SENSATION remote monitoring system that enables monitoring of patients with selected sleep disorders

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Abstract - SENSATION Integrated Project aims at promoting the health, safety and quality of life of people and protect the environment by reducing relevant accidents and thus the impact on environment through the application of novel micro and nano sensors and related technologies, of low-cost and high-efficiency, for physiological state monitoring. The focus of work is the brain activity, including the sleep and wakefulness states and their boundaries, stress, inattention and hypovigilance states, for hypovigilance detection, prediction and management as well as diagnosis, treatment and remote monitoring of sleep disorders. In this paper, a presentation of the application scenarios of the integrated medical system is being made.

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I. Introduction

Sleep disorders have a high prevalence in the general population: insomnia (10-20% of adults), sleep apnea syndromes (4-6%). They are responsible for high costs of diagnosis and treatment modalities. Diagnosis is usually done in sleep laboratories at the expense of cost in personnel and long waiting list. Remote monitoring could be an alternative to laboratory diagnosis. Currently 2/3 of sleep studies for diagnosis are performed in laboratory. The average cost of in-lab studies for the health care is 390 € / study. The average cost of ambulatory studies with EEG is around 120 € / study, i.e. 30% of the in-lab cost. 50% of users are not satisfied with their current practice of ambulatory monitoring, although they have a clear need for this technique to increase monitoring capacity (88%), reduce cost of investigation (85%), improve sleep quality (60%) and obtain better acceptance from the patient (76%). The expectations from ambulatory monitoring are: high diagnostic sensitivity (86%), high reliability of equipment (92%), low interference with patient's habits (94%). It is worth noting that 74% of users do not expect a fully automated interpretation of data. The indications cited are screening and follow-up of SAS, epilepsy, Periodic Leg Movements and also insomnia and narcolepsy. The actual standard mean cost of a polysomnography in the lab (500 €) and in ambulatory (238 €) i.e. less than one half of the laboratory cost. The monography of the health care process for sleep medicine in Paris showed a delay of more than 10 years for diagnosis of SAS in 25% of the patients and up to 5 physicians visited before referral to the sleep lab. In conclusion, there is a clear need for ambulatory monitoring of sleep disorders to decrease the burden of cost and long waiting lists, which is not well satisfied with the current health care system and commercially available equipment.

SENSATION explores a wide range of micro and nano sensor technologies, aiming to achieve unobtrusive, cost-effective, real-time monitoring, detection and prediction of human physiological state in relation to wakefulness, fatigue and stress anytime, everywhere and for everybody. SENSATION medical applications targeted cover the whole medical services spectrum, from diagnosis to treatment. A few sleep-related disorders are selected for such SENSATION applications.

II. Methods

The term remote monitoring system is used for a remote telemetry system that allows monitoring the patient from a distance. An example of distance monitoring is home monitoring, where a patient is monitored from his/her own home, thus allowing sleep specialists to analyze from a distance, the evolution of the patient. Another example of a remote monitoring system, is monitoring of certain vital signs during patients' daily activities; patient can be located anywhere, and recorded signals can be transmitted to a monitoring center.

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Medical application scenarios

Medical applications are focused both on sleep and sleepiness/drowsiness monitoring. SENSATION systems will be applied in the diagnosis of patients with insomnia, and/or hypersomnia complaints. The sleep disorders that are investigated in SENSATION are Insomnia and Obstructive Sleep Apnea.

Obstructive sleep apnea syndrome (OSAS) is the most common sleep breathing disorder and is characterized by the repetitive collapse or partial collapse of the pharyngeal airway during sleep and the need to arouse to resume ventilation. OSAS is most common in middle-aged, overweighted men and women. The prevalence has been estimated to be 4% for men and 2% for women. Apnea is defined as the cessation of airflow for a minimum of 10 sec. Hypopnea is defined as a reduction of 30-50% in airflow for a minimum of 10 sec. The definition of OSAS in adults, from the International Classification of Sleep Disorders, Diagnostic and Coding manual (ICSD) is as follows: (a) The patient has a complaint of excessive sleepiness or insomnia, (b) The patient may be unaware of clinical features that are observed by others, (c) There are frequent episodes of obstructed breathing during sleep, (d) Associated features include: loud snoring, morning headaches, dry mouth upon awakening and chest retraction during sleeping in young children, (e) PSG demonstrates more than five obstructive apneas >10 seconds in duration per hour of sleep (AI > 5/hr sleep) and one or more of the following: (i) Frequent arousal from sleep associated with apneas, (ii) Bradytachycardia, (iii) Arterial oxygen desaturation in associated with apneic episodes, (iv) MSLT demonstrates a mean sleep latency of less than 10 minutes, (v) Can be associated with other medical disorders

