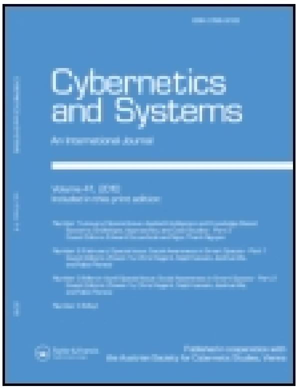

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Design and Development of a Mobile Cardiac Rehabilitation System

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Design and Development of a Mobile Cardiac Rehabilitation System

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In this article we present the design and implementation of a mobile cardiac monitoring system oriented to patients in Phase II and III of cardiac rehabilitation. The complete monitoring system involves both hardware and software design perspectives. At the hardware level, we present a T-shirt with a 12-lead ECG system and an embedded inertial sensor for the monitoring of activity and energy expenditure. At the software level, a modular cloud platform performs data processing to detect relevant cardiac events and to provide advanced visualization capabilities. As a case study, we have implemented our system at the Cardiac Rehabilitation program at Donostia University Hospital (Spain). Finally, the validation of the 12-lead ECG recording system is also presented and discussed.

KEYWORDS *activity monitoring, cardiac rehabilitation, ECG monitoring, mobile system, t-shirt*

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INTRODUCTION

Cardiac rehabilitation (CR) programs have been shown to be beneficial for improvement in mortality and morbidity outcomes (Taylor et al. 2004; Clark et al. 2005). They are oriented to patients affected by cardiovascular diseases (CVDs) such as coronary heart disease, myocardial infarction, or heart failure. CR programs have gained importance in hospitals and medical centers because CVDs are the leading cause of death all around the world and have a great medical and economical impact in our society. In fact, economists project that the worldwide cost of prevention and treatment of CVDs could amount to almost $47 trillion in the next 25 years (Laslett et al. 2010).

CR programs are based on four core components: exercise planning, nutritional counseling, risk factor management, and psychosocial interventions (Balady et al. 2007). In addition, they are divided into three separate phases differing in the level of supervision. Phase I begins right after the cardiac event, when patients are still under hospitalization; during this phase patients are under constant supervision due to their delicate condition. Phase II is initiated when patients are discharged; during this phase they have to return to the hospital three times per week to be monitored by physiologists in the CR department while performing certain exercises. Finally, during Phase III patients exercise on their own (i.e., unsupervised exercise) following the recommendations of physicians but maintaining periodic monitoring (Suaya et al. 2007).

CR programs are able to reduce further complications from CVDs. Moreover, exercise plans optimize patients' cardiovascular performance and restore their confidence. However, despite the importance of CR and of its aforementioned advantages, statistics show that a high percentage of patients are neither attending the CR sessions of Phase II nor following the recommendations for Phase III (Bethell et al. 2008). One of the main reasons is the commute to the hospital (McKee et al. 2013), because the time and effort required to attend the CR sessions discourages patients. Therefore, it is imperative to enable outpatient CR and provide systems that can monitor patients in the same manner as in a medical facility. In fact, outpatient CR is acquiring an increasingly important role (Suaya et al. 2007) because hospitalization periods are being reduced (Newby et al. 2000; Torp-Pedersen et al. 2011).

In our work we propose a mobile CR system that allows the remote monitoring of Phase II and III patients. Our solution is based on mobile devices worn by patients, which record data and send them to a cloud platform. The platform provides different services to physicians, who can access those data and visualize them in different views. In our approach, patients can perform the recommended physical exercises on their own, avoiding the commute to the hospital and maintaining the same level of supervision.

The goals of our system are to (1) minimize the commuting time of CR Phase II, (2) improve the monitoring of CR during Phase III, and (3) achieve a reduction in associated costs. For that purpose, our approach combines both software and hardware perspectives. At the hardware level we propose an easy-to-use wearable system that measures both the electrocardiogram (ECG) of the patient as well as physical activity and energy expenditure. At the software level we propose a modular cloud platform that analyzes these data with the aim of detecting relevant cardiac events and presenting them to physicians. Furthermore, the latter will be able to monitor more than one patient at the same time and, thus, the system will remain sustainable despite the increasing number of patients. Additionally, we have implemented the complete system, named GoCardio, as a case study in the CR program at Donostia University Hospital in Spain.

