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EXECUTIVE SUMMARY

This document is part of the WP 2, whose main objective is to evaluate the most efficient body sensors available and adapt them in order to be able to collect the required physiological data and store them in a proper way

The main goal of this document is to define all the requirements related to the sensor platform. From sensor types to data format and interfaces, this deliverable covers all the sensor related requirements.

DOCUMENT INFORMATION

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Date of delivery	**Contractual**	**31.08.2012**	**Actual**	
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1 INTRODUCTION

The principal objective of this document is to present the general requirements that should be taken into account in terms of data to be collected and analysed from the mobile monitoring system in the final set of sensors for AMROR. The document is divided into two parts. In the first part the significant types of measurements and their role in epilepsy monitoring are presented. In addition a review of some mobile systems for epilepsy monitoring is done. In the second part the sensor requirements are listed in the form of general requirements such as data format and housing and in sensor type specific requirements such as sampling rate and measurement interval.

This document is part of the requirements specification of the whole ARMOR-system. For specification of the other parts of the ARMOR system see D2.2 Real time data Requirements. D2.1 Functional and Non Functional Requirements of the ARMOR Services is dealing with sensor description need to perform data capture and start working on the algorithm that will minimize the channels needed for the final system. In this case, we are using commercial product.

2 STATE OF THE ART IN MOBILE EPILEPSY MONITORING

2.1 Sensors for monitoring of epilepsy

In the following significant types of measurements are presented and their role in epilepsy monitoring is depicted.

As ARMOR's main target are epileptic patients, it is vital to have electroencephalography (EEG) sensors present in the system, as it is an essential component in the evaluation of epilepsy. It has been shown that ambulatory long-term EEG recordings with intensive monitoring has lead to better classifications of seizures and treatment results [1]. Since 30-60% [1] of patients are unaware of their seizures, having these sensors present can lead to new results with optimal treatment. Without EEG recordings, false diagnosis may be made as various phenomena are similar to the resulting behavior of a seizure.

Electrocardiogram (ECG) is used to record the electrical activity of the heart. It is an effective means to help to rule out a seizure being caused by the way the heart is working. It has been noted that in some seizures, especially those located in the temporal lobe, experience a change in heart rate prior to or at the onset of the seizure [2]. A study showed an increase in heart rate of at least 10 beats/minute in 73% of seizures (93% of patients) and this occurred most often around seizure onset. In 23% of seizures (49% of patients) the rate increase preceded both the electrographic and the clinical onset. [3]. Such changes may clarify the timing of seizure onset and can be useful for seizure diagnosis and for automatic seizure detection.

Lotufo et al. [15] demonstrated sympathovagal imbalance in epilepsy, as showed by lower high-frequency (HF) power spectrum, standard deviation of normal-to-normal interval (SDNN) and the root mean square of successive differences (RMSSD) values when compared to controls. In addition, there was a trend for higher LF (lower frequency power spectrum) values in patients receiving pharmacotherapy. As lower vagal (HF) and higher sympathetic (LF) tone are predictors of morbidity and mortality in cardiovascular samples, these findings highlight the importance of investigating autonomic nervous system (ANS) function in patients with epilepsy. Assessing HRV might also be useful when planning therapeutic interventions, as some antiepileptic drugs can show hazardous effects in cardiac excitability, potentially leading to cardiac arrhythmia.

On the other hand HRV measurements have been shown to help seizure detection in some cases [16]. Di Genaro et al., 2004 observed a high incidence (92%) of ictal HR increase in tempotal lobe epilepsy seizures (preceding the EEG onset by 5 seconds). This suggests that the HR changes may be coupled to the functional impairment of neural circuits involved in sympathetic cardiovascular regulation, in the mesial temporal lobe structures.

Finally HRV changes have been observed in particular sleep stages in epileptic patients [17] and have been associated with sleep microstructure EEG elements of importance to epilepsy like K-complexes [18].

