ACTIVITY REPORT

THE SHERPAM PROJECT

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INITIAL DATE

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1. SCIENTIFIC CONTEXT OF THE PROJECT

Heart failure, Respiratory failure or people with peripheral artery disease require early detection of health problems in order to prevent major risk of morbidity and mortality. Evidence shows that people recover from illness or cope with a chronic condition better if they are in a familiar environment (i.e., at home) and if they are physically active (i.e., practice physical activity - PA). The goal of the SHERPAM project is to design, implement and validate experimentally a monitoring system allowing biophysical data of mobile subjects to be gathered and exploited in a continuous flow.

In short, SHERPAM project aims:

1. To develop a new generation of monitoring system that allows health monitoring at home, but also during all kinds of indoor and outdoor activities (at work, while shopping, practicing sports, etc.). This monitoring system should support different kinds of wireless network technologies (e.g. 2.5G/3G/4G, personal/corporate/community Wi-Fi hotspots) and tolerate network disruptions without ever losing important data.
2. To improve the recognition, quantification of Physical Activity (PA) and the estimation of energy expenditure (EE) associated with PA in healthy subjects and assess "in situ" the walking ability of people with peripheral artery disease (clinical purposes).
3. To study Patients and medical staff acceptance and approval related to these new technologies that could transform patient's care through clinical trial.

SHERPAM is a project that aimed at ensuring a medical health monitoring for cardiac patients while preserving users' privacy. Regarding data acquisition, many studies have been conducted to improve communication with health sensors. For instance, Hofer *et al.*[1] proposed a server-client RESTful architecture with a publish/subscribe mechanism running on Android devices with the aim of increasing the quality of care. However, no public-commercialized sensors were used but only a prototype. Also, Mihaylov *et al.*[2] proposed a cloud-based platform for supporting e-health services in order to detect abnormal behaviors in daily lifestyle that might indicate a change in health status. Implemented sensors used only the standard protocol ISO/IEEE 11073 despite the fact that this protocol is a minority in the sensors market. Rahmani *et al.*[3] presented the concept of a smart e-health gateway that served as a bridge for medical sensors between the home and the hospital. Similarly to previous works, commercialized sensors were not integrated.

With the exponential growth of wide-public sensors especially those implementing proprietary protocols, it is important to be able to use them. SHERPAM project uses commercially available sensors that anyone can buy as such (QStarz, Zephyr) whereas other projects do not do.

As for sensors manufacturers such as Nike, Fitbit, Xiaomi, these companies are interoperable only with their own ecosystem and not with others, which is not enough to ensure a complete health monitoring as no manufacturer can produce all type of sensors. Furthermore, these companies provide wellness monitoring whereas SHERPAM trends toward a medical monitoring.

Table 1 illustrates a comparison between these different projects.

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[1] Hofer, T., M. Schumacher, et S. Bromuri. « COMPASS: An interoperable Personal Health System to monitor and compress signals in chronic obstructive pulmonary disease ». In 2015 9th International Conference on Pervasive Computing Technologies for Healthcare (PervasiveHealth), 304-11, 2015. https://doi.org/10.4108/icst.pervasivehealth.2015.259186.

[2] Mihaylov, M., A. Mihovska, S. Kyriazakos, et R. Prasad. « Interoperable eHealth platform for personalized smart services ». In 2015 IEEE International Conference on Communication Workshop (ICCW), 240-45, 2015. https://doi.org/10.1109/ICCW.2015.7247185.

[3] Rahmani, A. M., N. K. Thanigaivelan, Tuan Nguyen Gia, J. Granados, B. Negash, P. Liljeberg, et H. Tenhunen. « Smart e-Health Gateway: Bringing intelligence to Internet-of-Things based ubiquitous healthcare systems ». In 2015 12th Annual IEEE Consumer Communications and Networking Conference (CCNC), 826-34, 2015. https://doi.org/10.1109/CCNC.2015.7158084.

Table 1. Comparison between different projects and SHERPAM.

	Market-Ready Sensors	Standard Protocol	Proprietary Protocol	Runs on Smartphone	Handles Users' Privacy	Medical
Hofer *et al.*		✓		✓	✓	
Mihaylov *et al.*		✓				
Rahmani *et al.*		✓				
Fitbit	✓		✓	✓		
Xiaomi	✓		✓	✓		
SHERPAM	✓	✓	✓	✓	✓	✓

2. ACADEMIC PARTNERS

Projects SHERPAM gathers research teams from several scientific domains and from several laboratories of Brittany (IRISA/CASA-Université Bretagne Sud, LTSI-Université Rennes 1, M2S-Université Rennes 2 and ENS Rennes, CIC-IT 1414-CHU of Rennes and LP3C-Université Rennes 2), in order to constitute a pluridisciplinary research consortium able to grasp and tackle the technical as well as the societal issues raised by these applications. Each research team had a solid experience in the following domain: i) IRISA/CASA around communication application, ii) LTSI in biomedical signal processing, iii) M2S in the measurement of physical activity behavior and in the study of exercise physiology, iv) LP3C in human factors and v) CIC-IT-1414 in the conduction of clinical trials.

3. DESIGN OF THE MONITORING SYSTEM

The monitoring system that has been designed and implemented in the framework of the SHERPAM project is shown on Figure 1.

