

Pre-clinical physiological data acquisition and testing of the IMAGE sensing device for exercise guidance and real-time monitoring of cardiovascular disease patients

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Abstract— Non-invasive monitoring of a patient's vital signs outside the medical centre is essential for the remote management of chronic cardiovascular diseases (CVD), such as Heart Failure (HF) and Coronary Artery Disease (CAD). In this work we present preliminary results from pre-clinical testing of the IMAGE sensing platform, a wearable device which we designed for wireless real-time data acquisition and monitoring of CVD patients' physiological responses, primarily while they are exercising. The device is capable of acquiring and on-board processing 3-lead electrocardiogram (ECG) and bioimpedance measurements, obtain multi-sensor oxymetry data as well as record torso movement and inclination. Pilot testing has so far primarily focused on optimising the hardware and experimental protocol, using healthy volunteers, while comparative trials against the gold standard 12-lead ECG Bruce protocol treadmill stress test have also started. A planned clinical study involving CVD patients is expected to commence within the next few months and provide more detailed experimental results, as part of a research and development effort into real-time exercise guidance and early-warning alert generation for patients and clinicians. The IMAGE device has been developed within the HeartCycle consortium, a biomedical engineering project co-funded by the EU 7th Framework Programme.

Keywords— Wireless Real-Time Data Acquisition, Portable Sensors, ECG, Bioimpedance, Oxymetry.

I. INTRODUCTION

Multiple research efforts have confirmed the importance of regular exercise during the rehabilitation phase of medical treatment for CAD patients [1]. Analysis of 22 randomized trials involving more than 4000 patients showed a reduction of 20% -25% in both general and cardiovascular-related mortality among patients receiving exercise-based rehabilitation after a myocardial infraction, compared to controls not receiving rehabilitation treatment [2].

Advances in information technology have made it possible for monitored and guided physical exercise during the CAD rehabilitation period to take place at home, with increased safety, convenience and other added benefits for patients, clinicians and the healthcare system [3]. Several

portable, wearable and even ingestible systems involving sensing and onboard signal real-time processing have been developed in the past three decades, in the framework of academic and industrial research projects [5, 6, 7]. More recent versions of such systems are typically capable of acquiring physiological signals, storing the data, transparently extracting and evaluating vital parameters in near real time, and in some cases generating alerts aimed at the patients, their carers or both.

Increasing hardware integration, miniaturization and power autonomy of such medical data acquisition devices enable their end users to incorporate them into their lifestyle, dramatically improving the amount and quality of acquired data. This approach is adopted by the EU FP7 co-funded project HeartCycle [8], which aims at the development of closed-loop, personalized, home care services for cardiac patients. The portable and wearable HeartCycle system enables physicians to telemetrically obtain readings from their patients while they are working, resting, exercising or sleeping in their regular surroundings, away from the medical centre.

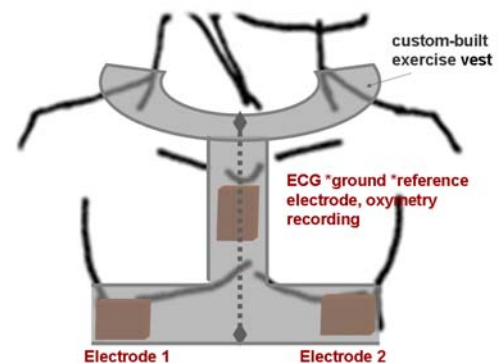


Fig. 1: The HeartCycle IMAGE sensor platform comprising the data acquisition electronics and elastic underwear vest.

The integrated data acquisition hardware platform developed within HeartCycle aims to provide a variety of medical measurements, acquired by multiple sensing devices.

Activity and lifestyle measurements such as time spent walking, lying down or running, the amount of oxygen contained in a subject's blood at any given time, fluid accumulation in the body, pulse and breathing rates are all measurements of particular interest to cardiologists how are monitoring the recuperation progress of their patients.

One of the main research and development directions within the HeartCycle project is for a guided exercise (GE) system, which will be capable of providing feedback information and real-time guidance to post-myocardial infarction (MI) patients while they are following their rehabilitation exercise program. Exercise in this respect helps preserve the patient's quality of life while augmenting their physical endurance and improving prognosis.