The autonomic nervous system obviously reflects brain activities and is strongly influenced by them. HRV as a recognized marker of ANS balance and dynamic changes appears as an excellent marker for seizure detection and follow-up especially if studied along with other ANS expressions

Many epileptic seizures incorporate motor phenomena during their course. Ictal motor activity can be captured and analysed with video and motion sensors (based on 3 dimensional acceleration sensors) in order to characterize a seizure. Body sensors are important as they can be used to discriminate changes in on-going activity due to seizures or physical activity, assisted by ECG (2). In epileptic patients, activity sensor focus has been on the distinction between seizure movements and regular nocturnal movements (4). In a recent presentation, a group used a motion classifier to extract and cluster information about patient motion by processing body motion signals (4). Unfortunately, they tested against only 2 seizure motion templates, and the project had no further presentations or publications since.

Galvanic Skin Response (GSR) acts like an ohmmeter, measuring the electrical conductance of the skin. Due to being closely related to electrodermal activity, it has been tested as a potential sensor for seizure detection (5). In a recent presenation (5), a prototype for GSR signal integrationm has been descriped, although missing an algorithm for GSR evaluation in terms of its contribution in seizure detection. Yet, it has been reported that spontaneous epileptic seizures may be correlated with large increases in electrodermal activity (6). These GSR changes appear to be significant in generalized tonic-clonic seizures and reflect massive sympathetic discharges, often continuing postictally (6).

Temporal loss of consciousness (TLC), which is a cardinal feature in many types of seizures, may also have alternative causes. Syncope is the commonest cause of TLC, due to cerebral hypoperfusion. Neurally mediated (vasovagal, neurocardiogenic or reflex) syncope can happen in up to 40% of the general population and can be misdiagnosed as epilepsy, particularly when it results to cerebral hypoxia and to a reflex anoxic seizure. Blood oxygenation level along with HR are vital signs to syncope diagnosis, which are therefore very useful in differentiating between epileptic and non-seizures.

In some cases of epileptic seizures, patients have a noted drop of oxygen level in their blood. Recent studies have suggested that the cases of Sudden Unexpected Death in Epilepsy (SUDEP) may have occurred due to the brain not instructing patients to continue breathing during seizures [7]. The finds demonstrated that complex partial seizures commonly lead to significant and prolonged oxygen desaturation due to hypoventilation, with saturation levels dropping below 80% in about one-third of seizures and below 70% in one-eighth [8]. These pauses in breathing can last from a few seconds to minutes, and can turn deadly as the oxygen level on the blood begins to drop.

In reflex epilepsies certain stimulus may bring on seizures. One is photosensitive epilepsy (PSE), where seizures are triggered by visual stimuli that forms patterns in time or space [9]. Diagnosis can be made by combining an EEG with a device producing Intermittent Photic Stimulation (IPS). This device produces specific types of stimuli that can be controlled and adjusted [10]. To have a sensor aware of flashing/flicker lights or regular moving patterns would enable the patients to avoid the provoking stimuli and in turn prevent a seizure.

2.2 Sensor systems for monitoring of seizures

In the past years there have been various sensor systems created for the monitoring of epilepsy, ranging from simplistic EEG monitoring systems to more complex ones that have real time monitoring of all sensors. In the following paragraphs some of them are presented.

The Multi-modal Intelligent Seizue Acquistion (MISA) system is a system based on full body motion data as a detection of epileptic seizures. This system used an AMG suit sensor system (Xsens MVN, mostly been used for gaming and film-making), applied for discriminating ictal from normal motion, based on RMS values of acceleration, angular velocity and muscle activity. The suit contained 16 sensors, and each sensor contained a 3D accelerometer, a 3D magnetometer, and 3D gyroscope, transmitting all recorded data over a bluetooth link. Magnetometers were used to help provide the graphical description of the subject in space. In order for muscle activity to be quantified, a 28 surface EMG electrode kit, resulting in 14 bipolar EMG channels, was placed over 14 muscles, recording at a sampling frequency of 1kHz with a bandpass filter of 1 Hz - 500 Hz. Collected results were processed and plotted in a scatter plot in order to investigate the possibility of distinguishing seizures from normal activity (11). Results were based on GTC, asymmetric tonic -versive, and myoclonic seizure motion patterns, versus specific predefined normal subject activities (chess, phone-calling, eating).