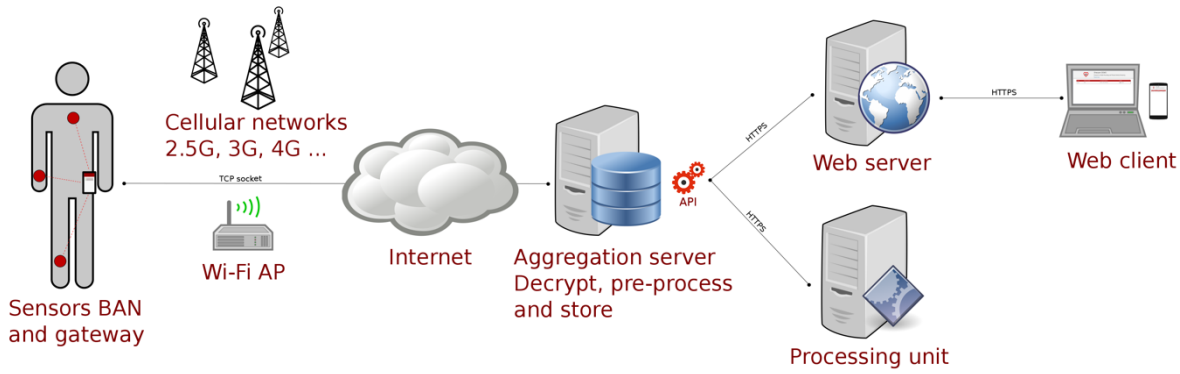

Figure 1 Architecture of the SHERPAM system

This system has been designed so as to cover all stages of data acquisition, transmission, and processing, while meeting the following criteria:

- **Extensibility:** Since distinct pathologies may require different types of data the system is not limited to a pre-defined, immutable set of sensors. On the contrary it is extensible so as to easily accommodate new types of sensors or data processing algorithms whenever needed;

- **Self-sufficiency:** The system allows that data acquired by sensors be processed either "locally" or on a remote site. Local processing makes it possible for the sensing system worn by a subject to run

autonomously –though possibly in a degraded mode– when no communication network is available. In contrast remote processing makes it possible to run advanced (CPU intensive) algorithms on the data acquired by the sensors.

- **Agility:** The system is agile regarding network connectivity, switching from cellular (2.5G/3G/4G) networks to Wi-Fi hotspots depending on their availability, but also depending on other parameters such as the nature of the data to be transmitted or the power consumption involved when using each kind of network.

- **Disruption-tolerance:** Transmissions in the system are “bundle-oriented”, which makes it possible to tolerate network disruptions (including long disruptions as can be observed in "white zones" that are not covered by any wireless network) without ever losing important data.

Details about the main components of the SHERPAM system are provided below.

SENSORS AND GATEWAY

DATA ACQUISITION

Sensors worn by a subject are used to acquire data pertaining to the subject's status (acceleration, gyroscope, heart rate (HR) or full-featured ECG, temperature, location, etc.). Data streams produced by these sensors are gathered by a portable “gateway”, which is also worn by the subject. This gateway pre-processes data, so they can be transferred to a remote site for storage and analysis. The sensors and the gateway together constitute a Body Area Network (BAN), and transmissions in this BAN rely on Bluetooth links (including Bluetooth Low Energy). Support for other transmission technologies (e.g., ANT+) may be included later in the system.

In the framework of project SHERPAM, the gateway is typically an Android smartphone running a dedicated application (see the screenshots in Figure 2), as this kind of device is readily available at reasonable cost, is programmable, supports several radio standards (e.g., Bluetooth, Wi-Fi and 2.5G/3G/4G), has enough processing power to handle data streams, and offers a nice user interface. Since the Android OS does not allow an application to load external classes at runtime, an original plugin system has been developed for this project's Android app. With this plugin system, software modules can be "plugged in" the application at any time, each module being designed to drive a specific type of sensor, or to process a specific type of data stream. With this feature, the Android app is highly modular, as new types of sensors or new data processing algorithms can be included at any time in the SHERPAM system, without requiring any update of the app itself. The Android application developed in the framework of project SHERPAM has been registered with the “Agence pour la Protection des Programmes” (registration number: IDDN.FR.001.540019.000.S.P.2015. 000.31230).

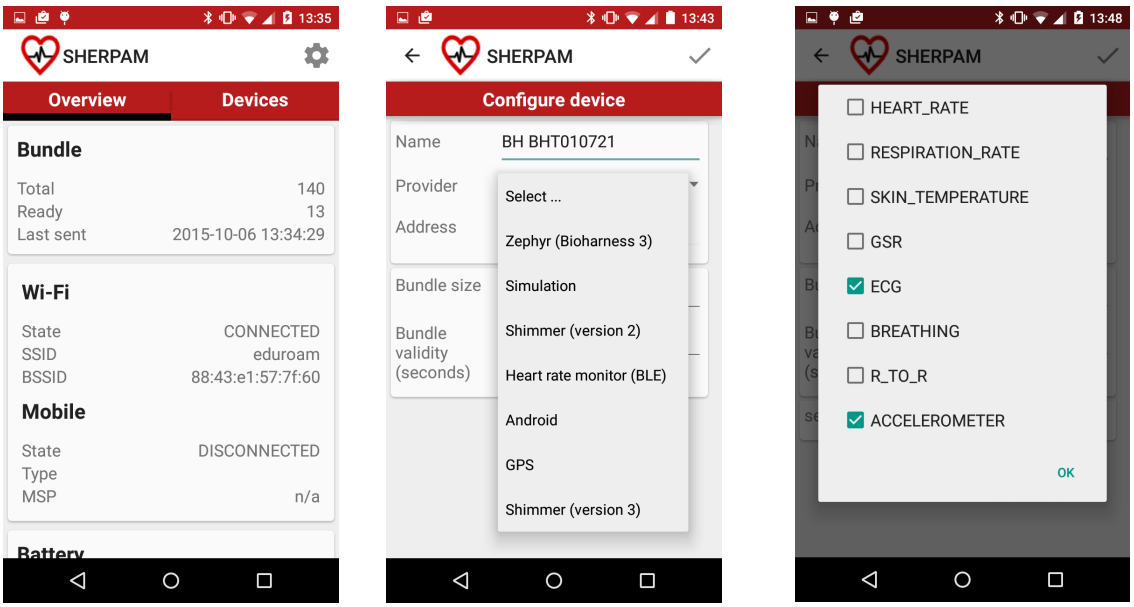

Figure 2: Screenshots taken from the Android application deployed on the gateway

DATA PRE-PROCESSING

As mentioned above, the gateway can pre-process the data it receives from the sensors before transmitting the output to a remote site for further analysis. This makes it possible to reduce the amount of data to be transferred, or to detect locally interesting patterns in these data. In the latter case, the subject can be warned directly by audible or visual notifications. Base algorithms such as the respiration cycle detection with breathing waveform signals and QRS complex detection with electrocardiogram (ECG) signals, originally developed and validated with Matlab / C ++ on desktop PC, have thus been ported to the Android app. The interest of the approach is illustrated in the schema below (Figure 3): key physiological features such as inspiration/expiration time, total respiration time, instant frequency as well as respiration amplitudes can be easily derived to characterize the respiration activities with reduced data volume (approximatively a compression rate of 10).

