

# Development and Clinical Evaluation of a Physiological Data Acquisition Device for Monitoring and Exercise Guidance of Heart Failure and Chronic Heart Disease Patients

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## Abstract

The HeartCycle EU research project aims to provide disease management solutions for cardiac patients. Developed within HeartCycle, IMAGE is a wearable device capable of acquiring ECG, bioimpedance, and acceleration measurements. The acquired signals are stored in onboard memory and processed, while the results are wirelessly transmitted in real time to a base station. Base station processed data is subsequently used to provide patients with real-time feedback during safety-sensitive recuperation exercise periods (guided exercise). While development of IMAGE is ongoing, evaluation of *existing prototypes' performance in clinical, domestic and outdoors environments* is also underway. In this work HR and BR comparative analysis results are presented based on standard treadmill stress test experiments (BRUCE protocol). A commercial portable device and gold standard 12-lead ECG stress test equipment are used in parallel with IMAGE for comparative purposes.

## 1. Introduction

Several studies have shown that regular and structured exercise during a cardiac rehabilitation program is beneficial for coronary artery disease (CAD) patients, with respect to both general and cardiovascular related mortality [2]. Monitored and guided physical exercise through e-health technology enables CAD rehabilitation 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 biomedical research [4, 5, 6]. These technologies bestow added value

upon pervasive healthcare applications, home care, etc, towards unobtrusively monitoring patients' health status anytime anywhere.

HeartCycle, a European Union FP7 co-funded project [7], aims at the development of closed-loop, personalized, home care services for cardiac patients, including remote monitoring of patients' vital signs using portable and wearable sensing systems. A guided exercise (GE) system being developed within HeartCycle will provide real-time feedback and guidance information to post-myocardial infarction (MI) patients while they are following their rehabilitation exercise program. Real-time processing of the acquired physiological signals enable the generation of advisory messages and alerts for the patient, increasing both the safety and effectiveness of exercise. The processed data will also enable healthcare professionals to monitor patients' progress and compliance.

A healthcare professional initially selects an appropriate exercise plan which can subsequently be updated. The patient exercises while the system constantly monitors whether the workload, heart rate and breathing frequency are within a safe and beneficial zone. This personalised performance zone is determined for each individual based on their health status and personal goals. Acquired data is analysed to show adherence to performance targets, intensity, duration and effectiveness. The overall progress and physiological parameter trends are 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 long term data repository and transmission station.

The aim of this work is to present results from pre-

clinical hardware optimisation testing of the IMAGE wearable sensing system carried out in the Lab of Medical Informatics of the Aristotle University of Thessaloniki. The points of investigation are: a) the partial and overall differences in quality from another portable system in the context of exercise in HeartCycle, b) the differences from the clinical golden standard in stress-test recordings, c) limitations, pitfalls and recommended improvements for the IMAGE sensing system under stress-test conditions.

## 2. Methods

An experimental setup and protocol were prepared in order to evaluate the performance of the IMAGE prototype sensing device against other wearable and gold standard electrocardiography (ECG) equipment. The sensors of primary interest are skin potential for ECG and heart rate (HR) extraction, bioimpedance for breathing rate (BR) extraction and 3-axis acceleration in order to determine posture and identify the nature and intensity of physical activity. The IMAGE prototype was designed with enough on board microcontroller computing power to be able to perform basic signal processing, including HR, heart rate variability (HRV) and BR extraction as well as posture and activity assessment.

### 2.1. The sensing devices - equipment

The 2<sup>nd</sup> generation IMAGE sensing device comprises two plastic, sealed electronic compartments, one containing the battery and the other the onboard electronics. The compartments are physically interconnected with each other via power supply and control lines. Each possesses a skin contact area with double metal electrodes (**Figure 1**). The system is capable of acquiring, amplifying, filtering, recording and wirelessly transmitting (via Bluetooth) physiological data to a user interface application running on a palmtop digital assistant (PDA). The data is produced by 3-axis acceleration, bioimpedance and ECG voltage sensors. Several models of custom-designed washable textiles have been developed and are currently being evaluated, aiming to maximise signal quality and wearer comfort.

The Zephyr Technologies (NZ) BioHarness BT is a commercially available wearable sensing device capable of measuring 3-axis acceleration, BR, ECG and skin temperature and is capable of wirelessly transmitting data to a PC via Bluetooth. It is supplied with a washable, wearable strap containing integrated fabric electrodes. It was selected for comparative study with the IMAGE device prototype because –unlike gold standard 12-lead ECG devices- it is wearable, power-constrained and does not rely on disposable adhesive electrodes, thus qualifying as a valuable additional comparative standard.

