

# INFORMATION SOCIETY TECHNOLOGIES (IST) PROGRAMME



## SENSATION

**507231**

**Report on definition of home care needs, security requirements, literacy and educational level, and attitudes of average patients in the target groups**

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**LIST OF ABBREVIATIONS**

AHI:	Apnea-Hypopnea Index
AI:	Apnea Index
ASDA:	American Sleep Disorders Association
AUTH:	Aristotle University of Thessaloniki
BAN:	Body Area Network
CBT	Cognitive-Behavioural Therapies
CNS:	Central Nervous System
D:	Deliverable
ECG:	Electrocardiogram
EDS:	Excessive Daytime Sleepiness
EEG:	Electroencephalogram
EMG:	Electromyogram
EOG:	Electrooculogram
FMRI:	Functional Magnetic Resonance Imaging
FR:	Frequency Range
ERP	Event-related Potential
HRV:	Heart Rate Variability
HF:	High Frequency
ICSD:	International Classification of Sleep Disorders
LF:	Low Frequency
MSLT:	Multiple Sleep Latency Tests
MEG:	Magneto encephalography
OSA:	Obstructive Sleep Apnea
OSAS:	Obstructive Sleep Apnea Syndrome
OSAHS:	Obstructive Sleep Apnea/Hypopnea Syndrome
PAT:	Peripheral Arterial Tone
PDA:	Personal Digital Assistant
PET:	Positron Emission Tomography
PDPU:	Personal Data Processing Unit
PSG:	Polysomnography
PVT:	Psychomotor Vigilance Test
RDI:	Respiratory Disturbance Index
REM:	Rapid Eye Movement
RIP:	Respiratory Inductance Plethysmography
RR:	Interval between two consecutive heart beats
SaO <sub>2</sub> :	Oxygen Saturation
SAS:	Sleep Apnea Syndrome
SD:	Standard Deviation
SDB:	Sleep Disordered Breathing
SRBD:	Sleep Related Breathing Disorders
SP:	Subproject
WAN:	Wide Area Network
WP:	Work Package

## EXECUTIVE SUMMARY

SENSATION 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 human physiological state monitoring. SENSATION is organised in 5 closely-related Subprojects (SPs), specifically:

- SubProject 1 “Stages definition, classification criteria and tools”.
- SubProject 2 “Micro and nano sensors development”
- SubProject 3 “Medical and Neurological applications”
- SubProject 4 “Industrial Applications”
- SubProject 5 “Cross-project Activities”

In SP3 we will integrate the developed sensors and algorithms from SP2 and SP1 into a complete distance monitoring system that will enable the “anytime, anywhere” monitoring of patients with selected sleep disorders. A distance monitoring system, the SENSATION System, will be developed where clinical, technical, organizational and practical issues need to be assessed. This system will be tested and evaluated through medical pilots.

Deliverable 3.1.2 aims to define the home care needs and identify the security requirements through literature survey and interviews with clinical experts for specific average patient target groups.

The term distance or remote monitoring system is used for a remote telemetry system that allows making a follow up of 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 (or remotely), the evolution of the patient. Another example of distance or remote monitoring system, is monitoring of certain vital signals during patients’ daily activities; patient can be located anywhere, and recorded signals can be transmitted to a monitoring center.

The current document presents 4 proposed distance monitoring medical applications to be developed in SP3, that are associated with the two sleep disorders that have been proposed in D3.1.1:

- Patients suspected for 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
- Patients who are treated for insomnia
  - Application 3: Evaluation of insomnia treatment
  - Application 4: Detection of drug induced hypovigilance

The first two are home monitoring applications whereas in the last two, patient’s physiological data is recorded 24 hours a day at any place, during daily activities. For each application the characteristics, skills, attitudes and tasks of the monitored patients are identified and the resulted user requirements are presented. The needs of

healthcare professionals, in order to perform a comprehensive clinical evaluation through the proposed methods, have also been defined. Requirements are presented separately for sensors, devices and clinician software, in order to facilitate the technical teams during design and development of each component.

## INTRODUCTION

In SP3 we will integrate the developed sensors and algorithms from SP2 and SP1 into a complete distance monitoring system, that will enable the “anytime, anywhere” monitoring of patients with selected sleep disorders. WP3.1 will provide the user requirements of this distance monitoring system.

During the first part (months 1-6) of WP3.1, current status of distance monitoring of sleep disorder applications has been assessed and two target groups have been proposed (patients with obstructive sleep apnea and patients with insomnia). This work has been reported in D3.1.1.

Between months 7 and 12, the aim in WP3.1 has been to define diagnosis and treatment applications and their requirements for the proposed target groups. We performed analysis of the main user groups, their tasks and working environments, taking into account up-to-date information on communication architecture and sensors availability from SP2. The purpose of the current deliverable is to present the results of this work. The methodology that was used has been based on the RESPECT framework [1], a user-centered design process developed by European Usability Support Centers.

Work in the following (and last) 6 months of WP3.1 will aim to investigate the feasibility of the proposed applications. Focus groups from SP2 (sensor developers and other technical teams) and SP3 (clinical groups) will perform walkthroughs of the defined task scenarios in order to validate the proposed functionality and identify parts that require change; user requirements will be re-iterated and finalised.

The medical applications that are defined in the present document are associated with the two sleep related conditions that have been proposed in D3.1.1:

- Patients suspected for 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
- Patients who are treated for insomnia
  - Application 3: Evaluation of insomnia treatment
  - Application 4: Detection of drug induced hypovigilance

For the first patient group two applications for home-based screening and diagnosis of obstructive sleep apnea syndrome have been proposed. In the first method, physiological parameters currently used in clinical practice for the diagnosis of OSAS will be measured through new sensors developed in SP2. The second method is based on a new technique, that will be developed in SP3, that uses Arterial Tonometry to extract respiration information. SP2 sensors will be used in this application.

For the second patient group, two new approaches on treatment evaluation of insomnia will be developed and evaluated. The first one is based on 24 hour physiological monitoring of patients who are treated for insomnia; patients will be monitored during their daily activities, in order to assess the effect of insomnia

treatment in patient's hyperarousal state. In application 4, a new method for hypovigilance detection through miniaturized sensors will be developed. This application can be used for dose adjustment of drugs acting on the Central Nervous System (CNS).

### ***Methodology***

Work done in WP3.1 between month 7 and month 12 was divided in the following tasks:

1. Defined the concept and general functions of four medical applications for the proposed groups in D3.1.1, taking into consideration the utilization of sensors from SP2 and signals from SP1.
2. Identified the physiological monitoring requirements for each application
3. Identifying the users, their characteristics and task scenarios for each application.
4. From 2 and 3, define requirements on sensors, devices and software clinician applications.

Task 1 has been supported by interviews with sleep clinicians, findings of literature search that was performed in the first 6 months of WP3.1 (reported in D3.1.1) and SP3 clinicians group discussions during the SENSATION meetings.

Tasks 2 and 3 have been supported by interviews and e-mail discussions with sleep clinicians and clinicians who have used home care systems with other types of patients (chronic heart failure, diabetes). The requirements were also discussed during the SP3 meetings. Furthermore, one patient who recently went through an unattended study at her home for OSAS was interviewed. We performed interviews to investigate if a patient's views were similar to expert's perception of users needs at home. We noticed that feedback was consistent (e.g. patient annoyed by wires and sensors in nose, intimidated with the use of complicated technological equipment).

### ***Structure of this document***

The document starts with the Lists of Figures, Tables and Abbreviations, followed by the Executive Summary.

The introductory section presents the purpose of the deliverable, methodology and structure of this document.

**Section 1** defines the two OSAS diagnosis applications.

**Section 2** defines the two insomnia treatment applications.

Each application and its requirements are defined separately using the following subsections:

***Clinical background:*** overview of current clinical procedures for the specific target group. Clinical background is common for applications 1 and 2 since they address the same clinical problem.

***Physiological data requirements for distance monitoring:*** signals that need to be remotely monitored for the specific target group and application.

**Usage Scenario:** scenarios showing actions of each user during the specific application.

**Users characteristics, skills and attitudes:** identification of physical attributes, educational and knowledge skills and attitudes of patients in each target group.

**Users tasks and needs for distance monitoring:** identification of tasks of each user and resulting requirements. Security requirements are included in this section. In this section detailed task analysis is presented.

**Section 3** presents an overview of the **security requirements** that are defined in the tasks lists of each application and lists briefly the **evaluation activities** that need to be defined and followed for each medical application.

**Conclusions** summarize the applications and define future work.

In the **APPENDIX** summary tables of the requirements for the PDPU device and PC applications are presented, aiming to show the similarities and differences across the four applications.

## 1. SCREENING AND DIAGNOSIS OF OBSTRUCTIVE SLEEP APNEA SYNDROME

**Aim:** To develop and evaluate two applications for home-based unattended studies for screening and diagnosis of OSAS, based on new easy to wear sensors developed in SP2.

### 1.1. *Clinical Background*

Sleep disordered breathing (SDB) is a synonym to sleep related breathing disorders (SRBD). It is an umbrella term that includes obstructive sleep apnea, central sleep apnea, alveolar hypoventilation syndrome and pediatric sleep apnea – as diagnostic entities. It is also an umbrella for measured phenomena, which are events of obstructive sleep apnea, mixed sleep apnea, central sleep apnea, hypopnea, obstructive snoring, respiratory related arousals and cheyne-stokes-respiration.

Obstructive sleep apnea syndrome (OSAS), the most common sleep breathing disorder, is characterized by the repetitive collapse or partial collapse of the pharyngeal airway during sleep and the need to arouse to resume ventilation. Sleep is thus disrupted, yielding waking somnolence and diminished neurocognitive performance.

#### **Patient characteristics**

Although obstructive sleep apnea syndrome occurs at any age, and is more prevalent in women than was previously thought, the typical patient is a male aged 30 to 60 years who presents with a history of snoring, excessive daytime sleepiness, nocturnal choking or gasping, witnessed apneas during sleep, moderate obesity, and often mild to moderate hypertension.

#### **Diagnostic Criteria**

Definition of obstructive sleep apnea syndrom (OSAS) in adults from the International Classification of Sleep Disorders Diagnostic and Coding manual is as follows [2]:

- The patient has a complaint of excessive sleepiness or insomnia. The patient may be unaware of clinical features that are observed by others.
- There are frequent episodes of obstructed breathing during sleep.
- Associated features include: loud snoring, morning headaches, dry mouth upon awakening and chest retraction during sleeping in young children.
- Polysomnographic monitoring demonstrates more than five obstructive apneas >10 seconds in duration per hour of sleep and one or more of the following: frequent arousal from sleep associated with apneas, bradycardia, arterial oxygen desaturation in associated with apneic episodes, with or without multi-sleep latency test that demonstrates a mean sleep latency of less than 10 minutes.
- Can be associated with other medical disorders

#### **Differential Diagnosis**

Other sleep disorders can produce symptoms similar to sleep apnea. The differential diagnosis of sleep apnea include the following:

- Excessive daytime sleepiness:
  - Narcolepsy.

- Idiopathic central nervous system hypersomnolence.
- Sleep-related periodic leg movements.
- Drugs, including sedatives, stimulants and alcohol.
- Endocrine disorders, including hypothyroidism, Addison's disease and hypothalamic disease.
- Psychiatric disorders.
- Insufficient sleep.
- Nocturnal dyspnea:
  - Cardiac disease.
  - Asthma.
  - Gastroesophageal reflux.
- Abnormal motor activity during sleep such as sleep-related periodic leg movement
- Polycythemia:
  - Chronic respiratory disease.
  - Right-to-left shunt.
  - Polycythemia Vera.

### 1.1.1. Current Diagnostic Procedures for OSAS

OSAS is a complex condition, which may be exacerbated or relieved by a number of physical and physiological factors.

Screening and diagnostic methodologies are based on:

**Physical Examination:** Professional groups recommend that patients with suspected OSAS undergo a complete physical and otolaryngologic examination including medical history and determination of body mass index (BMI).

**Interview with patient and bed partner:** Sleep questionnaires are used to evaluate common symptoms of OSAS, such as loudness and frequency of snoring. Patients and/or their bed partners are questioned about snoring patterns and intensity, sleep habits, gasping for air at night, limb movements, feelings of fatigue or falling asleep during the day, falling asleep at work or while driving, alcohol, caffeine, and sedative use, sleeping position, shift work, weight gain or loss, morning headaches, nasal congestion or obstruction, and observed sleep apnea.