Figure 3 : General schematic of the data flowchart

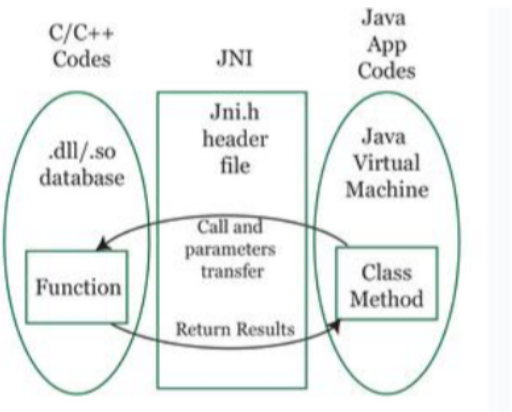

Figure 4 : Principle of converting C++ library to Java

The JNI library is typically used for this purpose (Figure 4) to convert pre-existing C++ source libraries to Java code executable in an Android system. The main difficulties however include the management of the fixed-lag online structure and the differences in data types (definition of **double/float** varies between architectures) that led to numerical errors under certain conditions. These implementations are validated by comparing with the results from the initial program on desktop computers (Mac and Linux OS).

DATA TRANSMISSION

The Android app that runs on the gateway is capable of both vertical handover (switching between alternative transmission technologies such as Bluetooth, Wi-Fi, and 2.5/3/4G) and horizontal handover (switching between networks that rely on the same technology), while performing bundle-oriented transmissions. These combined features make it very agile and able to cope with connectivity disruptions.

The data acquired by sensors are first assembled into bundles, which can be stored for a while on the gateway and be transmitted to the remote site when circumstances permit. A bundle is basically a collection of data samples, together with meta-information about these samples (data type, timestamps, priority level, etc.). Using bundles as transmission units in the SHERPAM system makes it possible to devise and implement adaptive strategies in the gateway. For example, when a connectivity disruption occurs, the order in which bundles are sent once the connectivity is reestablished may depend on the nature or priority level of the data samples contained in these bundles. Bundles containing urgent data may thus be transmitted first, while less urgent bundles are delayed or discarded. Using bundles also makes it possible to transmit data in short high-speed bursts, rather than in continuous low-speed streams. With this approach the radio circuits used by the gateway can be disabled most of the time, which significantly reduces the power drain on this device. Indeed, the Android app running on the gateway can deliberately disable all radio circuits in order to save power, enabling only the Wi-Fi radio every now and then to send all or part of the available bundles, and switching to cellular (i.e., 2.5G/3G/4G) transmissions only when Wi-Fi transmissions are not possible. Field experiments have shown that such an approach proves very effective to preserve the power budget of the gateway, multiplying its autonomy up to tenfold.

DATA AGGREGATION SERVER AND PROCESSING UNITS

The front-end of the “remote site” is an aggregation server, whose role is to receive the bundles sent by mobile gateways, to extract the data contained in these bundles, and to store these data so they can be accessed by processing units.

A processing unit is typically an application that subscribes with the server in order to receive all data pertaining to a given patient, and to process these data continuously and autonomously, looking for interesting patterns (for examples signs of arrhythmia in a stream of ECG samples). When a processing unit detects anything interesting or unusual, a notification can be sent automatically to medical staff, or directly to the patient.

A very basic processing unit has been developed to serve as a demonstrator in project SHERPAM. This unit is simply a Web server, which makes it possible to parse the data stored on the aggregation server, to visualize data sets (e.g., heart rate, respiratory rate, VMU, GPS) and to determine the physical activity based on users’ movement and speed.

A more advanced processing unit is now under development (Figure 6). This new unit offers a platform for patients, physicians and researchers, for both heart rate processing and physical activity

level. It allows patients to consult their history, and therefore, their progress. Regarding physicians, they can access their patients' records. As for researchers, the platform offers several tools to analyze ECG and physical activity measures. It allows to run third-party algorithms so researchers can evaluate their own work on recorded data. This unit also includes a tachycardia detector which aims at alerting patients and their physicians in case of cardiac rhythm disorder. Concerning physical activity, in addition to a path visualizer, a set of parameters are calculated such as physical activity level, user's speed, etc. Also, a classifier for physical activity has been implemented during H. Abdul Rahman's PhD and licensed at the APP (RACHA).

Figure 5. Zephyr sensor mounted on a chess strap.