Epidemiological surveys have shown that *insomnia* symptoms are extremely prevalent in the general population and that the prevalence increases with age, rising up to 50 %. The prevalence of insomnia diagnoses according to the DSM-IV classification has been estimated at about 6 %. Typical complaints: (a) Difficulty initiating and/or maintaining sleep, (b) A chronic non-restorative sleep or poor sleep quality, (c) Symptoms are often combined with daytime fatigue, clinically significant distress and/or impairment in daytime functioning.

Psychophysiological insomnia is a particular subtype of insomnia, characterized by an absence of obvious cause and by a specific chronic hyperarousal state. It is suggested that, in these patients, the meaning of stressful events is denied and repressed but manifests itself as increased physiological arousal. Patients develop learned sleep-preventing associations, consisting mainly of a marked over concern with the inability to sleep. Conditioned arousal factors further interfere with sleep, whether they are internal or external. Learned sleep-preventing associations and related conditioned arousal also tend to play an important role in most other forms of chronic insomnia. Without treatment, psychophysiological insomnia may last for years or decades. In some cases, it may gradually worsen over time, because a vicious cycle of insomnia develops.

SENSATION selected four distance monitoring medical applications to be developed within the project that are associated with the selected two sleep disorders:

- **Obstructive Sleep Apnea Syndrome**
  Application 1: Screening and diagnosis of Obstructive Sleep Apnea Syndrome through new miniaturized sensors
  Application 2: Screening and diagnosis of Obstructive Sleep Apnea Syndrome through Arterial Tonometry, Oximetry and Actigraphy

Innovation in both methods comes from the use of new easy to use sensors that are developed in SENSATION. In the first method, physiological parameters currently used in clinical practice for the diagnosis of OSAS will be measured through new sensors developed in SENSATION. The aim is to provide a home-based diagnosis tool that can detect all kinds of sleep disordered breathing (obstructive and central apnea, snoring, upper airway resistance syndrome), detect the amount, or severity (duration of events) and then also record leg movements. In application 2, in addition to the new sensors, a new method for extracting respiration from Arterial Tonometry is being developed and evaluated, for the development of a simplified technique that uses only three new sensors for screening and diagnosis of sleep disordered breathing. In both cases, the diagnostic tools are designed to be used by qualified sleep specialists as part of a comprehensive sleep evaluation.

- **Insomnia**
  Application 3: Home-based unattended assessment of the effectiveness of different treatments for psychophysiological insomnia using miniaturized sensors
  Application 4: Home-based unattended assessment of next-morning residual effects of hypnotic drugs on the level of daytime vigilance using miniaturized sensors

Innovation in both applications comes first from the use of new miniature easy to wear sensors that are developed in SENSATION. In application 3, an overall approach of treatment evaluation of psychophysiological insomnia through 24h remote physiological monitoring is proposed. The innovative part of this treatment scenario consists in the use of continuous monitoring of arousal level during the patient daily activities to assess treatment effectiveness. In application 4, the system to be developed could bring more relevant information regarding hypnotic-induced daytime hypovigilance than standard procedures. The continuous measurement of a patient vigilance level could help clinicians to limit their prescription to the safest dose of a psychotropic drug.

- **Clinical routine and medical emergencies**
  Application 5: Monitoring of patients during general anaesthesia
  Application 6: Monitoring patients with acute ventilatory failure due to COPD in the ICU (non-invasive ventilation)

