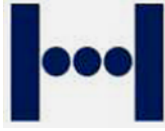




Intelligent Sensing Anywhere



Central Hospital of Coimbra



Faculty of Science and
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Coimbra
Department of Physics

Master Graduation in Biomedical Engineering

Project Report

Version 1.0

Sleep@Home's Validation

Remote Monitoring of Sleep Apnea

Syndrome Patients

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Abstract

Obstructive Sleep Apnea Syndrome (OSAS) is an important concern in today's society. It consists of repeated breathing interruptions during sleep, which cause early awakenings and sleep fragmentation. This condition is responsible for several health problems such as daytime sleepiness and, particularly in children, growth abnormality, hyperactivity disorder and decrease in school performance or intelligence.

Polysomnography (PSG) is the gold standard method for the diagnosis of OSAS and it consists in the complete monitoring of different vital signs, including the electroencephalogram (EEG) to assess the stages of sleep. To perform this exam, the patient has to stay overnight in a hospital environment, an unknown sleeping environment, which can therefore cause artifacts in the study.

Sleep@Home is a system that has been developed in order to solve this problem. It is a device composed of a video camera and an oximeter, to watch sleep and acquire data from heart rate and SpO₂. This system is designed for home monitoring and OSAS diagnosis support.

This study aims to test and validate the Sleep@Home system prototype, by comparing it with the gold standard method, PSG. Thirty five tests were made (15 in adults: 10 men and 5 women, 20 in children). After data processing it can be concluded that the used method is not very reliable comparing to PSG. The system can be improved by measuring more physiological variables and using better detection algorithms.

Key words (Theme): Obstructive Sleep Apnea, oxygen saturation, heart rate, home monitoring, diagnosis support, childhood.

Key words (Technologies): Oximeter, video camera, video server.

Resumo

O Síndrome de Apneia Obstrutiva do Sono (SAOS) é cada vez mais uma preocupação na sociedade actual. Este síndrome consiste em paragens respiratórias repetidas, durante o sono, ocorrendo posteriormente microdespertares, que podem causar diversos danos na saúde da pessoa, tais como: fadiga, sonolência diurna, menor rendimento de trabalho, doenças cardiovasculares; nas crianças pode afectar o crescimento, o aproveitamento escolar e a inteligência.

Para diagnóstico do SAOS, a Polissonografia (PSG) é o método *gold standard* que consiste na monitorização completa de sinais vitais, incluindo o electroencefalograma (EEG), para avaliação dos estadios do sono. Neste exame o paciente tem de permanecer uma noite em ambiente hospitalar, que lhe é “estranho”, o que pode causar alterações no estudo a ser realizado por “efeito de laboratório”.

O Sleep@Home é um sistema que tem sido desenvolvido para tentar solucionar este problema. É um dispositivo composto por uma câmara de vídeo e um oxímetro, com o objectivo de filmar o sono e adquirir os dados de saturação de oxigénio (SpO₂) e frequência cardíaca.

Este sistema é portátil e pensado para realizar estudos no domicílio, ou seja, vai permitir ao paciente dormir no seu ambiente habitual.

Este trabalho visa testar o protótipo deste sistema, comparando-o com o método *gold-standard*, PSG. Foram realizados 35 testes (15 em adultos: 10 homens e 5 mulheres, 20 em crianças) com o intuito de validar o Sleep@Home. Da análise dos testes efectuados nas nossas condições podemos concluir que o sistema não se mostrou muito fiável comparativamente ao método *gold standard*, sendo propostas possíveis alternativas para o seu melhoramento.

Palavras Chave (Tema): Síndrome de Apneia Obstrutiva do Sono, Polissonografia, SpO₂, frequência cardíaca.

Palavras Chave (Tecnologia): Oxímetro, câmara de vídeo, servidor de vídeo.

To my parents

Acknowledgments

To all of those who helped me, in different ways, along this path.

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Acronyms and definitions

SA	Intelligent Sensing Anywhere
CEI	Centre of Electronics and Instrumentation
PSG	Polisomnography
CHC	Centro Hospitalar de Coimbra
EEG	Electroencephalography
OSAS	Obstructive Sleep Apnea Syndrome
SpO ₂	Pulse Oxygen Saturation
LEPS	Sleep Pathology Laboratory
PC	Personal computer
REM	Rapid Eye Movement
AHI	Apnea/Hypopnea Index
GSM	Global System for Mobile Communications
EMG	Electromyography
EOG	Electrooculography
S@H	Sleep@Home
PAT	Peripheral Arterial Tone
TCP	Transmission Control Protocol
IP	Internet Protocol

1. INTRODUCTION

1.1 Motivation

The sleep-related disorders are an increasing problem in today's society and, in many cases, an evident health risk factor. In this case, we deal specifically with the Obstructive Sleep Apnea Syndrome (OSAS). According to Elliot *et al.* (1), about 93% of women and 82% of men that suffer from this syndrome are not aware of it, and more children are diagnosed with it.

Polissonography (PSG) is an expensive method which requires a specialized technician, as well as a room occupation in a hospital environment. There is already a waiting list for this exam, which is rising with time. All these factors lead us to think: why not develop a portable system where we can accomplish a remote monitoring and primary registry of this pathology?

1.2 Previous work

Sleep@Home has started in 2006 as an idea of the technology-based innovative company, ISA. Since then, it has been developed by a wide integrated team with elements from ISA and CEI, as well as by biomedical engineering final graduation students of 2006/2007, reaching now the prototype phase.

The Sleep@Home prototype, previously developed, is composed of a video camera, an oximeter and a video server where the data are stored. In this prototype phase, all connections are made via Ethernet cable. Therefore, the home-hospital remote transmission idea is not yet accomplished.

In the prototype validation follow-up, which will be approached here, the system version where the acquired data are remotely transmitted will be implemented. The data will be transmitted in real time, to the hospital, where a physician or technician may monitor it during the night. The physician may also arrive to the office in the day after the exam, analyze

it and make an appointment if the test is conclusive, that is, if it gives the perception that the patient suffers from OSAS.

1.3 Objective

The objective of this work was to validate the Sleep@Home system, comparing this method with the gold standard method, PSG.

The validation consists in the analysis of the variables that can be comparable with PSG, such as the correlation between the desaturation alarms and the registered events at the same time in the PSG. The index of Apnea/Hypopnea of the two methods, and the delta index (Δ) which represents an analogy between the value and the doctor final diagnose.

Finally, a statistical analysis and a subsequent conclusion of the review were made.

1.4 Involved entities

1.4.1 ISA - Intelligent Sensing Anywhere

Description: Company of technological basis, leader in telemetry, offering innovative remote management systems with an extensive variety of applications.

Address: ISA – Intelligent Sensing Anywhere
Rua Carlos Seixas, 9
3030-177 Coimbra
Portugal

E-mail/website : info@isalabs.com / <http://www.isalabs.com/>

1.4.2 CEI - Centre of Electronics and Instrumentation

Description: Research Group founded at the Physics Department of the University of Coimbra; it researches in certain areas such as Biomedical Instrumentation. This entity cooperates with national and international institutions, developing their research work in partnership.

Main Responsible: Prof. Doutor Carlos Correia

Address: Departamento de Física
Rua Larga
3004-516 Coimbra
Portugal

E-mail/website: correia@lei.fis.uc.pt / <http://www.cei.fis.uc.pt/>

1.4.3 CHC - Children's Hospital of Coimbra

Description: Paediatric Hospital, integrated in the Central Hospital of Coimbra, its role was to validate and test the Sleep@Home System in children.

Main Responsible: Dr. Helena Estevão

Address: Hospital Pediátrico de Coimbra
Avenida Bissaya Barreto
3000-076 Coimbra
Portugal

E-mail/website: correio@hpc.chc.min-saude.pt / <http://www.chc.min-saude.pt/>

1.4.4 CHC - Central Hospital of Coimbra (Hospital dos Covões)

Description: Central Hospital of Coimbra, where test in adults were conducted.

Main Responsible: Dr. José Moutinho

Address: Centro Hospitalar de Coimbra,
Quinta dos Vales
3041-801 S. Martinho do Bispo
Portugal

E-mail / website: secretariahg@chc.min-saude.pt / <http://www.leps@chc.min-saude.pt>

1.5 Team

The Sleep@Home team is composed of some elements, being two of them final Master Graduation students in Biomedical Engineer (Table 1).

Table 1: Sleep@Home Team.

Ana Sofia Pardalejo	Student	sofiapardalejo@gmail.com
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Eng. Paulo Santos	Supervisor (ISA)	psantos@isa.pt
Eng. José Malaquias	Supervisor (FCT)	jmalaquias@isa.pt
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Dr ^a Helena Estevão	Medical Supervisor	mhestevao@chc.min-saude.pt
Dr. José Moutinho	Medical Supervisor	josemoutinho@netcabo.pt

1.6 Work planning

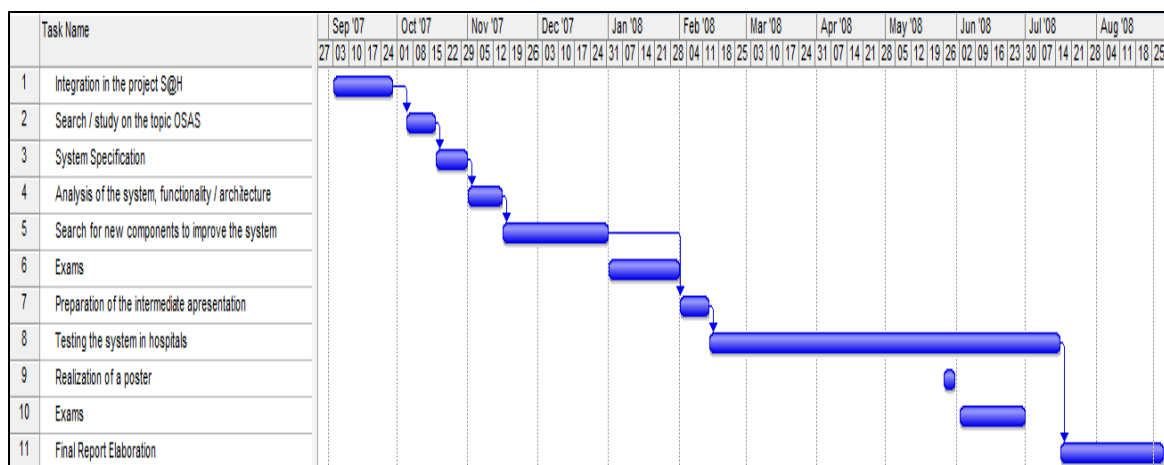
This work continues previous work performed during the past year. The planning of work was assumed, not only to develop an existing prototype, but also to validate it by testing it in hospitals, where sleep tests have been carried out, such as Polysomnography.

A study of documents as background for this work has been done in the first semester, as an intensive research on the theme of this system; Apnea syndrome, its causes, consequences, manifestations, diagnostic methods and treatment. Afterwards, the research for new components to improve the system was made. Finally a specification of the system was completed with my colleague Sofia Pardaleijo and Engineer Samuel Pereira.

The Sleep@Home tests, in hospitals, where started in February (second semester) of 2008. A total of 3 invalid tests were obtained due to interference with the hospital equipment, explained below, and then more tests were performed to verify the problem. After solution of the problem, 35 tests (15 in adults and 20 in children) were performed. A higher number of tests were made in children, since this project originally was delineated to be implemented in children.

The results of the tests were divided in two groups: children and adults, analyzed separately. After statistical analysis on the correlation between the Sleep@Home data and the data provided by Polysomnography, a conclusion to the medical validation was reached.

1.7 Gantt's Diagram



1.8 Report organization

After the introduction four main chapters are presented. The theoretical background of the disease is contextualized, the technologies already used for diagnosis are reviewed, and some approaches of validation of screenings are summarized. Developments describe the analysis, requirements and architecture of the system. Therefore this chapter works as a base and justifies the following ones: tests and results. Afterwards, the several tests made throughout the year are discussed, as well as the achieved results, in order to validate or invalidate the Sleep@Home system. This discussion continues on the final chapter – The Conclusion – where it is also suggested future work to improve the Sleep@Home system. Finally it is presented the student's personal final appreciation.

2. THEORETICAL BACKGROUND

2.1 Sleep Apnea-Hypopnea Syndrome

Sleep apnea is a respiratory dysfunction, characterized by repetitive episodes of upper airway obstruction that occur during sleep, usually associated with a reduction of blood oxygen saturation. Three types of sleep Apnea are described: obstructive, central or mixed. The most common kind of sleep Apnea is the obstructive one, OSA (1, 2)

Obstructive Sleep Apnea (OSA) is defined as the cessation of airflow during sleep, despite the presence of respiratory movements, preventing air from entering the lungs; it is caused by a pharyngeal obstruction and usually is accompanied by a snoring. These periods of 'pause of breathing', only become clinically significant if the cessation lasts for more than 10 seconds and occur more than 10 times per hour in adults (3).

The Central Apnea is defined as the interruption of command by the central nervous system to the breathing tissues, stopping the respiratory effort and the airflow. In mixed apnea there is a decrease on the breathing central command and an obstruction on the upper airways.

In simplified terms, an apnea occurs when a person stops breathing for 10 seconds or more. This definition includes complete interruption or a reduction upon 25% of airflow. Other definitions of apnea that may be used include at least a 4% drop in the saturation of oxygen in the blood, a direct result from the reduction in the transfer of oxygen into blood when breathing stops (4).

When an apnea occurs, sleep is disrupted. Sometimes this means that the person wakes up completely, but other times this can mean that the person comes out of a deep sleep and enters a shallowest level of sleep. Apneas are usually measured during sleep, preferably in all stages of sleep. An estimate of the severity of apnea is calculated dividing the number of apneas by the number of hours of sleep, giving an Apnea Index (AI). The greater the AI, the more severe the apnea is (5).

Hypopnea is a decrease in breathing that is not as severe as apnea. It is harder to measure and it is less precisely defined (6). Hypopnea occurs when there is reduction in

ventilation during sleep. As Apnea, hypopnea is associated with a 4% or higher drop in saturation of oxygen in the blood, and disrupt of sleep level.

A hypopnea index (HI) can be calculated dividing the number of hypopneas by the number of hours of sleep.

The Apnea-Hypopnea Index (AHI) is an index of severity that combines apneas and hypopneas. Combining them both gives an overall severity of sleep apnea, including sleep disruptions and desaturations. The Apnea-Hypopnea Index, as the Apnea and hypopnea indexes, is calculated dividing the number of apneas and hypopneas by the number of hours of sleep. Another index that is used to measure sleep apnea is the respiratory disturbance index (RDI), which is similar to the Apnea-Hypopnea Index. However, it also includes respiratory events that do not technically meet the definition of apnea or hypopnea, but do disrupt sleep (4).

The four major predisposing factors for upper airway obstruction include anatomic narrowing, abnormal mechanical linkage between airway dilating muscles and airway walls, muscle weakness, and abnormal neural regulation.

