Chapter 1 – Introduction

In this chapter, the document is contextualized, objectives are focused, the motivation and contains a small introduction of the involved entities in this project.

Chapter 2 – Theoretical Background

In this chapter, it is presented a theoretical presentation of respiratory disorders and more specifically Obstructive Sleep Apnea Syndrome (OSAS).

Chapter 3 – Technical Review

The purpose of this chapter is to present the state of the art of the several existent products and their functionalities.

Chapter 4 – Sleep@Home – Project Developments

Based on the previous, this chapter will seek the most effective and practical system for OSAS diagnosis.

Chapter 5 – Conclusion

This chapter presents the conclusions concerning the objectives set in the beginning of the project and ideas for the future.

2. THEORETICAL BACKGROUND

This chapter is intended to give some theoretical concepts to understand the physiology of sleep disorders.

2.1 Sleep Disorders

Disorders include sleep disorders such as difficulty sleeping or to keep oneself to sleep, disturbed sleep due to respiratory events or external factors (temperature, noise, etc) or sleepwalking.

The interruption and subsequent fragmentation of sleep is the cause of the negative effects associated with various sleep disorders – process vital to healthy function of the body – and as such is responsible for the health problems that may result from them(2).

In 1997 a first manual called *The International Classification of Sleep Disorders* was developed (3) (4), for the American Academy of Sleep Medicine, aiming to provide more accurate diagnoses and improve the forms of treatment for sleep disorders. In 2001 it was revised and about 88 of sleep disturbances were described among which was obstructive sleep apnea syndrome.

2.2 Obstructive Sleep Apnea Syndrome (OSAS)

First mention, of the respiratory disorders in childhood was in 1836. Charles Dicken's in your publication, *The Posthumous Papers of the Pickwick Club*(5), description a boy with 10 years, who spent most of the time to sleep and eat.

Sir William Osier (6), in 1982, explain first medical opinion about OSAS in children, commenting the symptoms on the day and sleep very disturbed at night. Osler described night and daytime symptoms as follows*: "At night the child's sleep is greatly disturbed; the respirations are long and snorting, and there are sometimes prolonged pauses, followed by deep, horsy inspirations. The expression is dull, heavy, and apathetic ... In long-standing cases, the child is very stupid-looking, responds slowly to questions, and may be sullen and crosses. Among other symptoms may be mentioned headache, which is by no means uncommon, general listlessness, and an indisposition for physical or mental exertion."*

In 1976, Guilleminault et al. (7) described a group of 8 children with OSAS, diagnosed for PSG. Futhermore, Guilleminault et al. (8) published a review of 50 children and adolescents with OSAS, concluding that the syndrome it was not uncommon and that the impact intellectual, cardiovascular and neuromuscular of the same should be considered.

The symptoms of OSAS including frequently snoring and snorts, gasps or intermittent pauses (at night), and daytime sleepiness may occur in adolescents. (Table 2)

Table 2 – Features that may suggest a sleep related OSAS (adapted (9))

During Sleep	Symptoms on waking	Daytime
• Snoring • Parents concerned about their child's breathing • Unusual posture during sleep • Listening apneas Cyanosis	• Difficult to awake in the morning • Irritability on waking	• Excessive sleepiness • Hyperactivity and behavioral disturbance • Learning and memory difficulties • Growth delay

The prevalence is estimated to be between 1-3% in the child population with a similar distribution among boys and girls. It is more frequent in children

between 2 and 6 years (preschool-aged), when tonsils and adenoids are largest in relation to the diameter of the upper airway (9).

OSAS is define by repeated episodes of upper airway obstruction, usually associated to a dessaturation of oxygen in the blood. It is characterized by apnea or hypopnea moments, following the breathing restore with micro-awakening, caused by brain stimulating triggered during the obstruction, which leads to a state of less profound sleep.

In childhood, an apnea is described as several periods of times in which there is a breathing interruption and an obstruction of upper airways occurs. The three categories of apnea are central, obstructive and mixed.

Central apnea occurs when the signal of the respiratory center for the muscles involved in the respiratory tract ceases or when the signal is interrupted. The muscles cease all movement as well as respiratory effort, and thus any air flow . The central apnea is common in neonates and infants, since the problems should be, often, the immatureness of their nervous system.

The **obstructive apnea** is the interruption of the air flow by a total airway obstruction, although there is respiratory effort. In Figure 1, is possible see the state of the upper respiratory tract and the (none) passage of the air during an obstructive apnea. If the obstruction is partial, there is still a diminutive passage of the air but with reduced flow, it is a period of **hypopnea**. The obstructive apnea is the most common type of apnea in children (10).

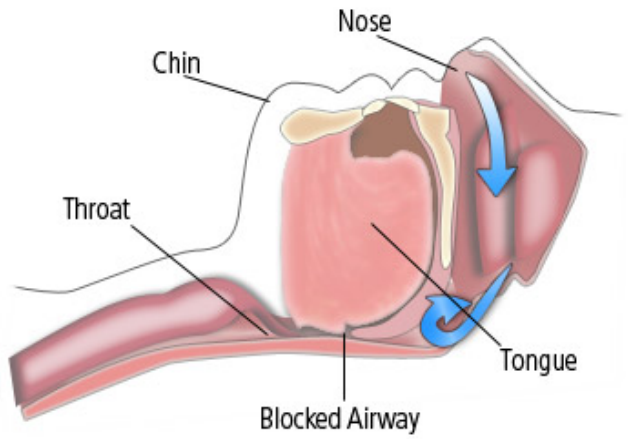


Figure 1 – Collapse the airway in the obstructive sleep apnea. *Source* (11)

The **mixed apnea** is a combination of central and obstructive apnea, involving either the decrease in respiratory control or the obstruction of the airways.

According to standard pediatric criteria (9), the apnea index was defined as the number of obstructive and mixed apneas, of at least two respiratory cycles duration, per hour of total sleep time. Although a hypopnea was defined as a partial obstruction characterized by a 50% or greater decrease of ventilation during at least two breath cycles or 30% associated with insaturation of 4%. Normally, the severity is calculated by the total number of apneas and hypopneas divided by the total sleep time; this is as Apnea/Hypopnea Index (AHI). In children, AHI of 1 – 5 events/hour is moderate, while in the most severe situations AHI is higher an 10 events/hour(12).

2.3 Diagnosis methods of OSAS

The diagnosis aims to not only to identify children who are at risk of presenting complications, to avoid prevention in cases who present no risk and to evaluate children who may suffer from post surgery complications in order to take appropriate precautions.

The methods of diagnosis that have been (scientifically) evaluated include:

a) History and Physical examination;

b) Video and snore documentation;

c) Oximetry;

d) PSG.

Several studies have shown that History and Physical examination can be brief and simple reports that allow a pre-diagnosis of OSAS. For example, OSAS needs to be distinguished from primary snoring (PS), which is defined as snoring without obstructive apnea. History and information given by the parents are not enough to perform a differential diagnosis between OSAS or PS (13).

Actually PSG is considered the standard method (gold standard), while the remaining considered as alternative methods. Sometimes more than one method of diagnosis is needed to identify more accurately the disorder in question.

Nocturnal PSG is the only diagnostic technique shown to quantify the respiratory process factors and abnormalities associated with sleep-disordered breathing. PSG involves recording of multiple physiologic variables including brain and heart signals (Electroencephalography (EEG) and Electrocardiography (ECG)), leg motion and eye motion (Electromyography (EMG) and Electrooculography (EOG)), blood oxygenation, respiration effort, air flow and others sensors. PSG requires monitoring, during the the examination, of specialized technical staff to control the records and to document the occurrence of events, which is most important for diagnosis.

PSG recordings provide the true assessment of sleep architecture and high quality, although it is very expensive and too many sensors attached to the child's body is highly intrusive. Besides, those exams are not very suitable for young children, not only because the trauma of sleeping in a hospital, away from their parents, which obviously affects the sleep quality, but also because children sleep patterns are

substantially different from adult sleep patterns, which are more broadly covered in the literature.

Nocturnal video/snore recording are important results to PSG, but are not enough.

Other studies have evaluated the pulse oximetry in the evaluation of OSAS. There are two advantages of nocturnal oximetry use compared with PSG: cost and convenience. Brouillette et al (14) performed oximetry in a group from the Montreal Children's Hospital with suspected OSAS and compared it with simultaneous full PSG. The study conclusions indicated that oximetry was useful when results were positives. In the other words, comparing nocturnal oximetry with PSG, they found positive predictive values (PPV) of 97% and negative predictive values (NPV) of 47%. Children with negative oximetry results indicate that additional study, such as PSG, is necessary for definitive diagnosis. Normally, these negative results were found in children with medical problems, such asthma, cardiac complications or obesity.

The negative implications of any respiratory sleep disorder, particularly OSAS, in the quality of life of children demonstrate the importance of their diagnosis for further treatment.

Besides PSG, there are other diagnosis methods as mentioned in the beginning of this section (2.3). Although they do not provide as complete information as the PSG in laboratory, they can be very useful as a means of screening or when in situations where it is not possible to perform the PSG.

Currently, new methods - less invasive than the PSG - and preferably using a small number of signals that facilitate and help the diagnosis of OSAS, have emerged and are the subject of several studies and investigations.

This project, based in the studies published, intends to explore the sensitivity of a classification system for the different types of apneas, as aim to support the OSAS diagnosis.

3. TECHNICAL REVIEW

More and more studies in this century, demonstrated the most importance of sleep apnea diagnose in children. This chapter analyzes some types of sensors/methods in the market.

3.1 Literature Review

The classification of the recording technology used for the diagnosis of sleep-related breathing disorders, proposed for the *American Sleep Disorders Association* (15) about different monitors used in diagnostic for sleep apnea, can be represented in:

Table 3 – Types of sleep-study monitoring devices

Type 1	• Minimum 8 channels • Is considered the gold standard in-laboratory	EEG, EOG, ECG, EMG, airflow, respiratory effort, SpO2, body position
Type 2	• Minimum 7 channels	EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort and SpO_2
Type 3	• Minimum 4 channels	Airflow and two channels of respiratory movement. Usually no EEG is monitored. SpO_2 or airflow.
Type 4	• 1 or 2 channels	

The Polysomnography (PSG), the gold standard technology for diagnosing OSAS, is defined a Type 1 and the portable monitors are classified for three types (2, 3 and 4).

Increased investigation in sleep studies, simultaneously with PSG limitations, triggered the search of alternative methods of diagnosis, not only simpler and economic but also performable in a family environment.

Interest and development of these alternative methods have been growing, mainly at the portable monitoring level. Recently, new devices have been developed capable of monitoring the sleep, the nocturnal breathing and oxygenation of the blood in patients at home. Likewise, more sophisticated equipment was also developed in order to enable the study (at home) equivalent to PSG in the laboratory.

The alternative methods, although they are not a complete means of diagnosis, may be useful in screening or in preliminary studies, in cases where there are not necessary resources to carry out the PSG.

A more attractive alternative to in laboratory testing is to evaluate children in their homes. In your ambience, the sleep is natural and feelings better.

The recent literature review, it is analysed the different portal devices in market and some applications in sleep centers. The number of signal monitored (channels) and the conclusions of sensibility/specificity tests are very important for the study validates and sleep disorders diagnosis.

***Table 4 – SleepScout™*(16)**

SleepScout™
(CleveMed)

7 channels

- Pulse oximetry
- Airflow
- Snore
- Thoracic and Abdominal Effort
- Body Position
- Thermistor or Blood pressure

2 additional channels

- ECG/EMG or EEG/ECG

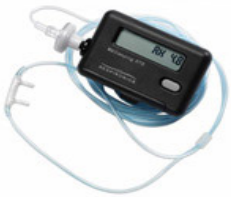
***Table 5 – PSG@Home™*(17) (18)**

PSG@Home™
(CleveMed)

- System upgrade to any system of PSG CleveMed, suitable for home monitoring
- System with 14 channels (EEG, EOG, chest and abdominal respiration effort, pulse oximetry, airflow, snore, body position, ECG, EMG)

***Table 6 - RUSleeping™ RTS Screener for Apneic Events*(19)**

RU*Sleeping*™ RTS Screener for Apneic Events
(Respironics)



1 channel

- Nasal cannula

***Table 7 – Stardust®*(20)**

***Stardust®* - Sleep Recorder**

5 channels

- Airflow sensor
- Effort sensor
- Oximeter
- Body position monitor
- Patient event monitor

***Table 8 - SleepStrip®*(21)**

SleepStrip® Disposable Sleep Apnea Sensor

1 channel

- Oral and nasal airflow sensor

***Table 9 – LifeScreen Apnea®* (22)**

LifeScreen Apnea®
Holter Oximetry Apnoea Assessment®

2 channels

- 3 sensors of ECG
- Oximeter

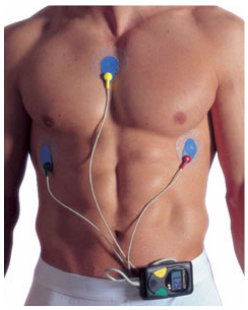


***Table 10 - ApneaLink™*(23)**

ApneaLink™
(ResMed)

3 channels

- Oximeter
- Airflow
- Snore

***Table 11 – NovaSom QSG™* (24)(25)**

NovaSom QSG™ 5 channels - Oximeter (finger oximeter) - Airflow - Respiration effort	

***Table 12 - Embletta™*(26)(27)**

Embletta™ 7 channels - Nasal cannula - Oral thermistor - Abdominal and chest movement - Oximeter - Body position and activity sensor - Snore	

The new technologies present in tables 4-12(for patent information, please consult Appendix I) do not replace the PSG. There is a need to establish development priorities for home screening and simple-diagnosis. It is not necessary to displace children (or adults) to a laboratory for studies of sleep, often distant from home. Is important refer that the nine devices mentioned in this chapter (tables) similar to the Sleep@Home. They were chosen because they provide portable monitoring in patients' home of, reducing the number of children submitted to a study in the sleep laboratory at a clinic or a hospital.