It is obvious that monitoring of patients in emergency-related applications is implemented by an already sophisticated automatically operating system, in order to ensure an early detection of possible problems that might

occur. However, there are some important parameters that are still not implemented in such a standard monitoring of patients. One of these parameters is the vigilance status of the patient. The vigilance or consciousness status of the patient is very important for a decision on further treatment of the patient and/or handling of emergency cases. Up to now, there does not exist any validated and easy to use system or sensor that results in an easy to interpret vigilance status assessment. The requirements of such a system are an easy and fast application of the sensor and an easy to understand result, for example a numeric scale of vigilance status. This is a basic requirement, since the personnel in an ICU or emergency room (ER) should not be given extra work and cannot be trained to interpret EEG-tracings, for example, for a classification of patients' vigilance status. A second important parameter which up to now has not been continuously monitored is the stress level of the patient. Although a standardized ICU or ER monitoring does include heart rate and blood pressure data collection, there still does not exist an easy to understand direct classification of stress levels. However, monitoring of stress levels is very important, in order to recognize possible problems of the patient at an early stage or to detect problems when the patient is not able to speak. Again, this system must include an easy and fast to apply sensor and an easy to understand result. One problem is that patients in the ICU and in the ER usually have more elevated stress levels than patients at home or in a ward. Thus, stress level increases must also be detected by the system even in already "stressed" patients.

SENSATION Medical Application	**Characteristics**	**Indicators**
Screening and diagnosis of obstructive sleep apnea syndrome through new miniaturized sensors	Home-based diagnosis, single night recording	Respiratory movements, Airflow, Blood gas measurements (Oxygen saturation), Heart rate & heart dynamics, Brain Activity, Eye movements, Eye lid closure and blinks, Muscle tone, Body posture Limb movements
Diagnosis of obstructive sleep apnea syndrome, using arterial tonometry, oximetry and actigraphy	Home-based diagnosis, single night recording	Vasomotor status – Sympathetic and Parasympathetic influences (arterial tonometry), Blood gas measurements (oxygen saturation), Heart rate & heart Dynamics, Body movements
Home-based unattended assessment of the effectiveness of different treatments for psychophysiolo-gical insomnia using miniaturized sensors	Home-based treatment follow-up, 24 hours recording for 4 weeks	Heart rate & heart dynamics, Brain Activity, Eye movements, Eye lid closure and blinks, Muscle tone, Core body Temperature
Home-based unattended assessment of next-morning residual effects of hypnotic drugs on the level of daytime vigilance using miniaturized sensors	Home-based treatment follow-up 24 hours recording for 3 days	Brain activity
Monitoring of patients during general anaesthesia	Emergency, point of care-surgery, continuous recording during surgery	Blood gas measurements (oxygen saturation), Heart rate & heart dynamics, Vasomotor status, Sympathetic & parasympathetic influences (blood pressure), Brain activity, Eye Movements, Eye lid closure and blinks, Muscle Tone, Skin resistance
Monitoring patients with acute ventilatory failure due to COPD in the ICU (non-invasive ventilation)	Emergency, point of care - ICU, continuous recording while in ICU	Respiratory Movements, Blood gas measurements (oxygen saturation), Heart rate & heart dynamics, Vasomotor status – Sympathetic and parasympathetic influences (blood pressure), Brain activity, Eye Movements, Eye lid closure and blinks, Muscle tone Skin resistance

Table 1 Overview of the proposed SENSATION medical applications

Sensor	**Technique**	**Indicator**	**Application**
ENOBIO or FLEXELECT	EEG	Brain activity	1, 3, 4, 5, 8
	EOG	Eye movements & Eye lid closure and blinks	1, 3, 5, 8
	EMG chin	Muscle tone	3
	EMG tibialis	Muscle tone	1, 3, 5, 8
	ECG	Limb movements	1
		Heart rate & heart dynamics	1, 3, 5, 8
ENOBIO pillow	EEG	Brain activity	1,5, 8
	EOG	Eye movements & Eye lid closure and blinks	1,5, 8
FLEXELECT	Skin Resistance	Stress levels	5, 8
	Shivering	Muscle activity	
FINGERING	Oxygen Saturation	Blood gas measurements (oxygen saturation)	1,2, 5, 8
	Heart rate	Heart rate	2
COMBINE	Inductive Plethysmography	Respiratory Movement	1
	ECG	Heart Dynamics and Heart Rate	1
ARTERORUB or BP	Arterial Tone + Data Fusion	Vasomotor status - Sympathetic and parasympathetic influences:	
		Arterial Tonometry	2
		Blood Pressure	5, 8
WRIST	Accelerometer	Body and limb Movements	2
MATSENSE	Muscular activity Electrical muscle stimulation	Body and limb movements, Respiratory movements, Body posture & heart rate	1a, 5, 8
Vitalsense (not a SENSATION sensor)	Thermometry	Core body temperature	3

Table 2 Sensors required for SENSATION medical applications

Communication in distance monitoring applications

In the distance monitoring applications we have proposed a communication architecture (figures 1 & 2), where sensors communicate wirelessly with a wearable patient device, the Personal Data Processing Unit (PDPU). This device collects all recorded signals from the Sensor Communication Module and then it either transmits them directly to the monitoring center or, if data processing is required, signals are first sent to a home PC and from there they are transmitted to the monitoring center.