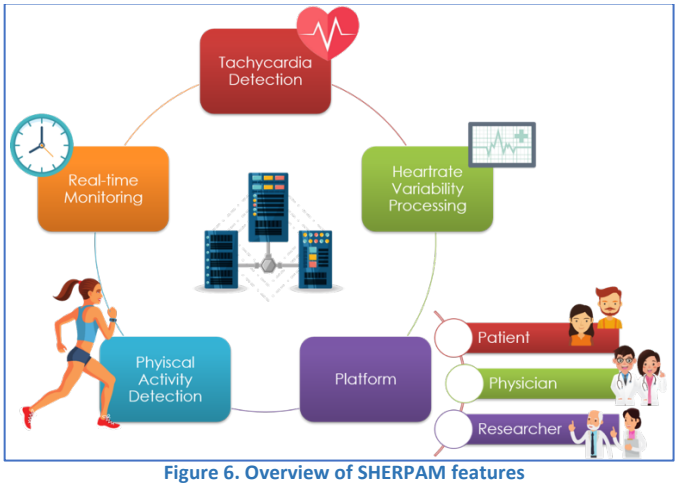

Figure 6. Overview of SHERPAM features

4. QUANTIFICATION OF PA AND THE ESTIMATION OF EE

IMPROVE THE RECOGNITION

One of the objectives of the SHERPAM project is to improve the recognition, quantification of physical activity (PA) and the estimation of energy expenditure (EE) associated with PA in healthy subjects. Indeed, a sedentary lifestyle is currently considered by the World Health Organization (WHO) as a major risk factor for morbidity and mortality. It is assimilated to a disease that would be the tenth leading cause of mortality in the world. The studies published since 1996 show a lower relative risk of death among active people compared to inactive people. Leitzmann et al. (2007)[4] show that a practice at a level similar to that of recommendations for moderate activity (at least 3 hours per week) or high-intensity activity (at least 20 minutes 3 times per week) reduces the risk of death by 30% compared to that of be inactive. The recognition and quantification of PA, as well as the estimation of the associated EE, requires the implementation of new signal processing algorithms on noisy measurements.

Our results made it possible:

(i) To validate and compare the accuracy of different sensors (Zephyr, Shimmer and Actigraph accelerometers, GPS) and their measurement variables (acceleration, speed, HR, RR) in the detection of PA and sedentary activities (Figure 7).

(ii) To test the robustness of the models developed (models based on spectral distances and reference model).

4 Leitzmann MF, Park Y, Blair A, Ballard-Barbash R, Mouw T, Hollenbeck AR, Schatzkin A. Physical activity recommendations and decreased risk of mortality (2007) Arch Intern Med.; 167(22): 2453-60.

(iii) To study the optimal distribution of sensors on the body in order to identify the categories of activities with sufficient precision (Figure 8).

(iv) To propose an innovative and new activity recognition platform.

(v) To collect an original database of free-living daily activity. It is worthwhile to mention that this database is probably unique.

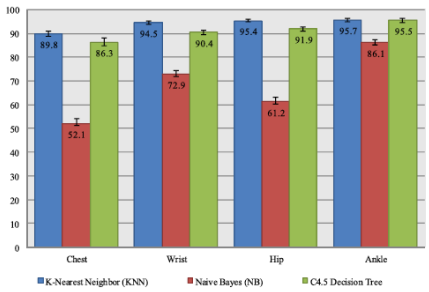

Figure 7. Overall classification accuracies per unit position for the three classifiers.

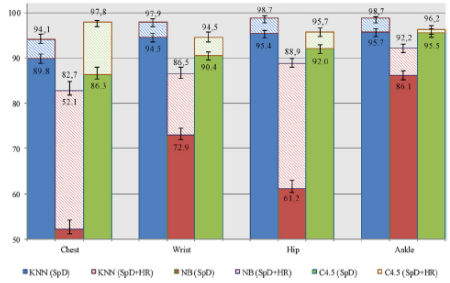

Figure 8. Overall classification accuracies and their standard deviations for each sensor position before and after including the normalized HR information.

BREATHING RATE ESTIMATION BASED ON ECG/PPG SIGNALS

Another objective of the SHERPAM project is to improve the continuous monitoring of respiratory variables. Indeed, respiratory failure affects millions of people (Schindhelm 2013)[5], for whom the lungs are unable to inspire sufficient oxygen (O_2) or expire sufficient carbon dioxide (CO_2) to meet the needs of the body. It is difficult to predict and can become life threatening. Continuous monitoring providing real time respiratory assessment is an efficient solution allowing for timely interventions. Minute ventilation (V_E), tidal volume (V_T), and RR are important variables in respiratory medicine and can be conventionally obtained from a spirometer (Chhabra 2015[6]; Miller et al 2005[7]). Despite its precision, it requires the use of a facial mask or mouthpiece, usually cumbersome to wear. Therefore, alternative methods have been developed to estimate respiratory variables from other body sensors, such as Visuresp (Emeriaud et al 2008[8]), LifeShirt (Hollier et al 2014[9]; Kent et al 2009[10]), respiratory magnetometer plethysmography (RMP) systems (RMP-S) (Gastinger et al 2010[11]).

Within the SHERPAM project, we have developed a RMP-S. Two PhDs have been devoted to the development of this RMP-S:

i) The first one proposed a new technique for estimating the respiratory volume (V) and associated ventilatory parameters (V_T, RR, inspiratory time (T_I), expiratory time (T_E), total time of a respiratory cycle (T_{TOT})) using data processing based on models of multilinear regressions (RML) and artificial neural networks (ANN). The main results show that ANN

[5] Schindhelm K H and Farrugia S P 2013 Methods and apparatus for monitoring and treating respiratory insufficiency US Patent 20130340758.

[6] Chhabra S K 2015 Interpretation of spirometry: selection of predicted values and defining abnormality Indian J. Chest Dis. Allied Sci. 57 91–105.

[7] Miller M R et al 2005 Standardisation of spirometry Eur. Respir. J. 26 319–38.

[8] Emeriaud G, Eberhard A, Benchetrit G, Debillon T and Baconnier P 2008 Calibration of respiratory inductance plethysmograph in preterm infants with different respiratory conditions Pediatric Pulmonol. 43 1135–41.

[9] Hollier C A, Harmer A R, Maxwell L J, Menadue C, Willson G N, Black D A and Piper A J 2014 Validation of respiratory inductive plethysmography (LifeShirt) in obesity hypoventilation syndrome Respir. Physiol. Neurobiol. 194 15–22.

[10] Kent L, O'Neill B, Davison G, Nevill A, Elborn J S and Bradley J M 2009 Validity and reliability of cardiorespiratory measurements recorded by the lifeshirt during exercise tests Respir. Physiol. Neurobiol. 167 162–7.