GE helps patients adhere to the prescribed exercise regimen, maximise their cardiovascular fitness and integrate fitness maintenance in their daily routine. It furthermore enables healthcare professionals to monitor patients' progress and compliance, as well as to timely alert the patients themselves should medical necessity arise. While exercising, the acquired physiological signals are processed in real time and pertinent advisory messages are generated for the patient, ensuring that the exercise is carried out at an optimum balance between effectiveness and health safety.

Initially, a healthcare professional selects an appropriate exercise plan, which is subsequently updated based on acquired physiological information, questionnaires completed by the patient and a medical expert's evaluation of the patient's overall health condition. The patient exercises while the system constantly monitors whether the workload, heart rate and breathing frequency are within the personalised safety and effectiveness thresholds, determined for each individual based on their health status and personal goals.

During the post-exercise recovery phase the rate of change in the user's vital signs is evaluated in order to assess fitness and cardiovascular risk and the user receives summary feedback on the exercise. The acquired data is analyzed on the basis of adherence to the target, intensity, duration, and effectiveness. The user's fitness level is updated and the weekly exercise plan altered accordingly. The overall progress and physiological parameter trends are made available to both the user and authorised carers.

The data acquisition system consists of the wearable *IMAGE* device, a custom-designed elastic exercise underwear vest, a wearable palmtop digital assistant (PDA) functioning as a short-range wireless interface between the user and the *IMAGE* device, and a *Patient Home Station* which manages patient questionnaires and reports, assesses overall health status and acts as a longer term data repository and transmission station.

The aim of this work is to present preliminary results from pre-clinical hardware optimisation testing of the

IMAGE wearable sensing system carried out in the Laboratory of Medical Informatics of the Aristotle University of Thessaloniki (AUTH) Medical School (Greece).

II. METHODOLOGY

A. *The IMAGE multi-sensor data acquisition device*

The *IMAGE* integrated sensing device developed within the HeartCycle consortium, is a platform aiming to achieve the aforementioned targets. It incorporates a 2-lead electrocardiograph, bioimpedance measurements and 3D accelerometry into a versatile wearable device which is worn on the chest using a specially designed elastic sleeveless shirt developed by another HeartCycle partner, the Finnish company Clothing+ (*fig. 1*).

The *IMAGE* sensing device is capable of acquiring data for time intervals longer than 8 hours, on board data processing and storage, as well as wireless transfer of acquired data to a nearby palmtop digital assistant (PDA) in near-real time using the IEEE 802.15.4 transmission protocol. The wearer of the device, be they a physically exercising subject or a heart-failure patient under medical observation, is kept within the information loop via their portable PDA device such as a smart mobile phone. User alerts are generated to alert or motivate the user and maintain a log of their daily physical activity, for instance regarding the estimated duration and quality of performed daily exercise, unusual trends in fluid accumulation in the chest or excessive stress suffered by the cardiovascular system.

While a user wears the *IMAGE* device and shirt, the data acquisition system records multiple-channel raw ECG, bioimpedance, oxymetry and gyroscopic acceleration signals. The raw signals are stored in internal memory, while also being processed in real time in order to extract additional parameters such as heart rate, breathing rate and activity intensity. Further processing attempts to automatically determine the type of activity being performed, evaluate the consistency (and therefore quality) of incoming signals, as well as generate instructions and motivational messages for the user.

B. *Experimental setup and protocol description*

The *IMAGE* device is at an advanced prototyping stage and is currently being pre-clinically tested by CSEM SA (Switzerland), AUTH (Greece) and the VTT Technical Research Center (Finland), all partner institutions within the HeartCycle consortium. The AUTH team is contributing to the hardware troubleshooting and optimizations and has established a pre-clinical trial protocol involving primarily healthy subjects. The protocol involves lying, sitting, standing, walking, running and static cycling activities and has

been designed to be experimentally compatible with standardized stress tests used by clinicians as diagnostic tools for heart failure and other cardiopathy patients. The IMAGE device is currently undergoing evaluation and will consequently be concurrently validated against regular cardiography equipment, on healthy subjects undergoing standard cardiac stress tests. This research is expected to be followed by further guided exercise clinical trials planned within HeartCycle.