**Standard Full Polysomnography (PSG):** Overnight polysomnography (PSG) is considered the golden standard of sleep apnea diagnosis. PSG provides objective data on the type and severity of sleep-disordered breathing. Candidates for PSG include patients with EDS and those with witnessed apneas; it is not routinely indicated for patients whose only symptom is snoring.

The key diagnostic finding in OSAS is episodes of airflow cessation at the nose and mouth despite evidence of continuing respiratory effort. Apnea is defined as the cessation of airflow for a minimum of 10 sec. Hypopnea is defined as a reduction 30-50% in airflow for a minimum of 10 sec. By the time most patients come to clinical attention they have at least 10 to 15 obstructive events per hour of sleep. However, recent data suggest that a high, upper-airway resistance during sleep (manifested by snoring) that is accompanied by recurrent arousals from sleep, even in the absence of apneas and hypopneas, can result in a clinically important, sleep-related syndrome. Therefore, the absence of outright apneas and hypopneas in a symptomatic patient may not definitely exclude a sleep-related respiratory disorder.

There is no single diagnostic approach that is appropriate for all situations. Clinicians need to perform a diagnostic test for OSAS in order to: [3]:

- i. Affirm the obvious diagnosis.
- ii. Evaluate the risk of patients and decide what is the most appropriate treatment.
- iii. Investigate the simultaneous existence of another sleep disorder.
- iv. Help in resolution of a clinical dilemma when dealing with non-specific symptoms.

For some patients diagnosis is obvious, and for those, a simplified screening test is likely to confirm diagnosis (i). For cases ii, iii, iv, however, a diagnostic evaluation would be needed. As mentioned in the previous paragraph other sleep disorders can produce symptoms similar to sleep apnea, therefore during a diagnostic evaluation patients are investigated for other sleep disorders that are most likely to be present. If the patient displays few signs of obstructive sleep apnea syndrome (OSAS) but the suspicion of OSAS exists, or if patient tests negative on a screening test in spite of clinical evidence to the contrary, a diagnostic evaluation is also needed. Laboratory overnight polysomnography (PSG) is the standard method for performing the diagnosis of sleep apnea.

PSG is performed by specially trained sleep technicians in a quiet, dark, temperature-controlled room with continuous video-monitoring. It usually involves the following:

- Monitoring of sleep staging using electroencephalogram (EEG), electro-oculogram (EOG), and electromyogram (EMG).
- Monitoring of respiration using chest and abdominal impedance plethysmography and surface intercostal EMG's.
- Assessment of airflow with oral and nasal thermistors.
- Monitoring of arterial oxygen saturation using continuous pulse oximetry.
- Monitoring of heart rate and rhythm using continuous electrocardiogram recording.
- Monitoring of nocturnal myoclonus using bilateral tibialis EMG leads.
- Measurement of snoring intensity.

### **1.1.2. Polysomnography in OSAS diagnosis**

In a PSG study, diagnostic and treatment outcome measures include the apnea index, or AI, which is defined as the number of apneic episodes per hour, and the apnea/hypopnea index (AHI) defined as the total apneas plus hypopneas during total time asleep divided by the number of hours asleep. The respiratory disturbance index (RDI) is the same as the AHI. Obstructive Sleep Apnea Syndrome should be properly quantified, not only by apnea index (AHI) but also by the length of apnea, degree and number of desaturations, limitation of air flow, cardiac manifestations associated with the breathing events. An AI of five events per hour of sleep is commonly used as a criterion of OSAS [4,5]. An overnight monitoring must demonstrate five or more apneas plus hypopnea plus respiratory effort-related arousals per hour of sleep [6]. The threshold level for the AHI that indicates the need for treatment has not been established, due in part to evidence suggesting that patients with relatively-mild,

sleep-disordered breathing may have increased cardiovascular disease-risk despite normal or slightly elevated AHI values [7].

Throughout the study, the laboratory technician observes the patient's breathing pattern, body position, restlessness and characteristics of snoring. From analysis of the recorded data, the technicians define total sleep time, sleep latency, arousals after sleep onset, time spent in nREM and REM sleep, central and obstructive sleep apneas, and the severity of OSAS in terms of the AHI. If the patient history strongly suggests sleep apnea but the polysomnogram results are negative, the physician reviews the anterior tibialis electromyogram to detect subtle changes that could indicate a variant form of apnea, upper-airway resistance syndrome or the physician may determine that a multiple-sleep latency test is indicated.

Table 1 shows the physical functions that must be monitored during a PSG exam.

Function	Indicator	Technique	Assessment Variable
<b>Respiration</b>	Airflow	Nasal Pressure	Apneas (through standard conversion to respiratory volume and standard apnea determination)
	Respiratory Effort	Inductive Plethysmography of the chest and the abdomen	Apnea, hypopnea, AHI
	Oxygen Saturation	Oxygen Saturation	Desaturation events
<b>Cardiovascular</b>	Arrhythmia	ECG (1 lead)	Arrhythmia events
	Heart Rate	ECG (1 lead)	Heart Rate variability calculation as well as cyclical variation of heart rate determination
<b>Sleep</b>	Sleep/Wake State	EEG EOG EMG	Total Sleep Time Sleep Latency Time spent in REM and nREM sleep (through standard sleep staging software)
	Sleep Arousals	EEG	Arousals after sleep onset
<b>Body Movement</b>	Body Position	Switch device	Threshold detection for different body positions
	Leg Movement	EMG tibialis	Detection of subtle changes in anterior tibialis electromyogram

**Table 1: Physical functions monitored in polysomnography for OSAS diagnosis**

As presented in D3.1.1, due to the high cost of PSG studies and limited availability of sleep labs, there is high interest in the role of simplified, unattended sleep monitoring for the investigation of sleep disordered breathing, that would allow the patient to be studied at home, rather than in the sleep laboratory. Ambulatory systems that can be used to record at home (unattended) the data listed above, have been developed and are being used in clinical practice. There are several such systems in the market (Type 1 or Type 2, listed in detail in D3.1.1.). Data is usually stored on an industrial

and standardised Compact Flash Card that is afterwards taken to the lab for analysis. Such systems may be effective in certain cases of diagnosis of OSAS, when used by a qualified sleep-specialist as a part of a comprehensive sleep evaluation [8]. Their main disadvantage is that they are not easy to use; installation of the electrodes is complicated and technician assistance is necessary. Often, due to technical artifacts, data is non interpretable and the study has to be repeated in the lab. Additionally, all electrodes are cabled to the main device and this disturbs the patients. In order to reduce the number of cables and electrodes, simplified solutions have been developed (Type 3 and Type 4 devices), that provide a subset of the variables listed in Table 1, and could be used in certain situations for screening only, according to clinician's judgment. Portable recordings used as an isolated procedure by unqualified clinicians may result in improper care and higher health care cost due to its application for inappropriate diagnostic indications [8].

Taking into consideration the above findings, we propose two new methods for screening and diagnosis of OSAS, that will be developed and evaluated for use in unattended setting:

**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 within 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 SP2. The aim is to provide a home-based diagnosis tool that can detect all kinds of sleep disordered breathing (obstructive, central apnea and others), 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 extraction of Respiration from Arterial Tonometry will be developed and evaluated, aiming to lead to a simplified technique that uses only three new sensors for screening and diagnosis of sleep disordered breathing.

In both cases, the diagnostic tools will be designed to be used by qualified sleep specialists as part of a comprehensive sleep evaluation.

## ***1.2. Application 1: Screening and diagnosis of Obstructive Sleep Apnea Syndrome through new miniaturized sensors***

### **1.2.1. Physiological data requirements for home based diagnosis**

We will develop and evaluate an application for home based screening and diagnosis of OSAS that will use innovative, easy to attach sensors that are connected wirelessly to a main device. Since no cables are involved, the risk of technical artifacts due to cables falling off during patient sleep is reduced. The patient may attach the sensors by him/herself and would sleep more comfortably. As a result, this method could be appropriate to use in an unattended setting (home).

An overview of the signals that will be recorded is provided in the table below:

Function	Indicator	Technique	Proposed SP2 Sensors
<b>Respiration</b>	Airflow	Airflow will be calculated from Resp. Effort	COMBINE : ("Belt" wrapped around chest)
	Respiratory Effort	Inductive Plethysmography of chest and abdomen	
	Oxygen Saturation	Oxygen Saturation	COMBINE (FINGERING will be integrated)
<b>Cardiovascular</b>	Arrhythmia	ECG (1 lead)	COMBINE (1 sensor integrated in "belt" that is wrapped around chest)
	Heart Rate		
<b>Sleep</b>	Sleep-wake State	EEG 1 lead	ENOBIO or FLEXELECT or ENOBIO pillow
		EOG 2 leads	ENOBIO or FLEXELECT
		EMG 1 lead	ENOBIO or FLEXELECT
<b>Arousals</b>	ANS Arousals		COMBINE
<b>Body Position</b>	Body Position (left, right, prone, supine, upright)	Not specified	COMBINE (1 sensor integrated in "belt" that is wrapped around chest)
	Leg Movement	EMG tibialis (single)	ENOBIO or FLEXELECT

**Table 2: Requirements on signals and sensors for home diagnosis of OSAS**

The current application includes sleep assessment. Different research teams debate about the importance of measuring sleep parameters in patients suspected for OSAS. NJ Douglas [9] states that there is no diagnostic and therapeutic value of sleep parameters in the management of OSAS. Scottish guidelines for OSAS diagnosis do not include sleep [10]. On the other hand, ASDA states that OSAS cannot be diagnosed without sleep assessment [8].

Taking into consideration different guidelines and policies in different countries, the current application will provide sleep-wake state evaluation. Clinicians will have then to follow the guidelines and policies in their country as to whether this functionality will be used or not.

Specifically the following sleep/wake states will be assessed:

- Wakefulness,
- light NREM sleep,
- deep NREM sleep,
- REM sleep.

### 1.2.2. Usage Scenario

After physical examination and interview, patient is suspected for OSAS. Patient is referred for a home-based study. He/she receives a device that looks like a mobile phone, a "belt" that is wrapped around the chest, a finger sensor, 1 sensor for the leg (EMG tibialis) and a nightcap where 6 sensors are embedded. No cables are involved. A sleep technician explains to him/her about the procedure and shows how the device and sensors are used. The sleep technician configures the device accordingly by setting recording, transmission and authentication parameters. He/she then, attaches

the sensors and nightcap on patient and tests for position and functionality. Patient prefers to have the body sensors (belt) attached; since there are no cables involved and he/she feels very comfortable, but prefers to remove the finger sensor, EMG tibialis and nightcap and attach them by himself/herself later at night. He/she also receives a simplified brochure with instructions and a phone number for assistance and then leaves. Before bedtime, patient attaches the nightcap, attaches the finger and EMG tibialis sensors and presses the “Record” button on the device. On the LED screen it is indicated that recording is on, patient leaves the device on the side table and sleeps. In the following morning, as soon as he/she wakes up, he/she presses the STOP button and then presses, “SEND”. On the LED screen of the device, he/she sees the message “Transmission successful”. Patient then, detaches the sensors. He/she has a scheduled appointment with his/her clinician later, in the afternoon.

At the monitoring center, data is received and stored in the database that is located at the monitoring center. The Sleep Technician, through her PC SENSATION Application sees that new data has arrived. He/she views the log file to see if any significant errors have occurred and requests for the combined report, that includes analysis of Apnea Hypopnea, Oximetry, Sleep, Heart Rate and Body position and graphical view of all events in common time scale so that synchronicity can be viewed. The report is then given to the sleep physician prior to patient visit so that he/she can perform a clinical evaluation.

### 1.2.3. Users characteristics, skills and attitudes

The users and their main task goals in application 1 are shown in the table below:

USERS	TASK GOALS	MAIN TASKS
<b>Patients suspected for OSAS</b>	To receive diagnosis comfortably	Uses equipment by him/herself at home for diagnosis for one-two nights Sleeps with equipment on Initiates recording, transmission Attaches/deattaches sensors by him/herself
<b>Technician at monitoring center</b>	To provide support to patients and clinicians	Demonstrates equipment to patient Configures equipment Receives Data from patient Provides Supports to patient
<b>Clinician at monitoring center</b>	To perform successful diagnostic evaluation	Introduces patient to the usage of this application/equipment Views the recorded and transmitted patient data and performs clinical evaluation

**Table 3: Users and main tasks for home-based diagnosis of OSAS**

#### Patients Characteristics

**Age:** Patients suspected for OSAS are adults, of any age and gender. Most often they are between 30 to 60 years old.

**Physical Attributes:** Often obese, therefore wearable components should come in all sizes.

**Educational Level:** Patients may belong to any educational level; we should assume minimum education during the development of system interfaces.