The Mercury system, developed in Harvard University, is a sensor network platform designed to support data-intensive applications that can adapt to fluctuations in resource availability and load (12). This system has a varied number of sensors, depending on the type of seizures patients have, but is mainly based on Intel's Shimmer Sensor. Typically, it consists of 3 sensors placed on the arms, 2 sensors on the legs and a base station installed in the patient’s home. Each sensor samples multiple signals from an accelerometer, a gyroscope, and other physiological data, and stores them raw into a local flash memory. An extra EMG sensor is placed on one arm and samples muscle activity at 500 Hz. This system is based on a round-robin driver, pocking sensors on the body in a predefined order. When a seizure is suspected, identified simply on threshold values of the incoming sensor signals, the driver retrieves instantly data from all sensors and alarms the system. This scheme saves power and data storage. Nevertheless, it's a simplified design, in terms of seizure detection-discrimination. The Mercury system has been so far used to capture up to 12 hours of accelerometer and EMG data per day for a 5-day period for epileptic patients.

Another group initially developed a multimodality wireless sensor platform for seizure detection using a microcontroller and they improved on this previous model by adding sensors to detect physical changes from clinical manifestations due to seizure activity. This was done to improve on the accuracy of embedded implementations of their seizure detection system based solely on EEG signals. The platform included a GSR sensor, a temperature sensor, and a rotational sensor. The sensor inputs were processed by a microcontroller, transmitted and received via Bluetooth wirelessly. It was reported that the sensor data were successfully captured, transmitted and received via the wireless settings [5].

A new design of a mobile epilepsy warning system for medical application was developed in [13]. This device was disguised as a wig/hat wired with EEG sensors and was invisible to the inexperienced eye. It consisted of a collector used for converting signals to data, Global Positioning System (GPS), PDA with Global System for Mobile (GSM) module and executed Artificial Neural Network (ANN) software to test current data with pre-learned data, and a calling center for patient assistance.

A miniaturized wireless ECG monitor to detect seizures from changes in the cardiac rhythm was developed in [14]. This monitor was created to extend to epilepsy patients that were severely physically and/or mentally challenged. The ECG was measured using ultra-low-power circuit for bio-potentials acquisition. As the occurrence of R-peaks in ECG signal was used, only 1 ECG lead was needed.

3 SENSOR REQUIREMENTS FOR ARMOR SYSTEM

In the general architecture the sensors are part of the whole AMROR system and are connected to the sensor interface of the ARMOR middleware. Figure 1 shows the sensor architecture within the ARMOR general view of ICT components (small diagram on top right of **¡Error! No se encuentra el origen de la referencia.**) presented in deliverable D2.2

In general, sensors used in the ARMOR wich are desribed in this document are integrated intelligent sensor systems for mobile monitoring of pysiological signals and environmental or context information. These sensors consist of a signal transducer (electrode, acceleration sensor, light sensor,...) whith specific analog frontend. After digitalization of the signal in A/D converter, a mobile processor (e.g. microcontroller) controlls the preprocessing, mobile online analysis, event handling and communication to the middleware.