2.1.1 Sleep Apnea Syndrome in Adults vs. Children

Obstructive Sleep Apnea (OSA) syndrome was described more than a century ago. However, OSA in children was first recognized in the 1970's (7).

Estimation from limited field studies suggests that up to 2% of all children may be affected; however, the prevalence of snoring in general paediatric population is much higher and has been estimated between 8-27% (7). On the other hand, Obstructive Sleep Apnea (OSA) is estimated to affect about 4% of men and 2% of women, but after the age of 50 years the risk is similar for men and women (4,8).

A decrease of the cross-section area of the upper airway is associated with decreased ability to maintain upper airway patency. In adults, the upper airway behaves as predicted by the Starling resistor model. The validity of this model was also confirmed in children, and, interestingly, the collapsibility of the upper airway in children was reduced when compared with that of adults. As predicted by the Starling resistor model, the collapsible segment of the

upper airway in children displayed less negative (higher and, therefore, more collapsible) pressures in children with OSA (7).

OSAS in children is associated with symptoms including common snoring, sleeping difficulties, and/or daytime neurobehavioral problems. Complications may include growth abnormalities, neurologic disorders, and *cor pulmonale*, mainly in severe cases (9). Other consequences are failure to thrive (weight loss or poor weight gain), mouth breathing, daytime sleepiness, daytime cognitive and behavior problems, including problems of paying attention, aggressive behavior and hyperactivity, which can lead to problems at school (10).

In adults, OSAS is associated with excessive daytime sleepiness (leading to cognitive defects and increased mortality attributable to susceptibility to motor vehicle crashes), pulmonary hypertension, and systemic hypertension (9).

In childhood, an apnea is defined as a complete obstruction of upper airways during not less than 2 breath cycles, while a hypopnea is a partial obstruction characterized by a 50% or higher decrease of ventilation during at least 2 breath cycles or 30%, if there is an associated oxygen desaturation of 2-4%. In children, the AHI thresholds to define the presence of OSAS are lower than in adults, ranging from 1 to 5 events/hour in the less severe cases, while in the most severe situations $AHI > 10$ (Table 2) (11,12,13).

Obstructive Sleep Apnea Syndrome (OSAS), is a common problem, not only and adults but also in children. In children it is more difficult to recognize and diagnose (12).

Table 2: Obstructive Sleep Apnea in Children defined by the *American Family Physician* (?). *Chen*

<u>PolysomnoGraphic Criteria for OSA in Adults and Children</u>		
<i>Criteria</i>	<i>Adults</i>	<i>Children (1-12 years old)</i>
Apnea-Hypopnea Index*	> 5	> 1
Minimum oxygen saturation (%)	< 85	< 92

2.1.2 Consequences and risks in society

Obstructive Sleep Apnea (OSA) is a disease associated with long-term morbidity and mortality (14). Morbidity can be caused by 4 immediate consequences of OSAS, which include sleep fragmentation, increased work of breathing, alveolar hypoventilation, and intermittent hypoxemia (15).

- Sleep fragmentation

When subjects were awakened at different intervals during the night in the following day they demonstrated lower performance and increased sleepiness. A frequent symptom can be daytime tiredness or fatigue. The consequences are significant deterioration in functions that require concentration or dexterity, retrograde amnesia, disorientation, and morning confusion. In addition, personality changes, aggressiveness, irritability, anxiety attacks, and depression may occur (7).

OSAS and excessive daytime sleepiness have a significant impact on daily functioning and quality of life. However, the condition is frequently underrecognized. This condition in children may lead to substantial morbidity if left untreated (7, 10).

Sleep fragmentation in adults affects neuropsychological and cognitive performance. This evidence is also present in children, and effects may be worse, because the child's brain is undergoing active developmental changes (14).

- Increased work of breathing

Hypoxemia, and increases in cardiac after load during the obstructive apnea event, can be a cause for hypertension in adults, which is a major cardiovascular manifestation of OSA in adults (7). Significant alterations in autonomic nervous system have been documented in children with OSA, and diurnal elevations in arterial blood pressure can occur.

A prominent clinical manifestation of increased work of breathing in children with OSA, is failure to thrive (FTT) and significant catch-up growth patterns have recently been reported.

A substantial reduction in resting energy expenditure was reported after adenotonsillectomy in children with OSA, FTT with concomitant gains in body weight and in insulin growth factor.

Pædiatric OSA involves the combination of increased energy expenditure, caused by increased respiratory effort and disruption of the pathways of growth hormone somatostatin (7).

- Alveolar hypoventilation

The alveolar hypoventilation causes hipercapnea. This is a condition where there is too much carbon dioxide (CO₂) in the blood, and frequently occurs among patients with different respiratory disorders.

- Intermittent hypoxemia

A severe consequence of intermittent hypoxia is elevation of pulmonary artery pressure due to pulmonary vasoconstriction, such that chronic intermittent nocturnal hypoxemia leads to development of pulmonary hypertension and *cor pulmonale*.

Intermittent hypoxia may lead to, in its long-term, deleterious effects on neuronal and intellectual function (7).

Several analysis and studies concluded that there is strong evidence for an association between OSA and cardiovascular disease and other diseases (Table 3).

Disease associations for Obstructive Sleep Apnea

Table 3: The clinical consequences of Obstructive Sleep Apnea (14) (adapted from Max Hirshkowitz).

Associated morbidity	Study evidence	Association ranking according to evidence
Obesity	Consistent systematic meta-analysis	A
Cognitive impairment	Consistent systematic meta-analysis	A
Hypertension	Cross-sectional analysis of prospective cohort studies, consistent systematic meta-analysis	A
Congestive heart failure	Cross-sectional analysis of prospective cohort studies; inconsistent systematic meta-analysis	B
Coronary artery disease	Cross-sectional analysis of prospective cohort studies; retrospective diagnostic cohort study	B
Cerebral vascular incidents	Cross-sectional analysis of prospective cohort studies; retrospective cohort study	B
Metabolic syndrome	Cross-sectional analysis of prospective cohort studies; retrospective cohort studies	B
Diabetes	Retrospective cohort studies	C
Cardiac arrhythmias	Case series; usual practice	C

2.2 Methods of diagnosis

2.2.1 PSG

Polysomnography (PSG) is the most commonly used test for the diagnosis of OSAS in laboratory. It is a *gold standard* to diagnose OSAS, determining the severity of the disease, and evaluating several other sleep disorders (16).

PSG consists of a simultaneous recording of multiple physiologic variables. Standard PSG includes a minimum of 8 channels EEG, EOG, EMG, airflow, oxygen saturation, respiratory effort, heart rate and body position.

PSG can directly monitor and quantify the number of respiratory events (i.e., obstructive, central, or mixed) and the resultant hypoxemia and arousals related to the respiratory events or even independent of the respiratory events (17).

Sleep studies usually use the overnight PSG, which means a long time of preparation, (one or two hours), eight hours for register and 2-3 hours to analyze the data. This test is very expensive (400-500€), and the study needs to be attended during the whole night by a trained technician, to ensure the quality of the study.

The Pædiatric Polysomnography has evolved from an extension of adult studies (19). However, in childhood PSG done in a sleep laboratory is more likely to induce a more disturbed sleep that may cause artifacts in the study and difficulties in its interpretation. In contrast, this problem does not seem to arise in home Polysomnography (18-20).

PSG is a complex study, and it is not available in many clinics, resulting in long waiting lists, which could be reduced with new diagnostic techniques. Some of the techniques are analyzed in the following subchapter, named “screenings”, because, in fact; they must be seen as a triage for a PSG that is the conclusive test for the diagnosis of sleep respiratory disturbance.

2.2.2 Screenings

The increased awareness of sleep apnea led to an increasing demand for the diagnosis in patients suspected of having the disorder. The characteristic pattern of sleep apnea – interruption or reduction of respiratory flow, presence of respiratory movements and desaturation – led to the development of more simple devices than PSG, portables and that could be used outside a sleep laboratory, such as at the patient's home. These devices use different combinations of signals used during PSG (21) and accordingly to their characteristics were classified by the American Sleep Disorders Association (16) into four types:

- Type 1: corresponds to the standard PSG;
- Type 2: monitors at least of seven channels (EEG, EOG, chin EMG, ECG or heart rate, airflow, respiratory effort and oxygen saturation) using the equipment outside a sleep laboratory, such as home; the study is not fully monitored by a present technician;
- Type 3: monitors a minimum of four channels, being at least two of respiratory movement and airflow, to define an event; generally the ECG signal is monitored .but no EEG signal is controlled.
- Type 4: includes only one or two channels of physiological signals and frequently uses only one channel (oxygen saturation or airflow) to detect a breathing event. No EEG signal is monitored.

Some of the Type 3 devices are described here and their sensibility/specificity's analysis is described next.

The **NovaSom® QSG At-Home Diagnostic** system is a bedside device that gives data to determinate respiratory events, snoring intensity, SpO₂, pulse rate and respiratory effort. It is presented as an alternative to the diagnosis of OSAS (22, 23).

SleepStrip® is a simpler device which intents to help to evaluate the need to request a more complete sleep study, determining the number of apneas through the variation of the respiratory air flow (24,25).

WatchPAT 100 analyzes oxygen saturation (SpO₂), cardiac beating and PAT signal (Peripheral Arterial Tone); with PAT and common oximetry data, identifying the respiratory events during sleep. This is a device used at home and some studies indicate that WatchPAT

100 is a good equipment for diagnosis and also for therapy control studies for patients in phase of treatment of OSAS (26).

The Embletta system is a small device used for diagnosis and follow-up studies during the sleep respiratory disturbance treatment. It can be used in hospitals or at home. Its sensors monitor a large amount of signals, which are: respiratory flow/pressure, oral flow, snore, abdominal movement, SpO₂ average, pulse rate and body position (27).

The referred devices are only some of the available in market, much more exist and new devices are always appearing.

2.2.2.1 Validation of screenings

Since there is a growing interest in using portable monitoring to study patients with suspicion of sleep apnea (21) their validation is a critical issue.

The validity of portable monitors to study patients with suspicion of sleep apnea is generally made by comparing their results with the *gold standard*, Polysomnography.

The first step in determining whether a portable monitoring device can achieve this goal, is to determine its accuracy in characterizing the presence and severity of sleep-disordered breathing events. This is the focus of most of the research papers published on portable monitors for OSA (16).

There are some commonly used approaches to compare two different methods, which have been designed to measure common variables, such as breathing disturbances during sleep. It is necessary to verify the agreement between them (28). These methods include Pearson's product-moment correlation coefficients, which have an advantage over other methods: the representation of a scale easily understood, but this can be misleading. Another method of analysis is an Interclass correlation coefficient which compares total variability and measurement error; this method is statistically superior to the one referred before, but this approach is not intuitive to a clinician and it is not normally used.

Sometimes, a clinician can accept that the measurement of breathing events, using a portable monitor, does not completely agree with Polysomnography. For this purpose analysis of sensitivity, specificity, and likelihood ratios (LRs) is used. On the other hand, this approach dictates that a patient can be classified as having or not the disorder based upon an arbitrary cutoff for the AHI that is different across studies. However, there is a wide spectrum of

severity of breathing events at night, and the AHI captures only a single dimension. In this way, there may be a large variability in the measurement, and a substantial proportion of information can be lost, in particular, information that could better classify a patient as having mild, moderate, or severe disease (28, 29).

Sensitivity is the proportion of patients with disease who have a positive test result or the true-positive rate, and specificity is the proportion of patients without disease who have a negative result, or the true-negative rate (28). Although, sensitivity and specificity are used to describe the utility of a diagnostic test, they have some limits, since they indicate the probability that the test result will be positive if the patient has the disease, and the probability that the test will be negative if the patient does not have the disease.

Another method of measuring agreement is a Bland and Altman analysis, where the difference between the two measurements for each subject is determined. It provides an estimate whether the two methods, on average, return a similar result (28).

The majority of the portable monitoring devices do not allow the determination of sleep time and use a total monitoring time: then the AHI cannot be calculated. Instead, researchers calculate the number of disordered breathing events per hour in bed or per hour of monitoring time and report this as the respiratory disturbance index (RDI).

Some studies were performed with different types of devices and according to evidence review and practice parameters data were not adequate to draw a conclusion, in some neither sensitivity nor specificity data were available. The evidence stated that data were not adequate to obtain a single conclusion. Overall, the level of evidence was low, although in some types it appeared to be potentially acceptable in the attended laboratory setting, but limitations were perceived (16).

Studies for screening purposes being accomplished at home are increasing. However, inevitable questions arise concerning the reliability and utility of data obtained under these conditions. Recent advances in technology have resulted in substantial improvements in remote data acquisition (29).

2.2.3 Pulse oximetry and video

Pulse oximetry has been proposed as an useful diagnostic and screening tool. The lack of airflow during apneic periods can lead to recurrent episodes of hypoxemia that can be detected on oximetry as variations in oxyhemoglobin saturation (SpO_2) (21,30).

Pulse oximeter determines arterial blood oxygen saturation by measuring the light absorbance of tissue at two different wavelengths and using the arterial blood pulsation to differentiate between absorbance of arterial blood and other absorbers (31).

As an effective screening tool for SAOS, pulse oximetry must be able to screen out patients without disease and detect patients with all levels of disease severity (30). Even if an oximetric study is not enough to detect OSAS, it is an important tool for a preliminary analysis especially because it can be easily done at the patient's home (32).

Williams *et al.* (32) described the use of nocturnal pulse oximetry to screen patients for OSAS. Using a decrease of 4% in oxygen saturation and a threshold of 90% (as criteria for significant desaturation) they found that pulse oximetry was specific but not sensitive to detect OSAS.

A new interpretation procedure for oximetry tracings looked at the desaturation/resaturation pattern without considering any threshold for arterial oxygen saturation (SaO_2) fall or minimal SpO_2 amplitude to be reached. This was justified by the inability of the test to confirm the diagnosis when the interpretation is based on rigid criteria defined by SpO_2 decline.

The analysis of SpO_2 variability alone is more than ever of first importance in the interpretation of oximetry tracings. Calculations of breathing events based on the interpretation of pulse oximetry may underestimate or overestimate the number of hypopneas and central apneas (33).

New calculation models for automatic readings should, therefore, include different forms of oxygen desaturation per time interval and not only count desaturations with a specified decline of 3% or 4% arterial oxygen saturation. Certainly, new models for automated pulse oximetry readings are based upon arterial oxygen saturation and pulse-rate variability. These methods will enhance the sensitivity and specificity of pulse oximetry in the diagnosis of sleep-breathing disorders (33).

Video recording is mostly a device that can help to diagnose SAOS, mainly in children. This allows a clinician to get information about body movements, arousals, apneas, chest retractions and oral breathing. This technique is frequently used so that parents can register at home moments of breathing disorders, in order to help later the physician decisions. The final results are not always the best in parent's video recordings, since intensive hours of sleep and image quality is not great. Therefore, essential information may be lost.