This article is structured as follows. Firstly, we introduce some background references relevant to CR platforms. Then, the general architecture of our mobile monitoring system is presented. Next, the current implementation of the platform is explained. Subsequently, the validation of one section our system is described and the future global validation test is discussed. Finally, conclusions and future work are summarized.

BACKGROUND

This section provides the reference background. It introduces the concepts of electrocardiography, physical activity estimation, and data and visual analysis techniques applied to cardiovascular data.

Electrocardiography

ECG allows a fast an accurate diagnosis of the heart's condition. It is based on the interpretation of the electrical signals generated by the exchange of ions during the heart muscle's contractions. An ECG system consists of (1) a set of surface electrodes attached to the skin to capture the electrical activity and (2) a device that amplifies and records these signals. The standard ECG recorded during the CR Phase I and II requires 12 leads (i.e., I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6). Each of these leads corresponds to a particular combination of the surface electrodes, and it allows viewing the heart's activity from a unique angle. The 12-lead ECG is essential for the accurate interpretation of particular arrhythmias and, significant changes in segments of the ECG signal may be isolated to a particular led set (Myers et al. 2009).

Most of the systems developed for clinical ECG signal monitoring (Shah and Anderson 2013) are expensive, bulky, and unpleasant for the patient; hence, they disturb the daily routines of the patient. On the other hand, some systems based on mobile devices and designed for portable monitoring have recently entered the market, such as Nuubo (Perez de la Isla et al. 2011), Vitaljacket (Cunha et al. 2010), and LOBIN (López et al. 2010). However, they are based on one- to five-lead ECG configurations, because they are mainly oriented as Holter devices. For the CR program, technological solutions providing the remote recording of the complete 12-lead ECG while being used by the patients on their own are still needed.

Activity Monitoring and Energy Expenditure

When a patient's ECG data are combined with a diary of the performed physical activity, physicians can analyze the recovery process and detect cardiac events that only appear under physical stress. For this reason, in the conventional CR, Phase II patients have to attend to CR sessions in which they are told at all times what exercise to perform. With the goal of achieving an out-of-hospital CR Phase II, it is imperative to develop a system that is able to autonomously detect the kind of activity that the patient is performing and its energy expenditure.

The most common and affordable method for automatic detection of the physical activity consists in using inertial sensors such as accelerometers or gyroscopes (Godfrey et al. 2008). Machine learning techniques can find patterns in the output data of these sensors and learn to distinguish among the physical activities with a high success rate (Mannini and Sabatini 2010).

On the other hand, the energy expenditure of a physical activity is measured in terms of metabolic equivalent of task (MET), which is the ratio of the metabolic rate during a specific physical activity to a reference metabolic rate (3.5 mL.kg^{-1}.min^{-1} by convention; Ainsworth et al. 2011). This ratio is obtained by measuring the oxygen cost of the activity and dividing it by the resting oxygen consumption of an average person. Nevertheless, it has been found that the MET can also be estimated by measuring the output of inertial sensors worn by the patient (Pärkkä et al. 2007; Staudenmayer et al. 2009).

As a result, with the data provided by one inertial sensor, a classification algorithm can predict the kind of activity that the user is doing, and a regression algorithm can estimate the energy expenditure. This methodology has been proven valid in both clinical settings and free-living environments (Jasiewicz et al. 2006; Saber-Sheikh et al. 2010).

Cardiologic Knowledge Mining and Visual Analytics

Due to the increasing number of CVD patients in our society, the time and effort required by cardiologists for a proper cardiac monitoring is overwhelming. Large amounts of cardiac data need to be analyzed per patient, where data analysis, classification, and visualization tools might reduce the required effort.