**Language:** Patients have any native language and not all of them speak english. Optimally interfaces should be in patient's native language. If not, single words and simple terminology should be used (e.g. STOP, OK, START).

**Experience with similar medical equipment:** Typically they have no previous experience with similar medical equipment; familiarity is limited to blood pressure device that most of them have used before.

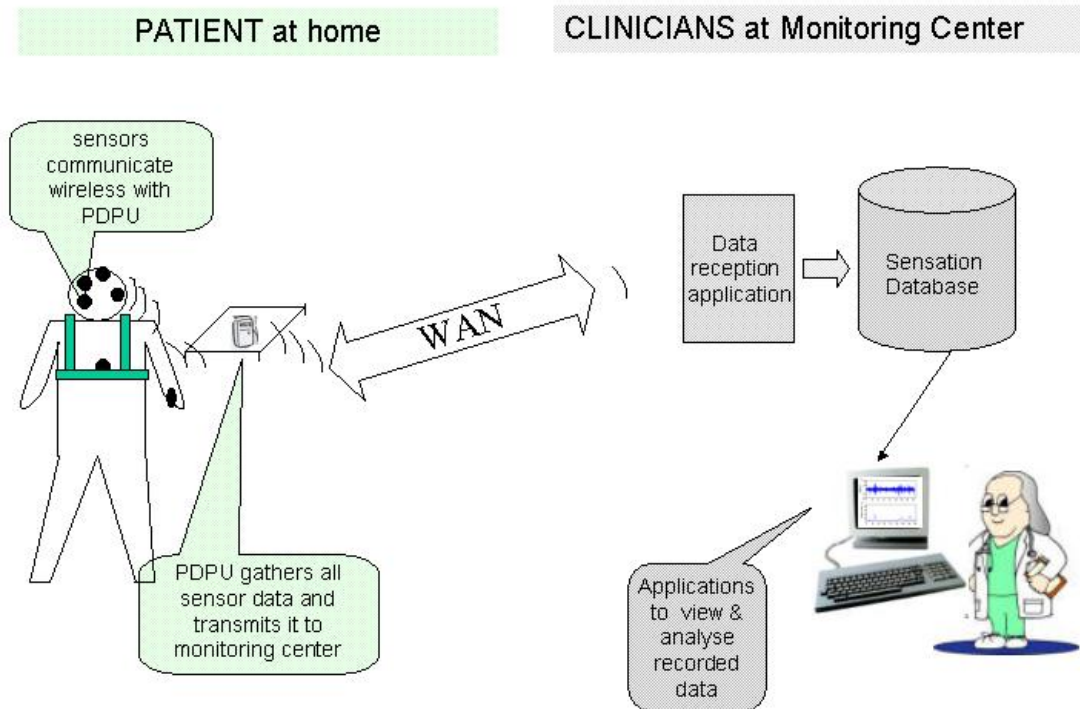
**Experience with other similar equipment:** Most of the patients will have used a cellular phone; therefore, PDPU device should use terms commonly used in cellular phones. Additionally, interfaces of popular cellular phones could be useful in the PDPU interface design.

We expect that patients who come for diagnosis to a sleep center, especially patients with severe symptoms (excessive daytime sleepiness and fatigue), would be highly motivated to receive a successful diagnosis. However, it should be expected that many patients may be intimidated with the use of complicated technological equipment. Therefore, devices should be designed to attract people who may have few skills in use of such systems. For example, sensors should be easy to attached, embedded, when possible, in wearable components (e.g. headcap, belt). It is very important to avoid the use of cables.

**Technicians at the monitoring center** are adult professionals with high education and familiarity with technological equipment for sleep studies. Use of a new system, such as SENSATION, will be easier if standard terminology used in sleep lab applications is used.

**Clinicians at the monitoring center** are adult professionals with high education and familiarity with sleep analysis applications. They are expected to have high motivation to use a new system that will allow for a better clinical evaluation, and that is easy to use. SENSATION Clinician Applications should use standard terminology and features of sleep lab applications so that clinician can easily use it.

Details on users tasks and requirements are presented in the following sections.



**Figure 1: Users and their interfaces in home based diagnosis for OSAS**

#### 1.2.4. Users tasks and needs for home based diagnosis

##### Data recording by Patient at home

Patient interface will include:

- A set of sensors that are integrated in a “belt” wrapped around the chest (COMBINE), a finger sensor and one EMG tibialis sensor (two electrodes) to be attached on the leg.
- A nightcap with 6 sensors embedded
- A device that is called Personal Data Processing Unit (PDU) and that will collect the recorded sensor data and transmit it to the monitoring center

##### Sensors

Name of the sensor	Purpose	Number of sensors	Frequency range Optimal (minimal)	Sampling Frequency Optimal (minimal)
COMBINE	“Belt” wrapped around the chest that includes: <ul style="list-style-type: none"> <li>• Inductive Plethysmography sensors for Resp. Effort</li> <li>• ECG sensor single lead</li> <li>• Body Position Sensor</li> </ul>	1	ECG: 0.1 – 100 Hz	ECG: 500Hz
FINGERING	Oxygen Saturation- finger	1	A 1 Hz sampling rate is sufficient for the output of SaO2 because the calculation is updated with each heart beat only.	
<b>Option 1: ENOBIO sensors:</b>				
ENOBIO or ENOBIO pillow	EEG 1 lead	2 electrodes	0.01 Hz – 90 Hz (0.1 – 40 Hz)	300Hz (200 Hz)
ENOBIO	EMG 1 lead	2 electrodes	15-2000Hz	200 Hz
ENOBIO	EOG 2 leads	2 electrodes	0.01 Hz-90 Hz (0.1 – 40 Hz)	300Hz (200 Hz)
<b>Option 2: FLEXELECT sensors</b>				
FLEXELECT	EEG	2 electrodes	0.01 Hz-90 Hz (0.1 – 40 Hz)	300Hz (200 Hz)
FLEXELECT	EMG	2 electrodes	15-2000Hz	200 Hz
FLEXELECT	EOG	2 electrodes	0.01 Hz-90 Hz (0.1 – 40 Hz)	300Hz (200 Hz)

**Table 4: Requirements on sensors for home diagnosis of OSAS**

### Recording/Communication requirements

- Data recording is continuous while patient is asleep, so sensors should operate continuously for 8 hours.
- Wireless Communication with PDPU for all sensors, especially for the leg EMG, because those long leads from the leg to a chest worn data sampler are very inconvenient.
- Wireless Communication with PDPU with ENOBIO pillow (if it is used).
- FINGERING: Most oximeters low-pass filter the SaO2 signal. The greater the filtering, the less likely brief, mild hypoxemic episodes are detected, so a variable setting for the averaging is needed with settings between 1 and 12 pulses
- Transmission to monitoring center could be done only once, after recording has been completed. No need for continuous or frequent transmission.
- Visualisation software of all recorded signals in common time scale needed. The evaluation of synchronicity is of utmost importance for the visual inspection.

### Requirements on Physical Characteristics

- Different colours could be used in sensors looking alike (ENOBIO/FLEXELECT), so that patient can easily distinguish them.
- Sensors for EEG, EMG and EOG should be embedded in a nightcap.
- Obese patients have high probability of OSAS; COMBINE “belt” should be available in large sizes.

### Other requirements

Sensors should be validated for safety (see also Security and Evaluation requirements) and (cross-) compatibility for the specific layout requirement (such as, proximity, no cross-talk or interference).

### PDPU Device

The PDPU is the patient's terminal equipment. It is similar to a mobile phone comparing size and power consumption characteristics. It is the only device of the home monitored patient that the patient can interact with.

<b>Requirements on PDPU Device</b>	
<b>Patient Task</b>	<b>System Requirement</b>
Patient initiates recording before going to bed	A sound reminder and message on LED screen should remind the patient that recording must start. RECORD button needed When recording is initiated, sensor recording should be synchronised, and recorded data stored in PDPU. Data should be securely transmitted from each sensor and securely stored in PDPU.
Data recording will be done while patient is lying in bed and is asleep.	Device is not on patient's body so that he/she can sleep comfortably. Optimally, the device could be placed on a side table, meaning that communication should be feasible in a distance of about a meter from the sensors.
Data recording is continuous while patient is asleep	Device should operate continuously for 8 hours
Patient STOPS recording when he/she wakes up in the morning.	STOP RECORDING button needed.
Patient transmits data to monitoring center	It is not necessary that data is transmitted as it is recorded. It could all be transmitted in the morning after recording has been completed. In this case, patient could initiate transmission. Transmitted data should include device and patient identification. Transmitted data is stored in patient's record Secure mechanisms (e.g. data encryption) during transmission. Authentication control. It is more convenient if transmission is done wireless to the monitoring center, but it is not a requirement
Patient reads error messages and confirmation messages	LED screen needed
Patient is informed in the following error situations: <ul style="list-style-type: none"> <li>• Electrodes are not positioned correctly</li> <li>• Recording cannot be performed (indicating the problematic channel(s))</li> <li>• Recorded signal is corrupted</li> <li>• Battery is low and device cannot function</li> <li>• Recording has exceeded 10 hours</li> <li>• Transmission cannot be performed</li> </ul>	Warning sound, and error description on LED screen Error handling application on PDPU Button to stop warning sound Patient should be informed (during training and through instructions in patient brochure) what to do in case of an error situation.
Patient knows status of device: <ul style="list-style-type: none"> <li>• If sensors currently recording</li> <li>• If device currently transmitting to database</li> <li>• Battery status</li> </ul>	Appropriate indication/message on LED screen

<b>Requirements on PDPU Device</b>	
Patient receives confirmation after data transmission has succeeded	Upon data reception and storage in SENSATION database, confirmation is returned to PDPU.
Patient cannot transmit recorded data	There should be capability of storage on flash memory, in case of transmission failure
Patient erases recorded data	ERASE DATA functionality This functionality should be available through a menu option NOT through a button. Confirmation should be asked prior to data deletion. If the PDPU device has enough storage for a whole night's recordings, then patient does not have to erase the data from the device. It can be erased by the technician at the monitoring center when patient returns the device and sensors. However, if the patient has to erase the data (e.g. a second night's recording) then this will be done only after he has been advised to do so by the technician at the monitoring center.
<b>Technician's Task</b>	<b>System Requirement</b>
Technician configures PDPU device for data transmission	Easy configuration and setup
Technician tests device's operation	Availability of test For testing purposes, device could also support connection through cables to the sensor
Technician configures recording channels	Easy configuration and setup

**Table 5: Users tasks and PDPU requirements for home based diagnosis of OSAS**

### **Data reception, storage and analysis at the monitoring center**

At the monitoring center, data is stored at the SENSATION Database. A SENSATION Application for the monitoring center, running on a PC, should be available. This application should enable access to remote PDPU and reception of transmitted data. This application will also enable the clinician to review the transmitted patient data through reports, raw data visualization tool and analysis software. The evaluation of synchronicity is of utmost importance for the visual inspection and has to be reflected in the raw data visualization tool.

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Communication with PDPU</b>	
Data is received from PDPU and stored in database; all security mechanisms apply in database and transmission.	
<b>Database</b>	
Requirements on database will be based on requirements set in SP1. Security mechanisms should apply in data storage, retrieval and update. Manufacturers may transmit in own data format that has then to be converted to format as defined in SP1.	
<b>Raw Data Visualisation</b>	
Capability to view all recorded signals (graphical raw data representation) and synchronicity of the signals Capability to select/customize the signals to be viewed	
<b>Data Analysis/Reporting</b>	
<b>Apnea Hypopnea Analysis</b>	AHI, classifications of apneas (Central, Obstructive, Mixed) and hypopneas, total number, mean duration and % time for each type of event
<b>EEG Analysis</b>	% of time awake, light NREM sleep, deep NREM sleep and REM, sleep period time, total sleep time, sleep efficiency, sleep latency, sleep onset time, sleep offset time, wake time, total awakenings, micro-arousal index

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Oximetry Analysis</b>	Histogram of O2 saturations, raw mean, median, SD, quartile ranges, minimum value, number of desaturations and Oxygen Desaturation Index (ODI)
<b>Heart Rate Analysis</b>	Histogram of heart rates along with raw mean, median, SD, quartile ranges, minimum value expressed in beats per minute
<b>Body Position Analysis</b>	For each of the four positions: total time in position, % of time in number of apneas and hypopneas.
<b>Synchronicity of recorded events</b>	Graphical view of events marked that enables to view the synchronicity of sleep stages and apnea events.

