

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

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The HeartCycle project is a European biomedical engineering research effort aiming to provide disease management solutions for heart failure and chronic heart disease patients, including co-morbidities such as hypertension, diabetes and arrhythmias. Developed by some of the authors within HeartCycle, IMAGE is a microcontroller-based, power-autonomous, 3-lead wearable device, capable of acquiring 2-channel ECG, 2-channel bioimpedance, 3-channel gyroscope acceleration and oxymetry measurements. The acquired signals are stored in onboard memory and processed, while the results are transmitted in real time via a wireless IEEE 802.15.4 link to an interface base station, such as a properly equipped PC or PDA. Processed data is available to clinicians wishing to continuously monitor their patients, as well as to patients requiring real-time feedback during safety-sensitive recuperation exercise periods (guided exercise). IMAGE is worn by the patient using purpose-designed undergarment vests while design choices allow for smart fabric washable electrode development in the future. While development of IMAGE continues, evaluation of existing prototypes performance in clinical, domestic and outdoors environments is also well underway in three HeartCycle partner sites. In the Medical School of the Aristotle University of Thessaloniki (Greece) IMAGE was initially evaluated by means of outdoors exercise routines involving 4 healthy volunteers, followed by similar experimentation entailing indoors exercise. Subsequently, gold standard BRUCE protocol treadmill stress test experiments were performed using a commercial portable device (Zephyr Bioharness BT) for comparative analysis. Parallel testing involving gold standard hospital equipment and chronic heart disease patients is planned next. Results to date show good correlation of the heart rate and breathing rate signals from the two devices, using both the onboard and off-line Matlab algorithms (typical mean HR difference  $< 4.48$ , BR  $< 0.87$ ).