A wide range of ECG data analysis and classification approaches can be found in the literature (Bozzola et al. 1996; Hedén et al. 1997; De Chazal 2000; Goldberger et al. 2000; Moody and Mark 2001; Al-Naima and Al-Timemi 2009). The Research Resource for Complex Physiologic Signals (Goldberger et al. 2000) is one of the most famous, where different databases and software tools are provided to the scientific community: (1) PhysioBank, offering a large archive of characterized physiological signal digital recordings, for both healthy subjects and patients suffering from different pathologies; (2) PhysioToolkit, offering a library of open-source software for physiological signal processing, analysis, and display; and (3) PhysioNet, offering an online forum for the dissemination and exchange of recorded biomedical signals and open-source software.

Classification approaches for both ECG (Rodriguez et al. 2005) and activity signals (Mannuni and Sabatini 2010) have also been published. In particular, several authors have proposed classification methods applied to 12-lead ECG signals (Bozzola et al. 1996; Hedén et al. 1997; Al-Naima and Al-Timemi 2009; De Chazal et al. 2000). In our work we will reuse available open-source tools for signal analysis and classification and we will translate then to a cloud context.

We will also work on the development of new visualization paradigms for high-level cardiac data. Visual analytics, the science of the analytic reasoning supported by visual interactive interfaces (Wong and Thomas 2004), integrates new computational tools for visual representation based on cognitive, perceptual, and design principles. The application of visual analytics techniques to cardiologic data visualization is intended to improve the efficacy and efficiency of cardiac monitoring systems and to facilitate the human–information relation. During the last years, new theories and paradigms have been proposed (He and Wu 2001; Rajendra Acharya et al. 2002; Gregg et al. 2010). In our work, we will focus on visualizations that facilitate and accelerate the monitoring of several simultaneous patients.

PROPOSED ARCHITECTURE

In this section we propose a generic architecture for mobile CR systems, oriented to allow remote monitoring of cardiologic patients. We propose a five-layer architecture (depicted in Figure 1) that combines both the hardware and software requirements. The layers include the sensor layer, communications layer, data handling layer, application layer, and user layer.

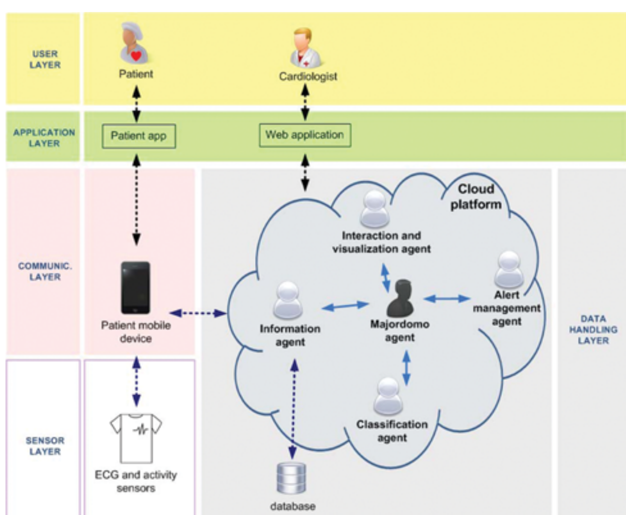

FIGURE 1 General architecture of the system.

The sensor layer contains the necessary sensors and electronics required to obtain ECG and physical activity information. For the acquisition of the former data, 10 wet sensors placed on the patient's torso will record the electrical activity of the heart (12 leads). These signals will be amplified and recorded by a special electronic system placed in a custom T-shirt. Physical activity will be recorded by an inertial sensor placed on the patient's hip.

The communications layer acts as a bridge between the sensor layer and the data handling layer. The data coming from sensors are compressed and sent to the patient's smartphone, which subsequently sends the data to the data handling layer located in a cloud platform. The communications layer is in charge of the communication channels and protocols between those layers. Because data transmission is the most energy-demanding task of the sensor layer, the data compression aims to improve the battery autonomy of the system.

The data handling layer is built in a cloud platform and it is in charge of storing and processing the data. Concretely, the tasks of this layer are to (1) store the data coming from the sensor layer; (2) analyze the ECG data, in combination with the physical activity information, to detect relevant cardiologic episodes defined by physicians; (3) handle the different alerts and recommendations based on the mentioned analysis; and (4) provide the required information to the application layer.