The video recorder, alone, is not able to detect the sleep stages. Such limitation makes impossible the REM sleep detection, where several breathing events happen; and another disadvantage is that eight hours of video is a very long time for a clinician to observe, a fact that indicates the need of selecting information.

A home video-recording during sleep has been suggested as the first step in the clinical evaluation of children suspected of having OSAS, and also as a screening method (34).

This technique can also be applied in parallel with overnight oximetry to identify some cases of breathing disturbances during sleep. This is the technique that is used in *Sleep@Home*.

3 DEVELOPMENTS

3.1 Analysis of the system

The Sleep@Home is an innovative system to monitor patients suffering of SAOS. The analyzed variables are the video signal and oxygen saturation given by oximetry (Figure1).

This system was made especially for children, because their frequent non cooperation is a constant problem in sleep laboratory studies. This solution can represent an advantage, considering that only one sensor is put on their finger and the video camera gets images in a non luminosity environment.

Moreover, this system can efficiently substitute the current method of video recording made by the child's parents which has a low reliability.

Afterwards, the possibility to create a system of OSAS selection has been analyzed. It would allow the detection of the syndrome at the patient's home and would also be portable and easy to use.

One problem Sleep@Home is aiming to solve is the huge amount of data to be analyzed in the hospital after sleep monitoring. With at least eight hours of video and oximetry data, it is convenient to process the information in order to show to the doctor only the useful data. The idea is to synchronize the video and the oximetry signal and to detect relevant events in each one: body movements and oxygen desaturations, respectively. After detecting these alarms, when there are available, the clinician would access this information and make his conclusions and decision.



Figure 1: Sleep@Home prototype.

3.2 Analysis of the requirements

In the future all the components of Sleep@Home will communicate remotely, however, for the time being this system is a simple equipment, based on the video surveillance system Look@It of ISA.

Sleep@Home is composed by a video server, which is a terminal that stores all images acquired by the video camera, saved on a txt file data provided by the oximeter. The video camera is analogic and has a high sensitivity; and the images are saved in the JPEG format. To guarantee that it is possible to get images in any light conditions, this camera has a good resolution to obtain images in 0lux, due to its 16 infrared leds, and reaches 30 meters (Table 4).

Table 4: The video camera main characteristics.

Parameters	Description
CCD type	Sony Super HAD 1/3"
Total N° of Pixels	410K
Resolution	470 TV lines
Luminosity	0.00 Lux, 16 Leds IV (30 meters of LED lightning distance, indoor)
IV filter	Removable
Lens type	Varifocal 3.8-9.5mm
Colour	Silver

To acquire oximetric data an oximeter whit RS232 input in the video server is necessary. The oximeter was obtained at Smiths Medical PM and his characteristics are available in Table 5. The video server receives the data packets sent by the oximeter and reads them, in a 1Hz rate, decodes and stores them (Table 5).

To store video and oximetry data, the video server must have a high storage capacity to record several hours of information. The variables that one needs to pay attention to are the size of oximetry data and resolution of the images, although the server is already prepared to substitute older registries. Then the oximetry data and images are stored in folders according to the date and time. These two variables are synchronized within each other and with the date and hour of the computer.

The video server is a Mini ITX terminal (Table 6), which works with the Linux operative system. However, it needs a network cable for a connection with the PC. This system only allows accessing the images if a local area network PC-Server is used. Nevertheless, it is possible to transfer the oximetry text file to the PC, by copying the file from the server, and then it is possible observe a sleep test to process and visualize the graphic data and alarms, but it is not possible to see the image (35).

Table 5: - Oximeter features (Micro Power Oximeter Board 31392B1).

Parameters		Description
%SpO ₂	Range:	0-99% Functional SpO ₂ (1% increments)
	Accuracy:	Adult: +/- 2 @ 70-99% SpO ₂ less then 70% is undefined Neonate: +/- 3 @ 70-99% SpO ₂ less then 70% is undefined
	Averaging:	8 beats
Pulse Rate	Range:	30 – 254 BPM (1 BPM increments)
	Accuracy:	Greater of +/- 2 BPM or +/- 2%
	Averaging:	8 seconds
Sinal Strength	0 – 8 indicates logarithmic strength of patients pulse from 30 to 254 BPM	

Table 6: The Mini TX video server main characteristics.

Parameters	Description
Memory	512 Mb RAM
Processing speed	1GHz
Hard Disk	200 Gb
Video Card	4 inputs
Oximeter input	RS232
Dimensions	-----
Weight	About 3Kg

3.3 System architecture

The architecture and requirements made last year by Samuel Pereira and Lara Aires (finalist students of Biomedical Engineering), are made with a physic and logic architecture, and the algorithms specificity was constructed to detect an event of apnea. In this chapter it has been made one adaptation, in order to explain the work done afterwards. The explanation of the functional characteristics of system is made in the next topics.

- **Physical architecture**

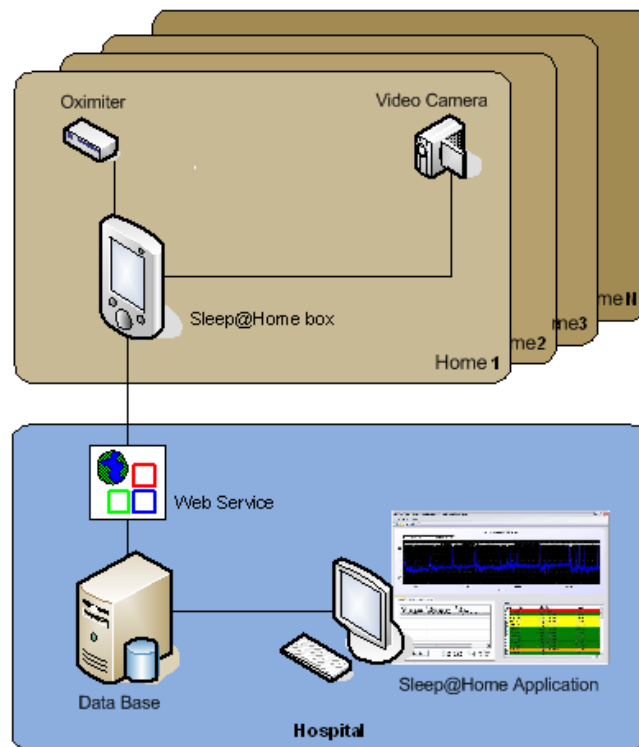


Figure 2: Sleep@Home architecture. In the final product, at the patient's home, all communications are wireless.

In the final product, in the final version of this system, Sleep@Home will be a wireless equipment, with remote transmission of data, through a web service making possible that, at the patient's home, the oximeter and the video camera to send data wirelessly to the data base of the hospital; and a clinician can check the data in a PC, or even in a PDA, connected to the hospital local network (Figure 2).

When an alarm occurs a message is transmitted and the part of the video corresponding to this event is showed. This year was decided not to send all the information, but only the essential one during the night, but all data are available for further studies.

The Sleep@Home practice aims to facilitate the exchange of data between the patient and the clinician (36).

At the moment, a complete prototype is concluded, and it will be presented through the following picture, which shows in a generic way the prototype's architecture (Figure 3)

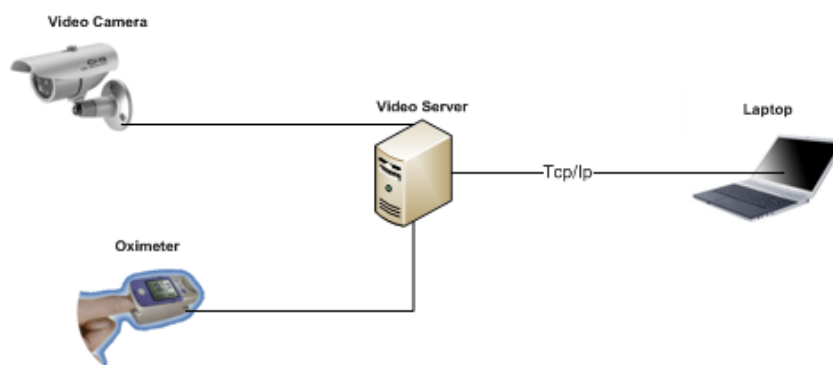


Figure 3: The prototype's architecture.

On this design the laptop has the function to help the user to command the server to start and finish the overnight test through the Sleep@Home interface. The interface shows the live images allowing the user to regulate the camera to the best position to acquire the images of interest.

To have an image in favorable conditions for the test it is necessary to position the video camera focusing the face and the thoraco-abdominal region of the patient. It is not necessary to frame the entire body, since to visualize the breathing episodes only the upper part of the body is important, although the abdominal muscles are also involved in respiration.

In this phase all connections were made by a cable, and do not present a remote transmission.

- **Logic architecture**

The data flow on the Sleep@Home system is simple (Figure 4). The camera is connected to the video server, and the images are acquired through the video camera and stored in the server in a JPEG format. This is what happens on Look@It system, in order to guarantee a higher data security in the case of lack of energy, compared to the MPEG format. While the oximeter sends data packets to the server, a routine decode, processes and stores the data in a text file. The oximeter returns several non-valid data which are eliminated by the routine.

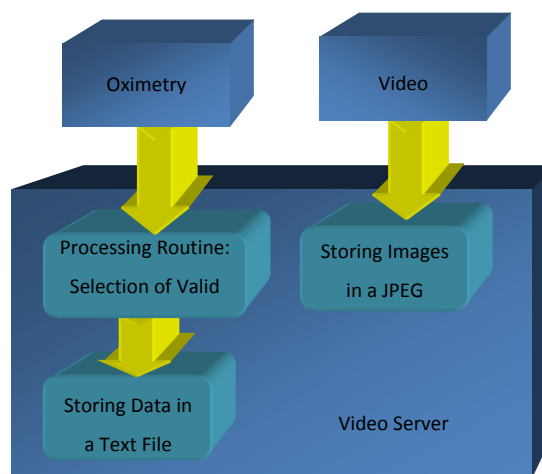


Figure 4: Data flow from the peripherals to the server (adapted by Pereira (35)).

The oximetry data are stored in a Text File inside the video server, and then transferred by the *winscp* program to the PC where they will be processed. After this the data can be opened with the Sleep@Home interface and alarms will appear, accordingly to the defined parameters for alarm detection (Figure 5). Each alarm is identified by an instant, and the nearest image is stored at the video server only with the temporal information that is synchronized by the alarm; which is possible only via a TCP/IP connection. In the interface of Sleep@Home the alarms, in terms of oxygen desaturation and a video clip, are shown. If oximetry file is now stored at the PC, and if the server is not connected it is possible to see only SpO₂, heart rate signals and the alarms but without video clip (35).

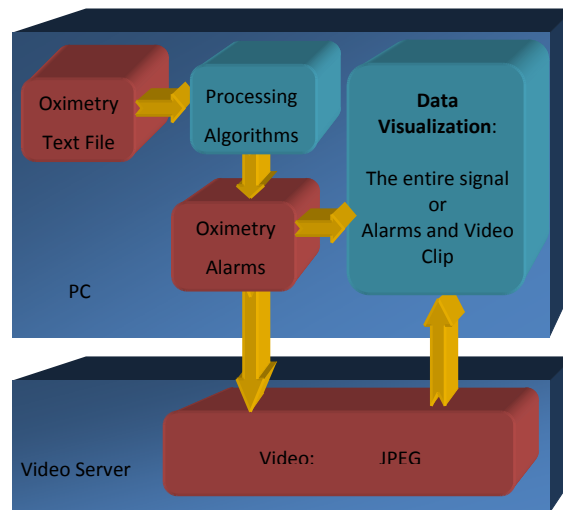


Figure 5: Data flow on the user's computer (adapted by Pereira (35)).

To detect events of OSAS it was necessary to create algorithms, in terms of oxygen saturation. The algorithms implemented in this system are described in Table 7.

The objective is to detect SpO₂ alarms; the heart rate signal is also processed but it only becomes an alarm if there is a great oscillation simultaneously with a SpO₂ alarm, indicating a more serious episode. Some interesting statistical results were obtained as well, such as minimum, maximum and average of SpO₂ and heart rate signals, also available in the interface as results part.

Table 7: SpO₂ algorithms in Pereira (35).

Algorithm	Result	Standard Thresholds
Decrease of oxygen saturation above a certain level, during a time interval, with fast reposition of normal values	Alarm indicating the instant of the event and the desaturation value	3% (SpO ₂ minimal desaturation)
Decrease of oxygen saturation above some level during a long time interval	Alarm indicating the instant of the event and the duration of the desaturation	5 seconds (Minimal Duration)
Cumulative time with low oxygen saturation	Time in minutes	92%
Variability of oxygen saturation	Delta index (Δ)	Not applicable

The delta index (Δ) was implemented to detect the variability of the oximetry signal.

In some patients, even if there is no significant desaturation above the threshold (i. e. 92%), but the SpO₂ signal can show a great variability (35).

This algorithm processes the signal of the overnight data resulting in a value that can give us useful information. If the value is under 0.6 it corresponds to a normal situation. If the result is above 0.6 it may not mean a pathological situation; more studies may be required or at least it requires a higher attention during the analysis of the other parameters.

4 TESTS AND RESULTS

“The validation of portable monitors for investigation patients with suspected sleep apnea generally has been studied by comparing their results with those of the accepted reference standard, sleep-laboratory based Polysomnography.”

Dr. W W Flemons, 2003 (28)

4.1 Methods

During this year, 35 tests in sleep laboratory were performed to validate this system. The tests included simultaneous registration of Sleep@Home and standard PSG in each patient.

The tests were made in two different hospitals: Pædiatric Hospital and a Sleep laboratory of Central Hospital of Coimbra, whit full consent of the patients, i.e., parental children consent and adults, with the support of trained technicians, mainly Dr. Helena Estevão (Pædiatrician) and Dr. José Moutinho.

To analyze the data, MicrosoftExel2007 files were used to describe the data of Sleep@Home and PSG. Four variables of comparison were analyzed.

- Comparison of events,
- index comparison,
- delta (Δ) index comparison with diagnosis,
- comparison of graphics.

4.1.1 Comparison of events

To compare the events (PSG) and respective alarms of Sleep@Home all the detected alarms shown in the interface were analyzed. They were compared to events in a report given by the software of a standard Polysomnography system. This comparison was made after adjusting simultaneously the event to the alarm. Two tables were built to this purpose with the data of PSG events and with the data of alarms. Each alarm was analyzed, and classified according to the visual analysis of the images available in the interface, and compared with the corresponding event detected in PSG. The events detected by Sleep@Home were classified through the images as: a (apnea); w (wakening); x (indefinite); m (movement); n (no image). In PSG events were classified by the usual staging rules as: OA (obstructive Apnea); CA (central Apnea); OH (obstructive hypopnea): w (wakening); d (desaturation); s (no observation); AR (arousal); MH represents RERA (respiration effort); MT (movement) (Table 8).