[11] Gastinger S, Sefati H, Nicolas G, Sorel A, Gratas-Delamarche A and Prioux J 2010 Estimates of ventilation from measurements of rib cage and abdominal distances: a portable device Eur. J. Appl. Physiol. 109 1179–89

seems to be a better estimator of V compared to RML. The higher accuracy of nonlinear models is probably due to the complexity of V_E.

ii) The second one, as a prolongation of the previous one, continue to explore new data processing methods (preprocessing, calibration, machine learning, …). For regression tasks, we seek to adopt advanced computing techniques to process more data and apply more complex and innovative estimation models, such as convolutional neural networks. A review article has been recently published in one scientific journal (Physiol. Meas.) whereas the original research results are submitted to the European journal of applied physiology in 2019 on the estimation of minute ventilation (V_E) during low to moderate intensities.

We also addressed the problem of obtaining an accurate estimation of RR, using only ECG or photoplethysmographic (PPG) signals to replace direct measurements, usually uncomfortable to wear during daily activities. Several respiration waveforms are derived from ECG or PPG signals based on amplitude, frequency and baseline wander modulations. It is however difficult to determine their optimal combination for RR estimation due to the noise and patient specificity. To determine the optimal combination, we used the notion of the respiratory quality indexes (RQI). Two methods are compared (Figure 9): the first automatically selects the modulation signal with highest RQI for RR estimation, while the second tracks the respiration modulation using the Kalman Smoother (KS) based on multiple modulation signals with highest RQI. These two methods are evaluated on two independent datasets, one benchmark DB with immobilized patients recordings (Capnobase from http://www.capnobase.org/) and the second with those performing daily activities. Our results outperform existing methods in the literature in both cases. Experimental results show that the RQIs coupled with a fusion algorithm increases the accuracy for RR estimations, in dealing with derived modulation signals.

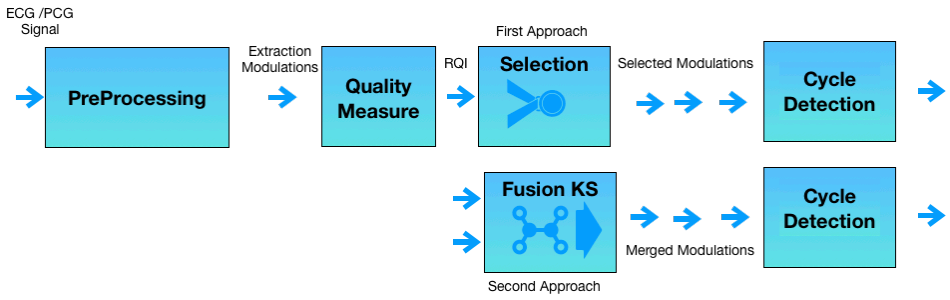

Figure 9 : The general architecture to measure the Breathing rate from PPG or ECG

Median and 25-75 percentiles (bpm), ECG signals of SHERPAM Dataset (10 subjects)						
	sit	stand	lie	drive	work	walk
Derived modulations						
RPA	6.9 (3.3-15.2)	5.7 (1.9-11.2)	4.1 (1.2-10)	12.8 (6.7-16.1)	7.1 (2.1-12.9)	12 (5.6-17.6)
RSA	1.4 (0.5-2.6)	4.4 (1.5-9.7)	1.3 (0.4-2.2)	4.4 (1.5-12.6)	2.2 (0.7-3.7)	5.5 (2.1-10.8)
AQRS	5.1 (1.6-11.3)	2.8 (1.4-6.6)	3.1 (1.6-8.4)	8.7 (2.7-12.4)	3.7 (1.4-10.2)	8.9 (4.7-13.5)
QRA	4.1 (2.1-10.3)	2.2 (0.9-5.4)	1.8 (1.1-4.7)	5.5 (1.1-10.8)	1.6 (0.7-6.6)	7.3 (5.6-14.4)
First Approach Selection						
SINUS	5.6 (2.2-15.2)	4.4 (1.5-10.4)	4 (1.8-7.4)	8.7 (2.5-15.1)	3.7 (1.2-12.2)	11.9 (6.1-15.1)
FT	1.3 (0.6-2.6)	3.4 (1.3-10.4)	1.2 (0.5-2.6)	3.3 (1.1-11.7)	1.2 (0.4-3.6)	4.1 (1.6-8.7)
Autocorr	1.4 (0.7-4.9)	3.1 (1.3-9.8)	1.3 (0.7-3.8)	4.1 (1.2-12.3)	1.4 (0.6-4.6)	6.4 (3.4-13.3)
Second Approach Fusion 2 inputs						
SINUS+ KS	2.2 (0.4-3.6)	1.1 (0.4-2.9)	1.2 (0.6-2)	2.1 (1.2-3.3)	2.1 (1.4-3)	1.8 (0.9-3.6)
FT+ KS	1.1 (0.4-2.2)	1.4 (0.5-3.1)	0.8 (0.3-1.6)	1.8 (0.8-3.7)	0.7 (0.1-1.4)	0.7 (0.9-3.6)
Autocorr+ KS	0.9 (0.3-1.9)	1.2 (0.5-2.3)	1.1 (0.4-2.2)	2.4 (0.6-4.3)	1.4 (0.6-2.5)	1.1 (0.6-2.4)
Complementery test Fusion m inputs						
SINUS+ KS	1 (0.4-3.2)	1.2 (0.4-3.1)	0.8 (0.4-1.9)	1.4 (0.4-2.5)	1.6 (1.5-2.2)	1.4 (0.6-2)
FT+ KS	1.1 (0.4-2.3)	1.2 (0.6-2.9)	0.6 (0.3-1.5)	1.1 (0.4-1.7)	1.2 (0.8-2.1)	0.3 (0.1-0.8)
Autocorr+ KS	1.1 (0.4-2.2)	1.3 (0.3-3.6)	0.7 (0.3-1.9)	1.2 (0.6-1.6)	1.4 (0.6-2.2)	0.7 (0.2-1.9)
Posterior Selection	0.9 (0.4-2)	0.7 (0.2-1.4)	0.5 (0.2-1.2)	1.1 (0.3-2.8)	0.6 (0.2-1.1)	2.1 (0.9-4.3)
Literature methods						
Karlen*	3.4 (1.3-6.2)	2.6 (0.9-5.7)	1.8 (1-4.4)	4.6 (2.1-7.2)	2.4 (1.2-5.2)	6.3 (4.3-11.5)
pimentel*	3.7 (1.3-9.2)	3.1 (1.3-4.8)	1.8 (1.1-3.9)	5.6 (1.7-8.4)	2.3 (0.8-4.7)	2.4 (1.2-5.2)

* Our implementation.