Following our previous work on architectures for decision support systems (Sanchez et al. 2013), an approach based on multi-agent systems is proposed in order to provide the needed modularity and scalability. More precisely, the aforementioned tasks of the data handling layer are assigned to five different agents (see Figure 1): (1) information agent, (2) classification agent, (3) alert management agent, (4) interaction and visualization agent, and (5) majordomo agent.

Interaction between agents follows a blackboard model (Craig 1995). The majordomo agent is in charge of the blackboard management and intercommunication of agents (i.e., it is the control shell of the blackboard system); hence, security- and synchronization-related issues are easily solved. The other agents are responsible for the main tasks of the layer. The information agent is in charge of the storing, accessing, and editing of the cardiologic and activity data of each patient. The classification agent examines these data to estimate the physical activity of the patient and, at the same time, to classify the relevant cardiologic events. The alert management agent scans the output of the latter agent in order to detect problematic cardiac episodes according to custom rules specified by the patient's physician. Finally, the interaction and visualization agent acts as a link between this layer and the application layer.

The application layer is in charge of the interaction between the users (patients and physicians) and the system. Patients will control the on–off switch of the system with an application installed on their smartphone. Moreover, should the need for guidance arise, this application will be able to help the patients with system setup. Physicians will be provided with a web application that, thanks to the interaction and visualization agent of the previous layer, will allow them to visualize the patients' ECG and physical activity data, get alerts from relevant cardiac episodes, and program

FIGURE 2 (Left) Patient placing the electrodes in front of a mirror. (Center) T-shirt with the electrodes and wires placed. (Right) T-shirt with the coat.

custom alerts. Lastly, the user layer encompasses the patients and physicians using the system.

SYSTEM IMPLEMENTATION

We have implemented the aforementioned architecture as a case study in the CR program at Donostia University Hospital in Spain. In this section implementation details of the system, named GoCardio, are presented.

Sensor Layer

The Integrated Circuit (IC) ADS1298 from Texas Instruments (Texas, USA, www.ti.com) was selected to obtain a 12-lead ECG. This device integrates eight instrumentation amplifiers with analogue-to-digital converters in one unique chip, as well as a serial peripheral interface for communication.

The 10 wet electrodes that correspond to a 12-lead configuration are placed as depicted in Figure 2. Two steps are needed to obtain the 12-lead ECG: Firstly, eight leads are obtained directly in the analogic domain and digitalized by the ADS1298 chip. Then, the other four leads are computed digitally combining the former ones. Table 1 presents the channel assignments and expressions to obtain each lead. The Wilson central terminal (WCT) is a virtual ground obtained internally in the ADS1298 chip by averaging in the analogic domain the electrodes E2, E3, and E4.

One of the key contributions during the implementation of the GoCardio system is the design of a T-shirt prototype, which is in charge of carrying the electronics and positioning the electrodes (depicted in Figure 2). Its main objective is to fulfill the requirements of usability and functionality of the system established by the clinical team.

The T-shirt consists of three parts. The first is the clothing (see Figure 2, left), which guides the patient to place the electrodes at the required locations. The second part (see Figure 2, center) encompasses the wires and the connectors. They follow a specific route to reduce the signal motion artifacts produced by the physical activity. This route was designed during the validation test described in the subsection Validation of the ECG Amplifier. The third and final part (see Figure 2, right) is a coat

TABLE 1 Assignment and Expression of Each One of the 12 ECG Leads

Leads obtained in the analog domain by the ADS1298		
1	Lead I	E3-E2
2	Lead II	E4-E2
3	V1	E5-WCT
4	V2	E6-WCT
5	V3	E7-WCT
6	V4	E8-WCT
7	V5	E9-WCT
8	V6	E10-WCT
Leads obtained directly in digital domain		
9	Lead III	Leads II-I
10	aVL	Leads I-II/2
11	aVR	-(Leads II + I)/2
12	aVF	Leads II-I/2

Note: E1 is used as ground.

that houses the electronics. It serves as an additional method to reduce signal motion artifacts.