A report by the *American Sleep Disorders Association* and *American Thoracic Society,* demonstrated that home tests for the screening of OSAS should be a Type 3 or lower (Type 2) (15). Type 4 (1 or 2 channels) has a good performance, but was given a low evidence rating.

The several conclusions of the different products studies indicate that only the clinical use of Type 2 portable monitors in either attended or unattended settings and some Type 3 monitors seemed to be potentially acceptable in the attended laboratory setting, but with some limitations.

These conclusions has also provided us (team project) will and strength to do better and to develop a simple, portable and efficient device.

3.2 Signals used for detecting events

This research assessed the performance and high-fidelity of signal monitoring by the different systems in detecting OSAS symptoms.

To start it is very important to distinguish between the terms “signal” and “channel”. In a system of diagnosis of sleep disorders, there are different channels that collect the various signals which will then be analysed. It is possible that a channel collects more than one signal. For example, an oximeter, usually detects the heart rate, the saturation of oxygen, among others, but it is a single channel.

One of the objectives of this project was to understand what are the most important signals for a diagnosis similar to the PSG, so as to reduce the costs and the other less attractive aspects of PSG, but always ensuring a proper screening of OSAS.

3.2.1 Oximeter

In sleep medicine, the pulse oximetry has as important role in the interpretation of PSG, but has lost status as the sole parameter for diagnosis of respiratory sleep disorders. In recent years, it has been discussed about the effectiveness of digital nocturnal oximetry as a tool for screening, to identify patients with respiratory sleep disorders. The need to reduce the cost for diagnostic procedures in sleep disorders has increased, while technological advances have developed portable pulse oximeter , reliable and of low cost (28).

Oximetry is a part of PSG and it is used to measure the **oxygen dessaturation** (SpO_2) and rate. It has been an essential tool in sleep medicine as it detects the rapid fluctuations in arterial oxygen saturation during sleep, which is a characteristic of sleep apnea patients. Thus it allows the early detection of respiratory disorders.

In the majority of oximeters it is possible to detect the **heart rate** (number of heart beats per unit of time).

Through pulse oximetry systems based on absorption of light by the blood on fingertip (same systems that measure oxygen saturation in the blood), we are able to get on a non-invasive **plethysmographic signal**. This signal represents the volume of arterial blood continuously (peripheral arterial tone - PAT) and presents a cyclical pattern due to the sync with the heart rate, to measure the pulse. Volume of arterial blood depends on blood pressure and also the degree of contractility of the arteries. Thus, the volume of blood to light absorption by the system of oximetry reflects on the recording of the plethysmographic signal (29).

The contraction of the muscles and the relaxing the arteries walls are controlled, among other mechanisms, by the autonomous nervous system that determines muscle tone. Depending mainly on the action of the sympathetic nervous

system or the parasympathetic nervous system the arteries will contract (vasoconstriction) or dilate (vasodilatation) respectively (30).

An event of apnea is associated with increased activity of the sympathetic nervous system. This activity, leading to vasoconstriction, is reflected in the plethysmographic signal as a reduction of the fluctuations size whose detection may be useful in identifying apneas.

Many PSG systems and some investigators use this signal for detecting apneas and hypopneas.

The study of the recognition of apnea events in children were based only on a plethysmographic signal as cited in the work of Gil E. et al. (31)(32). These authors have developed a method where the apnea events to detect are those longer than 3 seconds in which the magnitude of the signal is less than 33% of the normal range, referring to the previous cycles to the apnea event.

The method uses an algorithm that compares the decision to plethysmographic signal modified with a limit value. The method was applied to simulated signals and real signals and, in the both cases, the results suggest that the physiological plethysmographic signal contains information that may be useful in various fields of medicine, including on studies of sleep disorders since it provides information on the activity of the sympathetic nervous system (33).

Another author (Schnall et al. (34)) explains in his article that pulsatile finger blood flow patterns can be evidently diagnostic of OSAS and other settings of sleep disorders breathing.

The additional value of this type of diagnosis is the rapid efficiency and, in many cases, quickly followed by treatment Figure 2. In other, words, children do not have to go to long waiting queues for a test of PSG, in the few laboratories adapted to pediatric situations.

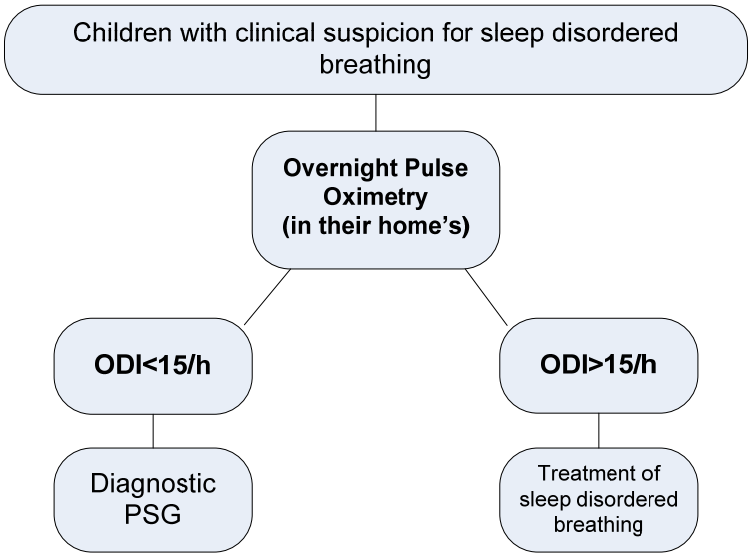


Figure 2 – Diagram of overnight pulse oximetry to screen for sleep disordered.
ODI: Oxygen Dessaturation Index (oxygen dessaturation per hour of sleep) – Adapted (35)

3.2.2 Respiratory parameters

The respiratory measures can be classified as direct, such as pneumotachograph to evaluate direct airflow; or indirect measures, using respiratory effort to estimate changes in airflow in the upper airways.

- ***Direct measures***

The standard method for quantifying and identifying airflow during sleep is the **pneumotachograph**, but it is not usual in detection of apnea of sleep, because it is uncomfortable and can disrupt sleep.(36)

The **nasal cannula** is connected to a specific pressure transducer that is a piezoelectric sensor (crystal). This crystal estimates the changes in air pressure, into the nostrils. During the inspiration, the air pressure is negative regarding atmospheric pressure and during expiration the pressure is positive, usually know as the fluctuations of nasal pressure.(37)

The extent of these changes in pressure can be used as qualitative and quantitative estimate of airflow in the upper airways.

The evaluation of the shape of the curve or airflow, usually sinusoidal, has also been used in assessing breathing.

It is a more sensitive and specific technique than a thermistor record of hypopnea awakenings and related increased in respiratory effort. The nasal cannula is not invasive, tolerated without difficulties and has been regarded as the best technology available for non-invasive monitoring of breathing during sleep, does not require calibrations for use.

The **thermistors** and **thermocouple** transducers are sensitive to changes in air temperature. The electrical resistance of the resistor changes in accordance to changes in air temperature during the respiratory cycle. The higher temperature of breath warms the sensor increasing the resistance and the flow inspiration cools the sensor, causing a decrease in resistance in thermistor or voltage in the thermocouple.

These sensors do not produce a quantitative and real measure of the volume of air that enters or outs the nostrils and mouth, but only an indirect and qualitative measure of the airflow, or whether there is respiration (airflow).

The waveform signal is generated by the nasal cannula detecting the fluctuations in pressure caused by inspiration and expiration. These fluctuations (inspiratory and expiratory) give different signals recorded from a thermocouple or thermistor. These signals are proportional to the flow. There is a theoretical possibility that applies a linearization of the pressure signal from taking its square root, but this has little influence in the shape of signal in most cases.

These sensors are susceptible to detection of obstructive sleep apnea and central sleep apnea but, unlike the nasal cannula, they are not sensitive enough to detect hypopnea as. This technique was widely used in the past due to lack of better techniques. Today, it has been replaced in most clinical laboratories and research by nasal cannula. (36)

- ***Indirect measures***

There are several methods of registering the respiratory effort during sleep such as the record the movements of expansion-retraction of the chest and abdomen, the diaphragmatic muscular activity or variations in esophageal swing pressure.

Measures of respiratory effort are very useful in assessing breathing, especially during periods of increased resistance of the upper airways, where the respiratory effort increases to continue adequate ventilation.

The measure of respiratory effort is essential to differentiate the central sleep apnea and obstructive sleep apnea. In central events there will not be respiratory effort, while during the obstructive event the respiration effort remains.

In some cases, the patients have signals and symptoms that propose obstruction of the upper airway, but the PSG made in sleep laboratory does not present many apneas and hypopneas to give a sleep apnea diagnosis . The esophageal pressure swing or just, **esophageal pressure** (PES) is the monitoring gold standard for determining the quantitative and qualitative respiratory effort and repetitive, gradual increases in negative intrathoracic pressures, during sleep.(38)

This process uses a flexible catheter and a pressure transducer of piezoelectric crystal. The catheter is flexible and of small diameter, with an inflatable balloon at the bottom, known as esophageal balloon. The balloon, inflated with 1 ml of the air, transmits the intrathoracic pressure using the pressure transducer. The quantitative record of esophageal pressure reflects the changes in effort, during the respiratory cycle.

The highest inspiration effort will be the most negative intrathoracic pressure. The balloon is extremely useful in diagnosis of the upper airway resistance syndrome (UARS).(39)

The use of a esophageal balloon requires trained technicians in its use. The catheter is inserted by the nostril after local anesthesia of the nasopharynge and placed in the esophagus. It should be positioned in the center third or bottom of the esophagus, scouting for suitable variations of intrathoracic pressure. However, some patients do not tolerate well the intra-esophageal catheter. In children, this type of surgery is unusual.

Despite increased interest in UARS and the diagnosing of PES, little literature has been published about this subject. (40)

Thoracoabdominal movements are an indirect flow measurement. (41)

Respiratory effort bands consist of a transducer that converts the kinetic energy into electrical potential. The goal of the system (transducer and band) is to register the change of thoracic and abdominal volume and generate an electrical signal transmitted to the polygraph. Therefore, the strapping does not records physical forces but the change in the expansion of chest and abdomen.

The rationale is based on the study of the amplitude of the swing movements of the thoracic and the abdominal compartments, and on the comparison of the synchrony between both movements. (42) In case of an obstructive apnea, there is a decrease and an asynchrony of the bands, resulting in a reduction in the amplitude of the sum of the signal from abdominal and thoracic bands. By contrast, during a central apnea, the thoracic and the abdominal compartments move, with which the signs from both bands and their sum are nil.

In Figure 3, shows a mixed apnea in OSAS children.(42) It is possible to analyze the central apnea (in first part) with stoppage of thoracic and abdominal movements and the obstructive apnea with “out-of-phase” thoracic and abdominal movements. The sum of the band movements were approximately zero.

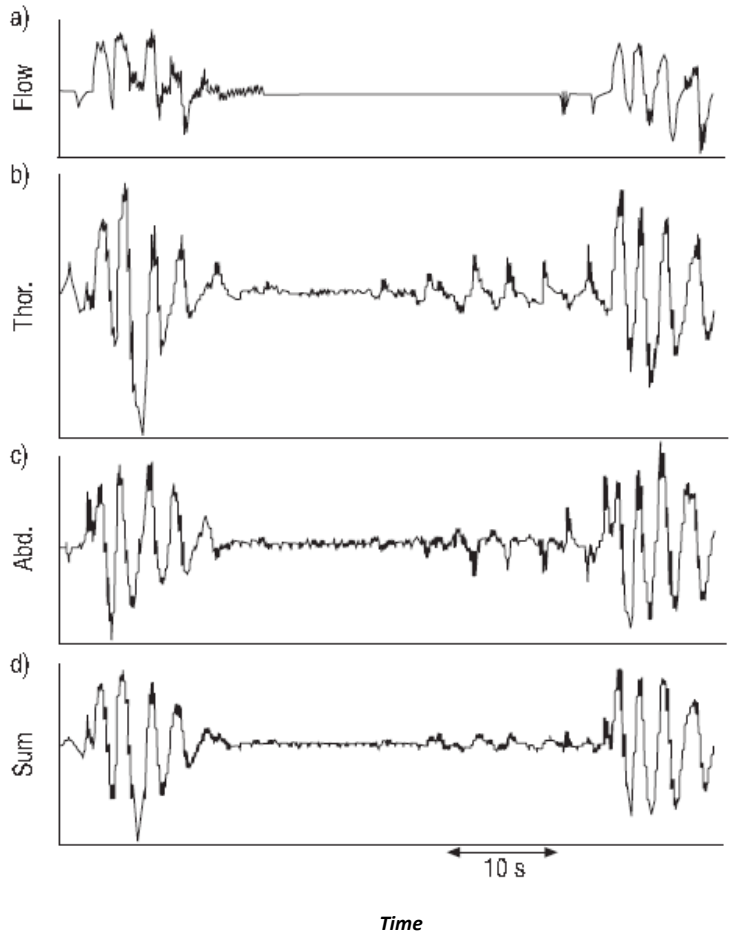


Figure 3 – The mixed apnea in children - *Adapted* (42).
a) Flow – estimated with nasal pressure recording for the PSG; b) Thoracic (Thor.) and abdominal (Abd.) were the signs provided by the respiratory bands movements; c) Sum is the adding of the signs recording by the thoracic and the abdominal bands.