Table 8: Example of data analysis.

Sleep@Home		PSG		
Alarms (h)		Events		SpO₂
1:06:39	m83	1:06:30	CAa	85
1:07:44	s86		s	87
1:08:48	a86	1:08:30	OHa	87
		1:09:30	OH	80
1:10:52	m86		MT	85
1:11:43	a87	1:12:00	OA	86
		1:12:30	OA	83
1:13:32	x80	1:13:30	OH	80
1:17:50	m87	1:17:30	OHa	88
		1:18:30	OH	83
1:20:51	m83		AR	83

Afterwards the two columns (Table 8) were adjusted for the same time displayed with a tolerance of 30 seconds, since a discrepancy of the clocks may occur and it would assign a margin of error. In order to make this task simpler, a code of Sql. Server 2005 (a database engine) was built. The program was settled up in two tables, one containing the different dates of Sleep@Home, and the other the several dates of the hospital equipment for each test performed to a patient. After the table's creation, a script in T-Sql to order the dates in ascending order was done. This code compares the different dates of the two tables and

identifies which is the date of small remaining, thereby increasing the order by dates. The code that was created is shown in Table 9.

Table 9: Script in T-Sql.

```

declare @data1 datetime
declare @data2 datetime
declare @evento1 nvarchar(50)
declare @evento2 nvarchar(50)

declare @DatasFinais table (Data datetime,Data1 datetime,Evento1 nvarchar(50), Data2
datetime,Evento2 nvarchar(50))

declare data1_cursor cursor for select data, evento from data1 order by data asc
open data1_cursor

declare data2_cursor cursor for select convert(SmallDateTime,data), evento from data2
order by data asc
open data2_cursor

FETCH NEXT FROM data1_cursor INTO @data1, @evento1
FETCH NEXT FROM data2_cursor INTO @data2, @evento2
WHILE @@FETCH_STATUS = 0
BEGIN

if(@data1=@data2)
begin
    insert          into          @DatasFinais          values
    (convert(SmallDateTime,@data1),@data1,@evento1,@data2,@evento2)
    FETCH NEXT FROM data2_cursor INTO @data2,@evento2
    FETCH NEXT FROM data1_cursor INTO @data1,@evento1
end
if(@data1>@data2)
begin
    insert          into          @DatasFinais          values
    (convert(SmallDateTime,@data2),NULL,','@data2,@evento2)
    FETCH NEXT FROM data2_cursor INTO @data2,@evento2
end
if(@data1<@data2)
begin
    insert          into          @DatasFinais          values
    (convert(SmallDateTime,@data1),@data1,@evento1,NULL,','@data1,@evento1)
    FETCH NEXT FROM data1_cursor INTO @data1,@evento1
end
end

FETCH NEXT FROM data1_cursor INTO @data1,@evento1
WHILE @@FETCH_STATUS = 0
BEGIN
    insert          into          @DatasFinais          values
    (convert(SmallDateTime,@data1),@data1,@evento1,NULL,','@data1,@evento1)
    FETCH NEXT FROM data1_cursor INTO @data1,@evento1
end

FETCH NEXT FROM data2_cursor INTO @data2,@evento2
WHILE @@FETCH_STATUS = 0
BEGIN
    insert          into          @DatasFinais          values
    (convert(SmallDateTime,@data2),NULL,','@data2,@evento2)
    FETCH NEXT FROM data2_cursor INTO @data2,@evento2
end

close data1_cursor
deallocate data1_cursor
close data2_cursor
deallocate data2_cursor

select isnull(CONVERT(nvarchar(8), data, 114), ''), isnull(CONVERT(nvarchar(8), data1,
114), ''),evento1,isnull(CONVERT(nvarchar(8), data2,114), ''),evento2 from @DatasFinais

```

4.1.2 Index comparison

An index of alarms per hour in Sleep@Home was created dividing all the events by the time of total register (TTR) in minutes and multiplying by 60 to give the result per hour. In order of enable the comparison the same processing was applied to the PSG results; e.g., the total number of events were divided by the total time of registration and multiplied by 60. Therefore, the Apnea-Hypopnea Index (AHI) referred in the results is related to the time of recording and not to time of sleep, as usually.

4.1.3 Delta (Δ) Index comparison with diagnosis

This index is given directly by the Sleep@Home software, as previously describe. The index was compared with the patient's diagnosis given by a specialist doctor.

4.1.4 Comparison of graphics

This comparison was done by visual analysis of the overlapping graphics, which enabled the comparison between the SpO₂ and the heart rate graphics, given by PSG and Sleep@Home, and additionally the hypnogram with sleep stages. In the example shown in Figure 8, a sleep fragmentation during the presence of desaturations can be seen (Figure 6).

This comparison is not mentioned in the results due to the lack of trust in the analysis.

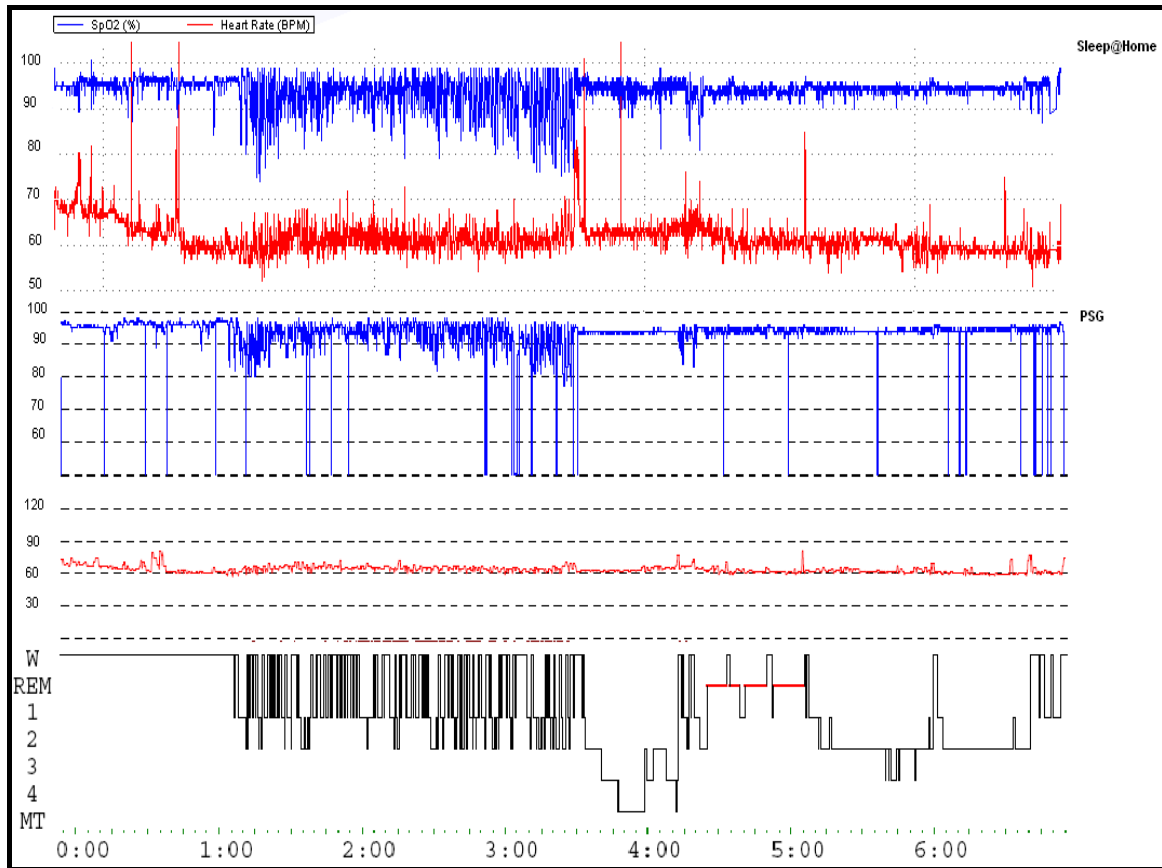


Figure 6: Comparison of graphics.

4.2 Statistical analysis

The statistical analysis was done using the SPSS vs16.0 version and included: means comparison by t-Student test for paired data and for independent samples, moment Pearson correlation of indexes, mean differences and limits of agreements between indexes, sensibility/specificity analysis and agreement between scored events in Sleep@Home and scored events in PSG.

4.2.1 Tests in the Pædiatric Hospital

In the Pædiatric Hospital, 20 tests were performed in children between aged between 1-13 years old.

4.2.1.1 Results

- **Comparison between the indexes in children**

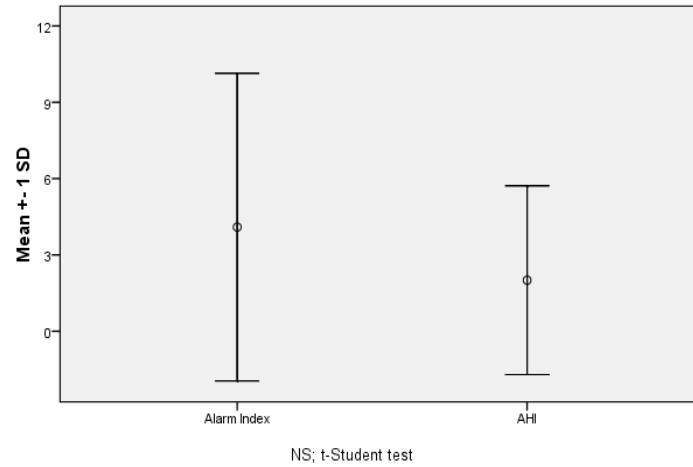
A comparison between the indexes of events (PSG) and alarms (Sleep@Home) was done using the paired t-Student test. No significant differences were seen (Table 10 and Graphic 1), but the alarm index was higher than AHI and a huge dispersion of results is evident. (Graphic 2).

Table 10: Comparison between the indexes in children.

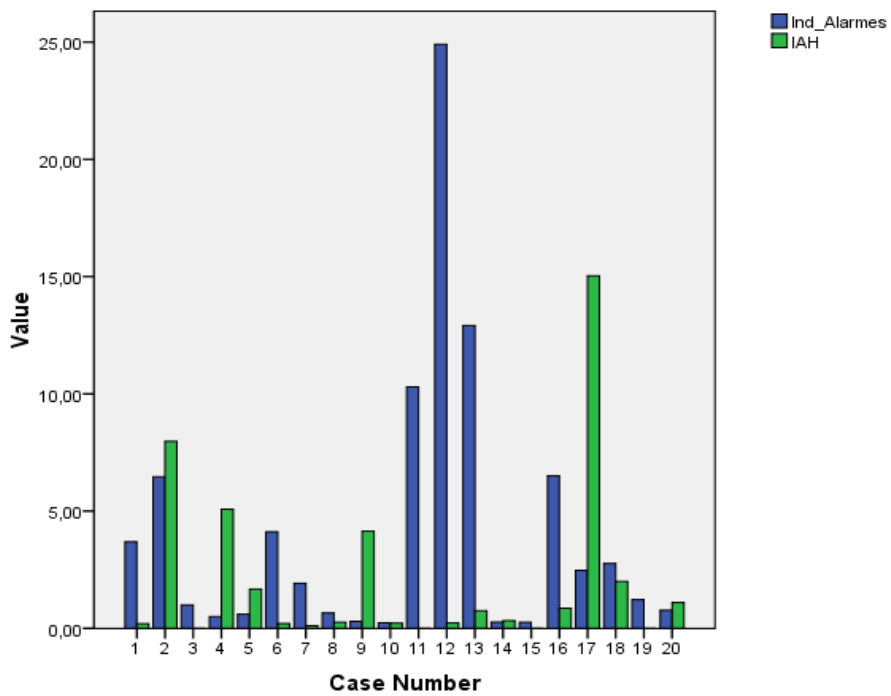
Index	n	X	sd	t	p
Alarms	20	4,0935	6,04622	1,261	,223
AHI	20	2,0085	3,71002		

n= number of tests, X= average, Sd= standard deviation, t= t-student; p=probability

Alarms index and AHI



Graphic 1: Index of Alarms and AHI in children.



Graphic 2: Comparison between individual indexes in children.

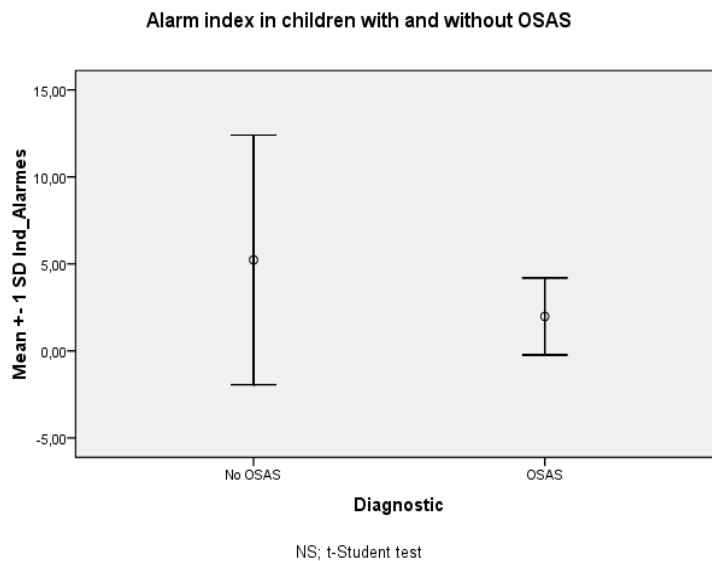
- **Index of alarms in children with and without SAOS defined by IAH**

As a second step the index of alarms in children with and without OSAS defined by AHI as > 1 in PSG, was analyzed. There were no significant differences but a higher index of alarms was found in children without OSAS (Table 11 and Graphic 3).

Table 11: Indexes of alarms in children with and without SAOS defined by IAH.

Index	Diag.	n	X	sd	t	p
Index of Alarms	OSAS	7	1.9814	2.21043	-1.156	0.263
	No OSAS	13	5.2308	7.17184		

Diag = diagnosis; n = number of tests, X = average, SD = standard deviation, t= t-student; p=probability



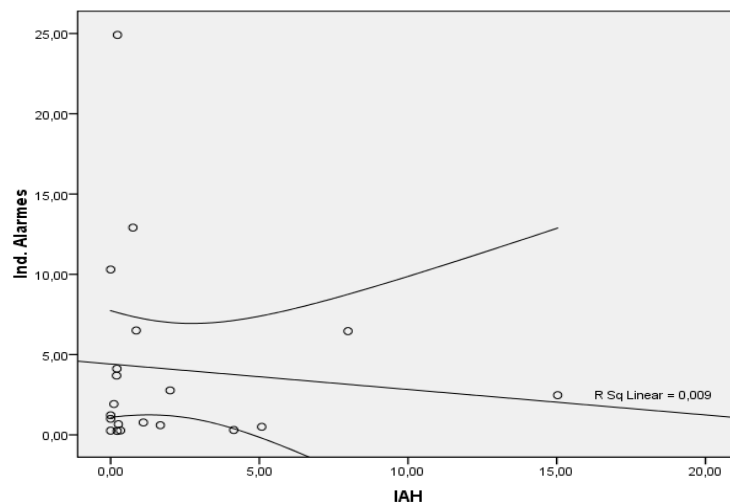
Graphic 3: Alarm index in children with and without OSAS defined by AHI.