Detection of the physical activity is done using the commercial sensor STT-IBS wireless inertial sensor manufactured by STT Engineering and Systems (San Sebastian, Spain; http://www.stt-systems.com/). The STT-IBS is a sensor with 9 degrees of freedom and includes three accelerometers (Ax, Ay, Az), three gyroscopes (Gx, Gy, Gz), and three magnetometers (Mx, My, Mz). This sensor is attached at the hip securely fastened to straps, in order to minimize motion artifacts. Data are sent to the microprocessor, which combines this inertial information with the ECG and sends the data to the mobile phone.

Communication Layer

Collected ECG and activity data are compressed using wavelets (Addison 2005) and sent by Bluetooth to the patient's smartphone. We propose the use of a Bluetooth 2.1 solution due to the fact that most mobile devices provide this communication protocol and its power consumption rate is suitable for this task. Subsequently, the smartphone sends data to the GoCardio Cloud Platform over 3G or Wi-Fi.

Data Handling Layer

A GoCardio Cloud Platform has been developed with Amazon Elastic Compute Cloud (Amazon EC2; Foster et al. 2008; Balduzzi 2012). Data generated in the sensor layer are encoded with JavaScript Object Notation and stored in a MongoDB NoSQL database (Chodorow 2013). These data are then classified by the platform. Three types of data processing are covered in our approach: (1) heartbeat classification, (2) activity classification, and (3) energy expenditure.

For heartbeat classification, a training data set was generated from the MIT-BIH Arrhythmia Database (Goldberger et al. 2000; Moody and Mark 2001). It consists of 48 records containing approximately 110,000 beats annotated and classified in 20 different classes. Feature extraction was performed with ecgpuwave, a well-known QRS detection and waveform limit location tool (Ashley 2004; Laguna et al. 1994). The heartbeat classifier was built with Weka (Hall et al. 2009) applying the C4.5 decision tree classifier, the IB1 nearest neighbor algorithm, and the naïve Bayes algorithm and measuring their accuracy with 10-fold cross-validation.

For the physical activity information processing two different neural networks are proposed (Staudenmayer et al. 2009). They are currently under implementation. The first one will detect the kind of activity that the user is doing among four different ones (i.e., walking, cycling, upper body workout, and lower body workout), and the second neural network will estimate the energy expenditure (METs). In order to train these neural networks, a database with example data is being created. This database is populated with data from 50 volunteers. During the acquisition session, each volunteer carries the STT-IBS inertial sensor and a portable gas analysis system to measure the oxygen consumption. The subject performs four different exercise routines while being supervised by a physician: (1) walking on a treadmill at different speeds and with different slopes; (2) cycling a stationary bike at different speeds; (3) upper body workout; and (4) lower body workout. Data coming from the inertial sensor are annotated for activity recognition and data from the gas analysis system are annotated for the energy expenditure estimation.

When risky situations are detected among the classified heartbeats and activities, alerts are raised by the system. For that purpose, a rule-based alert management system has been designed. Physicians can configure it by introducing the corresponding production rules. They follow an if—then—else structure and follow a rule syntax similar to RuleML (see Figure 3).

Application Layer

In the application layer, a physician-oriented web application has been implemented. It covers three levels: (1) prioritization of patients, (2) evolution of a patient, and (3) data from a patient's monitoring session.

The first level is responsible for the visualization of the state of the different patients at a certain time. The list of patients monitored by the corresponding physician

```
<?xml version="1.0" encoding="ISO-8859-1"?>
<RuleSet>
	<LoadRule>
		<RuleID>RT0001</RuleID>
		<Rule>If ( CLASS Beat with the PROPERTY Beat_Freq SMALLER THAN 50 ) then
			( CLASS Alarm with the PROPERTY Alarm_detected EQUALS TO Bradycardia )
		</Rule>
		<weight>100</weight>
		<AccordingTo>
			<classes>
				<class>GivenBySpecialist</class>
			</classes>
			<specialist>
				<specialistType>Cardiologist</specialistType>
				<specialistPlace>Hospital Universitario Donostia</specialistPlace>
```

FIGURE 3 Example of a rule.