**Table 6: Requirements for the monitoring center application in home diagnosis of OSAS**

### **1.3. Application 2: Diagnosis of Obstructive Sleep Apnea Syndrome, using Arterial Tonometry, Oximetry and Actigraphy**

#### **1.3.1. Physiological data requirements for home based diagnosis**

The aim of this application is to provide a simplified recording technique to detect Obstructive Sleep Apnea Syndrome.

The proposed method is based on the assumption that the analysis of the Arterial Tonometry signal amplitude can yield a good measure for the extent of obstructive sleep apnea for subjects with suspected OSAS [11].

Arterial Tone is a measurement of the pulsatile volume changes in the fingertip arteries, which reflects the relative state of the arterial vasomotor activity and thus indirectly, the level of sympathetic activation. Studies suggest that the arterial tone follows the changes of sympathetic activity with the course of obstructive apneas in a characteristic way and this allows a good recognition of apneas.

In the current application, we will develop and evaluate algorithms where respiration and sleep will be determined by Arterial Tone, movement will be determined by an actigraph, desaturation from oxygen saturation. The required sensors are only three, and emphasis will be placed in the development of algorithms for the extraction of respiration from Arterial Tone.

An overview of the signals that will be recorded is provided in the table below:

<b>Function</b>	<b>Indicator</b>	<b>Technique</b>	<b>Sensor</b>
<b>Respiration</b>	Apneas	Arterial Tone: Determination of Apneas from arterial tone, classification of central/obstructive apneas; algorithm to be developed in SP3	ARTERORUB
	Oxygen Saturation	Oxygen Saturation	FINGERING
<b>Cardiovascular</b>	Heart Rate	Arterial Tone: Pulse detection algorithm similar to pulse detection in oximetry	ARTERORUB
<b>Sleep</b>	Arousals	Arterial Tone: Determination of arousals from arterial tone signal amplitude, algorithm to be developed in SP3	ARTERORUB

Function	Indicator	Technique	Sensor
	Wake/Sleep State	Arterial Tone and Actigraph Determination of Wake/Sleep State from Arterial Tone and Actigraph; algorithm to be developed in SP3	ARTERORUB & ACTIWATCH
<b>Body movement</b>	Body Movement	Accelerometer	ACTIWATCH

**Table 7: Signals and sensor requirements for OSAS diagnosis based on arterial tonometry**

In the current application sleep-wake state will be evaluated. Specifically, we aim to develop algorithms where sleep/wake states can be detected from arterial tonometry and actigraphy. The sleep/wake states that we expect to identify are:

- Wakefulness,
- NREM sleep,
- REM sleep.

### 1.3.2. Usage Scenario

After physical examination and interview, a patient is suspected for OSAS. The patient is referred for a home-based study. He/she receives a device that looks like a mobile phone (PDPU), a wrist device (ACTIWATCH) and two finger sensors (FINGERING and ARTERORUB). He/she also receives a simplified brochure with instructions and a phone number for assistance. A sleep technician explains to him/her about the procedure and shows how the devices and sensors are used. The Sleep technician configures the devices accordingly by setting recording, transmission and authentication parameters. He/she then, attaches the sensors on patient and tests for position and functionality. The patient thinks that the attachment of the wrist device and the finger sensors is very easy. He/she removes them, receives a simplified brochure with instructions and a phone number for assistance and then goes home. Before bedtime, the patient attaches the finger sensors and wrist device. He/she activates the PDPU device, and presses the “Record” button. On the LED screen it is indicated that recording is on, the patient leaves the device on the side table and sleeps. In the following morning, as soon as he/she wakes up, he/she presses the STOP button and then presses, “SEND”. On the LED screen of the device, he/she sees the message “Transmission successful”. The patient then, detaches the sensors. He/she has a scheduled appointment with his/her clinician later, in the afternoon.

At the monitoring center, data is received and stored in the database. The Sleep Technician, through his/her PC SENSATION Application sees that new data has arrived. He/she views the log file to see if any significant errors have occurred and requests for the combined report, that includes analysis of Apnea Hypopnea, Oximetry, Sleep, Heart Rate and Body position and graphical view of all events in common time scale so that synchronicity can be viewed. The report is then given to the sleep physician prior to patient visit, so that he can perform a clinical evaluation.

### 1.3.3. Users characteristics, skills and attitudes

Applications 1 and 2 have the same users and content of 1.2.3 applies here as well.

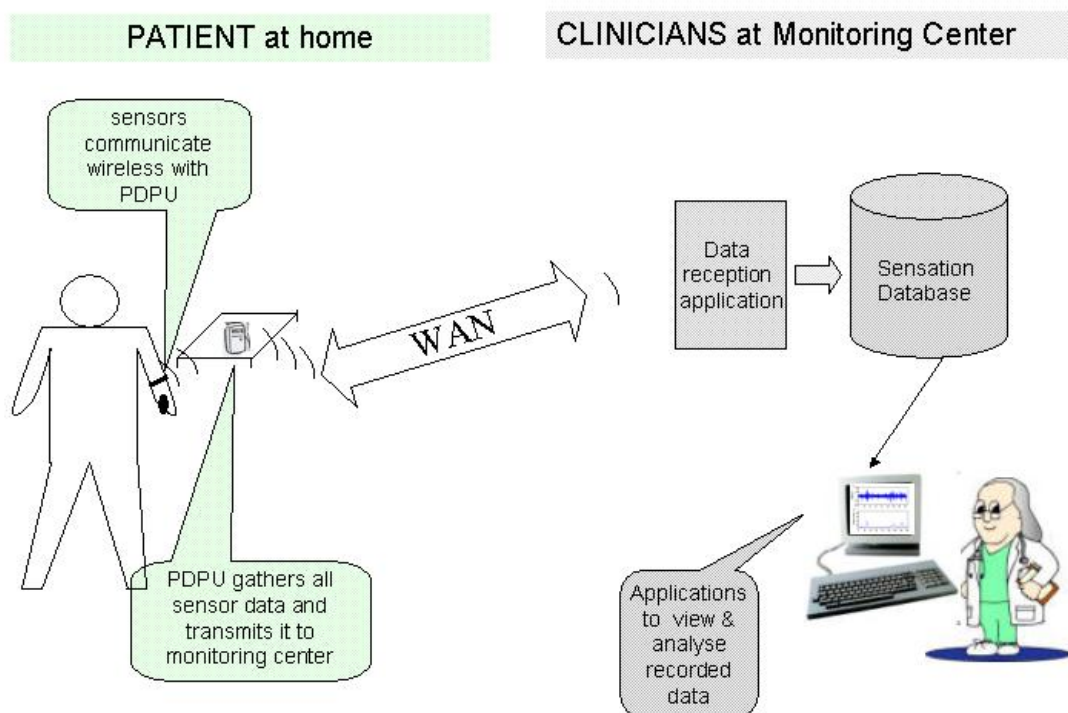


Figure 2: Users and their interfaces in home based diagnosis for OSAS (Application 2)

### 1.3.4. Users tasks and needs for home based diagnosis

#### Data recording by Patient at home

Patient interface will include:

- Two finger sensors, ARTERORUB and FINGERING.
- One wrist device, ACTIWATCH.
- A device that is called Personal Data Processing Unit (PDUU) and that will collect all the recorded sensor/ACTIWATCH data and transmit it to the monitoring center.

#### Sensors

Name of the sensor	Purpose	Number of sensors of this type	Requirements
ARTERORUB	Arterial Tone Heart Rate Changes	1	200 Hz sampling rate are sufficient. 100 Hz may be the minimum Visualisation Software for arterial tone and heart rate
ACTIWATCH	Body Movement	1	30 s time resolution, threshold mode, non-dominant hand, documentation of times when actigraph was taken off for brief

Name of the sensor	Purpose	Number of sensors of this type	Requirements
			periods Needs to communicate with PDPU Visualisation Software
FINGERING	Oxygen Saturation- finger	1	A 1 Hz sampling rate is sufficient for the output of SaO2 because the calculation is updated with each heart beat only. A variable setting for the averaging is needed with settings between 1 and 12 pulses Visualisation Software

**Table 8: Requirements on sensors for diagnosis of OSAS through arterial tonometry**

### **Recording/Communication requirements**

- Data recording is continuous while patient is asleep so sensors should operate continuously for 8 hours.
- Wireless Communication with PDPU for all sensors.
- Information on ACTIWATCH states that data is downloaded on a PC. It is preferable that ACTIWATCH communicates with the PDPU so that recording is in sync and all data can then be transmitted together to the monitoring center.
- Transmission to monitoring center could be done only once, after recording has been completed. No need for continuous or frequent transmission.
- Visualisation software of recorded signals in common time scale needed. The evaluation of synchronicity is of utmost importance for the visual inspection.

### **Requirements on Physical Characteristics**

- For this application two finger sensors are required. It needs to be examined how these two sensors will be worn together.
- Finger sensors should be rigid.

### **Other requirements**

Sensors should be validated for safety (see also Security and Evaluation requirements) and (cross-) compatibility for the specific layout requirement (such as, proximity, no cross-talk or interference).

### **PDPU Device**

As in the previous application, the PDPU is the patient's terminal equipment. Patient's tasks and requirements on this device are as listed in Table 5.

### **Data reception, storage and analysis at the monitoring center**

Data reception and storage procedures are the same as in the previous application; however the signals are different, therefore, requirements on the analysis software are different.

New algorithms developed in SP3 will be integrated in this application.

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Communication with PDPU</b>	
Data is received from the PDPU and stored in the database; all security mechanisms apply in the database and transmission.	
<b>Database</b>	
Requirements on the database will be based on requirements set in SP1. Security mechanisms should apply in data storage, retrieval and update. Manufacturers may transmit in own data format that has then to be converted to format as defined in SP1.	
<b>Raw Data Visualisation</b>	
Capability to view all recorded signals (graphical raw data representation) and synchronicity of the signals Capability to select/customize the signals to be viewed	
<b>Data analysis/Reporting</b>	
<b>Apnea Hypopnea Analysis (based on new algorithms developed in WP3.2)</b>	AHI, classifications of apnea and hypopneas, total number, mean duration and % time for each type of event
<b>Sleep/Wake analysis (from actigraphy and arterial tonometry algorithms developed in WP3.2)</b>	% of time awake NREM sleep and REM, sleep period time, total sleep time, wake time, total awakenings, micro-arousal index
<b>Oximetry Analysis</b>	Histogram of O2 saturations, raw mean, median, SD, quartile ranges, minimum value, number of desaturations and Oxygen Desaturation Index (ODI)
<b>Heart Rate Analysis</b>	Histogram of heart rates along with raw mean, median, SD, quartile ranges, minimum value expressed in beats per minute
<b>Synchronicity of recorded events</b>	Graphical view of events marked that enables to view the synchronicity of sleep stages and apnea events.

**Table 9: Requirements for the monitoring center application in home diagnosis of OSAS (application 2)**

## 2. INSOMNIA TREATMENT

### 2.1. Application 3: Evaluation of Insomnia Treatment

**Aim:** To investigate if 24h monitoring of hyperarousal level, temperature and sleep of patients, who are treated for insomnia, can be effective in the evaluation of insomnia treatment.

#### 2.1.1. Clinical Background

The timing and propensity of sleep are thought to reflect two interacting processes: an accumulated sleep need, (homeostatic process S), which increases with sleep deprivation and decreases during sleep, and a timing process (circadian process C), controlled by the circadian oscillator, an endogenous pacemaker residing in the brain's suprachiasmatic nucleus, which is basically independent of sleep and waking. Process C determines the times of onset and termination of sleep, respectively by changing the threshold of sleep need that will increase sleep propensity. Free-running studies suggest that circadian sleep propensity is associated with the circadian rhythm of core body temperature.