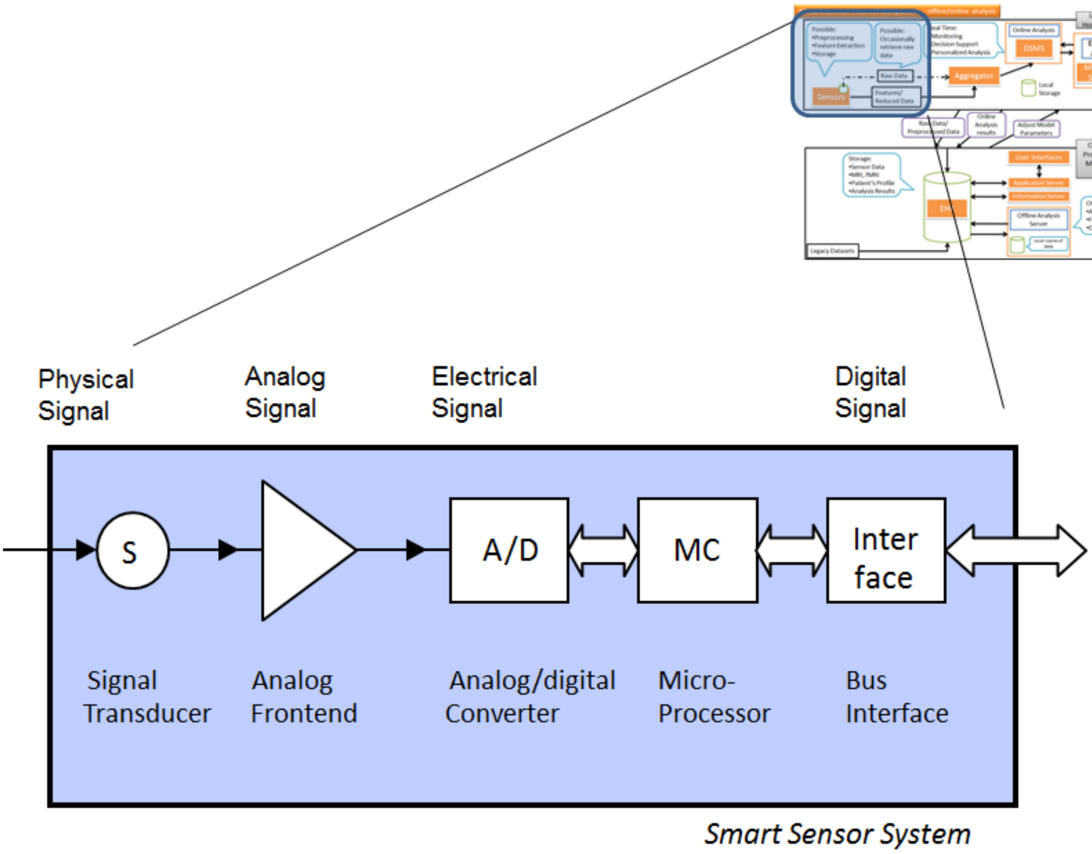

Figure 1: Diagramm of mobile Sensor System

The mobile sensor system may have different signal transducers or a multi-channel intput (in parallel or multiplexed) connected to one micro processor. The signal transducers could be physically integrated in the same housing as the information processing unit or could be wired to this unit.

In case of multi-channel and / or multi-signal sensor system, the sensor serves as a hardware aggregator for the different channels / signals. In case of multi sensor usage connected to one middleware platform, this platform serves as a software aggregator.

3.1 General Functional Requirements

This section summarizes all the general functional requirements.

Code	Title	Description	Impact
GFR01	Interfaces	Communication between the sensors and the aggregator will be performed both wireless and via USB.	High
GFR02	Data format	A suitable data format for recording, streaming and archiving sensor data from various recording systems and with various sampling frequencies should be chosen.	High
GFR03	Time Stamp	Time Stamp is added to the signal on sensor level.	
GFR04	Security	Wireless communication between the sensor platform and the middleware platform will be encrypted.	High
GFR05	User interface	configuration software will run on a PC or Laptop.	High
GFR06	User interface	Start of the sensor is done with configuration software	High
GFR07	Storage capabilities	The raw data will be stored on a microSD card.	High
GFR08	System architecture	The sensor module should be able to work with different types of transducers.	High
GFR09	System architecture	The sensor module should be able to work with different numbers of transducers.	High
GFR10	System architecture	The system should be able to work with different sensor modules.	High
GFR11	Embedded Software	The software on microcontroller will perform the data preprocessing.	Low
GFR12	Charging	Will be done either by the USB interface or	Low

		power plug.	

3.2 General Non-Functional Requirements

This section summarizes all the general non functional requirements.