One of the main issues the pre-clinical evaluation team is facing with the IMAGE device has been the presence of noise in the raw ECG and bioimpedance signals. Such noise can occasionally reach amplitudes greater than the signal itself and overwhelm the signal processing algorithms, thus finding its way into the extracted physiological parameters, such as the heart rate, breathing rate and oxymetry estimates. This is due to poor or unpredictable conductance of the dry electrodes and several possible causative factors are currently being investigated. The fact that noise levels vary during different types of physical activity, involving the same subject and setup, points to electrode movement due to vibrations, inconsistent electrode pressure applied by the underwear vest, skin sweating causing signal saturation, as well as dirt, grease and body hair altering conductivity on different skin patches of the same subject. A recent firmware update has improved the embedded signal processing algorithms, while experimentation with the placement of the electrodes on the body, the tightness of the elastic underwear vest and improved offline signal processing are all being used in order to alleviate the problem.

The latest November 2009 firmware update (v0.3 build 761) delivered noticeable improvements on the reliability of the ECG quality index and activity classification algorithms. The latter has since been correctly identifying the exercise activity most of the time, with the exception of cycling (under development).

III. RESULTS:

A male subject (35 years old) participated in a mostly outdoor exercise session for approximately 30 minutes. The routine comprised 2 min lying, 2 min sitting, 4 min walking, 3 min brisk walking, 7 min running, 4.26 min walking, 2.04 min sitting and finally 2 min lying. The device was running an older version of firmware (v0.2, build 686). Graphs based on acquired data from this test are presented in *fig. 2* and *fig. 3*.

The activity classification algorithm running as firmware onboard the IMAGE device correctly identified the type of activity performed by the subject (lying, sitting/standing, walking or running) most of the time. Most errors involve brisk walking which is occasionally mistaken for running, a

programming issue currently being resolved. Automated classification of additional types of physical activity, such as stair climbing and cycling, is being developed.

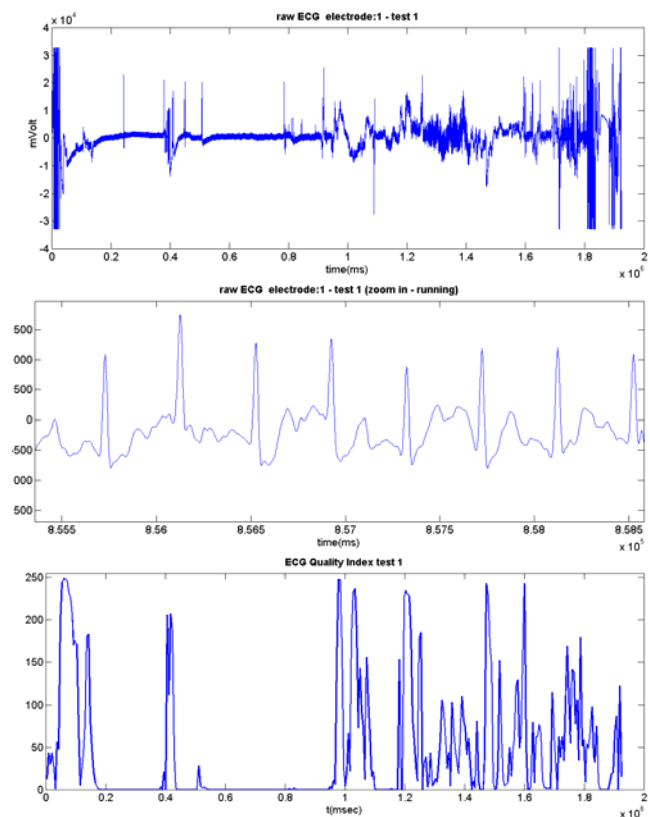


Fig. 2: A single electrode raw ECG recording of a half-hour exercise session (top), an 8-heartbeat detail of the same signal (bottom) and an estimated ECG signal quality index (based on both ECG leads; on a scale 0-255, 0=best).

Among the IMAGE sensor is the HR calculated from recordings from both ECG electrodes. Using the average of the same signals, HR was also calculated using the Physiomet algorithm with a sampling rate of 7 sec. The results from both methods can be seen in *fig. 3* (bottom).