Arousal levels also play a role in sleep initiation and whenever arousal level is reduced sleep propensity increases. Many studies have suggested that psychophysiological insomnia is associated to a stress-related hyperarousal state. These patients are supposed to have an increased wake propensity, meaning that their arousal level is sufficiently high to counteract the effect of the homeostatic and the circadian processes. Hyperarousal state could also affect the synchronisation of circadian rhythms by regularly recurring environmental signals, such as light/dark alternations. Hyperarousal can be estimated from indices of increased sympathetic activity (daytime or night-time LF/HF ratio; night time heart rate activation) or more simply by the assessment of wake time during a polysomnographic recording.

Treatment of psychophysiological insomnia includes behavioural and pharmacological components. In most countries, chronic hypnotic use is not recommended and alternative treatment such as light exposure or cognitive-behavioural therapies (CBT) have been proposed for patients suffering from insomnia. Light therapy administered at proper time during the daytime is supposed to enhance circadian rhythmicity in these patients, i.e. to strength their process C, whereas hypnotic drugs and CBT are supposed to lower their arousal level. CBT improves sleep by changing poor sleep habits and by challenging negative thoughts, attitudes and beliefs about sleep. These strategies include a broad range of treatments, from educational packages to purely behavioural strategies, including sleep hygiene, stimulus control, muscle relaxation therapy, sleep restriction therapy and cognitive therapy. CBT are generally administered as a package of 5 to 10 sessions dispensed at a one-week interval. Treatment outcome usually relies on subjective (self-report questionnaires, sleep diary monitoring), behavioural (actigraphy) and less often, in physiological measures (polysomnography).

Research which further characterizes the nature of the hyperarousal state encountered in patients with psychophysiological insomnia and its relationship to constitutional psychological, behavioral and physiological parameters, and which develops methods by which clinicians may identify or quantify this arousal, may be diagnostically and therapeutically useful. In this context, we aim to develop and evaluate a remote monitoring application in order to study:

- the effectiveness of treatment through assessment of hyperarousal level, temperature and sleep;
- the effect of specific treatment (such as light exposure, CBT or hypnotic drugs ) on markers of the homeostatic and circadian processes (i.e. of sleep debt and of circadian timing) on a night to night basis.

The **innovation** in this method will be based on:

- Use of new miniature sensors that allow monitoring of EEG and ECG.
- Continuous Assessment of hyperarousal state during patient daily activities.
- Overall approach of treatment evaluation of insomnia through 24h remote physiological monitoring.

### 2.1.2. Physiological data requirements for distance monitoring

**Patient group:** patients who have been diagnosed with and receive treatment for Psychophysiological insomnia (ICSD code: 307.42-0).

The current study will consist of a baseline period, a treatment period (light therapy, CBT or hypnotic drugs according to the centre usual practice) and a follow-up period.

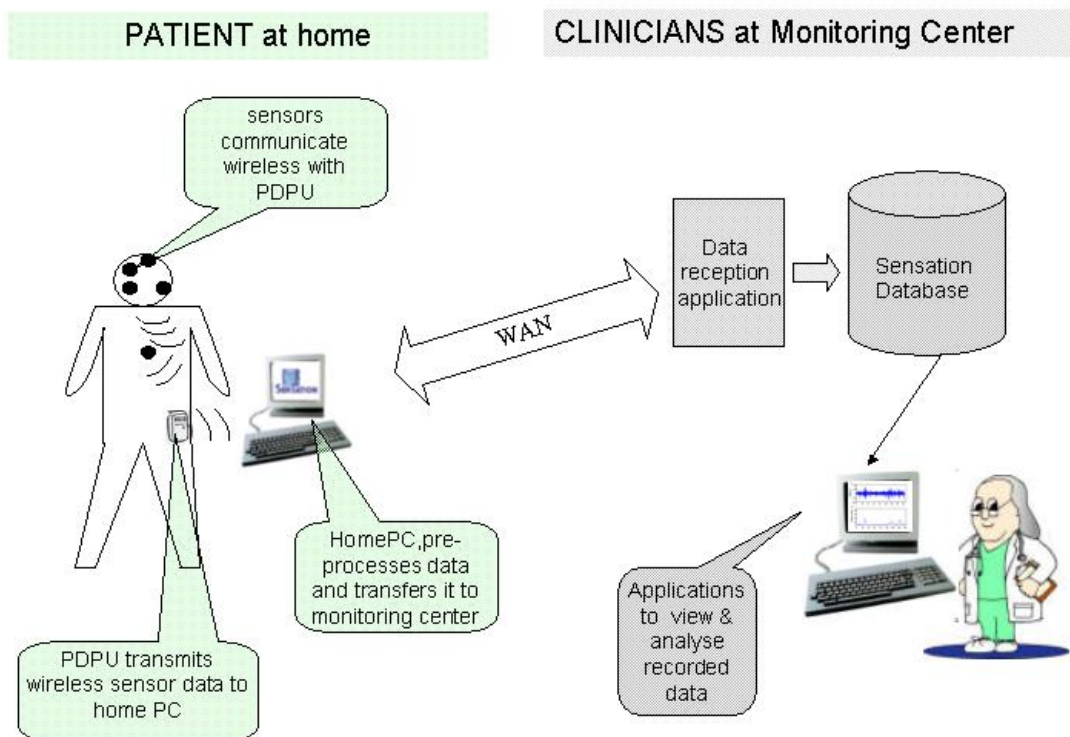
- ECG and body temperature will be monitored throughout the baseline period and follow-up period.
- During the night, when patient goes to sleep, EEG, EMG and EOG will also be monitored from the first days for the baseline and follow-up period.
- Only ECG will be recorded during the treatment period.

Patient will also provide subjective data, through a short questionnaire. Data will be transmitted once a day to the monitoring sleep center. Transmitted data will be analyzed through special software so that sleep clinician can examine patient's hyperarousal state, sleep and circadian rhythm information; temperature could provide circadian rhythm information as to whether they are phase-delayed or phase advanced. Based on that clinician can make assessment on treatment effectiveness. This new method will be compared to standard treatment evaluation procedures.

An overview of the assessment variables, indicators and sensors for this application is presented in the table below. The FLEXELECT sensor has been proposed here, however, ENOBIO could also be used.

Assessment Variable	Indicator	Technique	Proposed Sp2 Sensors
Strength of Hyperarousal	Sympathovagal Balance	24h ECG single lead	FLEXELECT (2)
Nighttime Cardiovascular Activation	Heart Rate		
Sleep	Brain Activity Eye Movements & Eyelid Closure Muscle Tone	EEG (2) EOG (2) EMG (2)	FLEXELECT (3) FLEXELECT (2) FLEXELECT (2)
Temperature	Temperature	24 h body Temperature, sampling rate of at least one t° measure/5 min at baseline and follow-up periods	No SENSATION sensor currently available, under investigation. Propose capsule and Vital sense monitor
Subjective patient data	Patient fills short questionnaire	Questionnaire on PDA or home PC with simple interface	

**Table 10: Signals and sensor requirements for insomnia treatment evaluation**



**Figure 3: Users and their interfaces in remote monitoring scenario for Insomnia Treatment Evaluation**

### 2.1.3. Usage Scenario

After diagnosis for psychophysiological insomnia and treatment prescription, sleep specialist explains to patient that in order to investigate a new method on evaluation of insomnia treatment he needs to be monitored on a 24-hour base. Patient agrees. On Day-1, a technician gives to the patient the necessary equipment: a device that looks like a mobile phone (PDPU device), a nightcap that has a set of 7 small sensors embedded and 2 ECG sensors. The two ECG sensors are attached on patient's chest. Core body temperature could be measured via an ingestible, biocompatible, and easy to swallow capsule that is disposable. It uses low-power radio frequency transmissions to communicate with the VitalSense® Monitor (Mini Mitter). No cables are used. The patient also receives a PC (preferably a laptop) with the SENSATION Patient Application. We will refer from now and on to this PC as Home PC.

Sleep technician configures the PDPU device accordingly by setting recording, transmission and authentication parameters. He/she asks the patient when it is more convenient for him to transmit the data and they agree that every morning data will be transmitted from the PDPU to the Home PC. The PDPU device has a menu and buttons through which the user can interact. Menu is used mostly for setup and configuration that is done by the technician, while buttons are for the main functions that a patient would do. Technician helps the patient to attach the nightcap and to set the device on his belt and performs a test recording. Recording is initiated by pressing the RECORD button on the PDPU. Technician then tests the functionality. After

testing has been successful, technician stops recording by pressing the STOP button. He/she then deletes the recorded test data after transferring it first to the center computer. The patient then takes off the nightcap. The patient should feel comfortable enough to attach the nightcap by him/herself at night for sleep recording. He/she re-initiates recording, (for ECG) and after receiving a simplified brochure with instructions and a phone number for assistance, he/she leaves the monitoring center to go home. Recording is now on, this can be confirmed by an LED button that is on, and ECG, is being recorded and saved in the PDPU. Before bedtime, the patient presses the STOP button to stop recording. The patient attaches the nightcap and re-initiates recording by pressing the START button again. The patient leaves the device on the side table and sleeps. In the following morning, after he/she wakes up, he/she presses the STOP button and takes off the nightcap. He/she transmits data to the Home PC. On the LED screen of the device, he/she sees the message “Transmission successful”. The patient then, confirms that data can be deleted from PDPU and initiates recording again. Data is now on the Home PC and from here it is transferred to the monitoring center; data transfer is remotely initialised by the sleep technician at the center through the WAN. The patient also fills in a simple questionnaire on the Home PC.

At the monitoring center, sleep technician has initiated the data transfer from the Home PC and data is received and stored in the database that is located at the monitoring center. The Sleep Technician, through his/her PC SENSATION Application views the log file to see if any significant errors have occurred and requests for the combined report, that includes analysis of Hyperarousal state, Nighttime Cardiovascular Activity analysis, Sleep analysis and Temperature Analysis. The report also includes patient’s answers to the questionnaire and is then given to the sleep physician. Assessment of clinical data is performed on a weekly basis.

#### 2.1.4. Users characteristics, skills and attitudes

USERS	TASK GOALS	MAIN TASKS
<b>Patients with psychophysiological insomnia</b>	To receive appropriate treatment	Uses equipment by him/herself at home and during daily activities Sleeps with equipment on Initiates recording Attaches/deattaches sensors by him/herself
<b>Technician at monitoring center</b>	To provide support to patients and clinicians	Demonstrates equipment to patient Configures equipment Receives Data from patient Provides Supports to patient
<b>Clinician at monitoring center</b>	To perform successful treatment evaluation	Introduces patient to the usage of this application/equipment Views the recorded and transmitted patient data and performs clinical evaluation

**Table 11: Users and main tasks for Insomnia Treatment Evaluation**

## Patients Characteristics

**Age:** Any adult age and gender, however, patients with psychophysiological insomnia who come to a sleep center are usually middle adults.

**Educational Level:** Patients may belong to any educational level, we should assume minimum education during development of system interfaces.

**Language:** Patients have any native language and not all of them speak English. Optimally interfaces should be in patient's native language. If not, single words and simple terminology should be used (e.g. STOP, OK, START).

**Experience with similar medical equipment:** Typically they have no previous experience with similar medical equipment; familiarity is limited to blood pressure device that most of them have used before.

**Experience with other similar equipment and PCs:** For this application, patients will use a PC at home. For this reason, patients should be familiar with basic PC use and computer terminology. Most of them will have used a cellular phone; therefore, PDPU device should use terminology and interface as close as possible.

We expect that patients who come for to a sleep center, especially patients with severe symptoms, would be highly motivated to receive a successful treatment. However, it should be expected that many patients may be intimidated with the use of complicated technological equipment. Therefore, devices should be designed to attract people who may have few skills in use of such systems. For example, sensors should be easy to attached, embedded, when possible, in wearable components (e.g. headcap, belt). It is very important to avoid the use of cables. PC applications should be intuitive.

**Technicians at monitoring center** are adult professionals with high education and familiarity with technological equipment for sleep studies. Use of a new system, such as SENSATION will be easier if standard terminology used in sleep lab applications is used.

**Clinicians at monitoring center** are adult professionals with high education and familiarity with sleep analysis applications. They are expected to have high motivation to use a new system that will allow for a better clinical evaluation, and that is easy to use. SENSATION Clinician Application should use standard terminology and features of sleep lab applications so that clinician can easily use it.