Code	Title	Description	Impact
GNFR01	Weight, Dimensions, Housing	The sensor platform will have to be as unobtrusive as possible to be convenience even during sleep. Technical limitations such as the battery consumption/ dimension might lead to bigger housings.	Low
GNFR02	Usability	The software for starting/stopping of the sensors will have a GUI and special attentions to user friendliness will be paid.	High
GNFR03	Calibration	Will be done by the producer/distributor of the specific unit.	High
GNFR04	Service	Will be done by the producer/distributor of the specific unit.	High
GNFR05	Distribution to the end-user	Will be done by the doctor or healthcare professional.	High
GNFR06	Time of use	The sensors should be able to measure at least 24 hours.	High
GNFR07	Price	Will depend on the number of units that will have to be used.	Low

3.3 Sensor requirements

This section summarizes all the sensor specific requirements.

3.3.1 EEG-Sensor / EOG-Sensor

Code	Title	Description	Impact
SR01	Sampling rate	The sampling rate may vary depending on the analysis that will be performed. Typical values for most clinical purposes are 200-250Hz.	High
SR02	Resolution	16 bit	High
SR03	Measurement characteristics	5.5 mV range, gain 1000, DC to 500Hz.	High
SR04	Number of channeld	The number of channels depends on the medical requirements but should not exceed	High

		12 channels.	

3.3.2 ECG- Sensor

Code	Title	Description	Impact
SR05	Sampling rate	The sampling rate will be 256 Hz.	High
SR06	Resolution	12 bit	High
SR07	Measurement characteristics	DC=560mV, AC=+/-5mV, gain 227 3db-bandwidth 1,6 up to 33Hz	High
SR08	Number of channels	For recording ECG to analyze HR, HRV and other time-dependent parameters one ECG channel is sufficient.	High

3.3.3 Activity-Sensor

Code	Title	Description	Impact
SR09	Sampling rate	The sampling rate will be 64 Hz.	High
SR010	Resolution	12 bit / 4 mg	High
SR011	Measurement characteristics	+/- 8g	High
SR012	Number of channels	Measurement of physical activity, movement and posture should be done with a 3 dimensional acceleration sensor.	High

3.3.4 GSR-Sensor

Code	Title	Description	Impact
SR13	Sampling rate	The sampling rate will be 32 Hz.	High
SR14	Resolution	14 bit	High
SR15	Measurement characteristics	2µS – 100µS	High
SR16	Number of channels	1	

3.3.5 SPO2-Sensor

Code	Title	Description	Impact

SR17	Sampling rate	The sampling rate will be 32 Hz.	Low
SR18	Resolution	12 bit	Low
SR19	Measurement characteristics		

3.3.6 Respiration

Code	Title	Description	Impact
SR20	Sampling rate	The sampling rate will be 32 Hz.	Low
SR21	Resolution	12 bit	Low
SR22	Measurement characteristics		
SR23	Number of channels	1	

3.3.7 EMG-Sensor

Code	Title	Description	Impact
SR24	Sampling rate	The sampling rate may vary depending on the analysis that will be performed. Typical values for most clinical purposes are 200-250Hz.	
SR25	Resolution	16 bit	
SR26	Measurement characteristics		
SR27	Number of channels	1 or 2 bipolar recordings	

3.3.8 Context, environmental signals

Code	Title	Description	Impact
SR28	Type of device	Smartphone or tablet with an integrated light and sound sensor.	Low
SR29	Analysis	Sound, light	Low

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APPENDIX 1 – ARMOR DELIVERABLE REVIEW FORM

ARMOR Deliverable Review Form		
Deliverable:	D2.4: ARMOR Sensor Requirements	
Reviewer(s):	George K. Kostopoulos, UoP	Alberto Fernández, S&C
Review Date:	28.08.2012	

Does the document cover the objectives and task description stated in the DoW taking also into account the overall project vision?

Yes [X]

No [ ]

Partly [ ]

Comments:

- …
- …

Is the Executive Summary in a publishable form? (This should be no longer than 2 pages, easy to understand by people outside the project, showing scope and result achieved)

Yes [x]

No [ ]

Partly [ ]

Comments:

- …
- …

Are the structure and appearance (layout, images etc.) compliant with the Quality Plan?

Yes [x]

No [ ]

Partly [ ]

Comments:

- …
- …

Table [x]. [title]