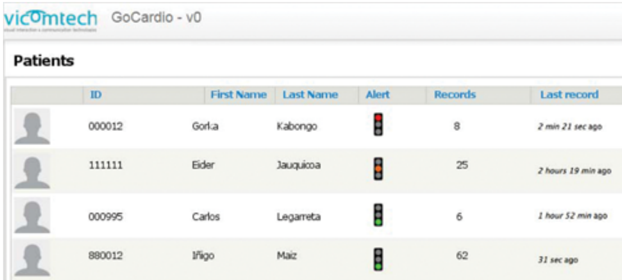

FIGURE 4 Patient selection UI.

is showed by the user interface (UI; see Figure 4). For each patient, various details such as name and ID are shown, as well as a traffic light, which encodes the risk associated with a patient and his health status by the red, yellow, and green colors. For a large number of patients, physicians will be able to prioritize medical efforts on patients with an associated higher risk.

The second level shows the graphical visualization of the evolution among different monitoring sessions of the selected patient in the previous level. In this way, a physician will know at a glance whether a patient is getting better or worse. The system also offers the possibility to filter the sessions both by date and by the alert level inferred from the risk of the anomalies detected in the recording. The physician can select a particular session for further analysis. Figure 5 shows a screenshot of an example UI.

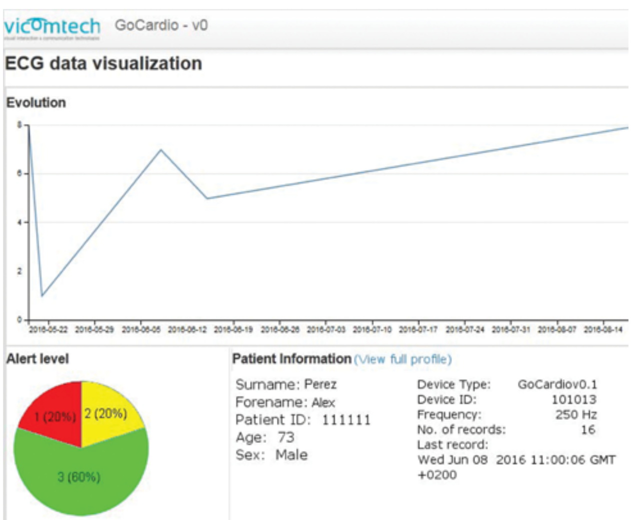

FIGURE 5 Summarization of ECG data of different sessions for a given patient.