### 2.1.5. Users tasks and needs for distance monitoring

#### Data recording by Patient during daily activities and during sleep

Patient interface will include:

- A set of 7 sensors that are embedded in a nightcap, 2 sensors for the chest (ECG).
- One temperature sensor.
- A device that is called Personal Data Processing Unit (PDPU) and that will collect the recorded sensor data and transmit it to the Home PC.
- A Home PC that is used for subjective data entry, data preprocessing and transfer to the monitoring center.

### Sensors

Name of the sensor	Purpose/number of sensors	Recording Requirements	Frequency range and Sampling Frequency(SF), recording requirements
FLEXELECT	ECG chest /2	24h recording continuous	Freq. Range 0.1-64 Hz, SF 256 Hz This is still high for RR analysis but will allow using the same FR and SF as for EEG.
FLEXELECT	EEG - head / 3	8 hrs recording during sleep, continuous at baseline and follow-up periods	Freq. Range 0.1-64 Hz, SF 256 Hz
FLEXELECT	EMG – chin / 2	8 hrs recording during sleep, continuous at baseline and follow-up periods	Freq. Range 0.1-128 Hz, SF 256 Hz
FLEXELECT	EOG – outer canthi / 2	8 hrs recording during sleep, continuous at baseline and follow-up periods	Freq. Range 0.1-128 Hz, SF 256 Hz
VitalSense?	Central Temperature	48h recording, at least one t° measure/5 min at baseline and follow-up periods	

**Table 12: Requirements per sensor for evaluation of insomnia treatment**

### Recording/Communication requirements

- EEG, EMG, EOG will be recorded during 3 nights at baseline and after treatment.
- ECG will be recorded during 3 days at baseline and after treatment as well as during the treatment period.
- Temperature will be measured continuously during two days, at baseline and after treatment.
- Wireless Communication with PDPU for all sensors.
- EEG, EOG, EMG, ECG sensors are attached on patient's body (BAN) and connection with the PDPU is required. PDPU will then transmit data to the Home PC and from there, technician at the monitoring center, initiates downloading to the monitoring center.
- Clinical Data Assessment will be done once a week, so there is no need for frequent transmission. Limitation of data storage will define how often data is downloaded to the Home PC and to the monitoring center.
- Visualisation software of recorded signals in common time scale needed. The evaluation of synchronicity is of utmost importance for the visual inspection.

### Requirements on Physical Characteristics

- Different colours and/or marks could be used in sensors looking alike, so that patient can easily distinguish them (e.g. ECG sensors).
- EEG, EMG and EOG sensors should be embedded in a nightcap.

**Other requirements**

- Special artefact rejection algorithms could be needed due to patient's motion.
- Sensors should be validated for safety (see also Security and Evaluation requirements) and (cross-) compatibility for the specific layout requirement (such as, proximity, no cross-talk or interference).

**PDPU Device**

<b>Patient Task</b>	<b>PDPU Device Requirement</b>
24h, ECG and Temperature recording will be performed, while patient is moving during daily activities and during sleep; ECG and temperature sensors and PDPU device are attached on patient's body while doing daily activities.	Device should not be heavy, could be attached on patient's belt Device operates continuously on 24-hour bases Device communicates wirelessly with sensors
EEG, EMG and EOG are recorded while patient is asleep Device could then be placed at side table so that patient sleeps comfortably	Sensors – PDPU wireless communication feasible in 1 meter distance
Patient initiates recording	RECORD button needed When recording is initiated, sensor recording should be synchronised, and recorded data stored in PDPU. Data should be securely transmitted from each sensor and securely stored in PDPU.
Patient stops recording when he needs to <ul style="list-style-type: none"> <li>• transmit/store recorded data</li> <li>• disconnect/reconnect a sensor</li> </ul>	STOP RECORDING button needed
Patient may need to PAUSE and RESUME recording	PAUSE and RESUME button needed
Patient transmits data from PDPU to Home PC It is not necessary that data is transmitted as it is recorded. It could all be transmitted once a day or more often only if there is limitation with data storage. Then patient initiates transmission	PDPU-Home PC communication application on the PDPU Data transmission should be wireless Data set will be large, possible need to compress data Secure transmission: Secure mechanisms (e.g. encryption) to guarantee safety Transmitted data should include device and patient identification for authentication control
Patient reads error messages and confirmation messages	LED screen needed
Patient is informed in the following error situations: <ul style="list-style-type: none"> <li>• Electrodes are not positioned correctly</li> <li>• Recording cannot be performed (indicating the problematic channel(s))</li> <li>• Recorded signal is corrupted</li> <li>• Battery is low and device cannot function</li> <li>• Memory is full and data has to be transmitted</li> <li>• Transmission cannot be performed</li> </ul>	Error handling application on PDPU Warning sound, and error description on LED screen Button to stop warning sound Error handling is very important and messages should be meaningful to user. Patient should be informed (during training and through instructions in patient brochure) what to do in case of an error situation.

<b>Patient Task</b>	<b>PDPU Device Requirement</b>
Patient knows status of device: <ul style="list-style-type: none"> <li>• If sensors currently recording</li> <li>• If device currently transmitting to database</li> <li>• Battery status</li> </ul>	LED button in different colours could be used in combination with appropriate message on LED screen Relevant Application(s) necessary for PDPU
Patient receives confirmation after data transmission has succeeded	Upon data reception and storage in SENSATION database, reception application at monitoring center returns confirmation to PDPU.
Patient changes batteries	Patient should not have to change batteries more often than once a day. Availability of batteries that could last for 24hours operation.
Patient stores recorded data on the PDPU	Capability of storage on flash memory, in case of transmission failure, so that data is not lost.
Patient erases recorded data	ERASE DATA functionality This functionality should be available through a menu option NOT through a button. Confirmation should be asked prior to data deletion. Patient will be prompted by the PDPU to erase data after it has been successfully transferred to the Home PC. However, if the patient has to erase the data for some other reason then this will be done only after he has been advised to do so by the technician at the monitoring center.
<b>Technician's Task</b>	<b>PDPU Device Requirement</b>
Technician sets where transmission will be done to.	Easy configuration and setup
Technician tests device's operation	Availability of test For sensor-device communication testing, device should support connection through cables to the sensor
Technician configures recording channels	Easy configuration and setup

**Table 13: Users tasks and PDPU requirements for evaluation of insomnia treatment**

### Home PC

A home-based PC is required where the "SENSATION Patient Application" will be installed. This PC should communicate wirelessly with the PDPU and over the Internet with the monitoring center. If high-speed line is not available, modalities of transmission will have to be adapted. All patient interactions with this application should be logged and the log file should be accessed by the technician at the monitoring center.

<b>Patient Task</b>	<b>Requirements on SENSATION Patient Application on Home PC</b>
Patient transmits the recorded data from the PDPU to the Home PC. Patient should preferably do that only through the PDPU interface.	PDPU- Home PC Communication application that receives data from PDPU wirelessly. Security mechanisms for secure data transfer and storage Data should not be erased from the Home PC by the patient.

<b>Patient Task</b>	<b>Requirements on SENSATION Patient Application on Home PC</b>
Patient answers to short questionnaire with subjective data	Simple graphical interface, preferably YES/NO answers Development of short questionnaire
Data transmitted (physiological data and answers to questionnaire) to monitoring center. It is preferable that data transfer is initiated by the sleep technician at the monitoring center.	Application for communication between monitoring center and Home PC. Data transmission is not necessary to be wireless Reception application should exist at the monitoring center Transmission initiated by technician at monitoring center Due to the large amount of data stored on the Home PC, pre-processing maybe necessary. Pertinent parameters will be extracted from physiological signals prior to transfer. Secure transmission: Secure mechanisms (e.g. encryption) to guarantee safety Transmitted data should include device and patient identification for authentication control
Applies to all tasks	A log file should be kept with all patient interactions with the SENSATION Application

**Table 14: Patient tasks and requirements on Home PC patient application for evaluation of insomnia treatment**

#### **Data reception, storage and analysis at the monitoring center**

In the current scenario, SENSATION Application at the monitoring center should access patient's Home PC and receive the recorded data. Therefore, communication requirements are different from those in applications 2 and 3. This application should also enable the clinician to review the transmitted patient data through reports, raw data visualization tool and analysis software. The evaluation of synchronicity is of utmost importance for the visual inspection and has to be reflected in the raw data visualization tool.

New algorithms developed in SP3 (WP3.3) will be integrated in this application

<b>Requirements on PC SENSATION application at monitoring center</b>
<b>Communication with Home PC</b>
Data is received from the Home PC and stored in the database; all security mechanisms apply in the database and transmission. Reception can be initiated by technician or can be done automatically at specific times
<b>Database</b>
Requirements on the database will be based on requirements set in SP1. Security mechanisms should apply in data storage, retrieval and update. Manufacturers may transmit in own data format that has then to be converted to format as defined in SP1.
<b>Raw Data Visualisation</b>
Capability to view all recorded signals (graphical raw data representation) and synchronicity of the signals Capability to select/customize the signals to be viewed
<b>Data Analysis</b>

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Sleep Staging Analysis</b>	% of time awake, sleep period time, total sleep time, wake time, sleep efficiency, total awakenings, micro-arousal index, Sleep onset latency, Number and Strength of hyperarousals Circadian timing
<b>ECG analysis</b>	Automatic RR detection
<b>Heart Rate Analysis</b>	Heart Rate Activation Detection meaning detection of abrupt heart rate increment ( <i>one activation = at least 6 successive RR with <math>RR1 &gt; RR2 &gt; RR3 &gt; RR4 &gt; RR5 &gt; RR6</math></i> ). ECG Power Spectrum Analysis (5 min time samples), Calculation of Sympathovagal Balance as the ratio LF/HF, Histogram of heart rates along with raw mean, median, SD, quartile ranges, minimum value expressed in beats per minute
<b>Temperature analysis</b>	Curve fitted temperature, minimum maximum values

**Table 15: Requirements for the monitoring center application in the insomnia treatment evaluation scenario**

## 2.2. Application 4: Detection of drug induced hypovigilance

**Aim:** Develop a new method for monitoring of hypovigilance during daytime

### 2.2.1. Clinical Background

Benzodiazepines and benzodiazepine-like drugs, such as zolpidem, are among the most commonly prescribed drug treatment for insomnia. However these drugs carry potential troublesome reactions, including memory and psychomotor performance impairment and next-day hangover effects. Of particular concern are epidemiological studies showing that benzodiazepines dose-dependently increased the overall accident risk with a factor of 1.5 to about 4 compared to control population, with appreciably higher risks during the first 4 weeks of prescription and with compounds having longer elimination half-lives.

Drug-induced hypovigilance is not specific to insomniac patients taking hypnotic drugs. It is a frequent cause of daytime dysfunctioning in every patient taking drugs acting on the Central Nervous System (CNS), the worst complication being related to accidents due to impairment in driving or in conducting machine.

The focus of this work will be to apply novel miniaturised methods of biomedical signal acquisition and processing to assess daytime vigilance of subjects on CNS acting drugs, optimally in their everyday life environment or at home care.

The **innovation** in this application is that the system to be developed could bring more relevant information regarding drug 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 CNS acting compound.

### 2.2.2. Physiological data requirements for distance monitoring

The primary aim of this application is to provide a new remote monitoring method for detection of hypovigilance during daytime through new miniaturised sensors. The developed method will be used to investigate the effect of CNS acting drug on vigilance against placebo in healthy volunteers as well as in a home-based setting. The results will be compared to standardised procedures assessing vigilance such as multiple sleep latency test (MSLT) and computerised vigilance tests, such as Psychomotor Vigilance Test (PVT ) and Leeds Psychomotor Test. A sleep deprivation model could also be realized to compare the effect of this behavioral model on hypovigilance level with the pharmacological one.

The method will use EEG signals and various algorithms based on temporal, spatial and frequency analyses.

Assessment Variable	Indicator	Technique	Sensors
Sleep/Wake Transition	CNS Activity	EEG - head /10 Features extraction and fusion algorithms	ENOBIO or FLEXELECT 12 sensors (10 + 2 references)

**Table 16: Signals and sensors for hypovigilance detection**

#### Required features extraction and fusion:

EEG is the easiest technique activity (equipment easy to obtain and implement, low cost) to assess CNS compared to functional magnetic resonance imaging (fMRI), magneto encephalography (MEG), positron emission tomography (PET) scan.. EEG contains a large set of information about activation of neuronal groups. The available ways to explore CNS activity based on EEG relies on several theoretical tools. The choice of the most efficient tools to underline a specific brain activity, or variation in brain activity depends on the data available and the experimental paradigm. That way, parameters extracted from continuous EEG are not the same than those computed from EEG recorded during a repeated stimulations test.