During a second experimental session involving an updated version of the IMAGE device (firmware v0.3 build 761), the same male subject followed a slightly modified exercise routine (2 min lying, 2 min sitting, 10 min walking, 10 min running, 10 min walking, 2 min sitting, 2 min lying). Oxygen saturation measurements were obtained in this session, using the electrode placed below the throat area.

A third exercise session involved a female subject (40 years old) static cycling for 14 minutes. Periodic noise artifacts were present in the ECG data obtained from one of the electrodes, a problem which was subsequently tracked down

to cabling problems. The raw ECG and extracted BR data from both IMAGE electrodes can be seen in *fig. 3* below.

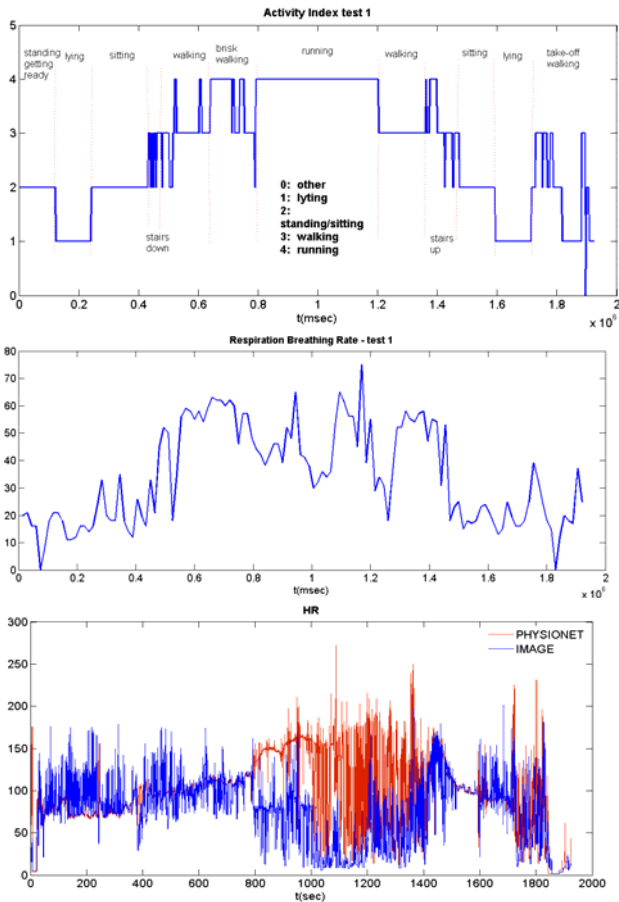


Fig. 3: Activity classification (top), breathing rate (middle) and heart rate (bottom), as estimated in real time by algorithms embedded in the IMAGE device. The bottom graph superimposes HR extracted by an offline algorithm running on a PC, based on single electrode data.

IV. CONCLUSIONS & FURTHER WORK

The IMAGE system, partly comprising a wearable dry electrode prototype device capable of acquiring multiple-channel physiological data for cardiovascular diseased patients, is being developed, improved and validated using healthy volunteers and gold standard medical data acquisition procedures. A pre-clinical evaluation experimental protocol was developed for this purpose, designed to identify noise, accuracy and reliability issues with the hardware and embedded firmware. The results show that the system is capable of acquiring, storing and processing multiple-channel ECG, bioimpedance and oxymetry measurements,

as well as wirelessly transmitting them to a base station in real time. There are several impediments being addressed at this prototyping stage, mostly involving noisy raw signals due to movement artefacts, saturation of the dry electrodes from sweat and the need to optimise a consistent level of pressure applied by the elastic exercise vest. Comparative signal processing between the firmware and offline algorithms indicates that there is additional room for improvement on the signal processing level, particularly for heart rate extraction.

Further work will involve more consistent exercise workloads by focusing more on indoor treadmill and static cycling, in order to obtain more reproducible and comparable –albeit less realistic– experimental results. Furthermore, comparative clinical testing of the IMAGE device against 12-lead ECG equipment undergoing the gold standard Bruce protocol treadmill stress test is already under way involving healthy volunteers and is expected to include CVD patients within the next few months.

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