- Correlation analysis of indexes in children

No statistical significant correlation was found between index of alarms and AHI (Table12 and Graphic 4)

Table 12: Correlation between index of alarms and AHI in children.

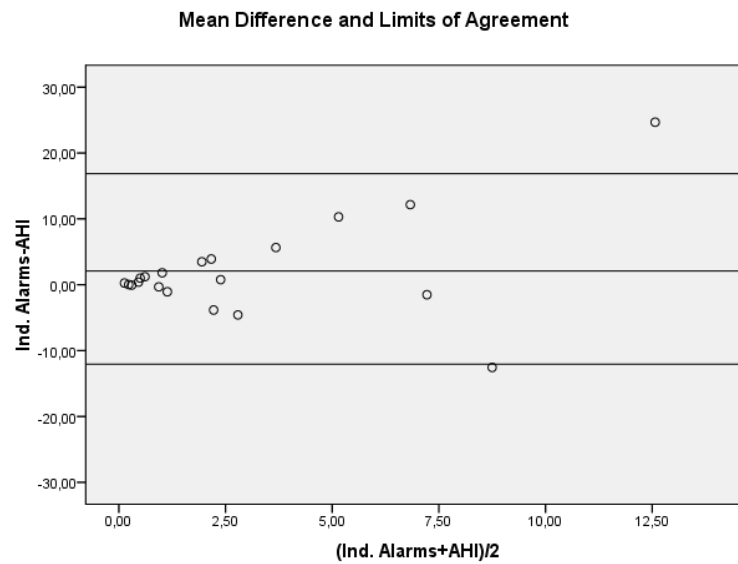
		Index of Alarms	IAH
Index of Alarms	Pearson's Correlation	1.000	-0.097
	Sig. (2-tailed)		0.683
	N	20.000	20.000



Graphic 4: Correlation between the index of alarms given by a Sleep@Home and IAH recorded by Polysomnography in children.

- **Mean difference and limits of agreement (Bland-Altman analysis)in children**

To estimate the ability of the two methods, Sleep@Home and Polysomnography, return, on average, a similar result, a Bland-Altman analysis was made (21). The mean difference between the two methods was 2.08 which suggest a systematic bias and wide limits of agreement (± 2 SD), up to 20 events per hour (Graphic 5)



Graphic 5: Mean difference and limits of agreement.

- **Sensitivity/Specificity of Sleep@Home to diagnose SAOS in children**

Defining the presence of OSAS with a AHI > 1 index of alarms in Sleep@Home for each case, showed 4 false negative results and 9 false positive results. Nevertheless the difference in the absolute value of indexes' value a concordant diagnosis was found in 3 cases (true positive) and absence of diagnostic in 4 cases (true negative) (Table 13)

Table 13: Sensitivity and Specificity.

Sensitivity and Specificity for AHI > 1

		Frequency	Percentage	Valid Percentage	Cumulative Percentage
Valid	FN	4	20.0	20.0	20.0
	FP	9	45.0	45.0	65.0
	TN	4	20.0	20.0	85.0
	TP	3	15.0	15.0	100.0
	Total	20	100.0	100.0	

FN-false negative; FP-false positive; TN-true negative; TP-true positive

This means that in general Sleep@Home for the diagnosis of OSAS:

- ✓ sub-evaluated the diagnosis in **20%** of the cases (False Negatives - FN)
- ✓ over-evaluated the diagnosis in **45%** of the cases (False Positives - FP)
- ✓ agreed with the diagnosis of SAOS in **15%** of the cases (True Positives - TP)
- ✓ agreed with lack of diagnosis of SAOS in **20%** of the cases (True Negatives - TN)

Therefore, the sensitivity of Sleep@Home for the diagnostic of OSAS in children was 42.9%, its specificity was 30.7%, the positive predictive value was 25% and the negative predictive value was 50 %.

• **Discriminated analysis of alarms in children**

In order to verify the correspondence of alarms to events (apneas and hypopneas) detected in Polysomnography, all the alarms were verified by the observation of video image.

Overall this comparison leads to the following results (Table 14):

Table 14: Alarms with Sleep@Home * Events in PSG crosstabulation.

Alarms with Sleep@Home * Events in PSG crosstabulation										
Count										
		Events								
		AC	AO	CA	MH	MT	OH	s	Total	
Alarms	3	2	54	4	0	0	244	0	307	
a	18	0	1	0	0	7	12	2	40	
m	184	0	0	0	0	5	6	14	209	
n	7	0	0	0	0	0	0	0	7	
s	110	0	0	0	0	0	0	0	110	
w	35	0	0	0	0	0	0	0	35	
x	180	0	3	0	1	7	4	3	198	
Total	537	2	58	4	1	19	266	19	906	

Alarms: a-apnea; m-movement; n-not image; s-not movement; w-wake; x-indefinite; **Events:** CA- central apnea; OA-obstructive apnea; MH=RERAS (respiratory effort); MT-movement; OH- obstructive hypopnea; s-not observation; d=desaturation.

Therefore the consistency between the two systems in detecting respiratory events was very low, indicating that video analysis *per se* was not reliable enough:

- ✓ number of alarms (Sleep@Home) in the 20 studies evaluated = **599**
- ✓ number of events (CA, OA, OH) on the 20 tests in PSG = **330**
- ✓ number of alarms (Sleep@Home) corresponding to events (PSG) = **26 (7.8%)**
- ✓ consistency between the viewing (by video) of alarms compatible with apnea and events in PSG (CA, OA, OH) = **22/330 (6.7%)**

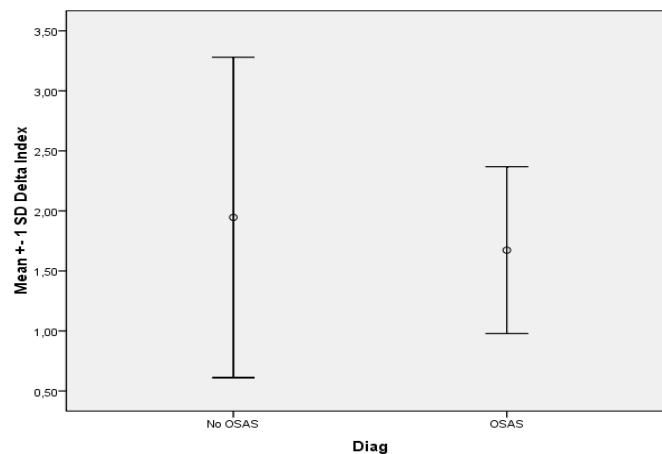
- **Delta index comparison with diagnosis in children**

The delta index was not significantly different in children with and without a final diagnosis of OSAS (AHI > 1) (Table 15 and Graphic 6).

Table 15: Delta index in children with and without OSAS.

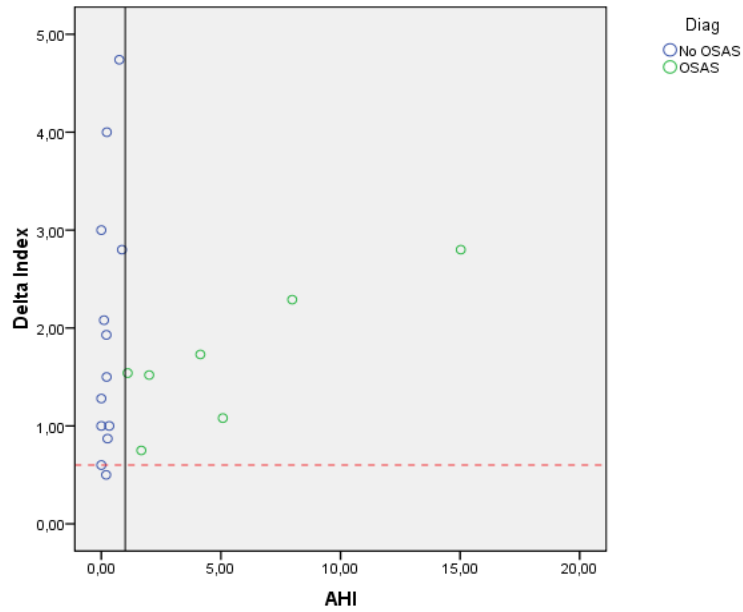
	Diag	N	Mean	Std. Deviation	t	p
Delta Index	OSAS	7	1.6729	0.69507	-0.502	0.622
	No OSAS	13	1.9462	1,33468		

Diag = diagnosis; n = number of tests, X = average, SD = standard deviation, t= t-student; p=probability



Graphic 6: Delta index in children with and without OSAS defined by AHI.

In fact, as shown in Graphic 7 only two children without the diagnosis of OSAS had a Delta Index $\leq 0,6$.



Graphic 7 : Relationship between Delta Index and AHI .Line in y axe represent the cut-off value for Delta Index; Reference line in x axe represented the cut-off for diagnosis of OSAS.

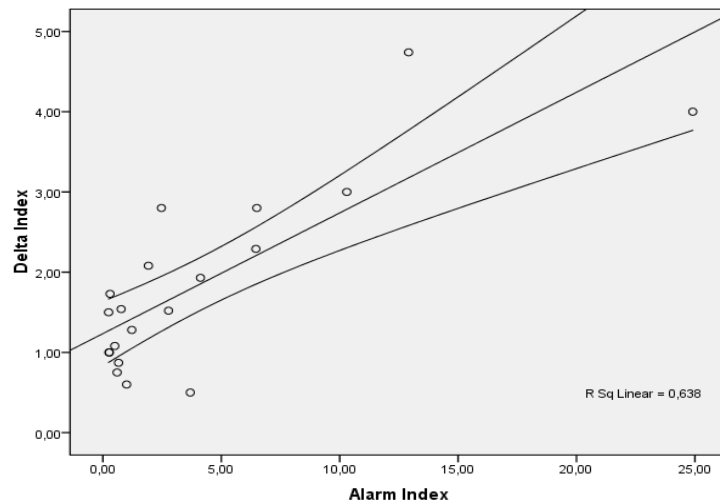
The reason for these results is that there is a strong correlation between the Delta Index and the Alarm Index (Table 16 and Graphic 8) and the Index of Alarm, as stated before, were not concordant with the diagnosis of OSAS.

Table 16: Correlation between index delta and alarms given by a Sleep@Home in children.

Correlations

		Delta Index	Alarm Index
Delta Index	Pearson Correlation	1.000	0.799**
	Sig. (2-tailed)		0.000
	N	20	20.000

** . Correlation is significant at the 0.01 level (2-tailed).



Graphic 8: Correlation between the index delta (Δ) and alarms given by a Sleep@Home in children.

4.2.2 Tests at the Central Hospital of Coimbra

Fifteen tests in adults were performed simultaneously with the Sleep@Home device and overnight Polysomnography in a sleep laboratory.

4.2.2.1 Results

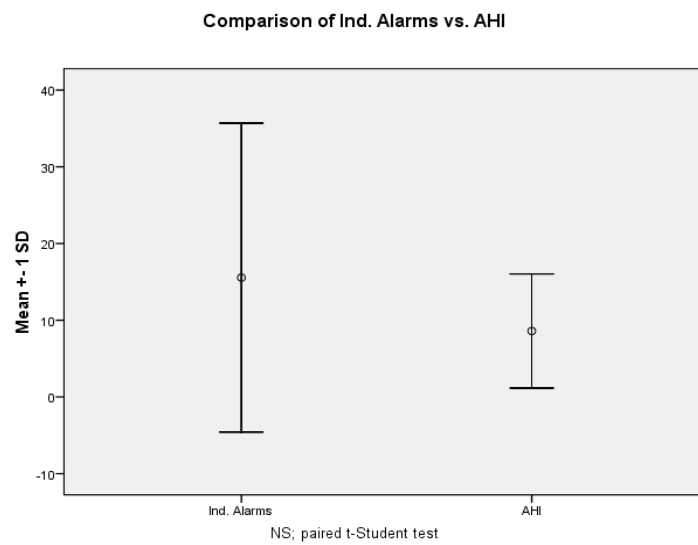
- **Comparison of indexes in adults**

The mean index of alarms was higher than the mean IAH, although without significant difference (Table 17 and Graphic 9). As in children a huge gap of differences is evident (Graphic 10).

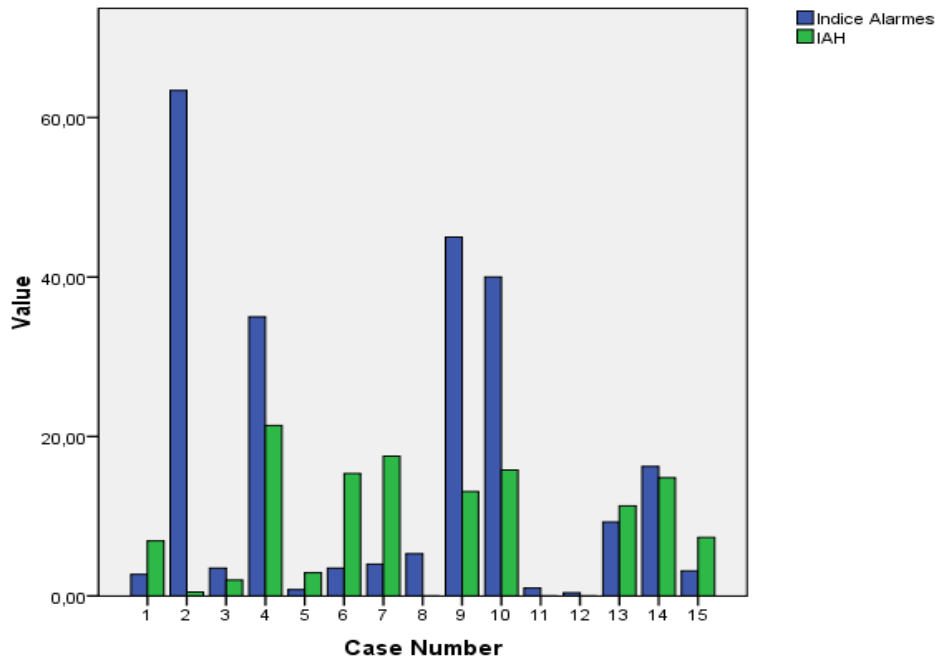
Table 17: Comparison of indexes in adults.

	n	X	Sd	t	p
Index of Alarms	15	15.5500	20.14207	1.369	0.192
IAH	15	8.5933	7.44005		

n- number of tests, X- average, Sd- standard deviation, t- t-student; p- probability



Graphic 9: Comparison of Index of Alarms vs AHI in adults.