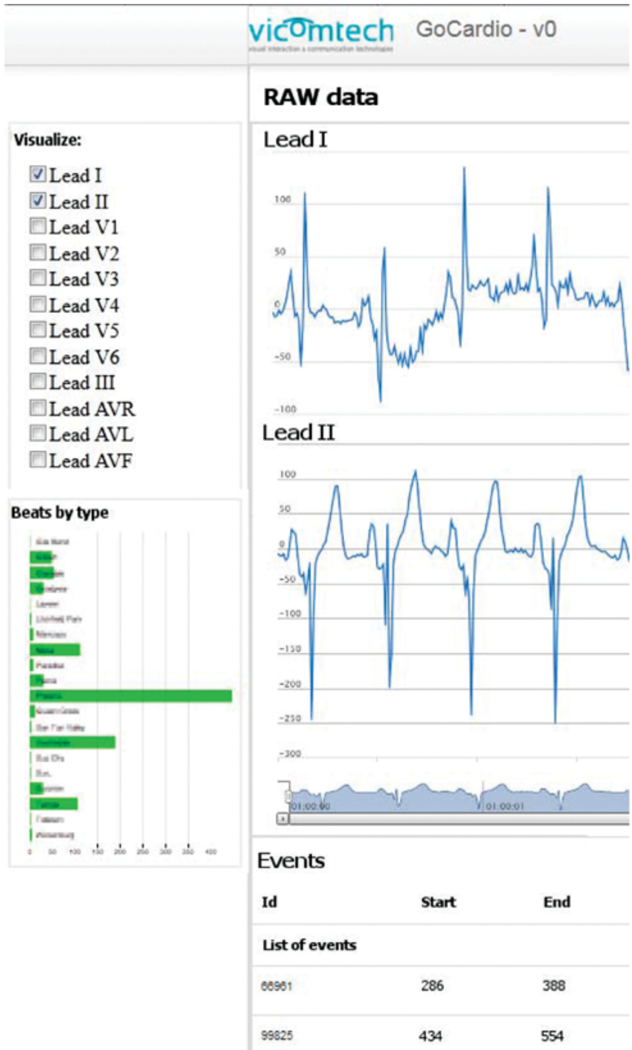

FIGURE 6 ECG visualization UI for a single session.

Level 3 shows the visualization of the data corresponding to a patient at a certain monitoring session (i.e., different ECG leads, activity information). Once the session to be analyzed has been selected, the system displays raw data of those leads that the user has selected in the left side of the UI. Figure 6 depicts a screenshot of an example UI. On the left side of the interface the distribution by type of classified beat is shown. At the bottom of the interface, detailed information about those classified beats and detected events is shown. Physicians obtain an overview of the entire session and have all of the information necessary to deepen the analysis of certain parts of the corresponding recording.

SYSTEM VALIDATION

In this section we focus on different levels of validation of the GoCardio system. First, the validation of the ECG processing unit is described, summarizing the most significant results. Then the test scenario planned for a complete validation of the GoCardio system is detailed.

Validation of the ECG Amplifier

Once the ECG acquisition equipment was set, a cardiologist approved the quality of the ECG signal under rest conditions. The behavior of the amplifier while the user was active was validated from measures of 11 volunteers, both male and female, under stress conditions while biking. The custom T-shirt described previously was not included in this study because it was under development at the time of the test. However, during this validation different wiring configurations were tested and the current one adopted by the T-shirt was selected, because it provided a higher signal-to-noise ratio.

Each volunteer executed the cardiac stress test twice. The first time, the stress test was executed while measuring the ECG using a commercial amplifier. The commercial amplifier was an adaptation for ECG of the BrainAmp amplifier provided by Brain Products GmbH (Gilching, Germany; www.brainproducts.com/). The second time, the amplifier developed for the GoCardio system was employed. As an example, Figure 7 shows a volunteer biking during the cardiac stress test and the V5 lead obtained with the commercial amplifier (top) and with the GoCardio one (bottom).

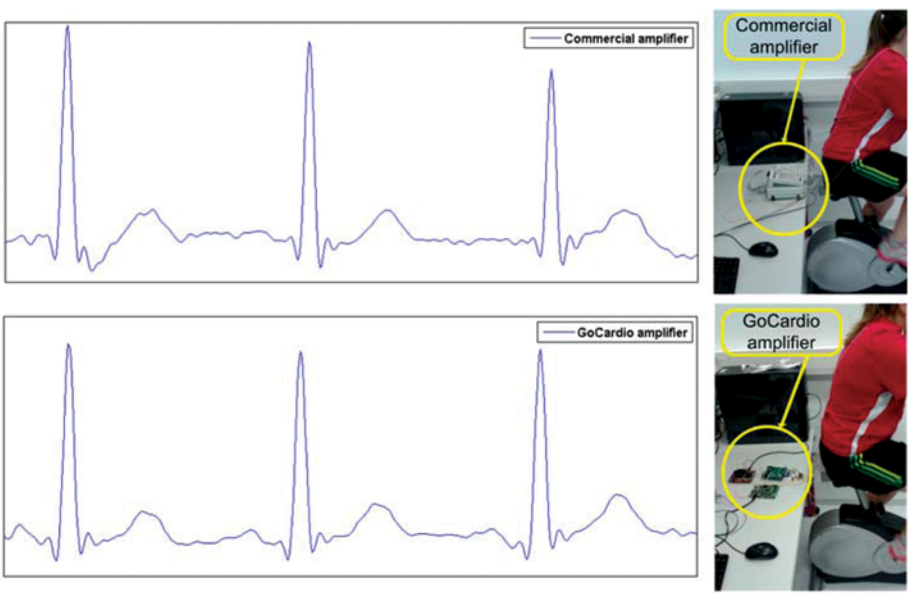

FIGURE 7 ECG signal obtained with the commercial amplifier (top) and GoCardio (bottom).