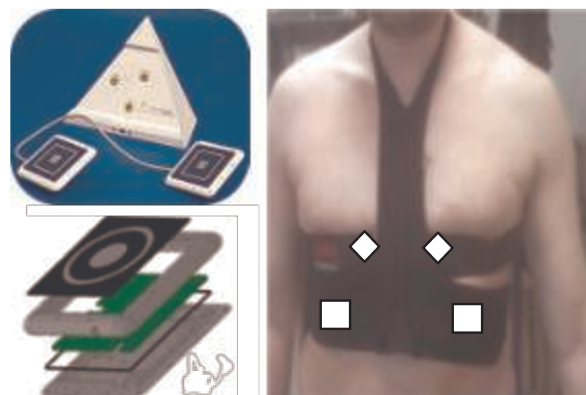


Figure 1: Anti-clockwise from top left, the IMAGE sensing device and cradle; anatomy of the electronics electrode compartment; male subject wearing both IMAGE (electrode placement indicated by boxes) and the BioHarness device (electrodes indicated by diamonds).

### 2.2. Experimental protocol

16 healthy volunteers were drafted to perform a BRUCE protocol gold standard cardiological stress test. The test was performed under constant medical supervision using a treadmill interfaced to a 12-lead wired ECG manufactured by Mortara Instrument, Inc (USA). The leads were attached to disposable adhesive electrodes containing conductive gel. Age, weight and height were recorded for each subject, while all subjects declared that they had not had a meal in the 2 hour period prior to undertaking the test. 12 subjects were male and 4 female, the age range being 26 – 41. Certain torso and neck length measurements were additionally obtained from each subject in order to improve the design of the textile vests used to attach the IMAGE device.

The stress test was terminated by the supervising physician when the subject reached a HR value somewhere between 80% and 100% of the maximum target calculated according to the BRUCE protocol, based on the subject's weight and age. Stress test termination was seamlessly followed by a 5 minute active recovery period during which the treadmill rolled flat at a slow walking speed of 1.5km/h.

Data was concurrently recorded by the Mortara 12-lead ECG equipment, the IMAGE prototype being tested and the BioHarness device used as a comparative standard for wearables. One of the researchers along with the supervising physician maintained time stamped voice and written annotations throughout the trial. The ECG sampling rate for the IMAGE device was set at 250Hz at 16 bit precision and 25Hz at 16 bits for bioimpedance. The averaging windows for HR and BR extraction were 5.5sec and 15sec respectively. The BioHarness sampling rates were 250Hz for ECG and 100Hz for bioimpedance.

### 2.3. Analysis

In order to investigate data quality from signals acquired by the IMAGE prototype system, the processed data was analysed vis a vis the other two devices. ECG comparisons were performed among all three devices, whereas extracted BR was compared only between IMAGE and BioHarness. Data from two subjects (subjects: 5,8) was deemed inappropriate for the present study due to inappropriate placement of the IMAGE device which lead to lost contact with the subject's body during the stress test.

Statistical tools such as CDF plots and Kolmogorov-Smirnov tests have been employed to describe the distributions corresponding to the differences in HR and BR values extracted by each of the sensor devices.

### 3. Results

Result analysis is based on HR and BR data extracted from the raw signals recorded by each device. In the case of the wearable sensor devices, the signal processing took place by algorithms running on board the devices in order to maintain realism and provide meaningful conclusions.

Table 1 shows the mean and standard deviation of the differences in extracted HR values per subject. Mean1 and std1 refer to values obtained by IMAGE minus BioHarness data, while mean2 and std2 refer to values produced by IMAGE minus golden standard data (Mortara 12-lead ECG). Significant deviations can be observed for subjects 1, 6 and 9.

Table 1. Mean and standard deviation of the difference in HR values recorded by IMAGE and Bioharness.

subject	mean1	mean2	std1	std2
1	16.1	28.36	37.93	54.05
2	-3.03	0.27	5.47	7.57
3	-1.36	0.97	5.63	5.99
4	-0.33	0.29	2.74	2.65
6	1.47	36.63	13.43	16.53
7	-0.04	0.86	6.23	4.9
9	13.09	15.25	28.32	25.19
10	-1.11	0.69	2.95	1.95
11	-0.44	-0.52	1.48	5.14
12	-0.24	-0.11	3.5	2.82
average	2,41	8,266	10,766	12,679

Concerning subject 1 the recordings were in all likelihood affected by profuse sweating, which was noted in the experimental annotations at the time. Subject 9 had very thin body for the textile garment used to attach the IMAGE prototype, cotton balls were used to keep the sensor devices fixed in their position, resulting in inadequate attachment to the body. Subject 6 had to use

an alternative 12-lead ECG system manufactured by General Electric (USA), which may be partly responsible for the observed deviation for the particular subject.

Table 2. Mean and standard deviation of the difference in BR values obtained by IMAGE and BioHarness.

Subject ID	mean	std
1	-6.92	7.91
4	-7.73	5.88
10	-6.21	9.26
11	4.34	7.8
12	4.93	9.69
average	-2,318	8,108

In order to obtain a quantitative and qualitative overview of the difference distributions mentioned in tables 1 and 2, cumulative distribution function (CDF) plots were employed for each set of signals. F(x) is the cumulative percent and defines the proportion of the distribution with values less or equal to x-axis values. The CDF plots can be used to extract the median (50th), 75th, and 90th percentiles from each distribution.