According to the SP1 deliverables and the literature on which those physiological works relies, to estimate a continuous vigilance value between active awake and sleep state, a large set of signal process has to be used, compared and merged. To reach this aim temporal, spatial and frequency EEG analysis methods are available.

Single-channel EEG signal may be processed in time domain to provide parameters associated to specific time-patterns (like ERP, sleep phasic events); it may also be analysed using non-linear methods, such as fractal dimension, or be embedded in so-called phase space, to calculate characteristics like correlation dimension. In frequency domain single -channel EEG signal may be processed using spectral analysis to provide the well-known variation of power in frequency bands. Spatial analysis requires multichannel EEG for studying

- maps of power in frequency bands, leading to spatial information about modification of brain area activity,
- stochastic relations between brain areas during a specific task - they can be quantified by synchronies (phase constancy between cerebral area activities) or coherence (constancy of linear relation between cerebral area powers),
- maps of fractal dimension or of other characteristics of signal complexity, calculated e.g. by symbolic dynamics methods.

The algorithms that will be produced in WP3.3 for evaluation of vigilance variation due to drug intake will rely on those methods and the fusion of data and features provided by each of them. For algorithm development and evaluation, standard equipment will be used and a pilot study will run. The pilot study will run in two phases: phase 1 at the lab and phase 2 at a home-based setting.

### 2.2.3. Usage Scenario

Physicians explains to the volunteer that in order to investigate a new method on evaluation of hypovigilance, he/she needs to be monitored on a 24-hour base during approximately 2 weeks. During the first phase, recording takes place at the lab, where, the volunteer uses equipment and performs tests with the help of the technician. Therefore, recording and transmission procedure will be learned by the subject during his/her stay at the center, in order to be able to use it by him/herself at home.

Then the volunteer receives the necessary equipment: the PDPU device (attached at the belt) and a set of 12 small sensors, embedded in a headcap (left side: prefrontal FP1, frontal F3, central C3, parietal P3, occipital O1, mastoid A1(reference) and on the right side: FP2, F4, C4, P4, O2, A2). The technician configures the PDPU device accordingly by setting recording, transmission and authentication parameters. He/she helps the volunteer to attach the PDPU device at the belt and the headcap.

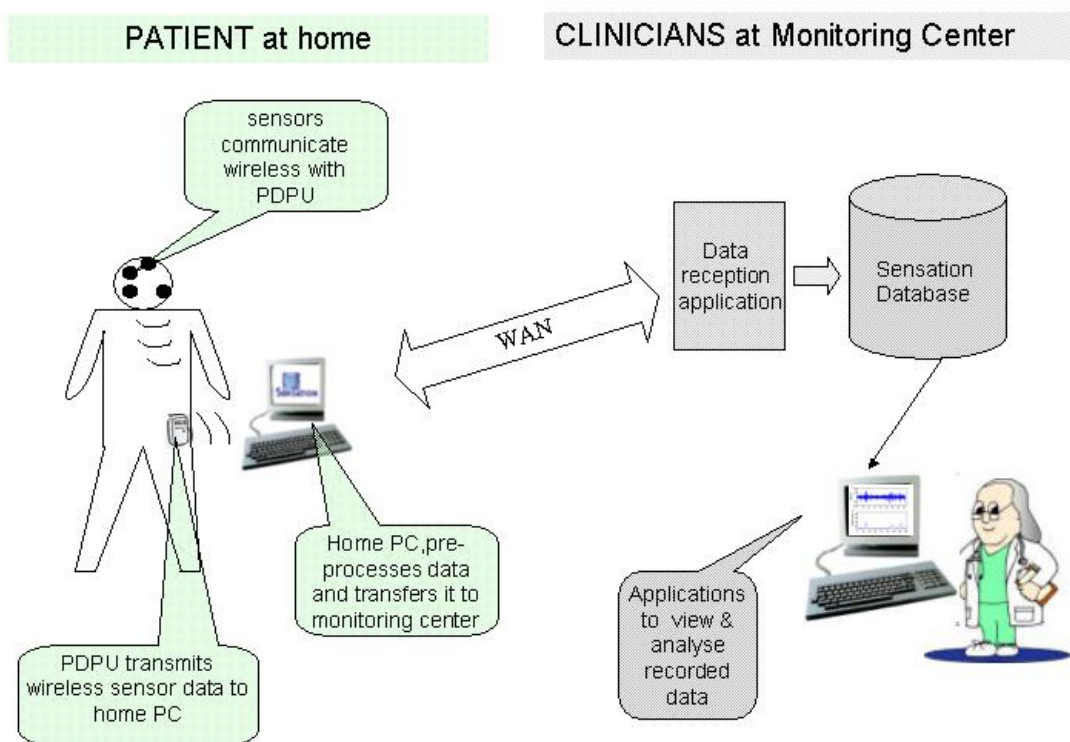
A baseline set of data is needed prior treatment. The subject will perform the following tests: PVT, Leeds psychomotor tests, driving simulator, MSLT. The same assessments will be performed after drug (benzodiazepine to be defined) or placebo administration. The subject will also be monitored for wake EEG throughout the day.

Then, the same subject will be allowed to go home with the necessary equipment: sensors (headcap) and PDPU. He also receives a PC (preferably a laptop) with the SENSATION Patient Application. We will refer from now and on to this PC as Home PC.

Before leaving the center, the volunteer should feel comfortable enough to attach the sensors by him/herself (through the headcap) for hypovigilance recording. He/she receives a simplified brochure with instructions and a phone number for assistance. He/she will also perform the PVT and Leeds psychomotor tests on the home-based computer at the same time during the day, after drug or placebo administration and will also be monitored for wake EEG. Before bedtime, subject will transmit data to the Home PC. This will represent a large amount of data and a pre-processing will be necessary before transfer. Pertinent parameters will be extracted from those physiological signals and sent to the center. The extraction will have to be performed by the home-based computer. Data is then transferred to the monitoring center; data transfer is remotely initialised by the sleep technician at the center through the WAN.

In the morning, before the next recordings PDPU batteries will have to be changed by the subject and impedance check on the sensors has to be performed through the test button on PDPU device. Then recording is initiated again by pressing the START button again. The PDPU needs to be remotely initialised by the technician at the center through the WAN and the local computer.

At the monitoring center, the sleep technician has initiated the data transfer from Home PC and data is received and stored in the database that is located at the monitoring center. The technician, through his/her PC SENSATION Application views the log file to see if any significant errors have occurred and requests for the last day's data: physiological and test data. Clinician performs evaluation through the special visualisation software.



**Figure 4: Users and their interfaces in remote hypovigilance detection scenario**

### 2.2.4. Users characteristics, skills and attitudes

USERS	TASK GOALS	MAIN TASKS
<b>Patients receiving CNS drugs</b>	To be monitored comfortably for hypovigilance in daily activities in order to receive best dose	Uses equipment by him/herself at home for monitoring for about 2 weeks Initiates recording, transmission Attaches/deattaches sensors by him/herself Performs vigilance tests on Home PC
<b>Technician at monitoring center</b>	To provide support to patients and clinicians	Demonstrates equipment to patient Configures equipment Trains patient and helps him/her during in lab testing (phase 1). Receives Data from patient Provides Supports to patient
<b>Clinician at monitoring center</b>	To perform successful evaluation of hypovigilance	Views the recorded and transmitted patient data and performs clinical evaluation

**Table 17: Users and main tasks for the hypovigilance detection scenario**

#### Patients Characteristics

Users of this application could be any patient taking CNS acting drugs.

**Age:** Any adult age and gender.

**Educational Level:** Patients may belong to any educational level, we should assume minimum education during development of system interfaces.

**Language:** Patients have any native language and not all of them speak english. Optimally interfaces should be in patient's native language. If not, single words and simple terminology should be used (e.g. STOP, OK, START).

**Experience with similar medical equipment:** Typically they have no previous experience with similar medical equipment; familiarity is limited to blood pressure device that most of them have used before.

**Experience with other similar equipment and PCs:** For this application, patient will use a PC at home. For this reason, patients should be familiar with basic PC use and computer terminology.

We expect that patients who will be highly motivated to be monitored are the ones with daily activities that are affected from drug-induced hypovigilance. However, it should be expected that many patients may be intimidated with the use of complicated technological equipment. Therefore, devices should be designed to attract people who may have few skills in use of such systems. For example, sensors should be easy to attached, embedded, when possible, in wearable components ( e.g. headcap, belt). It is very important to avoid the use of cables. PC applications should be intuitive.

**Technicians at a monitoring center** are adult professionals with high education and familiarity with technological equipment for sleep studies. Use of a new system, such as SENSATION, will be easier if standard terminology used in sleep lab applications is used.

**Clinicians at the monitoring center** are adult professionals with high education and familiarity with sleep analysis applications. They are expected to have high motivation to use a new system that will allow for a better clinical evaluation, and that is easy to use. SENSATION Clinician Application should use standard terminology and features of sleep lab applications so that clinician can easily use it.

### 2.2.5. Users tasks and needs for distance monitoring

#### Data recording by Patient at home

Patient interface will include:

- A set of 12 sensors that are attached on the head. It is preferable if sensors are embedded in a headcap.
- A device that is called Personal Data Processing Unit (PDPU) and that will collect the recorded sensor data and transmit it to the Home PC.
- Home PC that communicates with PDPU for data pre-processing and transfer to the monitoring center. It is also used for the interactive computerised vigilance tests.

#### Sensors

Name of the sensor	Purpose/number of sensors	Recording Requirements	Frequency range and Sampling Frequency(SF), recording requirements
FLEXELECT or ENOBIO	EEG - 12 Positions: (left side: prefrontal FP1, frontal F3, central C3, parietal P3, occipital O1, mastoid A1(reference) and on the right side: FP2, F4, C4, P4, O2, A2).	24h recording continuous	Freq. Range 0.1-64 Hz, SF 256 Hz

**Table 18: Requirements per sensor for detection of hypovigilance**

#### Recording/Communication requirements

- EEG will be recorded approximately for 2 weeks.
- Wireless Communication with PDPU for all sensors.
- EEG sensors are attached on patient's body (BAN) and connection with the PDPU is required. PDPU will then transmit data to the Home PC and from there, the technician at the monitoring center, initiates downloading to the monitoring center.
- Large amount of data is recorded and a pre processing will be necessary before transfer. Pertinent parameters will be extracted from those physiological signals and sent to the center. The extraction will have to be performed by the home-based computer.
- Data transmitted daily from patient's Home PC to monitoring center.
- Visualisation software of recorded signals in common time scale needed. The evaluation of synchronicity is of utmost importance for the visual inspection.

### Requirements on Physical Characteristics

- Different colours could be used in sensors looking alike, so that patient can easily distinguish them (e.g ECG sensors).
- EEG sensors should be embedded in a headcap.

### Other requirements

- Special artefact rejection algorithms could be needed due to patient's motion.
- Sensors should be validated for safety (see also Security and Evaluation requirements) and (cross-) compatibility for the specific layout requirement (such as, proximity, no cross-talk or interference).

### PDPU Device

As in application 3, the PDPU and the Home PC constitute the patient's terminal equipment. Patient's tasks and requirements on PDPU device are as listed in Table 13.

### Home PC

As in application 3, a home-based PC, where the "SENSATION Patient Application" will be installed, is required. This PC should communicate wirelessly with the PDPU and over Internet (or WAN) with the monitoring center. All patient interactions with this application should be logged and the log file should be accessed by the monitoring center technician.