Graphic 10: Comparison between individual Index of Alarms and IAH in adults.

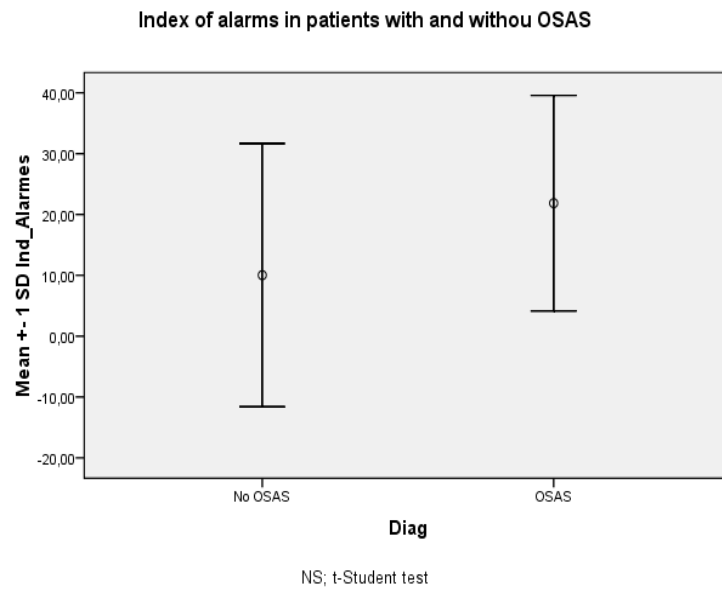
- **Comparison of index alarms in adults with and without OSAS defined by IAH**

The mean index of alarms was higher in patients with OSAS, defined as by $AHI > 10$ in Polysomnography, although no statistical significant difference has been found (Table 18 and Graphic 11).

Table 18: Indexes of alarms in adults with and without SAOS defined by IAH.

Index	Diag.	n	X	sd	t	p
Index of Alarms	OSAS	7	21.8600	17.71576	1.148	0.272
	No OSAS	8	10.0288	21.62725		

Diag- diagnosis; n- number of tests, X- average, Sd- standard deviation, t- t-student test; p- probability



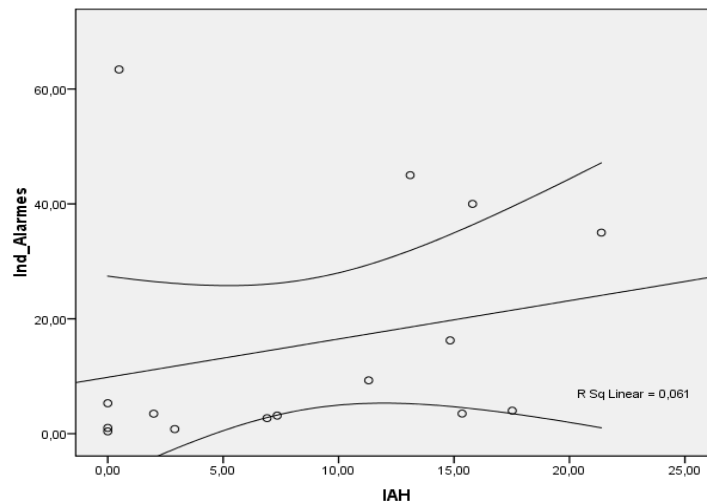
Graphic 11: Index of alarms in adults with and without OSAS.

- **Correlation analysis of indexes in adults**

No significant correlation was found between index of alarms and AHI. (Table 19 and Graphic 12)

Table 19: Correlation between index of alarms and AHI.

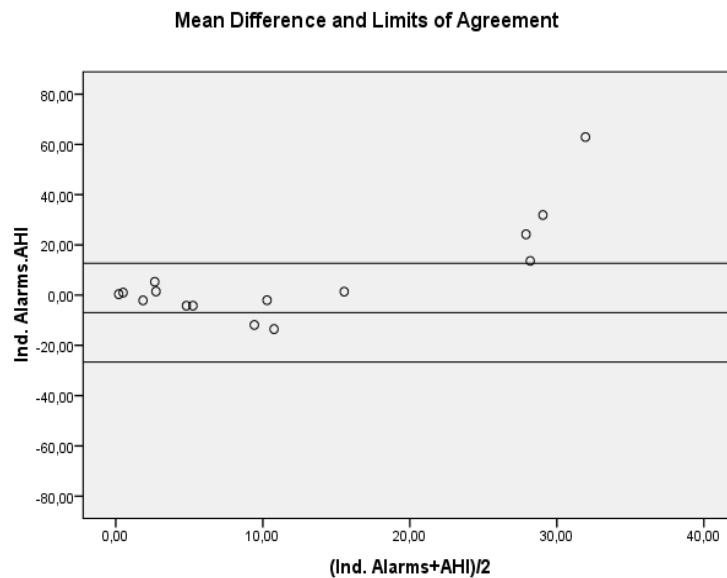
Correlations			
		Index of Alarms	AHI
Index of Alarms	Pearson's Correlation	1.000	0.246
	Sig. (2-tailed)		0.376
	N	15.000	15



Graphic 12: Correlation between a index alarms given by a Sleep@Home and AHI recorded by a Polissonography.

- **Mean difference and limits of agreement (Bland-Altman analysis) in adults**

As presented for children, analysis of mean difference and limits of agreement between the two tests were done. The mean difference was -6.95 events per hour, suggesting a systematic bias and wide limits of agreement, up to 20 events per hour (Graphic 13).



Graphic 13: Mean Difference and Limits of Agreement.

- **Sensitivity/Specificity of Sleep@Home for Diagnosis of SAOS in adults**

Defining the presence of OSAS with a AHI>10 as the index of alarms in Sleep@Home for each case showed 2 false negative results and 1 false positive result. Even though a difference in the absolute value of indexes a concordant diagnostic was found in 5 cases (true positive) and absence of diagnostic in 7 cases (true negative) (Table 20).

Table 20: Sensitivity and Specificity of Sleep@Home.

Sensitivity and Specificity for AHI>10					
		Frequency	Percentage	Valid Percent	Cumulative Percentage
Valid	FN	2	13.3	13.3	13.3
	FP	1	6.7	6.7	20.0
	TN	7	46.7	46.7	66.7
	TP	5	33.3	33.3	100.0
Total		15	100.0	100.0	

FN- False negative; FP- false positive; TN- true negative; TP- true positive

Therefore, the sensitivity of Sleep@Home for the diagnosis in adults of OSAS was 71.4%, and its specificity was 85.7 %, the positive predictive value was 83.3 % and the negative predictive value was 77.7 %.

- **Discriminated analysis of alarms in adults**

In order to verify the correspondence between alarms and events (apneas and hypopneas) detected in Polysomnography, all the alarms were verified by the observation of the video images.

Overall these comparisons lead to following results:

Table 21: Alarms of the Sleep@Home* Events in PSG crosstabulation.

PSG Events * Sleep@Home Alarms crosstabulation

Count								
	Alarms							
		a	m	n	s	w	x	Total
Events	3	4	54	0	14	61	7	143
OA	199	6	30	4	20	5	18	282
CA	9	0	3	0	1	0	0	13
MH	0	4	29	5	16	2	15	71
MT	0	6	80	2	48	9	14	159
OH	538	34	62	9	56	1	14	714
d	0	1	1	0	2	0	0	4
s	1	26	267	14	155	83	72	618
Total	750	81	526	34	312	161	140	2004

Alarms: a-apnea; m-movement; n-not image; s-no movement; w-wake; x-indefinite; **Events:** CA- central apnea; OA-obstructive apnea; HM-RERA, respiratory effort; MT-movement; OH- obstructive hypopnea; d=desaturation s-not observation;

The consistency between the two systems in detecting respiratory events was very low, indicating that video analysis *per se* was not reliable enough:

- number of alarms (Sleep@Home) evaluated in the 15 studies = **1254**
- number of events (CA, OA, OH) on the 15 tests in PSG = **98**
- number of alarms (Sleep@Home) corresponding to events in PSG (CA, OA, OH) = **263 (20.9%)**
- consistency between the viewing (video) of alarm compatible with apnea and events in PSG (CA, OA, OH) = **40 (4.05%)**

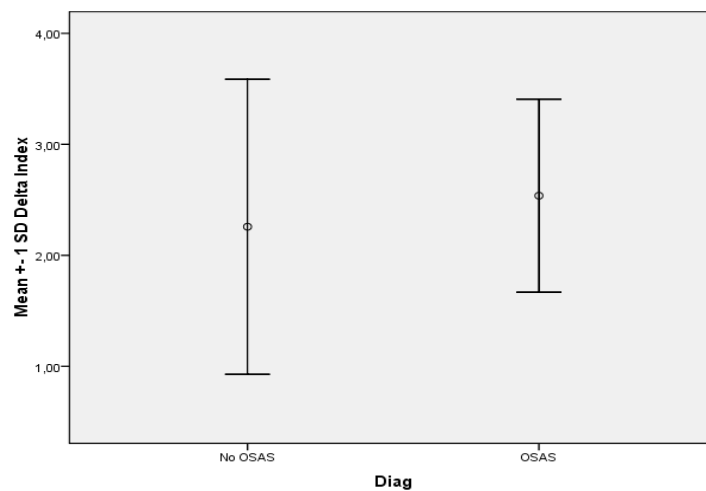
- **Delta index comparison whit diagnosis**

The delta index was not significant different in adults with and without a final diagnosis of OSAS (AHI > 1) (Table 22 and Graphic 14).

Table 22: Delta index in adults with and without OSAS.

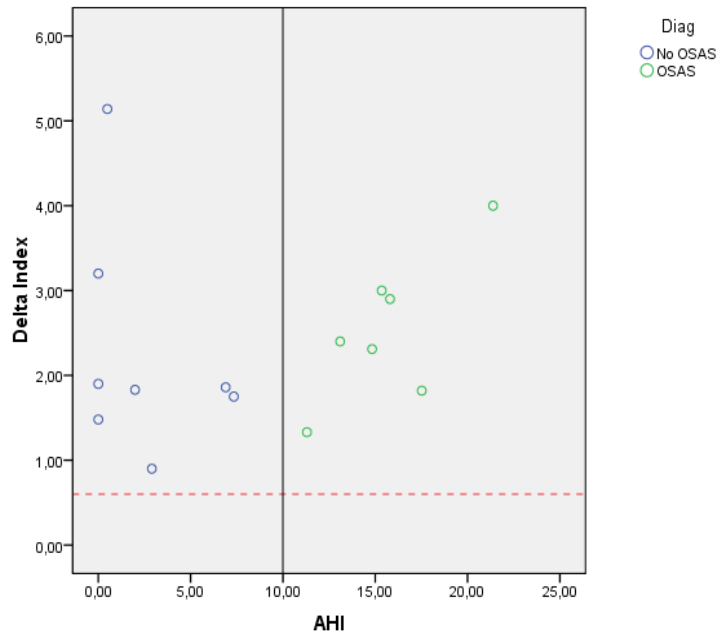
Diag		N	Mean	Std. Deviation	t	p
Delta Index	S	7	2.5371	0.86869	0.474	0643
	N	8	2.2575	1.32937		

Diag- diagnosis; n- number of tests, X- average, Sd- standard deviation, t- t-student test; p- probability



Graphic 14: Delta index in adults with and without OSAS defined by AHI.

In fact, as shown in Graphic 15 none of the individuals without the diagnosis of OSAS had a Delta Index $\leq 0,6$.



Graphic 15: Relationship between delta index and AHI. (line in y axe represent the cut-off value for Delta Index (0,6); Reference line in x axe represented the cut-off for diagnosis of OSAS (>10)).

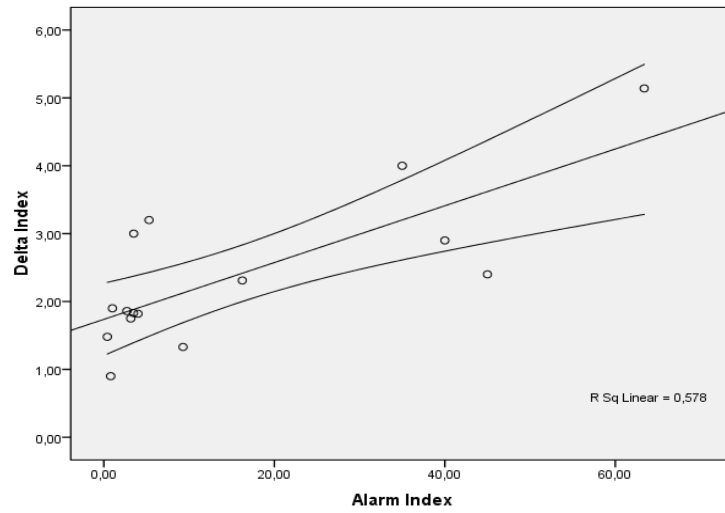
As in children, a strong correlation between the Delta Index and the Alarm Index was demonstrated which explains the inability of Delta Index to confirm or deny a diagnostic of OSAS (Table 23 and Graphic 16)

Table 23: Correlation between index delta and alarms given by a Sleep@Home in adults.

Correlations

		Delta Index	Alarm Index
Delta Index	Pearson Correlation	1,000	,760**
	Sig. (2-tailed)		,001
	N	15,000	15

** . Correlation is significant at the 0.01 level (2-tailed).



Graphic 16: Correlation between the index delta (Δ) and alarms given by a Sleep@Home in adults.

5 DISCUSSION OF RESULTS

5.1 Viability (specificity and sensitivity) of Sleep@Home

The data of the tests performed in children and adults revealed, globally, a difficult correlation between a monitoring system designed for screening (Sleep@Home) and a system which performs complete Polysomnography monitoring (PSG). The agreement between these two recording systems was low, with huge differences in indexes, comparing AHI with the alarms given by a Sleep@Home system. The analysis of data showed lack of correlation between the two indexes, in children as well as in adults, due to a high individual variability, i.e. a non-uniform behavior. In fact, there were cases where the number of alarms in the Sleep@Home system were higher than the events in PSG, and cases where the inverse occurred.

The Bland-Altman analysis, which can express the limits of agreement between the two devices revealed, both in children and adults, a systematic bias with limits of agreement great enough to underestimate or overestimate the index of the values in Sleep@Home at least two-fold the limits of diagnosis in adults.

The sensitivity and specificity analysis showed less performance of Sleep@Home as a diagnostic tool in children than in adults, even if in this case the values were lower than the data published for other screening systems. This result is somewhat surprising, since the basic screening tool of Sleep@Home is oximetry (which sets an alarm) and the level of desaturation associated to events is higher in children than in adults, due to the lower lung volume and lower oxygen reserves. This can be explained by the fact that, in our sample, children were less affected by disease than adults, but it does not explain why the index of alarms was higher in children without OSAS than in children with the disease.