During the PSG, the movement thoracoabdominal paradoxical is frequently found which means a possible obstructive apnea. Under normal conditions, the circumference of the chest during inspiration increases and decreases during expiration. By contrast, abdominal circumference increases during expiration and decreases during inspiration. In obstructive sleep apnea, in some cases, the chest circumference may decrease during inspiration and increase during expiration. This is called a paradoxical breathing and can also happen with no obstructive sleep apnea. (43)

The operation of the transducer can be a silicon tube filled with a liquid substance as conductor, sometimes mercury or a solution whose electrical resistance

varies with the length of the tube filled. The tube is inserted into an elastic strap that accommodated is comfortable around the chest (at the level of armpits) and another band is place around the abdomen just above the iliac crest of the patient.

The belts are simple to use, low cost and serve as a qualitative measure, but not quantitative, of respiratory effort. In very obese patients, the usefulness of these belts is more restricted, mainly by the difficulty of keeping them properly positioned during the examination.

3.2.3 Snore

The snoring is the most common form of manifestation of respiratory sleep disorders, and it is expected to affect 3 – 12% of children. (44)

The snoring attended by respiratory pauses or sudden inspirations can be a symptom of OSAS, UARS (Upper Airway Resistance Syndrome) or indicate a possible trend for these syndromes. Although the majority of children affected by respiratory sleep disorders snore, this condition is not an indicator of the presence of UARS or OSAS. Because of this duality of snoring, the screening of a possible existence of a more serious disturbance is necessary. The American Academy of Pediatrics recommends that all children who snores should be evaluated to discriminate between benign resonate and resonate as pathological symptom. (Figure 4)

Despite the fact that snoring is the most common symptom of OSAS, it is intensity, is not related to the severity of respiratory sleep related disorders.

Many authors consider the respiratory sleep disorders as a continuous spectrum of disorders in which an individual can progress or regress. (45) The degree of severity of an airway obstruction goes from mild obstruction, causing the snoring, to total obstruction, which results in as episode of apnea.

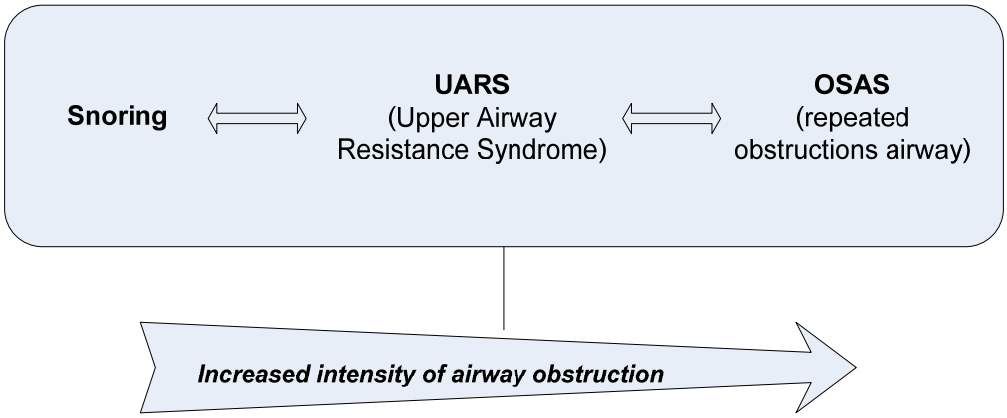


Figure 4 – Respiratory disorders of sleep and degree of severity of airway obstruction. *Adapted* (46)

Although the degree of severity of snoring should be unrelated to the upper airway obstruction severity, this signal when analyzed together with other channel (for example, video signal) may become important to identify the respiratory events observed in the oximeter, video, thoracoabdominal bands or elsewhere. (47) (48)

3.2.4 Body Position (and activity sensor)

The sensors of body position are usually fixed to the children's chest which generates a signal different for each position of the body. The monitoring of position becomes important in the diagnosis and treatment of cases of patients exclusively with respiratory pauses. Nonetheless, this method is also used to detect other causes or sleep disorders apart from respiratory conditions.

Cartwright (49) proves in his investigation that in adults there is a significance decrease in OSAS events, while the supine position[1] is not advisable. In

[1] *The supine position is a position of the body, with lying down the face up. In contrast, the face down, there is the prone position.*

contrast, this conclusion is not confirmed in children. Many authors explain in their studies, the effects of body position in breathing sleep disorders. (50) (51) These studies have reposted that sleep position does not affect the severity of OSAS in children. Inclusively American Academy of Pediatrics suggested that children breathe better when they sleep in the supine position.

Pereira et al. (52) (53) found that there is an increase in the respiratory index, when increased time is spent in the supine position in young children.

3.2.5 Electroencephalography (EEG)

The record of the EEG is the main parameter for the stages of sleep. From the electroencephalography it is possible to identify the specific graphics and recognize the different stages of sleep (stages I to IV of N-REM and REM sleep). (55)

The electrodes are placed according to the international system 10-20. For a study of sleep, are routinely used only the electrodes C3-C4 and O1-O2. The occipital electrodes serve to identify the beginning of sleep, as the high frequency components of the EEG are highly correlated to the level of consciousness of the child or adult patient.

The dominating frequency shifts to higher frequencies and lower amplitude, as the activity increases. The alpha rhythm (α, 8-12Hz) is typical of vigil and observed in regions beyond the brain. Beta (β, 16-20Hz) is a high frequency, as alpha. For lower frequency rhythms, it's necessary to focus on theta (θ, 4-8Hz) and delta (δ, 0.1-4Hz) during sleep.

The observation of breathing events during sleep with only one EEG sensor, will not detect the events of apnea or hypopnea, because the high frequency noise that occurs through REM sleep.

3.2.6 Electrooculography (EOG)

The EOG is a recording of the movement of the eyes, (56) that occur during REM sleep and the slow eye movements that occur during the transition vigil-sleep.

This is a channel, connected to a system of PSG that registers the signal and identify rapid eye movement sleep stage. An electrode is placed about 1 cm below the horizontal plane and slightly sideways, while the other is placed about 1 cm above and also slightly sideways.

This provision allows the identification of horizontal, vertical and oblique eye movements.

3.2.7 Electrocardiogram (ECG)

The ECG serves primarily to detect the frequency and cardiac arrhythmias and, contrary to heart disease diagnosis, does no require any other signal such as morphology. It needs only to demonstrate the QRS complex. (57)

3.2.8 Electromyography (EMG)

The muscle atonia[2] is one of the most characteristic features of REM sleep. PSG and the record of EMG is as criteria for REM sleep recognition and for recognition of awakenings. The electrodes are placed on the skin over the muscle tissue. (58)

[2] *The muscle atonia is a diminution of the skeletal muscle tone marked by a diminished resistance to passive stretching (4)*

Other EMG channels can be used in certain sleep disorders, such as anterior tibial muscle in the previous suspicion of periodic movements of the members and other sleep disorders.

3.3 Importance of fewer channels

As mentioned before, many OSAS patients currently do not have access to a laboratory with PSG. This urgent matter is acknowledged and there is an increasing interest in other approaches to diagnosis, portable monitoring, that have been proposed as an alternative to PSG in the diagnostic assessment of patients with suspected sleep apnea. (59)

Portable monitoring encompasses a wide range of devices that can record as many signals as does attended PSG or only one signal, such as with oximetry. In this project there were three types of portable monitoring investigated:

- Type 2 – comprehensive portable PSG.
- Type 3 – modified portable sleep-apnea testing.
- Type 4 – continuous single or dual bioparameter recording.

Based on the proposal of the American Sleep Disorders Association, see chapter 3.1, type 3 and 4 devices cannot score sleep and, therefore, do not meet some current medical diagnosis.

Usually, EEG, ECG and EMG signals are not recorded by portable monitoring, because they are very complex, require more cables and are most disturbing for children. For this reason, it was decided that the system Sleep@Home would not present any of these signs. But it is important to note, that signals are relevant to the detection of sleep. For example, only through the EEG it can be detected if the patient (child) is sleeping or awake, but for these situations we propose

another type of monitoring, video camera, which allows the detecting of the entire exam and where it is possible to identify some signs of how the child is sleeping.

Developing validated portable monitoring devices is urgently needed.

4. SLEEP@HOME – PROJECT DEVELOPMENT

In this chapter are arguing the choices and decisions based on revision of current literature and the knowledge of other team: students, doctors and sleep technicians.

4.1 Sleep@Home Analysis

Sleep@Home is a result of work done below final project in Biomedical Engineering, beginning in 2006/2007, under a work in various entities, the University of Coimbra, Pediatric Hospital of Coimbra and ISA.

During this period, a prototype A was developed in order to be able to validate the system, having been tested in a hospital environment and outwork. Following the tests, the results were positive and interesting. The hardware and the software have shown good performance, but it is important continue testing the algorithms and the alarms (several statistics results and delta index).

In the end, the mains goals have been met and it was possible to establish a good synchronization of the various components of the system, detect alarms and visualization.

The main objective this year was the certification and validation of Sleep@Home – Prototype B. This validation will be achieved through a fair number of **clinical trials** and **improved level of hardware**, by the *American Sleep Disorders Association*.

As it has been mentioned, this project was developed by a team composed by two elements during a year. The student Ana Sofia Pardalejo was responsible for the analysis and selection of the hardware components for the best results and increased clinical validity. The other student, Rafaela Inácio developed a plan of clinical tests for validation of the system; and its graphical interface was developed by the ISA team. Tests were conducted at the Hospital Centre of Coimbra – Pediatric Hospital (tests in children) and General Hospital (tests in adolescents and adults).

4.2 System Architecture

In **September of 2007**, the prototype A had a basic architecture. At this stage, the system was controlled (Start/Finish) by an interface on a laptop to begin the exam and again to conclude. The oximeter and video camera connected to the video server and the data packets - text files (.txt) - for oximeter and JPEG images format are stored on the video server, for further analysis and consult. (Figure 5)

After an analysis of the system architecture (Prototype A), it was concluded that it was necessary to integrate more components so as to make the Sleep@Home more credible and consistent, thus achieving the minimum requirements for a medical device Type 3 (Airflow and two channels of respiratory movement. Usually no EEG is monitored - *Table 1*). During this year, dedicated entirely to the project, several literary sources and other medical products within the same area of Sleep@Home were searched to analyze the strengths and weaknesses for each proposal. The conclusions aimed for a more comfortable and more complete possible for OSAS screening. (Figure 6)

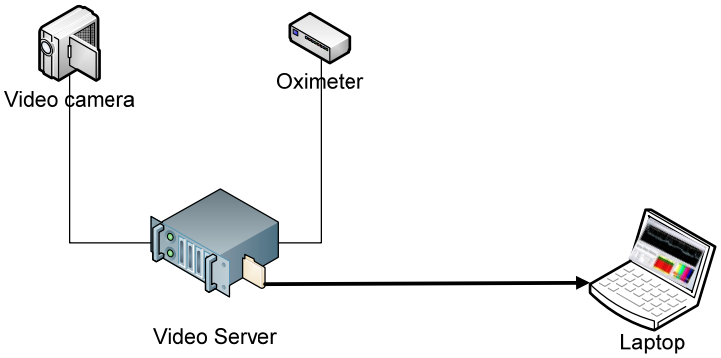


Figure 5 – Architecture of Prototype A

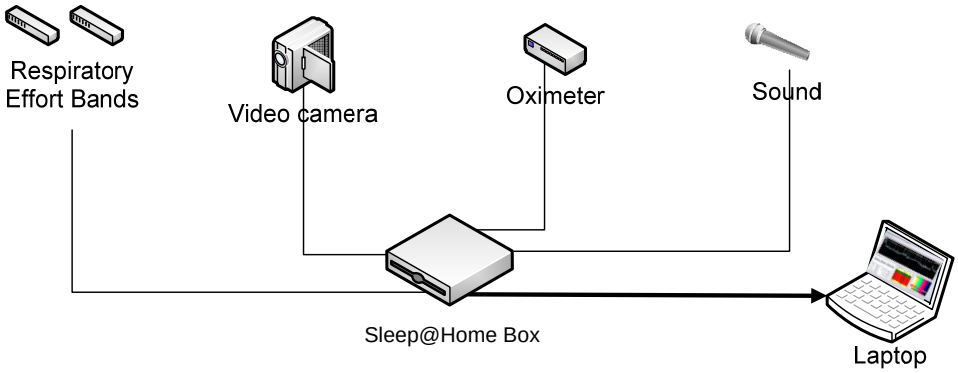


Figure 6 – Architecture of Prototype B

4.2.1 System architecture in modules

The Sleep@Home, as a whole, will have four modules (Figure 7):

- **Acquisition Module** – Will be monitoring the biomedical signals, image and sound; this part of system will be work on the patient's home.
- **Transmission Module** – It makes the connection between the module of acquisition and the Database. The data acquired by the first, when the monitoring is completed, will be sent to the hospital

center via ADSL or UMTS/HSDPA, as available. In the inability to use these means, the equipment will be returned and the data transfer will be made locally in Healthcare Unit. This module contains data compression and security processes.

- **Database** –The database will store all the data monitored during the examinations of sleep. This module will be work in a hospital, as the nest module.
- **User Interface** – An application will show users stored data in the Database. In this module operates a sub-processing module detects events that suggest sleep apnea situations. From this module, the user can still manage data in the Database .

The data of the peripherals components are concentrated and processed in the Sleep@Home Box. The transmission manages the transfer of data to ensure the safety in the process of storage in Database. From the application, technicians and doctors can observe the night examination period.

The prototype B has components that are extremely important for sleep apnea detection. The future developments will require the creation a new medical device, portable, easy to use and efficient. Therefore, in this chapter, we intend to describe the performance of each of its parts will function. All the technical requirements needed to have the prototype in conditions will be submitted in several validation tests, in clinical environment.