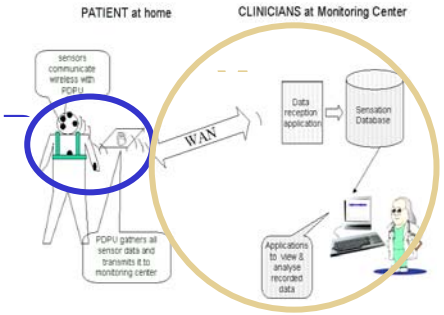

Figure 1 Communication for applications 1 and 2

Wireless communication in the BAN (between sensors and PDPU) is achieved through the Sensor Communication Module (SCM), meaning that it mainly depends on the decision of the sensor developers to design their sensor to connect with the SCM. Manufacturers of the wearable sensors are aware of this requirement and FLEXELECT, ENOBIO, FINGERING, WRIST, ARTERORUB **will support** wireless communication with the PDPU. They will connect to the SCM and the SCM will communicate wirelessly with the PDPU. Feasibility of this wireless connection depends also on the amount of data that will be transferred.

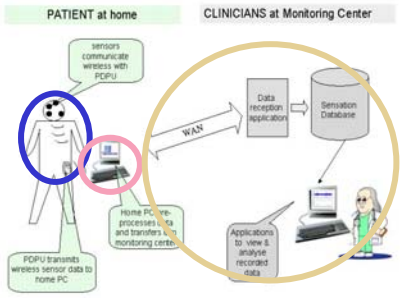

Figure 2 Communication for applications 3 and 4

SENSATION integrated system for medical applications

As depicted in Figure 4, the SENSATION architecture consists of the following modules:

1) The *SENSATION portal* that:

- features J2EE-based applications and provides:
- Membership Management: creation and management of Users, Groups, Roles and domains
- Presentation Services. Internet access is only required by the users
- Integration services allowing deployment of HTML and non HTML applications via the Portal
- Reporting/accounting/logging
- Handling of all data requests

2) The *Signal Reception and Archiving* module that includes modules for the reception of all signals required in the different applications (e.g. EEG, EOG, EMG etc) and is responsible for the archiving of the above signals.

3) The *Signal Processing and Viewing module* that includes viewers for relevant signals together with processing modules as defined within the applications' implementation.

4) *Patient Data module*. In the Patient DB, patient's Demographic data, Medical data and details about the services provided to the patient are stored. The portal resources are used for data exchange between the DBs and the applications.

5) The *Business logic for service definition* module. It is the main Business Logic that ties the Portal functions together.

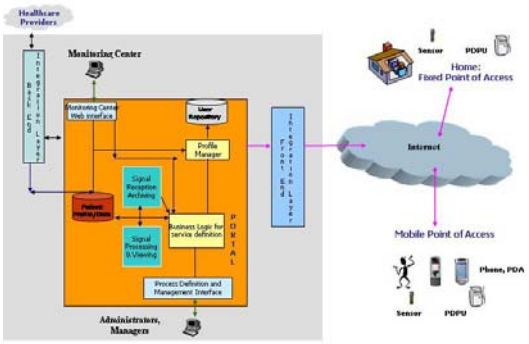

Figure 4. SENSATION Medical System Architecture

III. Discussion

The proposed services provide both the selected patient population and doctors with complete mobile management of their diseases and a monitoring mechanism and management system that delivers benefits to patients, clinicians and payers. The proposed systems takes advantage of recent technological advances in sensors, algorithm development, computing, networking and mobile wireless telehealth to provide an integrated platform for continuous patient monitoring. Thus, the proposed platforms enhance the effectiveness of health care and improve health standards and in the same time will help patient to continue to some normal and work activities in order to be an 'active' citizen.

IV. Acknowledgements

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