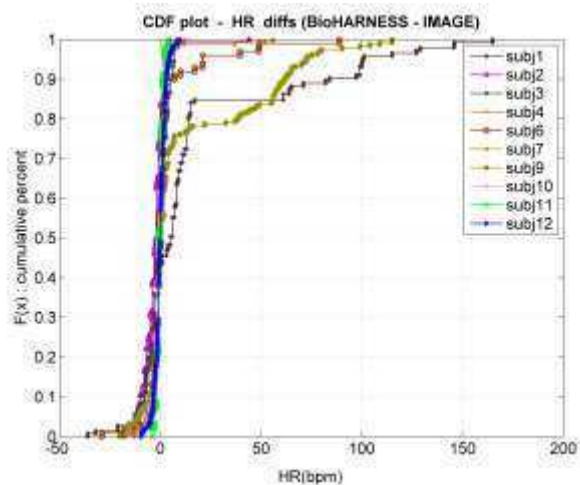


Figure 2. CDF plots per subject of HR difference distributions between the wearable sensing devices [BioHarness (HR) - IMAGE (HR) ]

HR values recorded with the General Electric system (subject 6) from a rather different distribution. The median value for most of the distributions is positive, while a 2-sample Kolmogorov-Smirnov test indicated different distributions ( $p < 0.05$ ).

In Figure 2 we can see that about the 80% of the distributions have values in the range [-10 +10]. The distributions are primarily negative, which indicates constantly higher HR values recorded by the IMAGE device in comparison with the HR obtained by BioHarness.

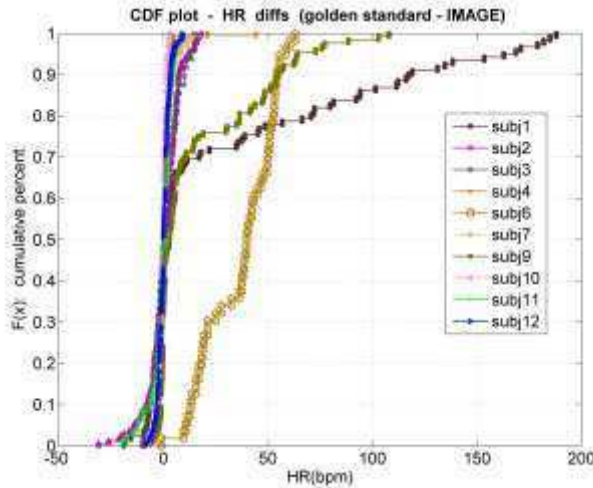


Figure 3. CDF plots per subject of HR difference distributions between the gold standard 12-lead ECG equipment and the IMAGE prototype sensing device [gold standard (HR) - IMAGE (HR)]

Evidence supporting this assessment is provided by the fact the median value of all distributions in Figure 2 is negative. A 2-sample Kolmogorov-Smirnov test shows that the distributions do not have the same structure ( $p < 0.05$ ), indicating that the different recordings from the two devices are not regular for every subject.

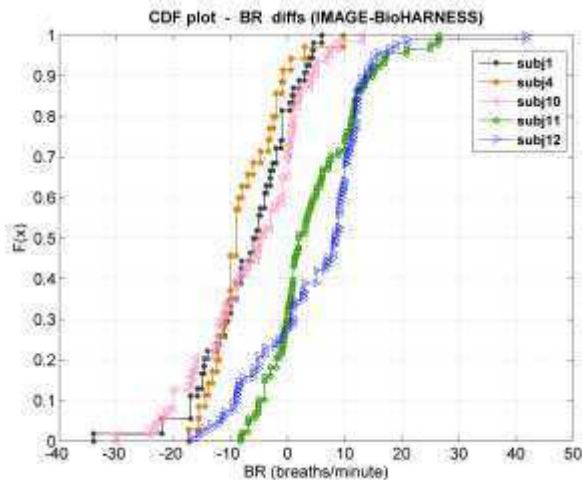


Figure 4. CDF plots per subject of BR difference distributions between the two wearable sensing devices [BioHarness (BR) - IMAGE (HR)]

Figure 4 and Table 2 show significant differences concerning BR values. The proportion of contributions corresponding to negative values is due to the IMAGE device generally providing lower BR values than the BioHarness. Two-sample Kolmogorov-Smirnov test indicated again different distributions ( $p < 0.05$ ).

The textile vests used to attach the IMAGE device, as

well as the BR extraction algorithms are constantly being improved, partly using feedback from this study. It needs to be noted that assessment precision for BR recordings is also hindered by a large difference in the averaging signal processing window between the two wearable systems, an issue currently being addressed.

#### 4. Conclusions & further work

Evaluation of IMAGE device recordings versus a commercial portable device and gold standard 12-lead ECG stress test equipment indicated satisfactory correlation in HR values, despite the fact that IMAGE is at a prototype development stage. Our experimentation indicates that most of the deviations among the signals were due to poor attachment of the IMAGE device on the body, focusing design efforts on further improving the textile vests as well as the on board BR signal processing algorithms. Further investigation using the next generation textile vests should further clarify this matter.

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