To describe each of the modules of the prototype B and its components, the following points are presented:

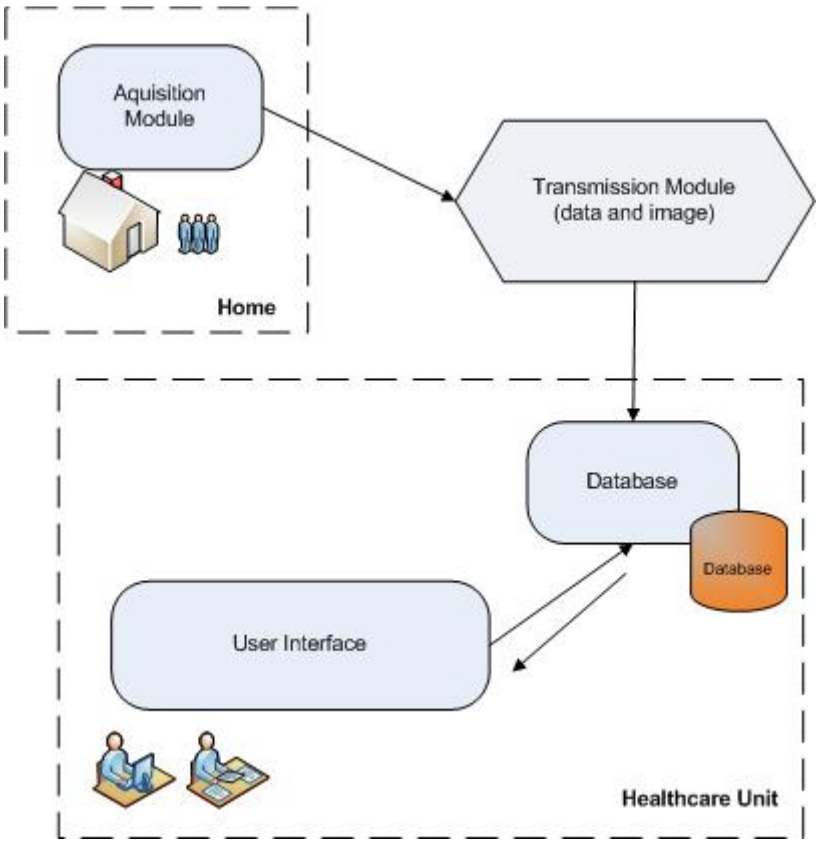


Figure 7 – Modules of the system Sleep@Home.

There are several **Acquisition Modules** (also identified as Sleep@Home Box) distributed by patients homes, where the biomedical parameters are monitored. This monitoring is done through the Box and has the capacity to acquire, store and compress all data locally monitored during the sleep period. After this period, the data is transmitted (**Transmission Module**) and stored remotely in the **Database** installed on the server network. The user has access to the data of signals monitored in the patient's home, through **Interface** with features that process the data automatically in order to detect clinical events with meaning.

▪ ACQUISITION MODULE

Oximeter

A commercially available Smiths Medical PM 31392B1 Micro Power Oximeter Board (Appendix A) was used to collect patient oxygen saturation (%SpO_2) readings for the new system. The oximeter not only monitors continuous the %SpO_2 but also the heart rate and plethysmographic measurements (important clinical signals).

To monitor the oximetry data, an oximeter and a RS232 input are necessary in the Sleep@Home Box. The oximetry routine that runs in the box was developed last year. (Figure 8)

Figure 8 - Medical PM 31392B1 Micro Power Oximeter Board (adapted)

The oximeter sends data packets at a 60Hz frequency, but in each packet and for each parameter (Figure 9) only some values are valid. As such, the routine has been improved in order to detect all valid data in a period of a one second and then it

writes to the txt file according to the template on Figure 9. Thus oximetry can be taken from the data at an equivalent rate of the oximeters used in the Paediatric Hospital.

In the case of oximeters, the Central Hospital operates with a transmission of some information each three seconds. When these exams were taking place, special caution was needed concerning this statistical analysis

YYYY-MM-DD HH:MM:SS:MMM Beep, Pleth, Bargraph, AvgSpO_2, RealSpO_2, HeartRate, Flags RedGain, IRGain

Figure 9 – Template of an oximetry text line.

Parameters (in order): Date, time, signal beep, plethysmography, mathematical average of the SpO_2 signal SpO_2 over a small window of time (, instant SpO_2, heart rate, gain of red and gain of infrared.

The option has been to maintain the same oximeter because their routine was very efficient in event detection by monitoring SpO2, plethysmography signal and heart rate.

The plethysmographic signal was not monitored last year. According to medical opinion, there is a common relation between the occurrence of the arterial vasoconstriction state and the activity of the sympathetic nervous system. This is really important since before REM sleep stage and the end of the apnea event, there is a visible state of vasoconstriction.

The algorithm of detection for this type of alarm, plethysmographic signal, requires a search of mathematical functions in literature. In case of oximetry this project, the PAT signal (the same a plethysmographic signal) of the fingertip returns this signal at a rate of 60Hz, therefore returning to the original routine of the oximeter.

Respiratory effort bands

The respiratory effort bands is the new component of prototype B It increases the performance and offers more detailed confirmation of clinical events.

The integration of this new component is based in researched articles and several medical opinions. In chapter *3.2.2 Respiratory parameters, it has* been mentioned that thoracoabdominal movements are an indirect flow measurement in which reduction of amplitude and inspiratory curve alteration can be detected.

Masa et al. (61), present that the potential advantage of thoracoabdominal bands over nasal cannula is that the registered signal by the bands is not dependent on the patient having to breathe exclusively through the nose. Besides, thoracoabdominal bands are already commonly used in PSG to evaluate whether apnea events are obstructive or central. Therefore, the thoracoabdominal bands could be used in combination with a thermistor or as a complement to other methods that can detect apneas or hypopneas, for example nasal cannula.

The bands chosen are the most commonly used in Healthcare Units. (Figure 9)

Figure 10 – Respiratory Effort Bands (Appendix B)

The connector of the belt (s) connects to the input of PSG recording system. In case of the Sleep@Home (Prototype B), it was necessary to implement a compatible circuit for the monitored signal amplifier.

The circuit was elaborated with the help of NI Multisim10® (Appendix C). This tool offers simulate simulation of the signal monitored by the bands. The main purpose of this simulation is to test the signal before the construction of the circuit in PCB, avoiding unnecessary costs if there are errors in the project. There are very PCB designers, for example, Altium® designer, OrCAD® and others.

Airflow

In clinical practice, a thermistor is the most used method to detect the nasal and oral flow in conventional PSG.

However, the thermistors have long time responses , the airflow can compromise the PSG leading to several false negative and the temperature of the exhaled gas is relatively unaffected by changes in the volume exhaled.

Different methods have tried to identify the respiratory effort-related arousal, without esophageal pressure measurement:

- Alteration in the flow curve obtained by nasal cannula;
- Alteration in the flow curve obtained by continuous positive airway pressure (CPAP);
- Pulse transit time;
- Sum from inductance plethysmography.

After analysis of various products on the market, it was possible to verify that practically all have detection by the airflow.

This interpretation, with reference to the classification of monitoring systems presented by the American Sleep Disorders Association, leads to the following

conclusion: the presence of a sensor for monitoring the oral and nasal flow is important for the medical community, being a factor of greater accuracy and of diagnosis.

Although this component is not to be a part of the prototype B, an acquisition would be of greater value, because it could enhance the product Sleep@Home. In future projects, this is an issue to consider. In project future, been attention for this.

Video camera

In prototype A, the video camera was analogue and the signal was stored in JPEG images format. Choice of this equipment was based on the video surveillance system Look@It (a product by ISA).

To ensure that it's possible to get images in any light conditions; this video camera can get images with good resolution without luminosity, due to its 16 infrared leds, and reaches 30 meters (approximately).

Currently, in the prototype B, it was suggested an implementation of a webcam, because it has a good performance, it's less expensive than one night surveillance camera, as used in the system Look@It and also provides a digital format of the image that will be compatible with a box already implemented; however, this suggestion was discarded because webcam software in the market is constantly updating and cannot be guaranteed the same routine in several studies of sleep, because the Sleep@Home may be obsolete.

The video camera to implement in the prototype can be IP or analogue. Everything will depend on the costs and capital gains with each. The next chapter it will introduce the expenses for components of new prototype.

Sound

The audio signal has low precision therefore not a good method to guarantee that the child has not OSAS, but the sound, synchronized with video, would be very important to help the clinical staff to recognize breathing episodes.

Several authors, including physicians and sleep studies technicians refer sleep as an important diagnosis when associated to another channel, such as a video camera. Therefore, it was considered very important to integrate a snoring microphone (Detects snoring noise during sleep recordings), which is applied to the child's neck. There are also snoring sensors (Small lightweight detects snoring vibrations during diagnostic testing. The sensor is specifically designed to pick up the frequency range of snoring vibrations), available in the market. This type of sensor is widely used in case studies whether with children or adults to detect snores, asphyxia or respiratory efforts, aiding the video images.

Figure 11 – Snoring Microphone

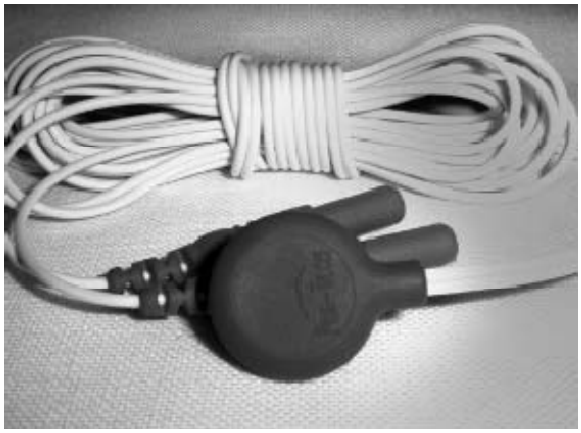


Figure 12 – Snoring Sensor

Box

The Sleep@Home box is a new concept, implemented to improve the performance of the new prototype B. However, it changes the level of programming of all components connected to the box: oximeter and video camera, which already existed in the prototype, and implementation of new routines for the bands of respiratory effort and sound.

It was a great effort to achieve the goal of making the box with small dimensions, conditions for their robust design and easy to transport, compared to the characteristics of the previous video server.

More details about the Sleep@Home are available in the next table.

Table 13 – The Sleep@Home box's main characteristics

BOX of LexSystem (54)	• **LIGHT** (Appendix D) • **NEO** (Appendix E) Both with option: - ADSL Chip: Conexant, ANSI T1.413 Issue 2, ITU-T G.992 (G.dmt) and G.992.2 (G.lite)
MOTHERBOARD of LexSystem (55)	• **CI945C** (APPENDIX F) (only in NEO, 4 –door RS232, max: 4Gb, SATA) • **SI852A** (APPENDIX G) (only 4 input analogue video, 2-door RS232, max: 1 Gb, IDE) • **CV700C** (APPENDIX H) (4-door RS232, max:1Gb, SATA)
HARD DRIVE	• HDD 160Gb 2.5'' (can be achieved, approximately 15 tests in MPEG4 (720x480 30fps) or 62 tests in JPEG (640x480 1 fps))

In box:

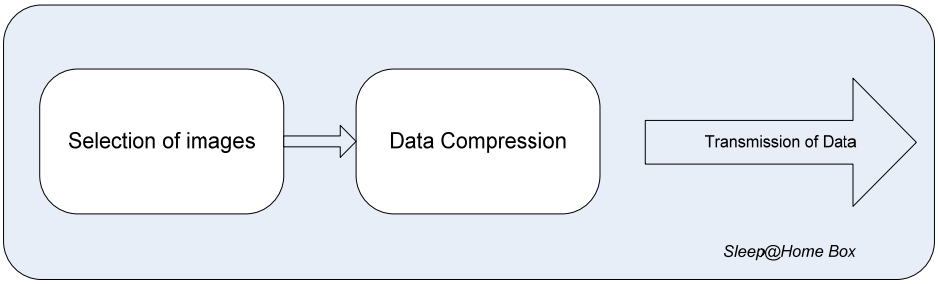


Figure 13 – Architecture logical of Sleep@Home Box

Figure 14 – Sleep@Home Box and oximeter. (Jun 2008)

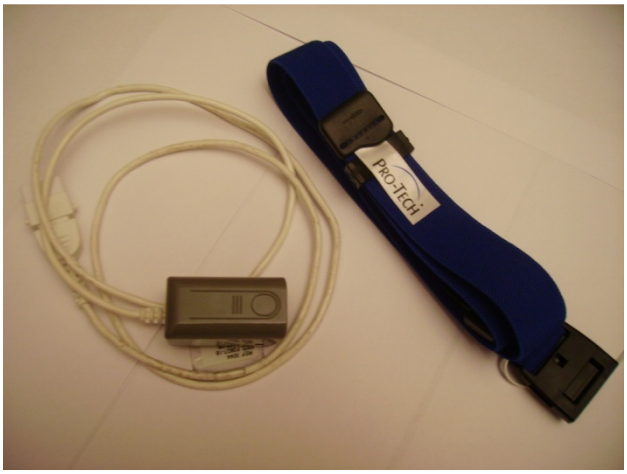


Figure 15-Components of Sleep@Home (Jun 2008)

- **Selection of images**

The objective is to only acquire images of events with clinical interest. Thus, an algorithm was created in order to record an image only in the presence of several factors:

- Low saturation detected by the oximeter (below 92% - this limit is alterable in order to trigger a detection at other percentages);
- Movement detection by the camera;
- Sound detection (snore)

- Curve changes in the respiratory flow
- Curve changes in the respiratory bands (abdominal and thoracic)

  These last two factors have not yet been integrated (as the algorithm has not yet been developed). They are a part of the future development proposal.