The signal-to-noise ratio of each amplifier was calculated in order to compare the quality between them. The registered ECG under PQRST segments was considered signal and the rest was considered noise. No statistically significant difference was found between the two amplifiers (11 subjects, paired t-test $p = 0.7341$), suggesting that the GoCardio amplifier provides standard development results in accordance with the Quality Management System (DIN ISO 13485).

Regarding the ECG signals captured while the user was performing physical activities, it was observed that they were strongly affected by (1) the movement of the volunteer, (2) the location of the electrodes, and (3) the path followed by the wires. These aspects were taken into consideration for the design of the T-shirt, which is expected to improve the quality of the measured ECG.

Beyond this first experiment, once the T-shirt is manufactured, future tests will be carried out in order to validate the whole sensor layer under final conditions.

Validation of the Complete GoCardio System

To validate the complete GoCardio system, a test scenario was designed that will be conducted in the forthcoming months. The aims are twofold. Firstly, it will provide an independent data set to validate the physical activity recognition and energy expenditure estimation algorithms of the data handling layer. Secondly, physicians will evaluate GoCardio as a valid tool in terms of performance, usability, and utility of the platform.

Forty patients (20 men, 20 women) from Donostia University Hospital (Spain) will participate in the experiment. These patients are in Phase II and III of the CR process, and they are of different ages and physical conditions.

During the test, each participant will carry the complete sensor layer of the GoCardio system (i.e., the ECG recording system, the T-shirt, and the inertial sensor) and a portable gas analysis system to measure the oxygen consumption. The test will consist of four different exercise routines that are actual workouts of the hospital's CR program: walking on a treadmill at different speeds and with different slopes; cycling a stationary bike at different speeds; upper body workout; and lower body workout.

Data will be processed in the GoCardio cloud platform and the physicians will evaluate the performance of the application. In addition, the classification rate of the physical activity classifier and the accuracy of the energy expenditure estimation system will be assessed.

CONCLUSIONS AND FUTURE WORK

We have presented a complete CR monitoring system that covers both hardware and software perspectives. Our approach allows patients to perform physical exercise on their own while they are monitored with the same rigor as in the conventional CR of Phase II. In this way, commuting to the hospital is avoided, which is the most problematic aspect of CR and the main reason for its lack of success. From a clinical perspective, our system enables a supervised monitoring of CR of Phase III.

Additionally, hospital resources are reduced in terms of equipment (e.g., treadmills, static bikes) and staff (e.g., physicians, nurses).

At the hardware level, the proposed solution involves an inertial sensor fixed to straps and a 12-lead ECG recording system, whose electronics are housed in a custom T-shirt. The setup of the sensors can be done by patients with no external help, thanks to the straps and the T-shirt. In addition, they reduce the motion artifacts that are generated by the wires and electrodes while the patient is exercising.

At the software level, a cloud platform based on a multi-agent systems paradigm was proposed. ECG and activity data are stored in it, and different classification and interaction services are offered. The platform is able to detect the kind of activity that the user is doing and the intensity level. The combination of this information with the 12-lead ECG will provide physicians with tools able to detect cardiac events and to analyze the evolution of the patient. Furthermore, the cloud platform assists them by automatically detecting these events and by reducing the amount of time required to process the data in a multipatient scenario.

Finally, in this article an implementation of the designed platform was presented. The technical aspects of each level are described and explained, and the validation test performed for the 12-lead ECG recording system is shown.

As future work, the complete developed platform will be validated with real CR patients in a clinical setting. This validation will be twofold. First, the remaining technical aspects will be validated, such as the accuracy of the physical activity estimator or the reliability of the cardiac event detector. Second, physicians will evaluate the system in terms of usability and utility. Finally, an economic impact analysis will be conducted with real data in order to compare this novel cardiac rehabilitation method against the conventional one.

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