Figure 10 : Performance comparison of the proposed approach with methods reported in the literature

This original approach of combining RQI and fusion has been published in the journal of IEEE transactions on biomedical engineering while the method itself and compared databases are publicly available at https://github.com/dge996/BR-estimation-with-KS for the science community. Related works have also been accepted by the international conferences such as computing in Cadiology, addressing the problem of RQI performances and further enhancement in the fusion model. A software is currently under licensing at APP. A first contact was also established with Mindray company during the last computing in cardiology conference and bilateral scientific exchanges were initiated and confident agreement was signed.

5. CLINICAL IMPLICATION OF THE SHERPAM DEVICE

CLINICAL TRIAL

The objective of the SHERPAM device is to record health data and PA monitoring data by broadcasting them in real time on a secure server, via a dedicated application which has been developed on smartphone. Thus, SHERPAM aims at favoring the safety of the physical practice to subjects with risk factors for health or to patients, in particular with cardiovascular diseases. SHERPAM device is currently tested in a clinical trial lead by the CIC-IT 1099 Inserm in the University Hospital of Rennes. The material is given during 3 weeks to every participant (30 all in all) for a monitoring of its PA on a daily basis. The system includes an ECG, motion sensors, GPS, all transmitting in real time the acquired data on a secure server via a mobile phone using internet connection and its specific application SHERPAM. During the trial, few interviews and questionnaires are conducted by a psychologist after 7 days of use and at 21 days, in order to study the acceptability of the device. Ten participants with cardiovascular disease and 10 healthy cyclo-tourist subjects have been included in this trial, as well as 7/10 participants with lower extremity PAD. Several problems/questions were reported by the participants and are mentioned on the SHERPAM website.

PSYCHOSOCIAL STUDY

The main goal of the psychosocial study in the SHERPAM project was as a first step to provide contextual usage understanding and specification in order to support the engineering process conception. Secondly, it consists in measuring user's acceptability during the clinical trial. At first, an analysis of the individual, social and organizational determinants was realized. This work was based on 3 types of data collection: analysis of current practices in monitoring PA assessment, conducting a series of interviews with expert professionals in order to collect the current needs and uses of monitoring devices and operation of regulatory literature governing the suitability for use. The results allowed the characterization of several psychological factors (such as comfort, ease of use, memorability, and learnability determinants, ability to wear, feedback on the correct placement, social influence, support for users…) that have an impact on the use of the SHERPAM medical device. These psychological factors were also used to develop the acceptability questionnaires for the clinical trial accorded to the literature on acceptability of e-health technological device.

In order to prepare the clinical trial, a study was conducted to develop the usability of SHERPAM device allowing participants to be autonomous with the device. Authors explain that failure to use with no functional defect would be attributed to inefficiency of the user manual[12]. To avoid this, the SHERPAM's user manual was co-designed with the technical team to allow the user to access to information according to 2 levels: a progression step by step and an understanding of the device with a quick location of information in case of punctual researches. Users have been associated in pre-test situation of use to be sure the information and the device matches their needs. Results led to change some features of the device.

A measure of acceptability and usability have been also realized during the pre-test. It will enable us a comparison with the results of the acceptability study during the clinical study to demonstrate the efficiency of the co-design between the human and social sciences and the engineering sciences.

Currently, the clinical trial is underway. The study's final objective is to measure the SHERPAM device's intention to use and to define which psychological factors are correlated with this intention between the 3 populations.

"*According to Nielsen 80% of problems can be identified through an evaluation of six people if the test deals with one profile and by three or four people per group if the deals with several groups*"[13]. In our study, each group is composed of 10 persons. Nielson has demonstrated the percentage of identified errors increase up to 5 persons (more than 50% detection), to stabilize around 8 to 10 persons. Beyond this number, adding testers very little increases the detection (Nielsen & Molich, 1990[14] ; Nielsen, 1993[15])

Valentin, Lancry & Lemarchand[13] have specified that the number of required testers also depends on the types of products and the context of investigations "*dynamic and realistic situations allow one to situate the action better and to output more results than static presentations or simulations ».* Sherpam device is tested in real situations, they used the device at home in their daily lives. To complete the statistic study, we choose to pass the acceptability questionnaires with semi-structured interviews to have some qualitative informations.

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12 Ganier F., « Évaluer l'efficacité des documents techniques procéduraux : un panorama des méthodes », Le travail humain 2002/1 (Vol. 65), p. 1-27

13 Valentin, A., Lancry, A. & Lemarchand, C. (2010). La construction des échantillons dans la conception ergonomique de produits logiciels pour le grand public. Quel quantitatif pour les études qualitatives ?. Le travail humain, vol. 73(3), 261-290. doi:10.3917/th.733.0261.

14 Nielsen J. & Molich R. (1990). Heuristic evaluation of user interfaces, in J. Carrasco & J. Whiteside (eds), Proceedings of acm chi'90 Conference on Human Factors in Computing Systems, 1-5 April, Seatle, wA, p. 249-256.

15 Nielsen J. (1993). Usability Engineering, London, Academic Press.

The statistic study can be done only at the end of the clinical trial but we can already done some qualitative results. The 3 populations Sherpam device's considered overall the device as easy to use. Its allow them to follow their physical activity, to know better theirs limitations, the data transmission on a medical service (CHU Rennes) is a big interest for them.