As long as one “alarm” from these factors occurs, the camera will start, if not started before.

- **Data Compression**

Image compression algorithms were developed, to shorten the storage space and to enable data upload via UMTS/HSPDA.

The sound is independent from the image, being compressed in mp3 format.

These are all real-time processings.

After the sleep test, there is a final compression of all data.

- **Data Transmission**

After final compression, data will be sent through ADSL, UMTS ou local network at the hospital (This procedure is still undergoing tests)

▪ TRANSMISSION MODULE

There has to be a Web Service at the hospital. This Web Service consists in a routine that assures security in the data insertion process into the database, when it’s being remotely transmitted by a http protocol. This is the only link between the

patient's home and the hospital, being a unidirectional communication (from the patient's home to the hospital).

For the remote data transmission, a communication protocol has been created between the box and the Web Service in order to assure that the images are only deleted in the box after data reception confirmation.

- **DATABASE**

The database stores the data sent by the Web Service. It stores all the patients' data as well as all users (physicians and technicians) which can include comments to the several testing and proceed the data analysis.

- **INTERFACE**

The application, developed in Visual C+ on .NET platform, has suffered several changes since the previous application developed in the 2006/2007 project. In this new application, the new components are already considered and presented.

4.3 Sleep@Home - 3 versions proposed

From the first contact with prototype A, in September of 2007, and from meetings with physicians and technicians, new ideas came up and we moved toward a prototype B.

This chapter proposes the Sleep@Home as product able to adapt itself to the various cases of suspicion of obstructive sleep apnea. According to the severity of

the symptoms presented in the clinical history (history and physical examination), the physician can choose from one of three versions:

Table 14 –Sleep@Home Versions

LIGHT VERSION	STANDARD VERSION	ADVANCED VERSION
• Oximeter: - % SpO_2 - Heart rate - PAT	• Oximeter: - % SpO_2 - Heart rate - PAT • Thermistor • Respiratory effort bands	• Oximeter: - % SpO2 - Heart rate - PAT • Thermistor • Respiratory effort bands
• Video Signal	• Video Signal • Sound	• Video Signal • Sound • Alarms • Portable screen • Pajama
Type 4	***Type 3***	***Type 3***

The ***Light version*** presents a Type 4 solution that monitors the less precise cases in sleep disorders. It's a very simple system, with the prototype A features.

The ***Standard version*** is a Type 3 solution, that assures some accuracy in the results, as the selected channels record four bio signs: $\%SpO_2$, heart rate, airflow and abdominal and thoracic respiratory effort bands.

Lastly, there is a more complete version, regarding the monitoring level to which the parents have access, called ***Advanced version***. This version contains a portable screen portable within a limited radius, in which it is possible to visually monitor the child sleeping. Various alarms are triggered when unsual events are detected or rather different sounds (from a normal night sleep), such as asphyxia or agitated awakenings.

The idea for a pajama for this version was analised and considered a desirable requisite, in case the system is wired-based, since these would go through the suture, and therefore not bothering the child during monitoring. After considering Drª Helena Estevão opinion on the matter, it was concluded that a pajama gives the advantage of not presenting to the child the visual idea of the amount of wires in contact with his body. Nevertheless, a gown would suffice as long as it can be easily dressed or undressed without moving or disconnecting any sensor, allowing the exam to continue without the child waking up.

5. CONCLUSION

5.1 Concluded Objectives

Through the course of a year's work, the Project and its objectives suffered changes as the system analysis progressed.

In an early stage, there was a period devoted to contextualize the matter in hands: apnea/OSAS, its causes and consequences, diagnosis methods and very purpose of beginning this project.

A report was created summarizing an analysis to the current literature, the products currently in the market and used in most clinical units,. This document was created with purpose of defining tasks, goals and specifications to the development of a new, more efficient and precise architecture that was less expensive and provided a state of well-being to children by not altering their sleep environment.

The choice of components has shown that the results could have been more rigorous, therefore avoiding the high rate of false negatives registered this (academic) year in the clinical tests on prototype A compared with the PSG (gold standard method. Nonetheless, the presented conclusions refer to the the research and architecture of prototype B, rather than the clinical test results of prototype A.

But the work is not over. It is important to continue testing the hardware, the interface and the algorithms.

Futurely, it is important to establish contact with several technical crews from different hospital units and clinics in order to test the Sleep@Home in their consults, allowing some feedback concerning the system: learning its limitations and qualities, what can be improved and the main assets of the system.

5.2 Future Work

5.2.1 Prototype B Conclusion

Based on prototype B current status, it is expected that it will be soon fit to be tested in a hospital environment.

Concerning the oxymeter, vídeo camera and microphone, there is currently an algorithm able to detect alarms and common episodes of apnea, nevertheless it is still necessary to develop an algorithm capable triggering alarms for all factors: Decrease of SpO_2, movement detected by the video camera, snore, analysis of obstructed airways moments through the curves that represent respiratory effort bands and, if it is implemented, the thermistor, that measures the temperature variations reading the exhaled air (higher temperature) from the inhaled air (lower temperature) or the nasal cannule measuring the decrease of nasal pressure.

As for the respiratory effort bands, it is necessary that the built circuit evolve into a PCB layout circuit.

5.2.2 Accelerometers

While elaborating the specifications document, it was established as a goal the development of accelerometers for the project, based on the use of motion sensors (body sensors) of PSG.

Abrupt movement detection is eventually associated to the sleep apnea disorder (for example, restless legs syndrome).

In the beginning of the academic year, some research was made about the creation of a small device that could be integrated in small boxes (of the size of a wristwatch) that would be attached to the wrist and the ankle. The idea was kept in

standby due to the autonomy of the system; according with Dr Helena Estevão, the child's body position during her rest period is very important, hence the study should be continued.

5.2.3 Hardware development

What makes this Project more expensive and "unsuitable" (price wise) is the need to acquire rather expensive components from specialized companies.

In fact, if the development was performed by the company, it would be possible to greatly reduce the costs when compared with the prices practiced by the companies supplying medical material/accessories.

Soon it should be made about what hardware can be developed internally: oxymeters, respiratory effort bands, microphones and what costs are involved. Maybe this way, Sleep@Home can be more viable and competitive against other systems.

5.2.1 Remote Transmission

One of the most important features of Sleep@Home will be its remote transmission of audio, video and monitorized data from the patient's home to the clinical unit, via UMTS or ADSL. This task will have to be carried through in the future.

5.2.2 Portable screen and pajama

The integration of a screen may serve as an assurement for the parents about the sleep monitoring of the children and later it can integrate an application that instruct on-screen the assembling steps. Whenever a component is malfunctioning, this information will be reported on-screen.

The screen could display real time images in order to better position the camera to the best angle. This would assure the user that everything is working properly and in the best possible conditions

5.2.3 Target population

Since the beginning, Sleep@Home was designed for children because the market doesn't have any product oriented solely for this segment of the population, disregarding often that this is a demanding and very sensitive group and might experience growth difficulties as well as lesser intellectual development due to sleep deprivation. Hence the importance of the specifications made: video camera/microphone and the screen where parents can monitor at a distance their children's sleep.

However, this narrows the market where this system can be commercialized, since that in adults the apnea syndrome and hypopnea is very serious and with irreparable health consequences. Therefore, an early and effective tracing might be the future, in many consults, this way avoiding the long queues for a PSG exam.

5.2.4 Sleep@Home screening disposable

As mentioned through the article, there are several groups of patients that can benefit from an apnea and hypopnea diagnosis in their homes. With the Sleep@Home, a tracing for obstructive sleep apnea syndrome can be done in a simple and effective way, no longer being necessary a trip to the hospital.

A great number of people feel the phobia of spending a night in an hospital environment with a countless number of wires attached to their bodies, continuously

monitoring signals. This leads to the analysis and research for portable devices and wireless technologies.

One of the groups that present an incidence percentage above average is the group of children with Down syndrome, around 20-50%, whereas the normal values for the child population are 1-3%. In the clinical history of those children, snoring, amygdale hypertrophy and agitated sleep are very common thus sleep apnea study might be pertinent. (64)(65)

Nowadays, a lot of studies are carried out in adults diagnosed with fibromyalgia (66), as this group also presents several data in their clinical history that meet the possible symptoms for a obstructive sleep apnea. Fibromyalgia is present in 0,5% of the male population and 3,4% of the female population. According to data gathered in 1995 (67), respiratory sleep disorders affect 76-90% of these patients compared with 10-30% in normal subjects.

5.3 Final Appreciation

During this past year, and during the Sleep@Home, I felt that I was contributing to an innovative and useful system that would improve the life quality of many children and their families. I realized the importance of the multidisciplinary background a biomedical engineer must have and all that can be developed in health care field.

The idea of a child spending a night in a laboratory, with countless sensors attached to her body, is certainly not a pleasant one. Thus the drive to develop a more pleasant solution avoiding runs to the laboratory, despite the fact the system does not replace the PSG.

The opportunity of integrating a business enterprise environment and the learning of several matters concerning new technologies, made me grow on a professional and personally level.

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ATTACHMENTS

APPENDIX A

Data Sheet Smiths Medical Pm 31392b1 Micro Power Oximeter Board

APPENDIX B

Data Sheet CT2™ Effort Sensor, Respironics

APPENDIX C

Circuit elaborated with the help of NI Multisim10®

APPENDIX D

Light System Case

APPENDIX E

Neo Series

APPENDIX F

CI945C Series

APPENDIX G

SI852A

APPENDIX H

CV700C Series

APPENDIX I

"Pesquisa de Patentes relacionadas com o Sleep@Home"

APPENDIX A

smiths

The Smiths Medical PM, Inc.
ADVANTAGE

- Extremely low power consumption
- Micro size
- Cost effective
- Outputs $\%SpO_2$, Pulse Rate, Signal Strength Bargraph, Plethysmogram and Status bits data
- Genuine BCI® reusable & disposable sensors available

Currently offering the lowest typical power draw in the market at 22mW typical power INCLUDING the finger sensor

MICRO POWER OXIMETER BOARD

Low power, micro size, easily integrated

The ***MICRO POWER OXIMETER BOARD*** enables easy OEM integration for fast, reliable SpO_2 and Pulse Rate measurements on any patient from neonate to adult. Serial communication at 4800 Baud provides the host system with $\%SpO_2$, Pulse Rate, Signal Strength Bargraph, Plethysmogram, and Status bits data. This Pulse Oximeter PCB consumes only 22mW of power from a single 3.3V voltage source and has a compact size of 39mm wide by 20mm deep by 5.6mm high. An assortment of compatible Oximeter sensors and patient attachments are available through Smiths Medical PM, Inc. For more information visit www.smiths-medical.com

MICRO POWER OXIMETER BOARD

SPECIFICATIONS:

SpO_2:

Range:	0-99% functional SpO_2 (1% Increments)	
Accuracy:	Adult:	±2 at 70-99% SpO_2 less than 70% is undefined
	Neonate:	+3 at 70-99% SpO_2 less than 70% is undefined
Averaging:	8 pulse beat average and instantaneous	

Pulse Rate:

Range:	30-254 BPM (1 BPM increments)
Accuracy:	±2 BPM or ±2% (whichever is greater)
Averaging:	8 second average

Signal Strength:

0-8 indicates logarithmic strength of patients pulse from 30-254 BPM

Bargraph:

0-15 segments

Plethysmogram:

0-100, auto-gained for highest resolution

Dimensions:

Length: 1.53 inches (39 mm)
Width: 0.8 inches (20 mm)
Height: 0.22 inches (5.6 mm)

Flags:

Pulse Beep
No Finger in Sensor
Sensor Unplugged
Searching for Pulse
Searching Too Long
Lost Pulse

SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE

Software Revision:

X.XX format transmitted upon reset or power up

Serial Communication Logic Levels:

CMOS 3.3V voltage levels (isolated by / from host)

Power Requirements:

6.6mA at 3.3VDC electrically isolated
(22mW typical power)

Serial Communications:

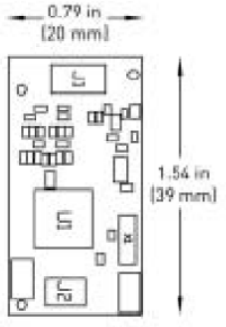
Data is transmitted from the oximeter board to the host at a rate of 60 packages per second. Data is formatted in 5 byte packets. The communication setting is 4800 Baud, One Start Bit, Eight Data Bits, No Parity, One Stop Bit.

The Micro Power Oximeter Board communicates with the host computer through a single, high-speed asynchronous serial channel at 3.3V CMOS levels. Data provided to the host includes %SpO_2 (8 pulse beat average as well as instantaneous), Pulse Rate, Signal Strength Bargraph, plethysmogram and Status Bit data. The host can synchronize the plethysmogram waveform. Using instantaneous SpO_2 values supplied by the board, the host can implement it's own averaging algorithm.

Part Number:

31392B1

Micro Power Oximeter Board
(Actual Size)



For more information, please call Smiths Medical PM, Inc., Patient Monitoring and Ventilation at 262-542-3100 or 800-558-2345 or your Smiths Medical distributor

smiths

Smiths Medical PM, Inc.
Patient Monitoring and Ventilation
N7 W22025 Johnson Drive, Waukesha, Wisconsin 53186 USA
Phone: 262-542-3100 Fax: 262-542-0718 Toll-Free: 800-558-2345
www.smiths-medical.com

APPENDIX B

PRO-TECH®

CT2™ Respiratory Effort Sensor
User Guide

Pro-tech® Services, Inc.
1338 Harbour Pointe Blvd SW
Mukilteo, WA 98275, USA
Tel: 425-322-0300 Fax: 425-322-0301
Toll Free: 000-919-0900
EMail: sales@pro-tech.com
www.pro-tech.com

EC REP Advena Ltd. Hereford HR4 9DQ UK.