There are many possible explanations for these results. First many events in PSG occurred without cutoff limit other than the criteria to define them (absence or reduction of respiratory flow, for example), independently of the level of SpO₂ reached. In the Sleep@Home system a SpO₂ lower than 92% was settled as necessary to define an alarm. This was particularly true but it is not exclusive in adults with a low basal oxygen saturation. When

it reaches 92%, Sleep@Home began processing alarms, even if there is not a fall of 3-4%, necessary to be considered a desaturation (Figure 7). As a suggestion for future work it could be create an algorithm to calculate the basal saturation of the patient, during the first minutes of exam.

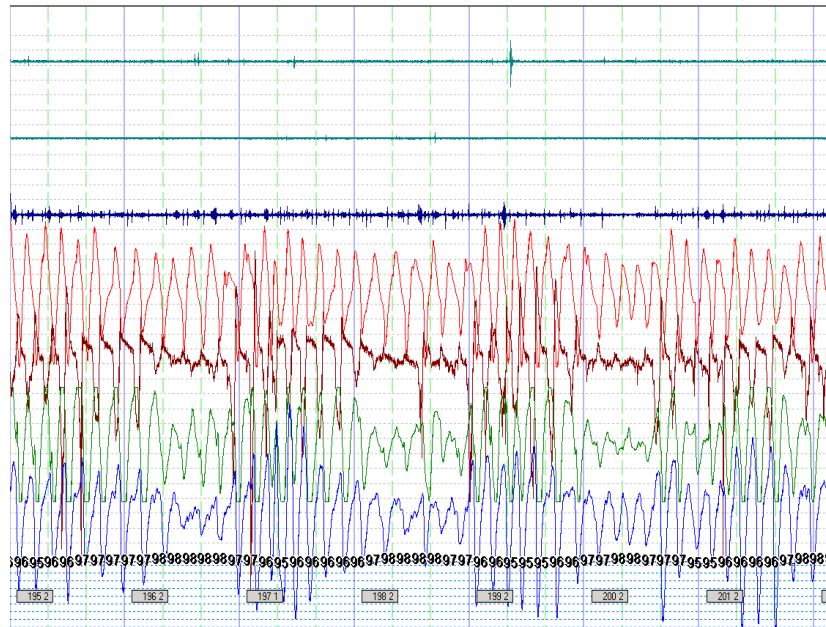


Figure 7: Hypopneas without desaturations.

Another feature that can be observed in Figure 8 is that Sleep@Home gives an alarm at the instant of desaturation, and events like apneas occur moments before. This gap can be caused by artifacts if the image is given only at the moment of desaturation. An algorithm could be created in order to show the image corresponding to the alarm 30 seconds before and 30 seconds after the desaturation.

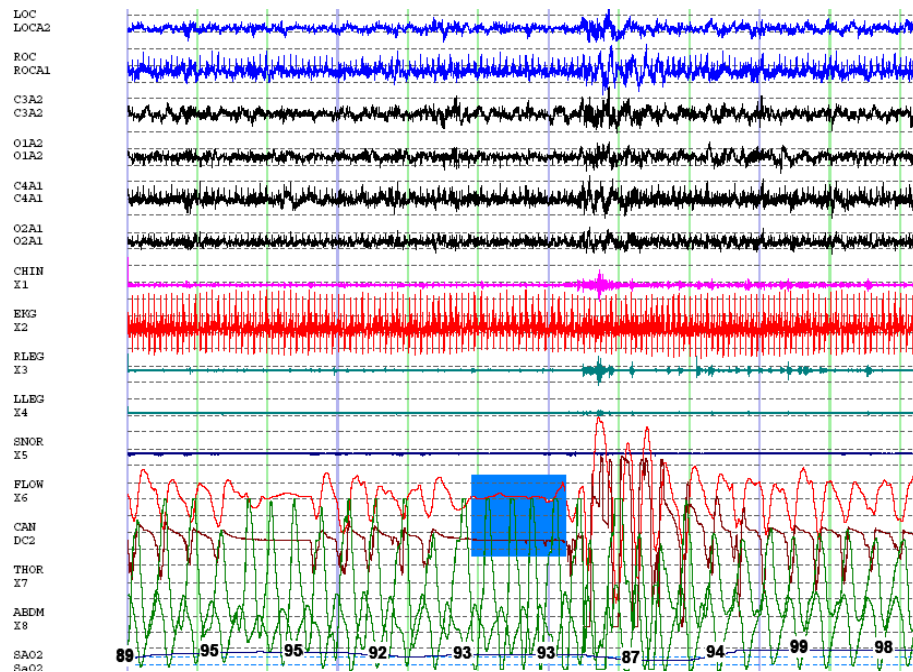


Figure 8: Desaturation after the event.

Another reason for the high false positives rate found in the Sleep@Home system is associated to the fact that movements *per se* can cause a fall in saturation, related to changes in heart rate. As oximetry uses the pulse wave to read the level of saturation, these changes in the pulse wave can lead to a transient reduction of signal and consequent reduction of the level of saturation measured, which, in fact, does not correspond to an event. An attempt to overcome this problem using the image captured by the camera was not very successful. In children, the visual analysis of alarms scored as “movement” corresponds only to 34.9% of the total number of alarms (40.7% if the visual score of alarms as “wake” is summed); in adults the values are 41.9% and 54.7%, respectively, but 18.6% of the visualizations scored alarms as “movement” corresponding to events (the value turns to be 19.7% if the visualization scored alarms as “wake” are taken into account). Therefore, detecting movement in alarms by visual analysis of the image cannot exclude all the false positive alarms and, on the other side, cannot even exclude the presence of an event because an arousal or awakening with movement frequently follows an apnea or hypopnea.

A possible way to overcome this problem is looking to the rate of desaturation. In fact, as represented in (Figure 9), at least in adults, the rate of desaturation in the presence of movement is much briefer than the desaturation that occurs with events. This hypothesis must be verified, particularly in children, and, if confirmed, can lead to the correction of these artifacts, creating an algorithm in alarms considering the falling rate of SpO₂. It is suggested to

create a filter to annul those alarms, caused by simple movements and which do not correspond to events of apnea.

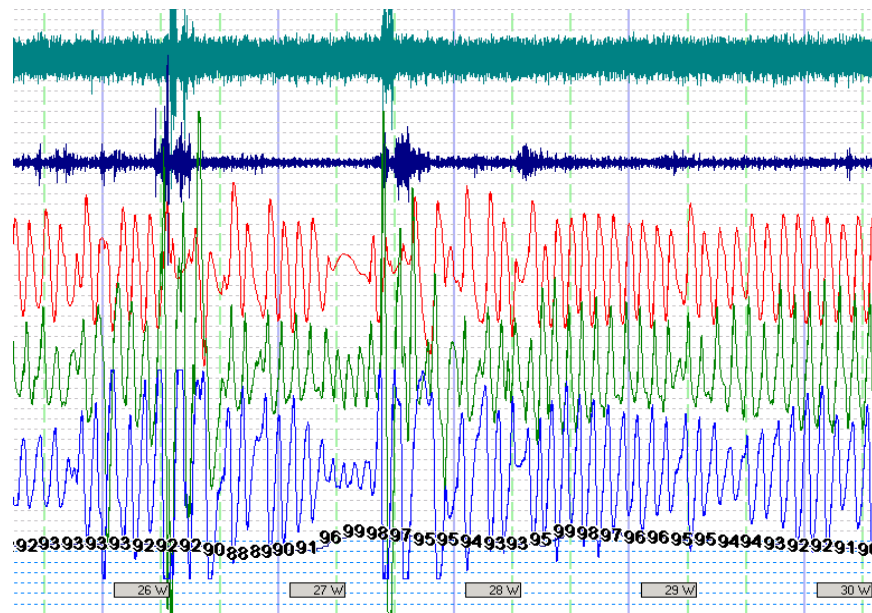


Figure 9: Desaturation due a movement in patient awakening.

Otherwise visual analysis of the image registration was not very useful in detection of events. In fact, only 6.7% of the images in children and 4 % in adults scored as “Apneas” correspond to real events scored in PSG. This low rate can be explained by the fact that the images were obtained with the patient covered by sheet and blankets, which did not allow a complete visualization of thoracic and abdominal movements. We believe that in these conditions where the images are captured it will be difficult to detect paradoxical respiratory movements that can be interpreted as obstructive apneas.

Another limitation in the images observation is the absence of simultaneous sound recording. Snore is a marker of OSAS, its characteristics, together with more or less prolonged interruptions and the “explosive” sound that usually appears when the obstructive event ends, could be helpful in visual scoring of images.

Another important feature is that the oximeter of the Sleep@Home gave different values from the oximeter at the hospital. This difference can be caused by a routine at the frequency of 1Hz of our oximeter, i.e., it gives a value to each second, and the hospital made a routine of 3Hz giving the average of 3 values. Errors in the measurement of SpO₂ may also have

occurred, since the value was only removed through visual analysis of the available graphic in the interface of the Sleep@Home (Figure 10).

About Delta index the results don't confirm the idea that the cut-off value can differentiate between patient with and without OSAS.

The comparison of the graphics displayed in subchapter 4.2.4, shows a similarity between the two graphics (but not 100% feasible as explained before).

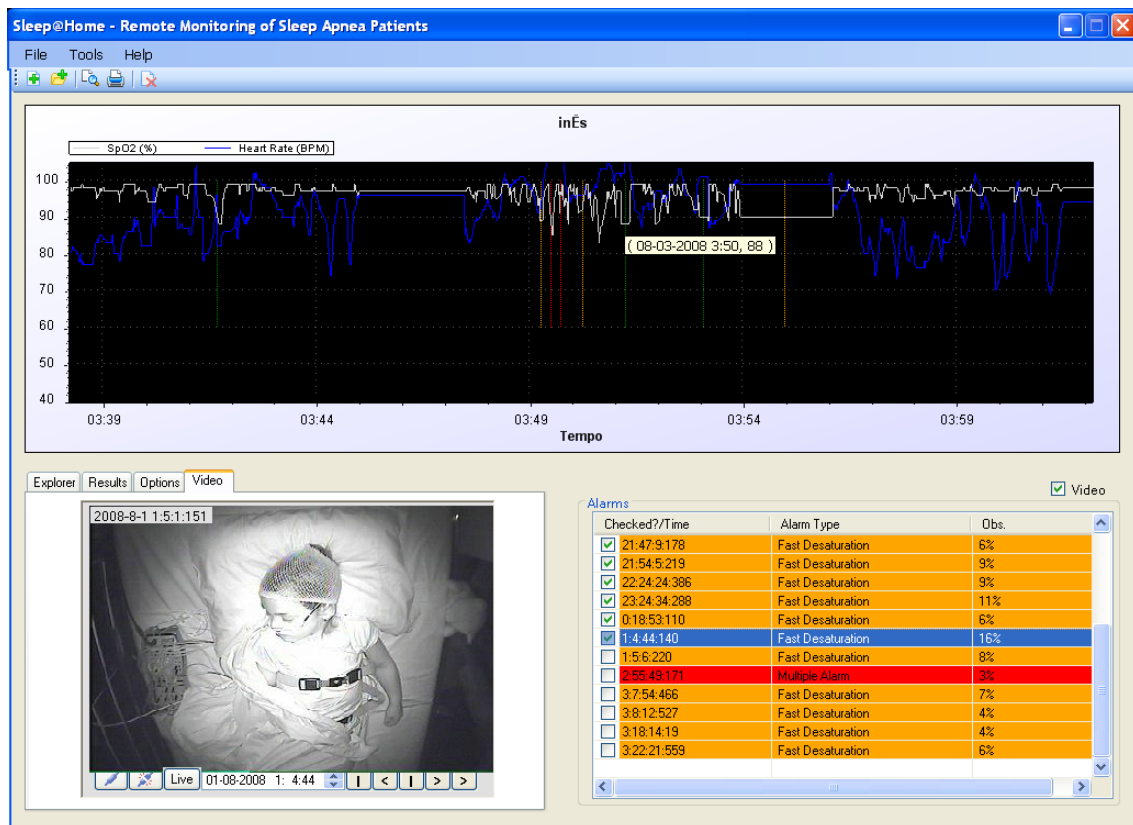


Figure 10: Figure showing possible artifacts in the measurement. The respective values are given only in the graphic.

5.2 Limitations of the System

In the Sleep@Home system, after to all tests were made, same limitations were found. The causes of this limitation must be considered for future improvements.

In what concerns the alarms given by Sleep@Home, in the these alarms are shown in order of classification (Fast Desaturation, Long Desaturation) and not in the order of hours of event. The Doctors say it is preferable that the alarms are shown by time of occurrence, because it is more interesting to perform the test throughout the night.

Another limitation regarding the alarms is the absence of a list of alarms and the correspondent level of saturation which can lead to errors, if the measurement is only given by a graphic.

Among the results available with the Sleep@Home interface, errors were observed, such as a maximum level of SpO₂ (%) and maximum of heart rate, because the given value is highly abnormal (Figure 11).

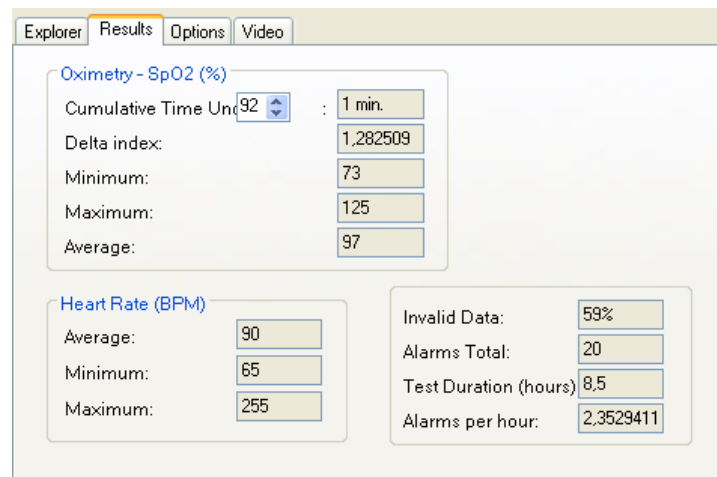


Figure 11: Artifacts in results, given by Sleep@Home.

Another featured related to the video is that the image observed in the video corresponds only to the alarm that is displayed at that moment. In a sequence of alarms it is impossible to observe an image corresponding to an alarm before that. For instance, in Figure 10 the image seen corresponds to the alarm signaled in blue; searching previous alarms cannot display the correspondent image.

The synchronization of video with alarms is not at 100%, because the duration of the video before and after an alarm is not well defined. Cases exist where the video clip is shown 2 minutes before and 5 minutes after, and in other 4 minutes before and 2 minutes after. Another point that was already considered during last year, was that if an alarm did not have a corresponding image, the image nearest is showed. After analyzing some images, this issue has become confusing.

Another observation is that the oximeter used in the system is not the most appropriated; it is too strapped, which becomes a nuisance after a few hours for the patient due to the finger's sweating. There were some cases in which the patient said "my finger seems to be burning". On the other hand the perspiration induced by this oximeter can affect the quality of the signal.