Interests are different between the 3 group. For the cardiovascular disease and healty cyclotourists groups, to be really useful the device SHERPAM should propose alerts when the maximum heart rate will be reached, they hope an analysis of the ECG could be done for detect anomalies and prevent some health problems.

The AOMI group don't have ECG's monitoring, they consider the device as an accompanying tool for the walk but the main question is not the device's acceptability but the walking's acceptability. In fact walking is very painful for them, only patients which already practice walking seems to see a real utility. But all the patients, walker or not, are interesting to have informations about their walking ability more specifically the maximum distance between stop for pain et the recovery time. It's important for them that the medical team have this result, they hope a better medical monitoring.

Finally, for all the 3 groups primary results show to be more useful SHERPAM application will have to propose sessions history to note their evolution or their performance and the GPS data reliability will be improve. The device should also be proposed in a watch to limit the worn equipment and to have data accessible during the training (more specifically fort the cardiovascular disease and cyclotourists groups).

Let us specify that SHERPAM project has helped to systematically consider the human factor in the conception of e-health devices. This psychosocial methodology has been duplicated with two others projects of e-health devices for the automatic detection of falls and the detection of fragility helps the seniors' home care.

A CLINICAL APPLICATION: MONITORING PEOPLE WITH PERIPHERAL ARTERY DISEASE

CONTEXT

One of the key applications developed during the SHERPAM project was related to the monitoring of outdoor walking sessions in people with lower extremity Peripheral Arterial Disease (PAD). In the management of PAD people, it is recognized that supervised walking exercise is an efficient therapeutic strategy to improve walking capacity (Fakhry et al., 2012)[16]. Unfortunately, supervised walking exercise is often not prescribed because of treatment cost, transportation difficulties and lack of insurance reimbursement. Home- or community-based walking programs have been scientifically proven as an efficient alternative strategy, provided an adequate exercise regimen is planned. This raises the issue of what is really performed by the patient and how to adequately monitor the walking program. The use of wearable monitors should overcome these issues, but a recent study showed that the use of a popular consumer wearable monitor compared with usual care did not improve walking capacity following a home-based walking program (McDermott et al., 2018)[17]. The SHERPAM project aimed to develop a dedicated application using previously available wearable monitor to manage home-based walking programs in PAD people.

PRESENTATION OF THE ANDROID APPLICATION

16 Fakhry F. et al. J Vasc Surg. 2012 Oct;56(4):1132-42. doi: 10.1016/j.jvs.2012.04.046.
17 McDermott MM et al. JAMA. 2018 Apr 24;319(16):1665-1676. doi: 10.1001/jama.2018.3275.

A dedicated smartphone app for the assessment of outdoor walking capacity in PAD people was developed on Android (Figure 11). The smartphone app – named ***SHERPAM AMWalC*** for Ambulatory Monitoring of Walking Capacity - enables the PAD participant to manage walking sessions through different dedicated graphical interfaces: i) entry of the targeted walking duration; ii) management of both Bluetooth connection with an external GPS receiver (Qstarz BTQ1000XT™) and satellites reception by the receiver; iii) automatic detection by the app of walking/stopping bouts using a specific algorithm; when a stop is detected a pop-up window together with a phone vibration is emitted. The participant indicates whether the walking stop was due to pain or not. If yes, the participant selects the pain level reached before to stop using a validated pain scale.

GPS data are continuously transmitted to the smartphone, which stores and then transmits the data to a distant aggregation server using available radio technology (e.g., Wi-Fi or 4G). At the end of the walking session a summary is shown to the participant and then is automatically sent to the medical staff. A WEB interface enables the medical staff to visualize and re-analyze data.

The App is currently under testing in a population of PAD people, through a clinical trial carried out as a part of the SHERPAM project.

The *SHERPAM AMWalC* app offers new opportunities against commercially available wearable monitors (e.g., Fitbit, Garmin, Polar, etc.): i) whereas consumer-level devices focus on metrics to assess physical activity (e.g., total daily steps), the *SHERPAM AMWalC* App enables the clinician to assess the walking ability of PAD participants, which is of clinical value here. For this purpose, specific algorithm for walking and non-walking bouts identification have been developed; ii) the identification of stops induced by lower limb(s) pain to specifically assess symptoms-limited walking periods is made possible; iii) Help and feedbacks to the PAD participants are provided to manage their walking session; iv) the use of a previously validated GPS receiver for health studies.

VALORISATION

The ***SHERPAM AMWalC*** smartphone app has been registered at the "*Agence pour la protection des programmes*" under reference IDDN.FR.001.450027.000.S.A.2018.000.31230, in April 2018.

The ***SHERPAM AMWalC*** smartphone app could be potentially implemented in a new and specific e-health platform that is under development at the University Hospital of Rennes. This e-health platform is funded in part by the "*Agence Régionale de Santé*" and is dedicated to the follow-up and the individual support of patients (not only PAD) in order to implement PA assessment or home-based walking programs. This partnership with the university hospital of Rennes could be a first way to disseminate the use of our smartphone app by: i) supporting the use of the app in a clinical context, and benefiting from a technical support; ii) initiating discussion about a potential industrial transfer with the start-up company that is implementing the e-health platform at the university hospital (Exolis® company).

Finally, the development of the ***SHERPAM AMWalC*** app has been valued by a funding of the SFETD ("*Société Française d'Etude et de Traitement de la Douleur*") and APICIL foundation. A postdoctoral funding has also been obtained to develop and improve signal processing methodologies in order to analyze the walking pattern of people with PAD. These new methodologies will be embedded in the app and/or in the web interface.