CE

OM9364, Rev D

English
CT2™ Respiratory Effort Sensor User Guide

Intended Use & Features
The CT2 Piezo Respiratory Effort Belts are intended for use during sleep disorder studies to detect respiratory effort for recording onto a physiological recorder. The CT2 Piezo Respiratory Effort Belt design combines the piezo sensor element and strap into a single belt with a quick release buckle for easy patient setup and disconnect.

Warning
Sensor must be connected to an electrically isolated input. Patient injury could occur if not connected properly.

Caution Statements
This product is for diagnostic purposes only and is not to be used as an apnea monitor or in a life supporting or life sustaining situation. Federal law restricts this device to sale by or on the order of a physician.

Specifications

Operating Temperature	5°C (40°F) - 40°C (104°F)
Storage Temperature	-20°C (-4°F) - 60°C (140°F)
Operating/Storage Humidity	15 - 95% Non-condensing

Sizing the CT2
The CT2 Respiratory Effort Belts are designed to provide the maximum degree of body coverage within both the pediatric and adult populations. The two belt sizes will fit individuals within the following size ranges.

Adult Size	72 - 200cm (28 - 80 inches)
Pediatric Size	27 - 86cm (10.5 - 34 inches)

If a larger size belt is required add one or more 46cm (18inches) extension straps (sold separately, pn1592).

Sensor Installation
1. Position the belts around the patient's abdomen and thorax and snap the buckle in place as shown in figure 1.
2. The belt should be adjusted to fit snuggly (but not to the point of patient discomfort). Note: For best results patients should be lying down when tightening.
   - To tighten, tilt the buckle and pull the ***front*** strap through the buckle loop until snug. Then position the strap retainer to avoid bunching of the overflow.
   - To loosen, tilt the buckle and pull the ***back*** strap through the buckle loop until a proper fit is achieved.

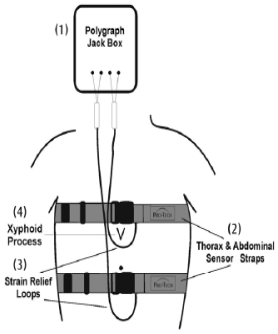


Figure 1

Instrument Connections
Plug the belt's connector(s) into the appropriate input of your recording system.
Note: When disconnecting from the recording system grasp the connector(s) firmly. Do not pull on the wire leads as this can damage the connectors. Damage caused by pulling on the wire leads is not covered under the warranty.

Instrument Settings
Sensitivity - Approximately 50-75 µV/mm. Adjustment of the sensitivity up or down is typically required. Response is dependent on such variables as sensor application and patient effort.

Low Frequency Filter/Time constant - .16 Hz or lower **/** 1 second or longer. Shorter time constants will significantly attenuate waveforms.

High Frequency Filter - 5 -15 Hz

Cleaning
The belt may be safely soaked in a warm *(Do not use hot water)* hospital grade laundry detergent for cleaning and then air dried. Avoid contact of the cleaning solution with the connector(s).

Warranty
Pro-Tech Services, Inc. warrants this product to be free of defects in materials and workmanship for a period of one year from the date of purchase. Should any product prove defective in workmanship, materials or performance during the warranty, the sole liability of Pro-Tech Services, Inc. is limited to repair or, at its option, replacement of the product with no charge for parts or labor. Under no circumstances shall Pro-Tech Services, Inc. be liable for any loss or damage, direct, consequential, or incidental, including property damage or personal injury arising from the use of, or the inability to use this product. This warranty is rendered void and Pro-Tech Services, Inc. cannot be held liable for conditions resulting from: damage, marginal performance or malfunctions caused by: misuse, abuse, neglect, improper line voltage, power fluctuations, or any adverse environmental conditions, tampering, unauthorized modifications, adjustments or repairs to the product or its accessories. This warranty is in lieu of all other warranties, expressed or implied, and is extended only to the original purchaser. Features and specifications are subject to change without notice.

Francais
CT2™ Capteur d'Effort Respiratoire Piezo Guide de l'utilisateur

Utilisation prévue & fonctions
Les ceintures d'effort respiratoire piezo CT2 sont prévues pour détecter l'effort respiratoire lors des études de troubles du sommeil, pour raccordement à un enregistreur physiologique. La ceinture d'effort respiratoire piezo CT2 combine l'élément capteur piezo et sa bande de fixation dans une ceinture simple équipée d'une boucle à ouverture rapide facilitant le branchement et le débranchement.

Avertissement
Les capteurs doivent être raccordés à une alimentation élec-triquement isolée. Risque de blessure du patient en cas de branchement incorrect.

Attention
Ce produit est destiné à un usage strictement diagnostique. Il ne convient nullement de l'utiliser à des fins de monitorage d'apnée, ou de soutien ou entretien de la vie. Ce produit contient du latex naturel qui peut causer des réactions allergiques. La législation fédérale des États-Unis limite la vente de ce dispositif à un médecin ou à sa prescription.

Caractéristiques

Température d'exploitation	5°C (40°F) - 40°C (104°F)
Température de stockage	-20°C (-4°F) - 60°C (140°F)
Taux d'humidité d'exploitation/stockage	15 - 95% sans condensation

Sélection de la taille de la CT2
Les ceintures d'effort respiratoire CT2 sont conçues pour offrir une couverture optimale du corps en pédiatrie comme pour les patients adultes. Les deux tailles de ceintures sont adaptées aux individus correspondant aux tailles suivantes:

Taille adultes	72 - 200 cm (28 - 80 pouces)
Taille pédiatrie	27 - 86 cm (10,5 - 34 pouces)

Si une plus grande taille de ceinture est nécessaire, il est possible d'ajouter une ou plusieurs 46cm (18 pouces) sangles d'extension (vendues séparément, pn1592).

Installation du capteur
1. Placez les ceintures autour de l'abdomen et du thorax du patient et refermez la boucle, comme illustré à la figure 1.
2. La ceinture devra être ajustée de façon à serrer très légèrement le patient (sans causer d'inconfort). Remarque: pour une plus grande efficacité, les patients devront être couchés lors du serrage de la ceinture.
   - Pour resserrer, basculez la boucle et tirez la sangle ***avant*** à travers la boucle jusqu'à ce que la ceinture soit correctement serrée, puis mettez en place le passant de fixation de la sangle, pour maintenir en place la longueur non-utilisée.
   - Pour desserrer, basculez la boucle et tirez la sangle ***arrière*** à travers la boucle jusqu'à obtention d'un serrage adéquat.

« Voir l'illustration »
(1) Boite de connexions du polygraphe
(2) Attache du capteur de thorax/ Attache du capteur abdominal
(3) Boucles de soulagement d'effort
(4) Processus de Xyphoid

Branchement de l'instrument
Branchez les connecteurs de la ceinture dans la prise appropriée de votre système d'enregistrement.

Remarque: Attrapez fermement les connecteurs pour débrancher l'appareil du système d'enregistrement. Ne tirez pas sur les fils, sous peine d'endommager les connecteurs. Tout endommagement occasionné en tirant sur les fils ne sera pas couvert par la garantie.

Réglages du dispositif
Sensibilité – Environ 50-75 µV/mm. Il est typiquement nécessaire de régler la sensibilité vers le haut ou le bas. La réponse dépend de variables comme l'application du détecteur et l'effort du patient.

Filtre basse fréquence/ Constante de temps - .16 Hz ou moins **/** 1 seconde ou

plus. Des constantes de temps plus faibles atténuent considérablement la forme des ondes.

Filtre haute fréquence - 5 – 15 Hz

Nettoyage

La ceinture peut être immergée en toute sécurité dans un détergent hospitalier *(ne pas utiliser d'eau chaude)* pour la nettoyer, puis séchée à l'air. Évitez tout contact des connecteurs avec la solution de nettoyage.

Garantie

Pro-Tech Services, Inc. garantit ce produit contre tous vices de matériaux ou de fabrication pendant une période d'une année à compter de la date d'achat. Au cas où un vice de fabrication, matériau ou performance deviendrait apparent durant ladite période de garantie, la responsabilité de Pro-Tech Services, Inc. serait strictement limitée à la réparation ou, à son gré, au remplacement du produit sans frais de pièces ni main-d'œuvre. Pro-Tech Services, Inc. ne pourra en aucun cas être tenue responsable de pertes ou dommages, fussent-ils directs, indirects ou accessoires, y compris tous dommages matériels ou personnels imputables à l'usage, ou à l'incapacité d'usage de ce produit. La présente garantie sera réputée nulle et de nul effet et Pro-Tech ne pourra nullement être tenue responsable dans les circonstances résultant de dommages, faibles performances ou mauvais fonctionnements imputables à tous abus, modifications, reglages ou reparations du produit ou de ses accessoires. La présente garantie est offerte au lieu et place de toutes autres garanties, expresses ou tacites, et est limitée à l'acheteur original du produit. Les fonctions et caractéristiques du produit sont sujettes à modification sans préavis.

Deutsch
CT2™ Piezo-Atmungsbewegungssensor Gebrauchsanweisung

Anwendungsgebiet und Funktionsmerkmale

Die CT2 Piezo-Atemaufwandsgürtel sind zur Verwendung bei Schlafstörungsstudien vorgesehen und dienen zur Ermittlung des Atemflusses und dessen Aufzeichnung mit einem physiologischen Aufnahmegerät. Der CT2 Piezo-Atemaufwandsgürtel ist so ausgelegt, dass das Piezo-Sensorelement und der Gurt in einem Gürtel mit rasch lösbarer Schnalle kombiniert sind, was ein leichtes Anbringen und Abnehmen beim Patienten ermöglicht.

Warnhinweis

Sensor müssen an einen galvanisch isolierten Eingang angeschlossen werden. Wenn sie nicht vorschriftsmäßig angeschlossen werden, könnte dies zu Gesundheitsschäden bei Patienten führen.

Vorsicht

Dieses Produkt ist nur für Diagnosezwecke vorgesehen und darf nicht als Apnoe-Überwachungsgerät oder in einer lebenserhaltenden Situation benutzt werden. Lt. Bundesgesetz (USA) darf dieses Gerät nur von einem Arzt oder auf seine Anordnung hin verkauft werden.

Technische Daten

Betriebstemperatur	5°C (40°F) - 40°C (104°F)
Lagertemperatur	-20°C (-4°F) - 60°C (140°F)
Betriebs-/Lagerluftfeuchtigkeit	15 - 95% nicht kondensierend

Auswahl der geeigneten Größe des CT2

Die CT2 Atemaufwandsgürtel sind so ausgelegt, dass sie einen Höchstgrad an Körperabdeckung sowohl in der pädiatrischen als auch der erwachsenen Population abdecken. Die zwei Gurtelgrößen passen für Personen in den folgenden Größenbereichen:

Erwachsenengröße	72 - 200 cm (28 – 80 zoll)
Kindergröße	27 - 86 cm (10,5 – 34 zoll)

Sollte ein größerer Gürtel erforderlich sein, können ein oder mehr 46cm (18 zoll) Verlängerungsgurte hinzugenommen werden (separat erhältlich unter Bestellnummer 1592).

Sensorinstallation

1. Die Gürtel um Abdomen und Thorax des Patienten anlegen und Gürtelschnalle wie in Abb. 1 gezeigt einrasten lassen.

2. Der Gürtel sollte fest, aber nicht zu fest anliegen (nicht so fest, dass es dem Patienten unangenehm ist). Hinweis: Die besten Ergebnisse sind zu erreichen, wenn der Patient beim Anziehen des Gürtels liegt.

- Um den Gürtel fester anzuziehen, die Gürtelschnale neigen und den ***vorderen*** Gurt durch die Schnallenschleife ziehen, bis der Gürtel fest sitzt. Dann den Gurthalter so positionieren, dass sich die überschüssige Gurtlänge nicht faltet.
- Um den Gürtel zu lockern, die Gürtelschnalle neigen und den ***hinteren*** Gurt durch die Schnallenschleife ziehen, bis die gewünschte Passform erreicht ist.

„Siehe Abbildung"

(1) Polygraph Anschlußplatte
(2) Sensorband auf Brust/ Sensorband auf Bauch
(3) Entspannungsschlaufen
(4) Prozeß Xyphoid

Geräteanschlüsse

Stecken Sie den/die Anschluss/Anschlüsse des Gürtels in die entsprechende Eingangsbuchse Ihres Aufnahmesystems.

Hinweis: Wenn Sie die Verbindung mit dem Aufnahmesystem wieder lösen, fassen Sie den Anschluss bzw. die Anschlüsse fest an. Ziehen Sie nicht an den Kabeln, da dies die Anschlüsse beschädigen kann. Durch Ziehen an den Kabeln entstandene Schäden sind nicht durch die Garantie abgedeckt.

Geräteeinstellungen

Empfindlichkeit - Ca. 50-75 µV/mm. In der Regel ist eine Anpassung der Empfindlichkeit nach oben oder unten erforderlich. Die Reaktion richtet sich nach variablen wie Sensoranbringung und Atemanstrengung des Patienten.

Niederfrequenzfilter/Zeitkonstante - 10 Hz oder darunter / 1 Sekunde oder länger. Bei kürzerer Zeitkonstante kommt es zur signifikanten Schwächung der Wellenformen.