Patient Task	Requirements on SENSATION Patient Application on Home PC
Patient transmits recorded data from PDPU to Home PC Patient should preferably do that only through the PDPU interface.	PDPU-Home PC Communication application that receives data from the PDPU wirelessly. Data should not be erased from the Home PC by the patient.
Patient performs PVT and Leeds monitoring tests	PVT and Leeds monitoring tests should run on Home PC Instructions available/ HELP
Patient transmits data (physiological and test data ) to monitoring center It is preferable that data transfer is initiated by sleep technician at the monitoring center.	Application for communication between monitoring center and Home PC. Data transmission is not necessary to be wireless Reception application should exist at the monitoring center Transmission initiated by monitoring center Due to the large amount of data stored on the Home PC, pre-processing maybe necessary prior to transfer. Secure transmission: Secure mechanisms (e.g. encryption) to guarantee safety Transmitted data should include device and patient identification for authentication control
Applies to all tasks	A log file should be kept with all patient interactions with the SENSATION Application

**Table 19: Patient tasks and Home PC requirements for hypovigilance detection scenario**

### Data reception, storage, and analysis at the monitoring center

Data reception and data storage procedures are the same as in the previous application. Data analysis requirements are different. New algorithms developed in SP3 (WP3.3) and possibly in WP4.4, will be integrated in this application

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Communication with Home PC</b>	
Data is received from the Home PC and stored in the database; all security mechanisms apply in the database and transmission. Reception can be initiated by the technician or can be done automatically at specific times	
<b>Database</b>	
Requirements on the database will be based on requirements set in SP1. Security mechanisms should apply in data storage, retrieval and update. Manufacturers may transmit in own data format that has then to be converted to format as defined in SP1.	
<b>Raw Data Visualisation</b>	
Capability to view all recorded signals (graphical raw data representation) and synchronicity of the signals Capability to select/customize the signals to be viewed	
<b>Data Analysis</b>	
<b>Detection of Hypovigilance</b>	Algorithms developed in WP3.3 will be integrated Expert system from WP4.4 could also be integrated

**Table 20: Requirements for the monitoring center application in the hypovigilance detection scenario**

## 3. SECURITY AND EVALUATION REQUIREMENTS

### 3.1. Security requirements

The analysis of users tasks and requirements in the previous sections has shown that the problems pertaining to the security of the current application could be seen that fall within the following two areas of the SENSATION System:

- The security of information residing in the mobile home-care units, i.e. sensors and PDPU and their communication (BAN).
- The security of information as it travels in the LAN between the PDPU and the Home PC.
- The security of information as it travels 'over the air' or through the telephone lines and the Internet, between the PDPU and the data repository of the monitoring centers. Depending on the technology that will be used to for this data transmission, special security requirements may apply.
- The security of information as it travels 'over the air' or through the telephone lines and the Internet, between the Home PC and the data repository of the monitoring centers. Depending on the technology that will be used to for this data transmission, special security requirements may apply.

- The security of information residing and processed within the monitoring center.

Security requirements in each component have been listed in tables 5, 6, 13, 14, 15, 19 and 20.

Sensors and devices that patients will use must have been validated for safety and (cross-) compatibility for the specific layout requirement (such as, proximity, no cross-talk or interference). They should also be tested for skin irritation and should not be allergenic.

They should be compliant with European guideline about biomedical devices safety (93/42/CEE and 90/385/CEE) and with guideline of electric safety (EN60-601-1).

### 3.2. Evaluation Requirements

Requirement	Application
New sensors will be evaluated separately in the SP2 Work Packages	ALL
Only sensors validated for safety in WP2.9 will be used in the pilot applications.	ALL
Applications 1 and 2 as a whole will be tested after integration (WP3.5) in lab environment against standard PSG. The protocol needs to be defined in WP3.2	1 and 2
New algorithms will be evaluated separately in SP3 Work Packages (WP3.2 and WP3.3)	ALL
In order to evaluate application 3, this method has first to be applied to patients before treatment has started in order to obtain baseline data. Then the application has to be evaluated in real conditions, i.e. patient monitored during daily activities	3
Hypovigilance Detection expert system developed in WP4.4 could be compared with method developed in application 4	4
Evaluation protocols will be defined in detail in WP3.2 and WP3.3	ALL

**Table 21 Overview of evaluation requirements for the proposed applications**

#### 4. CONCLUSIONS

Requirements for distance monitoring of patients suspected for OSAS and patients receiving treatment for insomnia have been presented in detail in the previous sections. Sensors and data fusion algorithms for each application are different; however, users tasks and requirements for the PDPU device and PC applications are similar (Tables 23, 24 and 25) and could be supported by common interfaces.

Medical Application	Target Group & Scenario	Sensors to be used	Communication requirements
Screening and diagnosis of Obstructive Sleep Apnea Syndrome through new miniaturized sensors	<b>Target Group:</b> Patients suspected for OSAS <b>Scenario:</b> Unattended home based recording of signals currently used for OSAS diagnosis through new easy to use SENSATION sensors. 8 hours recording overnight, during sleep	COMBINE FINGERING FLEXELECT OR ENOBIO OR ENOBIO pillow	BAN-PDPU Wireless communication PDPU transmits data to monitoring center Single transmission to monitoring center
Screening and diagnosis of Obstructive Sleep Apnea Syndrome through Arterial Tonometry, Oximetry and Actigraphy	<b>Target Group:</b> Patients suspected for OSAS <b>Scenario:</b> Unattended home based recording through a simplified technique that will be developed in SP3 and uses limited number of signals and SENSATION sensors. 8 hours recording overnight, during sleep	ARTERORUB FINGERING ACTIWATCH	
Evaluation of Insomnia Treatment	<b>Target Group:</b> Patients diagnosed with psychophysiological insomnia and receive treatment. <b>Scenario:</b> 24h monitoring of hyperarousal state through a new method developed in SP3 and through new SP2 sensors	FLEXELECT or ENOBIO Temperature sensor	Sensors to PDPU (BAN, wireless) PDPU to Home PC (LAN) Home PC to monitoring center (WAN) Once a day transmission to monitoring center
Detection of drug induced Hypovigilance	<b>Target Group:</b> Patients receiving CNS drugs <b>Scenario:</b> 24h monitoring of hypovigilance through new SP2 sensors	FLEXELECT or ENOBIO	

**Table 22: Medical applications summary**

Work in the following (and last) 6 months of WP3.1 will aim to investigate the feasibility of the proposed applications. Direct communication of the clinical group that will perform each pilot study and the respective development team (sensor and application developers) is needed at this point. Focus groups from SP2 (sensor developers) and SP3 (clinicians and application developers) will perform walkthroughs of the defined task scenarios in order to validate the proposed

functionality and identify parts that require change; user requirements will be reiterated and finalised.

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## 6. APPENDIX

<b>Requirements on PDPU Device</b>	
<b>Requirement</b>	<b>Application</b>
<b>Physical characteristics</b> Device should not be heavy, could be attached on patient's belt	3 and 4
<b>Communication with sensors</b> Device communicates wirelessly with sensors Sensors – PDPU wireless communication feasible in 1 meter distance (when device positioned on side table – for EMG tibialis sensors)	ALL
Communication with: <ul style="list-style-type: none"> <li>• COMBINE</li> <li>• FINGERING</li> <li>• FLEXELECT OR ENOBIO</li> <li>• ENOBIO PILLOW</li> <li>• ARTERORUB</li> <li>• ACTIWATCH</li> <li>• Temperature sensor (still not defined)</li> </ul> Recording from the sensors should be synchronised	1 1 and 2 1, 3 and 4 1 2 2 3
<b>Operation</b> Device operates continuously with minimum 8 hours of continuous operation (application 1 and 2) and on a 24-hour basis (applications 3 and 4) Patient should not have to change batteries more often than once a day. Availability of batteries that could last for 24hours operation.	
<b>Interface</b> LED screen needed, where messages can be displayed Warning sound, Button to stop warning sound	ALL
RECORD button needed When recording is initiated, sensor recording should be synchronised, and recorded data stored in PDPU. Data should be securely transmitted from each sensor and securely stored in PDPU.	
STOP RECORDING button needed.	ALL
Recording Reminder through sound and message on LED screen	1 and 2
PAUSE and RESUME button needed	ALL
ERASE DATA functionality This functionality should be available through a menu option NOT through a button. Confirmation should be asked prior to data deletion. If the PDPU device has enough storage for a whole night's recordings, then patient does not have to erase the data from the device. It can be erased by the technician at the monitoring center when patient returns the device and sensors. Patient will be prompted by the PDPU to erase data after it has been successfully transferred to the Home PC. However, if the patient has to erase the data for some other reason then this will be done only after he has been advised to do so by the technician at the monitoring center.	ALL ALL 1 and 2 3 and 4 ALL
<b>Data Transmission</b> It is not necessary that data is transmitted to monitoring center as it is recorded. It could all be transmitted once a day or more often only if there is limitation with data storage. Then patient initiates transmission.	ALL
Data could be transmitted in the morning after recording has been completed. In this case, patient could initiate transmission. PDPU communicates through the WAN with the monitoring center.	1 and 2

Transmitted data should include device and patient identification. Transmitted data is stored in patient's record Secure mechanisms (e.g. data encryption) during transmission. Authentication control. There should be capability of storage on flash memory, in case of transmission failure It is more convenient if transmission is done wirelessly to the monitoring center, but it is not a requirement Upon data reception and storage in SENSATION database, confirmation is returned to PDPU	ALL
PDPU-Home PC communication application on the PDPU Data transmission should be wirelessly Data set will be large, possible need to compress data	3 and 4
<b>Error handling</b> Error handling application on PDPU Patient is informed in the following error situations: <ul style="list-style-type: none"> <li>• Electrodes are not positioned correctly</li> <li>• Recording cannot be performed (indicating the problematic channel(s))</li> <li>• Recorded signal is corrupted</li> <li>• Battery is low and device cannot function</li> <li>• Memory is full and data has to be transmitted</li> <li>• Transmission cannot be performed</li> </ul> Patient should be informed (during training and through instructions in patient brochure) what to do in case of an error situation.  Patient knows status of device: <ul style="list-style-type: none"> <li>• If sensors currently recording</li> <li>• If device currently transmitting to database</li> <li>• Battery status</li> <li>• If device has successfully sent data to the monitoring center or Home PC</li> </ul>	ALL
Easy configuration and setup	ALL
Availability of test For testing purposes, device could also support connection through cables to the sensor	ALL
<b>Security</b> Requirements in information security and device safety as defined in section 3.	ALL

**Table 23: Overview of requirements for the PDPU device**

Requirement	Application
<b>Communication with PDPU</b> PDPU-Home PC Communication application that receives data from PDPU wirelessly.	3 and 4
<b>Communication with Monitoring Center</b> Application for communication between monitoring center and Home PC. Data transmission is not necessary to be wireless. Reception application should exist at the monitoring center Transmission initiated by monitoring center Due to large amount of the data stored on Home PC, preprocessing maybe necessary prior to transfer.	3 and 4
Questionnaire application with preferably YES/NO answers and simple graphical interface	3
PVT and Leeds monitoring tests should run on Home PC Instructions available/ HELP	4

<p><b>Security and Safety</b>  A log file should be kept with all patient interactions with the SENSATION Application  Log file should be accessed by technician in monitoring center  Requirements in information security and device safety as defined in section 3 (e.g. secure mechanisms such as encryption are required to guarantee safety  Transmitted data should include device and patient identification for authentication control )  Data should not be erased from the Home PC by the patient.</p>	3 and 4
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**Table 24 Overview of requirements for the Home PC application**

<b>Requirements on PC SENSATION application at monitoring center</b>	
<b>Requirement</b>	<b>Application</b>
<p><b>Communication with PDPU</b>  Data is received from PDPU and stored in database; all security mechanisms apply in database and transmission.</p>	1 and 2
<p><b>Communication with Home PC</b>  Data is received from Home PC and stored in database; all security mechanisms apply in database and transmission.  Reception can be initiated by technician or can be done automatically at specific times</p>	3 and 4
<p><b>Database</b>  Requirements on database will be based on requirements set in SP1.  Security mechanisms should apply in data storage, retrieval and update.  Manufacturers may transmit in own data format that has then to be converted to format as defined in SP1.</p>	ALL
<p><b>Raw Data Visualisation</b>  Capability to view all recorded signals (graphical raw data representation) and synchronicity of the signals  Capability to select/customize the signals to be viewed</p>	ALL
<b>Data Analysis/Reporting</b>	
Synchronicity of recorded events	ALL
Apnea Hypopnea Analysis (standard methods)	1
Apnea Hypopnea Analysis (from arterial tonometry, oximetry and actigraphy)	2
EEG Analysis	1
Sleep/Wake analysis (from actigraphy and arterial tonometry algorithms developed in WP3.2)	2
Sleep Staging Analysis	3
Oximetry Analysis	1 and 2
Heart Rate Analysis	1 and 2
ECG analysis	3
Body Position Analysis	1
Temperature analysis	3
Detection of hypovigilance	4

**Table 25: Overview of requirements for the monitoring center application**

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