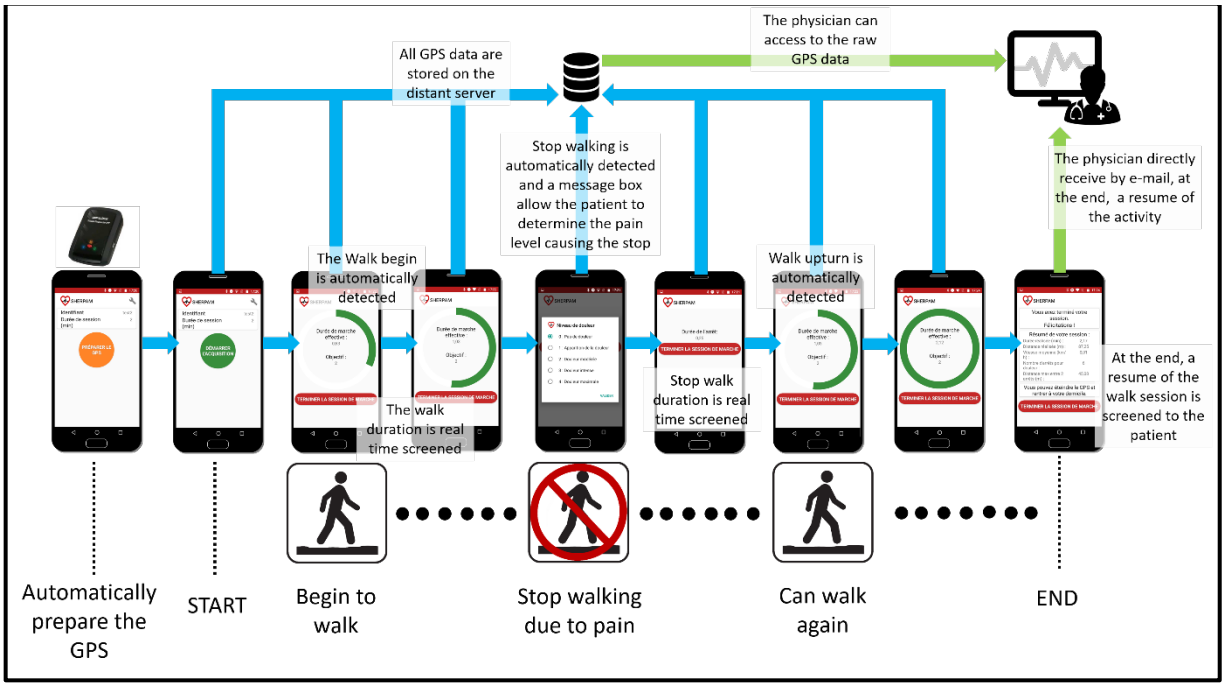

Figure 11 Schematic description of the SHERPAM AMWalC Android application and the corresponding data aggregation server.

6. SHERPAM IN BRIEF

SCIENTIFIC OUTPUTS

- Constitution of four different original databases: i) subjects in free-living activities, ii) people suffering from PAD during walking, iii) cyclo-tourism subjects and iv) patients suffering from cardiovascular disease.
- Design of a recognition system capable of identifying a variety of activities (rest, domestic activities, sports activity, walking, running, cycling, stairs) from data recorded in a free-living scenario.
- Proposition of a real-time Bayesian detector.
- Design of a robust estimation method for respiratory rate estimation based upon RMP and ECG.
- Proposition of a portable device to estimate ventilation during light to moderate exercises using the magnetometer plethysmography and machine learning strategies in dealing with patient diversity.
- Implementation of an agile disruption-tolerant transmission system for mobile health monitoring
- Conception of a web-server application for visualizing, processing, making decision on the collected data.
- Evaluation of the acceptability of the device in ecological situation with three types of users: healthy cyclo-tourist subjects, cardiovascular patients, people suffering from PAD.
- Modification of the features proposed by the SHERPAM application following the pre-tests of acceptability and usability of the device:

MAIN DOCUMENTS WRITTEN (OUTSIDE THE PUBLICATIONS)

- Coordination and writing of a clinical trial with three targets.
- Questioning the acceptability of the project as a whole and designing questionnaires of acceptability specific to the SHERPAM project.

- 3 Software Licenses at the APP. A fourth is currently under finalization.
- Co-design and drafting of a user manual of the device for the users whose objective is to favor the usability of the latter and thus not to affect the evaluation of its acceptability during its prolonged use.

AWARDS AND SOCIO-ECONOMIC VALORISATION

- Honorable Mention Award for the oral presentation in the International Conference on Ambulatory Monitoring of Physical Activity and Movement (ICAMPAM'17).
- The psychosocial methodology has been duplicated with two other projects of e-health devices (FEDER Sylver @Home, ANR ACCORD) with AZNETWORK and RF-TRACK companies.
- A first contact was established with Mindray company after conference Cinc2018 (consent agreement signed) for possible exchange of the respiration rate estimation algorithm.
- Running discussion for potential deployment of the SHERPAM AMWalC app at the University Hospital of Rennes, as a part of a Telemedicine project funded in part by the "*Agence Régionale de Santé*". Within this framework, point to point exchanges with Exolis® company were established.
- The SHERPAM AMWalC app has been valued by a funding of the "*Société Française d'Etude et de Traitement de la Douleur" and APICIL Foundation*
- Several relationships with associations were established (participation in the clinical trial): the cyclo-tourism association, the association Heart and Health.
- A collaboration with the Shandong Cancer Hospital is established (joint publications in CinC 19), for respiration prediction with PPG modulations in precise lung cancer radiation treatment, supported by the National Natural Science Foundation of China (grant 81530060)

UNIVERSITY TRAINING

- The SHERPAM project has allowed courses at the academic level to be implemented between some of the partners (ENS Rennes and LTSI). This educational collaboration will serve as a foundation in the implementation of an EUR project ("Ecole Universitaire de Recherche") in *Digital Sport Sciences*.

SCIENTIFIC PRODUCTION

- The scientific production is fully reported on the website and is presented:

https://SHERPAM.cominlabs.ubretagneloire.fr/publications;jsessionid=BE850B4A86A2FFF878160DD9FDFB589F