Hochfrequenzfilter - 5 - 15 Hz

Reinigung

Der Gürtel kann gefahrlos in einem warmen *(KEIN HEISSES WASSER VERWENDEN)* Krankenhaus-Reinigungsmittel eingeweicht und anschließend an der Luft getrocknet werden. Es ist zu vermeiden, dass die Reinigungslösung in Kontakt mit dem Anschluss bzw. den Anschlüssen kommt.

Garantie

Pro-Tech Services, Inc. gewährleistet für einen Zeitraum von einem Jahr ab Kaufdatum, dass dieses Gerät frei von Material- und Verarbeitungsschäden. Falls der Sensor vor Ablauf dieser Frist ausfällt, ist die Haftung von Pro-Tech Services, Inc. nach jeweils eigenem Ermessen auf die Instandsetzung oder den Ersatz des Geräts ohne Berechnung von Kosten für Ersatzteile oder Arbeitsleistung beschränkt. Pro-Tech Services, Inc. haftet unter keinen Umständen für jegliche unmittelbaren oder mittelbaren Verluste, Schäden, Folge- oder Nebenschäden, Sach- oder Personenschaden infolge der Verwendung oder der Unfähigkeit zur Verwendung dieses Geräts. Diese Garantieerklärung gilt als rechtsverbindlich, und Pro-Tech Services, Inc. kann nicht für Missbrauch, unsachgemäßen Gebrauch, Fahrlässigkeit, unzweckmäßige elektrische Spannung, Stromschwankungen, jegliche widrigen Umfeldbedingungen, Verfälschungen, unberechtigte Veränderungen, Justierungen oder Reparaturen des Gerats und seiner Zubehörteile haftbar gemacht werden. Diese Garantieerklärung ersetzt alle anderen ausdrücklichen oder stillschweigenden Garantien und kann nur vom ursprünglichen Käufer geltend gemacht werden. Änderungen der Funktionen und technischen Daten des Gerats ohne vorherige Ankündigung vorbehalten.

Italiano
CT2™ Sensore Piezo per lo Sforzo Respiratorio Guida all'Uso

Caratteristiche e uso previsto

Le cinture piezometriche per sforzi respiratori CT2 sono destinate all'impiego negli esami dei disturbi del sonno per rilevare gli atti respiratori da registrare su un registratore fisiologico. Il prodotto integra l'elemento sensore piezometrico e la cinghia in una cintura singola con fibbia a rapido disinnesto, per una facile applicazione e sconnessione sul paziente.

Avvertenza

Sensore dovono essere collegati ad un ingresso elettricamente isolato.
Il collegamento errato può causare infortuni al paziente.

Dichiarazioni cautelative

Questo prodotto va usato esclusivamente a scopo diagnostico e non come monitor per l'apnea né per l'assistenza o il supporto delle funzioni vitali. Questo prodotto contiene lattice di gomma naturale, una sostanza in grado di provocare reazioni allergiche. La legge federale (USA) limita la vendita di questo dispositivo a medici o dietro prescrizione medica.

Specifiche

Temperatura di funzionamento	5°C (40°F) - 40°C (104°F)
Temperatura di conservazione	-20°C (-4°F) - 60°C (140°F)
Tasso di umidità di funzionamento/ conservazione	15 - 95% senza condensa

Dimensioni del CT2

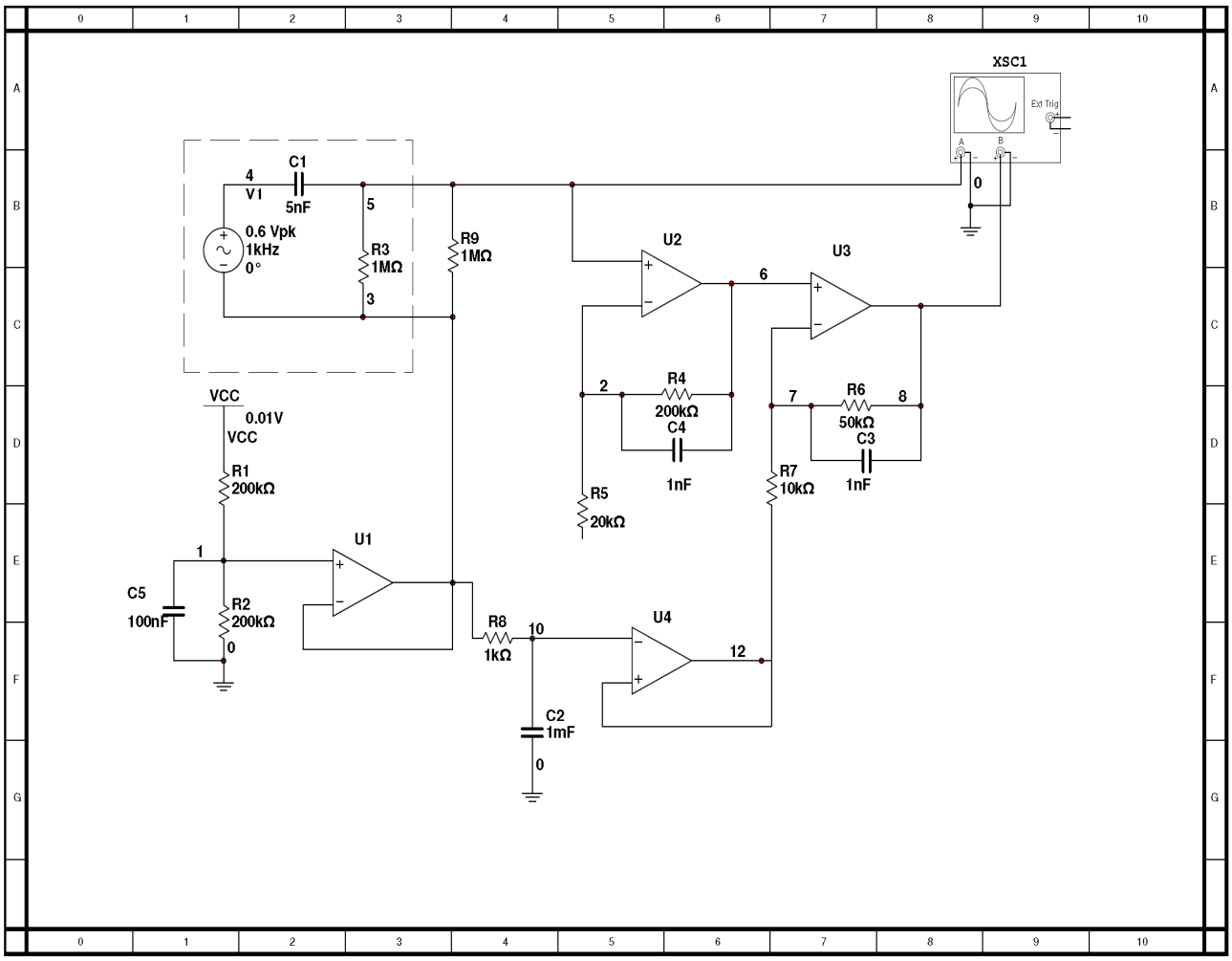
Le cinture per sforzi respiratori CT2 sono progettate per fornire il massimo grado di copertura corporea nei pazienti sia pediatrici sia adulti. La cintura è disponibile in due dimensioni adatte per le seguenti tipologie di paziente:

Adulto	72 - 200 cm (28 - 80 pollici)
Pediatrico	27 - 86 cm (10.5 - 34 pollici)

Se occorre una cintura più grande, aggiungere una o più cinghie 46cm (18pollici) di estensione (vendute separatamente, pn1592).

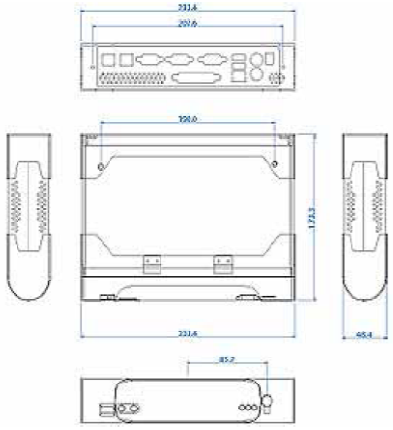
APPENDIX C

Circuit elaborated with the help of NI Multisim10®



APPENDIX D

Lex SYSTEM Embedded System.



LIGHT

Low Cost System Case
Fanless up to 800Mhz CPU Model SBC Board

Description: :

Light Case was featured with Simple, Compact, Small, Stylish.
It can be applied as Thin Client, NetWork Device, Set-Top Box, VPN, VOIP and POS system. Major Material is Aluminum for good heat solution.
Light System Case provides 1 x 2.5" Slim HDD Space.
For VIA EDEN 400/533Mhz CPU, Light System can provide Fan-Less Solution.

Technical Data :

Dimension	48.5 H x 234 W x 175 D mm
Material	Aluminum + Plastic (Out-Side Cover)
Color	Blue / Silver
Weight	1 Kgs (Include M/B)
Storage Space	2.5" HDD x 1
LED Light	Power / Network / HDD
Front Connector	2 x USB, Mic-in, Lin-out

M/B information: (Please reference M/B specification) :

SBC Board Model	Description
CV860A	1~3 Lan
CV862A	Pin Head connector
CV860B	Lan, TV-out
CV860C	4 Com Ports

CV863A	2 PCMCIA Slot / 4 Lan
CV866C	4 Com Ports, LVDS
SV823A	4-16 Video in
MV823A	2 IEEE1394 / Video in & TV-out, LVDS (option)
MV823S	1 Lan, TV-out

Option (Function inside the case):

Wireless Lan	Chip : ATMEL , USB Interface , 802.11b Standard , Driver :Win98,ME,2K,XP,Linux, 128bit WEP Encryption Support
56K Modem(ST)	Chip : ST , USB Interface , Driver : Win98,ME,2K,XP,Linux
56K Modem(CX)	Chip : Conexant , USB Interface , Driver : Win98,ME,2K,XP.
ISDN	Chip : Cologne, ISDN Standard ETSI Euro ISDN, Driver : Win98,ME,2K,XP,Linux
ADSL	Chip : Conexant , ANSI T1.413 Issue 2, ITU-T G.992(Gdmt) and G.992.2(Glite) Annex A,B . Driver : Win98,ME,2K,XP,Linux , No WinCE


CV860A


CV860B


CV860C


SV823A


MV823A


MV823S

APPENDIX E

Embedded System

NEO Series

NEO Series

NEO Chassis without top-cover

Application :
Thin Client, Network device, Set-Top Box, VPN, VOIP, DVR and POS system

M/B information: (Please refer to M/B specification)

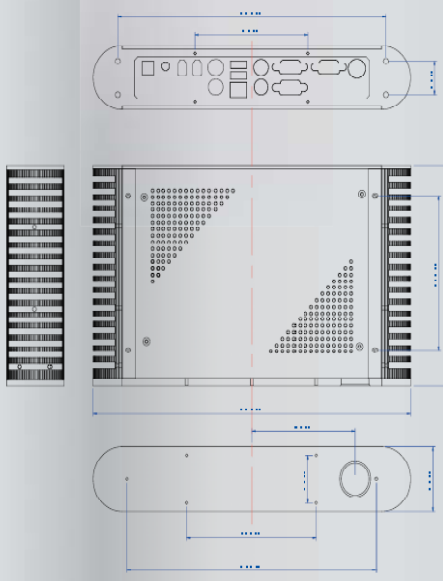
M/B Model	Description
CI945A	Core 2 Duo solution / 4 LAN / PCI / Mini PCI / PCMCIA / SATA
CV700A	3 LAN
CV700C	4 COM Ports
CV763A	2 PCMCIA Slot / 4 LAN
MV700A	Twin view/ Video in, LVDS(option)
CI852A	4 LAN
CI852C	4 COM ports / PCI 104
SI852A	4~16 Video in
MI853AW	2 IEEE1394 / PCI / DVI / TV-Out / Wide range DC-IN

Technical Data :

. Dimension	50 H x 275 W x 172 D mm
. Material	Aluminum
. Color	Black
. Weight	2 Kgs (Inc. M/B)
. Storage Space	1 x 2.5" HDD

Option (CV763A are excluded)

Wireless Lan	Chip: ATMEL , USB Interface , 802.11g Standard , Driver: Win98,ME,2K,XP,Linux, 128bit WEP Encryption Support
56K Modem(CX)	Chip: Conexant , USB Interface , Driver: Win98,ME,2K,XP,Linux
ISDN	Chip: Cologne, SDN Standard ETSI Euro ISDN, Driver: Win98,ME,2K,XP,Linux
ADSL	Chip: Conexant , ANSI T1.413 Issue 2, ITU-T G.992(G.dmt) and G.992.2(G.lite) Annex A,B Driver: Win98,ME,2K,XP,Linux



Wireless Lan

Lex SYSTEM®

APPENDIX F

Embedded Solution CI945C Series

New Product
POS application

CI945C Series

Application

POS, KIOSK, Information desk, Automation control

Features

CORE 2 DUO, SATA, LVDS, 4 COM, Mini PCI, PCI, Touch Screen, WDT/DIO

POS

Specifications

CPU type	Intel Core 2 Duo / Core Duo
. Front Side Bus	533/667 MHz
. MB Chipset	Intel 945GME/GM + ICH7M (82801GBM)
. Graphics	Intel Gen 3.5 Integrated Graphics Engine Dynamic Video Memory Technology(DVMT 3.0) Higher performance MPEG-2 decoding
. LVDS	Supports data format of 18 bits/36 bits
. Memory	DDR2 SODIMM(max. 4GB)
. IDE	Ultra ATA 100/66/33, 1x 40 pin 2.54mm, 1x44 pin 2.0mm Support Compact Flash card type II for ATA interface
. SATA	Two SATA ports with independent DMA operation supported on ports 0 and 2
. Audio	Intel High Definition Audio Specification Rev.1.0 Compliant
. LAN	2 x Realtek RLT8101E 10/ 100 Mbps or Intel 82573L 10/100/1000 Mbps Supports PCI Express™ 1.0a Intel 82573L or Realtek RLT8101E LAN Chip
. IO function	4 x RS232 Supports IrDA 1.0/ASKIR protocol Supports PS2 keyboard and mouse
. USB	9 x USB 2.0
. Touch Screen	USB interface Touch screen controller Supported 4- , 5- , 8- wire Analog Resistive touch screen. USB 1.1full speed sample rate max. (300points/s)
. DIO & WDT	Hardware digital Input & Output, 4xDI / 4xDO Hardware Watch Dog Timer, 0~255 sec programmable
. Expand interface	1 x Mini PCI for only PCI rev: 2.2 interface 1 x PCI gold finger for only PCI rev: 2.2 interface
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system -12V support (optional)
. Dimension	200 x 150 mm

. Operation Temperature: 0 ~ 60° C
. Operation Humidity: 5~95% @ 60°C, non-condensing

Available Chassis

Neo, Twister, Tino

Ordering Information

. CI945C	TBD

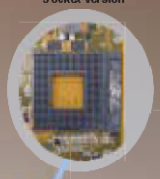
POS
KIOSK
Information desk
Automation control

Lex SYSTEM®

APPENDIX G

Embedded Solution SI852A Series DVR application

Socket Version



SI852A Series

Application

Video Surveillance for building monitoring, Access control & mobile PC.