The placement of the camera was also a problem. Since the camera has no support, often it was necessary to "drag-mobile" for the camera in order to obtain a good view of the patient and this situation was precarious and unsafe.

Finally, the graphic of Sleep@Home is only available after the tests were finished, and it was considered that the ideal situation was to show the graphics during the course of the test run.

5.3 Technical Problems

During the performance of the tests, some problems were detected.

The tests of Sleep@Home began in March 2008, but only three were available in children from the eight that should be disclosed, because the technician turned off the Sleep@Home in the middle of the night, duo to interference with a hospital system. Other tests failed to start.

The visible interferences are described in following Figures,
If the hospital system had already been connected, when the Sleep@Home system was started in the interface, the following message is displayed (Figure 12).

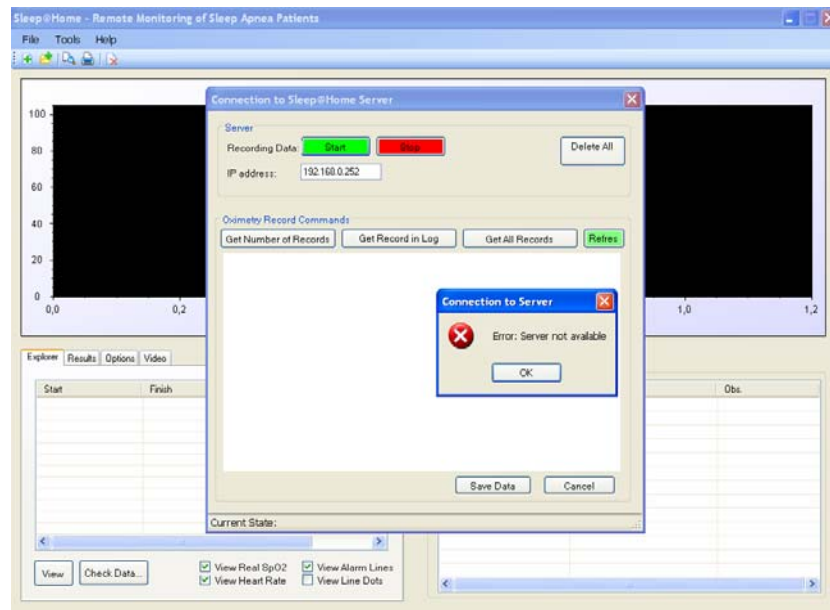


Figure 12: Displayed message when an interference occurred and a new test could not be started (Error: Server not Available).

When it was possible to start a new test, sometimes it was not possible to connect the camera (Figure 13). After turning off of the hospital system and restart of the laptop, the study could begin in good conditions.

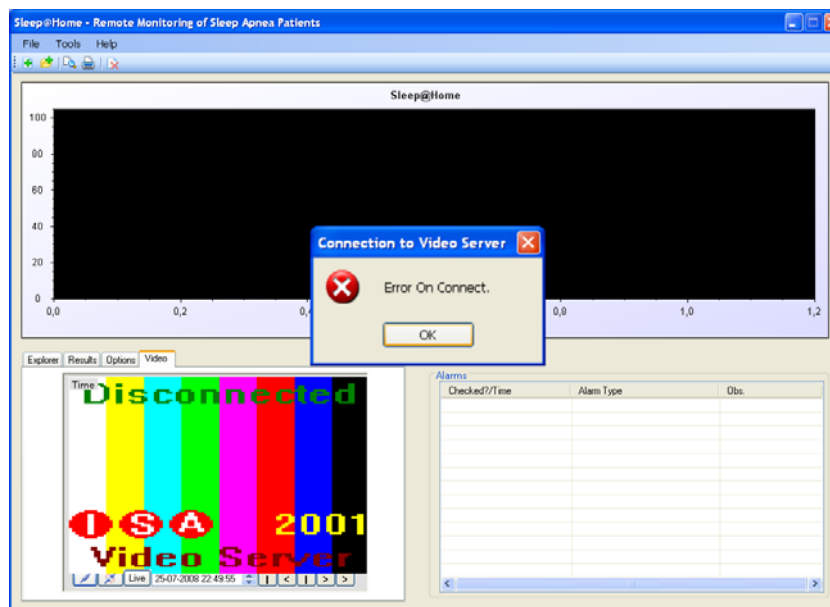


Figure 13: Displayed message when the camera could not be connected (Error on connect).

Another situation occurred when after connecting the Sleep@Home system, an interference artifact appeared in the Hospital system (Figures 14 and 15).

The artifact was frequently seen in the brain sensors (EEG), since they are very sensitive, and use different filters.

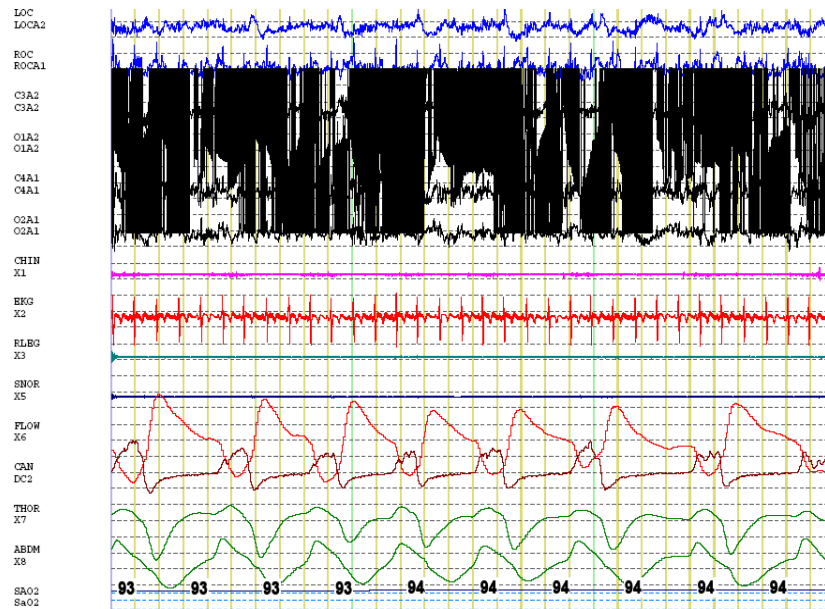


Figure 14: Artifacts in Hospital system1.

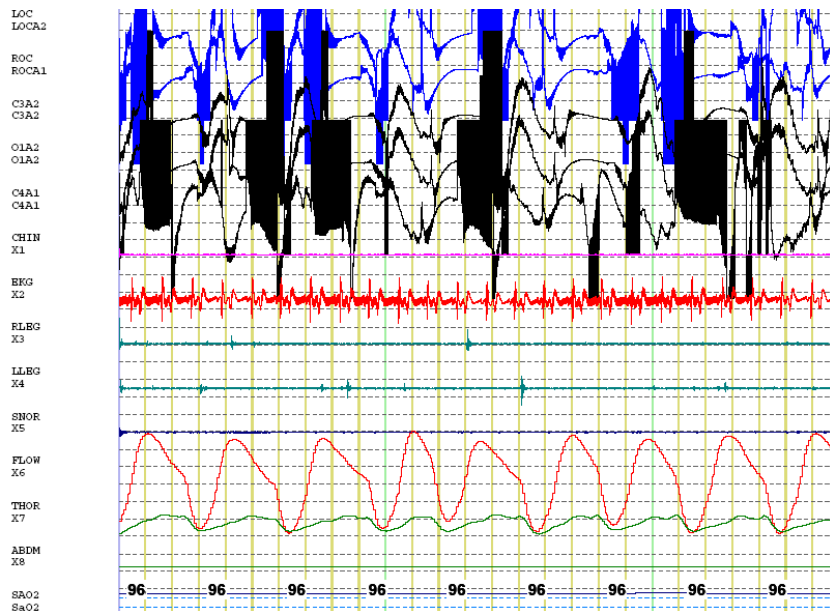


Figure 15: Artifacts in Hospital system2.

In April 2008, some tests were conducted to detect the origin of these interferences. In *a posteriori* analysis several solutions to this problem were tried, such as alteration of server alimentation; video cable, and method of oximetric acquisition. Afterwards, a checkup of the system was made, including a verification of the electric insulation of the power supply. Initially it was thought that the interference was done by the oximeter, but after some tests it was found, that the interference was coming from the server. Connecting the server with an oscilloscope¹ a big oscillation was observed. To solve these problems a connection of the server to earth with an alligator cable was made. After that the system worked without interferences.

Finally, another problem, outside interferences, occurred in two of them tests performed, the file after saving, could not be opened to view the data in a graphical interface, and the following image was displayed (Figure 16).

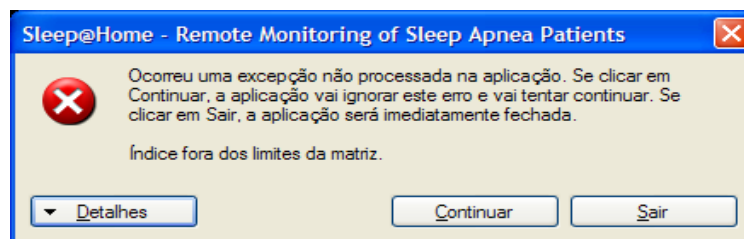


Figure 16: Sleep@Home did not process the application.

¹ An **oscilloscope** is a type of electronic test equipment that allows signal voltage to be viewed. The oscilloscope is one of the most versatile and widely used electronic device (37).

6 CONCLUSION

6.1 Concluded objectives

After a long period of tests and intensive analysis of data, it is possible to confirm that the objectives were concluded but not in the way it was expected.

This study of viability of the Sleep@Home showed that the system is not adequate to diagnose SAOS. The results stand for an insufficient quality of the detection of events. The system lacks enough sensibility and specificity.

Algorithms for alarms detection are not the most adequate. Filters for the artifacts are needed, such as movement artifacts, and to significant desaturation above the threshold (i.e. 92%). Other questions should be re-looked at, such as video sampling.

However, with some adaptations, and with the acquisition of more variables, such as sound, bands of effort, and movement sensors, the results could be different.

The initial objectives of this project/study were successful: analysis of the sensitivity and specificity of the Sleep@Home was made and a conclusion was made possible

6.2 Future work

This sub-chapter aims to think about the work that can be done in order to try to improve the system and to confer to it a higher efficiency to detect apnea events. Some solution for the aroused problems and suggestions of different forms of solution used in this project are presented.

6.2.1 Algorithms' revision and creation

After data acquisition with the Sleep@Home, some questions emerged since the obtained results did not meet our expectations.

One of the possible explanations for these results lies in the algorithms to detect alarms. One might conclude that in some of these algorithms, the used criteria may not be the most appropriate. One of these algorithms has a threshold limit of saturation that has to attain a minimal basal saturation during the first moments of register, with the patient lying down. It should be read only after the patient is in a horizontal position, and after that reduction of 3-4% of this basal level should disclose an alarm.

According to Dr. Helena Estevão, in her appreciation, it is important that Sleep@Home can give two different alarms: one for desaturation, and other for the movement without desaturation. And the alarm of movement should permit an observation of the related image one minute before and after this alarm, and give the correspondent saturation.

Taking into account that the events of apnea happen some seconds before the desaturation, the alarm should trigger off a few moments before, and the image should be sent 30-60s before and after this alarm to perceive the movements.

The filters' creation is also important, for example an alarm caused by movement, as when there is movement there is also desaturation.

The algorithms' creation related to events is also considered important, mainly for children.

6.2.2 Inclusion of audio record and other variables

Snore is a significant characteristic of respiratory problems, often associated with SAOS; therefore audio record is important.

Although snoring during sleep time has no correlation with the severity of the pathology, i.e. there are some patients that snore, but do not have SAOS. If crossed with other signals, namely video recording, it could be a very important variable to help the system. As previously said, the doctors of the project, and technicians that collaborated in this project, stated that sound synchronized with video would be very important to help the medical staff to recognize breathing episodes. This is essential to filter some artifacts in the video, to help to classify an event as apnea, and thus excluding some false positives.

Other important variables to improve the system, are bands of respiratory effort, which have been studied also in 2008 by my colleague Ana Sofia Pardaleijo.

The PAT signal is a measure of vascular response based upon the amplitude and duration of changes in peripheral arterial blood flow, in a fingertip. The autonomous nervous functions change with sleep stages and show characteristic changes associated with sleep disorders. Therefore, continuous monitoring of autonomous nervous functions during sleep can be used for diagnostic purposes (38).

PAT is a plethismographic signal and the oximeter returns this signal at a rate of 60 Hz. Therefore, this signal could be included in this project, making easy the interpretation of abnormal respiratory and cardiac situations easier. Some tests were conducted in 2007, and the results are available. Nevertheless, this variable has not yet been implemented, and more tests should be done.

6.2.3 Studying other oximeters and camera position

As stated before, in this study some problems occurred with the oximeter, concluding that it is not adequate children, since it has a spring, being easier to fall out of the child's finger, i.e. the size of the oximeter was not in accordance to the size of the child's finger. In adults other kinds of problems were found, one of them being that the oximeter was too much strapped, not letting the finger to "breath", and along time it was annoying for patients.

Another problem that must be taken into account is the length of the cable of the oximeter. The oximeter must have a large cable that is connected to the server and has to be able to reach the bed. That was not observed in this study.

The camera must be positioned in a good place, in order to acquire good images which revealed itself to be very difficult. To solve this problem we must consider a situation in which the camera has a support itself, where it can be adjusted to different situations. Another possible idea is to use a camera with zoom to improve the images in the video record.

6.2.4 Remote transmission

Remote transmission is an important characteristic of Sleep@Home, to transmit the video, oximetric and heart rate signals from patient's home to the hospital will be available in next version of Sleep@Home.

This characteristic aims to create solutions to fight the large waiting lists and a major advantage for patients who live far from the hospital.

Another advantage is that a direct monitoring in real time of the patient by clinicians may be possible. It can also become an important tool for patients who have to use ventilation equipment throughout the night, so the clinician can also observe its evolution or problems along the evolution of the disease.

6.3 Final appreciation

This project was important for the acquisition of essential skills for my future work. In this study a very great experience was acquired. Working in a hospital with the clinicians gave me an idea of the reality of the disease and of the patients suffering from this disease. The methods for diagnosis and treatment were also seized in this environment. The relationship between the people who work in this setting enabled me to learn how a sleep laboratory works, and what are the further steps when patients have a positive diagnosis.

This project, which is part of the Biomedical Engineering course, revealed its multidisciplinary features, and gave me a good performance in this area.

The Integration in ISA, a company with an innovative spirit, which has already been given awards worldwide, has provided a real vision of the world of work and of scientific investigation. Furthermore, I also acquired skills in electronic components, market products, and in the functional system Sleep@Home.

It was very gratifying to participate in this project in this academic year, increasing my interest in developing technologies in a biomedical area.

In conclusion, this was a good experience in all its features.

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