Features

Intel P-M/C-M | Twin View | 4~16 Video-in | WDT/DIO | LVDS | TV-OUT

Specifications

. CPU type	Intel Pentium M/ Celeron M 1GHz- Dothan processor
. Front Side Bus	400/533 MHz
. MB Chipset	Intel 82852GM/ 82852GME(Socket) + ICH4
. Graphics	Integrated with Intel 82852GM/GME Shared system memory up to 64MB
. LVDS	Support data format of 18 bits/36 bits
. Memory	1 x DDR SDRAM (max. 1GB)
. IDE	Ultra ATA 100/66/33, 1x 40 pin 2.54mm, 1x44 pin 2.0mm Support Compact Flash card type II for ATA interface
. Audio	AC-Link for Audio CODEC, AC'97 2.1
. TV-Out	Analog S-Video for SDTV, for all NTSC & PAL
. LAN	1 x Realtek 10/100 Mbps (optional Realtek/Intel Gigabit) Intel 82541PI or Realtek RLT8100C/RLT8110SB LAN Chip
. IO function	1x RS232, 1x RS232/422/485 Supports IrDA 1.0/ASKIR protocol Supports PS/2 keyboard and mouse
. Video-In	4 ports with Conexant Fusion 878A video codec
. USB	6 x USB 2.0
. DIO & WDT	Hardware digital Input & Output, 8xDI / 8xDO Hardware Watch Dog Timer, 0~255 sec programmable
. Expand interface	1 x Mini PCI
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system
. Dimension	200 x 150 mm

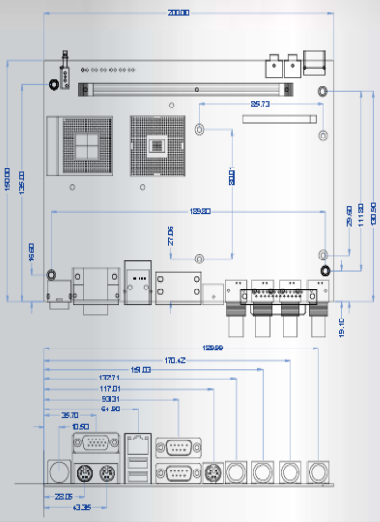
. Operation Temperature: CF Card : 0~60°C ; 2.5"HDD : 0~45°C

. Operation Humidity: 5~95 % @ 60 °C, non-condensing

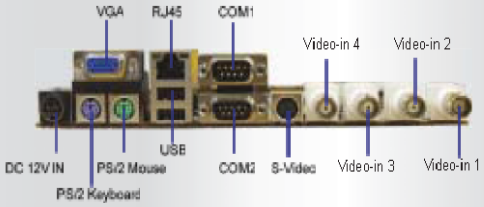
Ordering Information

. SI852A-4SR10	1 chip (Conexant BT878A) with 4 video-in channels
. SI852A-4UR10/4URXX (socket)	4 chip (Conexant BT878A) with 4 video-in channels
. SI852A-4HR10/4HRXX (socket)	4 chip (Conexant BT878A) with 16 video-in channels

Dimension



Back Panel



Testing environment

Model name : SI852A-4UR10
CPU : Intel Celeron M 1GHz
Chipset : Intel 82852GM and Intel 82801DB ICH
OS : WIN XP
Testing Program 3D Mark 2001 SE

Fanless solution with CF card

Chassis Temperature	Light	Neo	Twister	Tino
0°C	Pass	Pass	Pass	Pass
40°C	Pass	Pass	Pass	Pass
45°C	Pass	Pass	Pass	Pass
60°C	Pass	Pass	Pass	Pass

Fanless solution with 2.5" HDD

Chassis Temperature	Light	Neo	Twister	Tino
0°C	Pass	Pass	Pass	Pass
40°C	Pass	Pass	Pass	Pass
45°C	Pass	Pass	Pass	Pass

Testing environment

Model name : SI852A-4URXX
CPU : Intel Pentium M 2.13GHz
Chipset : Intel 82852GME and Intel 82801DB ICH
OS : WIN XP
Testing Program 3D Mark 2001 SE

Fanless solution with CF card

Chassis Temperature	Twister	Tino
0°C	Pass	Pass
40°C	Pass	Pass
45°C	Pass	Pass
60°C	Pass	Pass

Fanless solution with 2.5" HDD

Chassis Temperature	Twister	Tino
0°C	Pass	Pass
40°C	Pass	Pass

Lex SYSTEM

APPENDIX H

Embedded Solution CV700C Series POS application

POS

CV700C Series

Application
POS/ KIOSK/ Industrial Control Solutions

Features

VIA Eden/C7 | 4 COM | SATA

Specifications

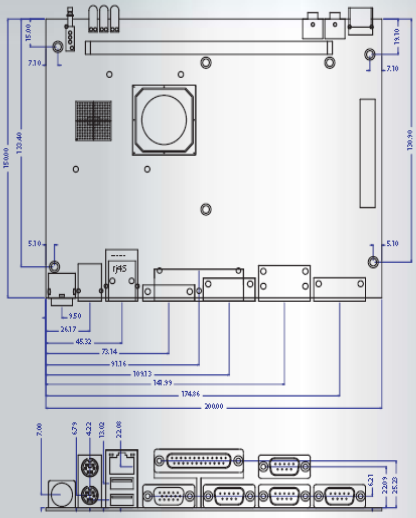
. CPU type	VIA Eden(V4)/ C7 nano BGA2 400 pin, L1/L2 128K on die
. Front Side Bus	400/533 MHz
. MB Chipset	VIA CN700 + VIA VT8237R Plus
. Graphics	Integrated with VIA CN700
	Shared system memory up to 64MB
	MPEG-2 hardware VLD
. TV-OUT (option)	NTSC(M, J) or PAL(B,D,G,H,I,M,N,Nc)
. Memory	1 x DDR II SDRAM 533/400 (max. 1GB)
. IDE	Ultra DMA-133/100/66 transfer protocols
	1x 40 pin 2.54mm, 1x44 pin 2.0mm
	Support Compact Flash card type II for ATA interface
. Audio	AC-Link for Audio CODEC, AC'97 2.1
. LAN	1 x Realtek 10/100 Mbps (optional Realtek/Intel Gigabit)
	Intel 82541PI or Realtek RLT8100C/RLT8110SB LAN Chip
. IO function	3 x RS232, 1xRS232/422/485
	Supports Hardware Monitor Controller
	Supports IrDA 1.0/ASKIR protocol
	Supports PS2 keyboard and mouse
. USB	7 x USB 2.0
. SATA	One channel connector
	SATA drive transfer rate is capable up to 150MB/s
. Expand interface	1x Mini PCI for only PCI rev: 2.2 interface
. Power	On board DC +12V convert to +3.3V/+12V/+5V for system
. Dimension	200 x 150 mm

. Operation Temperature: 0 ~ 60 °C
. Operation Humidity: 5~95% @ 60 °C, non-condensing

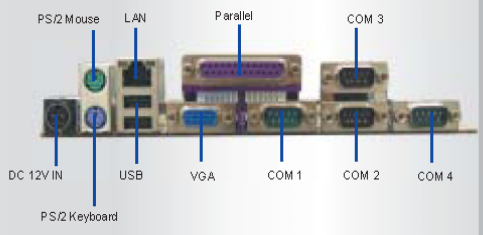
Ordering Information

. CV700C-1R50E	1 LAN, 500MHz, VIA Eden(V4) processor
. CV700C-1R10C	1 LAN, 1GHz, VIA C7 processor

Dimension



Back Panel



Testing environment

Model name : **CV700C1R10C**
CPU : VIA V4 C7 1000MHz
Chipset : VIA CN700 & VIA VT8237R PLUS
OS : WIN XP
Testing Program : 3D Mark 2001 SE

Fanless solution with CF card

Channel / Temperature	Light	Neo	Twister
0°C	Pass	Pass	Pass
25°C	Pass	Pass	Pass
40°C	Pass	Pass	Pass
60°C	FAN	Pass	Pass

Fanless solution with 2.5" HDD

Channel / Temperature	Light	Neo	Twister
0°C	Pass	Pass	Pass
25°C	Pass	Pass	Pass
40°C	FAN	Pass	Pass

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APPENDIX I

Pesquisa de patentes relacionadas com o Sleep@Home[3]

"Infant blood oxygen monitor and SIDS warning devices"
Nº Patente: 6047201
Data Publicação Patente: Abril 4, 2000
Descrição: O aparelho é composto por um oxímetro colocado no pé dos bebés com vista à detecção da saturação arterial de oxigénio e da frequência cardíaca. O dispositivo comunica com um pequeno monitor via rádio onde são mostradas as leituras relativas à frequência cardíaca e saturação de oxigénio. O monitor soa um alarme se estes valores forem inferiores aos predeterminados.
URL: http://www.google.com/patents?id=vUYEAAAAEBAJ&printsec=drawing&zoom=4&dq=sleep+apnea+device%2B+oximeter%2Bcamera#PPA1,M1, 22 de Agosto de 2008

"Apparatus and method for diagnosing sleep apnea"
Nº Patente: 7169110
Data Patente: Jan 30, 2007
Descrição: Aparelho para diagnosticar a apneia do sono detectando a cessação temporária da respiração durante o sono. Baseia-se nos princípios da oximetria de pulso.
URL: http://www.google.com/patents?id=PMN-AAAAEBAJ&printsec=abstract&zoom=4, 22 de Agosto de 2008

"Method for providing a remote diagnostic"
Application number: 10/951,713
Data Patente: Abril 6, 2006
Descrição: Permite a monitorização remota do doente em casa. Funciona com uma câmara e um oxímetro de pulso, no entanto pode integrar outros sinais como o ECG, pletismografia ou sensores acelerómetricos para a detecção da postura e movimento.
URL: http://www.google.com/patents?id=U5GbAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep+apnea+device%2B+oximeter%2Bcamera%2Bportable, 22 de Agosto de 2008

[3] *This work has made in collaboration with Vânia Almeida.*

"Sleep apnea screening and/or detecting apparatus and method"
Nº Patente: 5797852
Data Patente: Agosto 25, 1998
Descrição: Aparelho portátil para uso na cama do paciente. Usado para detecção de apneias com base em sons respiratórios capturados por dois microfones.
URL: http://www.google.com/patents?id=sm4mAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory#PPA15,M1, **22 de Agosto de 2008**

"Apparatus for detecting sleep apnea using electrocardiogram signals"
Nº Patente: 7025729
Data Patente: Abril 11, 2006
Descrição: Sistema permite o diagnóstico de apneia de sono com base num sinal de electrocardiograma (análise intervalos RR) e com derivação do sinal respiratório.
URL: http://www.google.com/patents?id=c3V3AAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory, 22 de Agosto de 2008

"Portable integrated physiological monitoring system"
Nº Patente: 6083156
Data Patente: Julho 4, 2000
Descrição: Com vista ao uso em ambulatório integra diversos sensores, EEC, ECG, oxímetro de pulso, estetoscópio, sensores de temperatura, sensores de fluxo respiratório. Todos os sensores estão ligados a um computador portátil.
URL: http://www.google.com/patents?id=TogDAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory, 22 de Agosto de 2008

"Ambulatory patient health monitoring techniques utilizing interactive visual communications"
Nº Patente: 5544649
Data Patente: Agosto 13, 1996
Descrição: Sistema de monitorização em casa que consiste num sistema que integra vários equipamentos e uma câmara que permite a monitorização diária. Embora mais relacionado com o AAL pode ser utilizado em aplicações específicas como o de diagnóstico de doentes com síndrome de apneia do sono.
URL: http://www.google.com/patents?id=pnkoAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bdevice%2Bportable%2Bambulatory#PPA1,M1, 22 de Agosto de 2008

"Sudden infant death syndrome monitor"
Nº Patente: 5505199
Data Patente: Abril 9, 1996
Descrição: Detecção de distúrbios durante o sono em bebés. O sistema é composto por uma câmara de vídeo, sensores de movimento (sem contacto com o bebé) e um oxímetro.
URL: http://www.google.com/patents?id=mBkiAAAAEBAJ&printsec=abstract&zoom=4&dq=sleep%2Bapnea%2Bhome%2Bmonitoring%2Boximeter%2Bcamera#PPA1,M1, 22 de Agosto de 2008