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# Towards Closed-Loop Personal Health Systems in Cardiology: the HeartCycle Approach

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***Abstract*—HeartCycle is a large-scale EU integrated project aiming to provide a complete disease management solution for cardiovascular disease patients, with emphasis on Heart Failure (HF) and Coronary Artery Disease (CAD) patients. The project develops innovative technologies and services to facilitate remote management of patients at home and motivate them to be compliant to treatment regimes and to adopt a beneficial lifestyle. HeartCycle aims to develop a personalised care system, integrating care at home with professional care in the hospital embedding health delivery feedback loops both at the professional and patient levels. In this paper, we present the three major systems that HeartCycle consists of, namely, the Heart Failure Management system, the Guided Exercise system, and the Assessment system. For each of these systems we summarise the current research and development efforts conducted, as well as the challenges faced towards their embodiment in actual healthcare delivery.**

## I. Introduction

HeartCycle is an EU large-scale integrated project aiming at researching, developing and validating innovations for the next generation of disease management systems. The HeartCycle Consortium involves 20 partners from 10 European countries, demonstrating a balanced multidisciplinary team of industrial partners, research institutes, academia, and medical hospitals. The project started in March 2008 and has a total duration of 48 months.

Research and development in HeartCycle is structured in such a way to cover a number of complementary issues that are needed to be developed for the final system to be operational and tested, taking into account besides scientific and technical aspects, application concepts and business development including socio-economic analysis. More specifically, the technical work involves dealing with the development of the necessary sensors and parameter extraction methods, a sophidticated multi-parametric analysis framework along with decision support models, as well as the infrastructures at the patients' and the professionals' sides (the so-called patient and professional loops).

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In essence, HeartCycle started from the application viewpoint by investigating, analysing and validating the needs of patients and professionals for specific disease management solutions. During the first two years of the project, the goals have been to establish the process allowing to create and further develop its major concepts (use cases) in a way that the insights gained are accepted by the stakeholders of both medical community and business, as well as to use these concepts so as to develop requirements and specifications for the innovations used in the clinical validations, while at the same time commiting further research on all the technical aspects elaborated in the project.

Based on the identified needs, the following major concepts have been developed: (a) *Disease management* for heart failure (HF) patients including health maintenance and medication management; (b) *Guided Exercise* for coronary artery disease (CAD) patients, and (c) *Assessment procedures* for both patient groups, including innovative sensor measurements, personalized healthcare processes, as well as risk stratification strategies. For each one of the above concepts, a separate system is proposed as part of a generic platform for remote disease manegement for cardiovascular patients.

Currently, HeartCycle is developing, implementing and validating the above concepts to a maturity level that allows their operation and embodiment in clinical test beds. Important aspects in this regard involve testing the technical feasibility, the user acceptance in CAD and HF groups, and the innovative manner to deliver improved healthcare to patients and reduce workflow for professionals, presented by the HeartCycle concepts.

In this paper, we present the major concepts and components as regards the research and development activities withing HeartCycle.

## II. The HeartCycle Concepts & Components

### A. The Heart Failure Management System

The Heart Failure Management system in HeartCycle is based on the commercial platform Motiva®, developed by Philips. Motiva® is an interactive healthcare platform that connects patients with chronic conditions (e.g. chronic HF) to their healthcare providers via the home television and a broadband Internet connection. Motiva® automates disease management activities and engages patients with personalized daily interactions and education delivered

through the home television. The system enables healthcare providers to motivate behaviour change through user-friendly technology, helping them to meet their goals as regards improved patient compliance, telehealth program efficiency, and lower healthcare costs [1].

In addition to automated vital sign monitoring, patients are supported by: (a) *educational material* delivered as videos, with topics relevant to their individual healthcare needs; (b) *actionable feedback* about vital sign measurements to help patients track progress toward personal goals; (c) *motivational messages* from caregivers to help encourage healthy lifestyle choices for diet and exercise; (d) *health related surveys* that evaluate patients comprehension, motivation, and self-efficacy levels, providing also subjective information to the remote caregiver about their current health status.

All members of the care team can access the clinical application to review the patients' guidelines-based careplan defined at enrolment, the trended survey responses, and the vital sign measurements. A care manager can monitor the health status of many patients, and is alerted if vital parameters or survey responses indicate a need for follow-up.

The Heart Failure Management system has been designed based on an off-the-shelf solution (Motiva®), in order to take advantage of the offered functionalities. Nevertheless, adaptation of some of them and additions of new features has been perfomed according to the requirements of the project-depicted vision. The main tasks of the Heart Failure Management system are to provide therapy to the patient, and to provide education and coaching. To some extent, the content of the therapy and the education and coaching is determined automatically by the system, but involvement of human care professionals remains essential. This model is depicted Fig. 1.

Patient data are collected by letting the patient measure vital body signs and fill-in questionnaires. These data are processed by the system locally at home, resulting in direct feedback messages. In addition, patient data are also shown to the care professional, who interprets them and may decide to change the therapy (e.g. reduce the Beta Blocker dose) or to advice particular education or coaching. For reasons of manageability, the work has been split in the following major parts (Fig. 1):

(a) The *Education & Coaching* part [2], which defines how the system educates and coaches HF patients on a variety of topics. These topics may be related to background information (e.g. the cause of HF, or tips for travelling) or to self-care behaviours (e.g. medication adherence, nutrition, or physical activity). The approach is based on the one proposed by the NHS Heart Manual [3], in which patient is given choice and control, and where the patient selects the topics that he/she would like to address.The goal of this section is to describe the approach for education and coaching in the Heart Failure Management system and the relevant clinical study.

(b) The *Patient Data Collection* part, which defines symptom-related questionnaires, the measurement of vital body signs, and the direct feedback. To offer the appropriate care, the system and care professional should know whether the patient has particular symptoms. For the HF trial, symptoms such as breathlessness, oedema, chest pain, and so forth have been identified.

(c) The *Therapy Messages* part, which defines the detailed therapy-related messages to be given to the patient (e.g. reduce the Beta Blocker dose). These inform the patient about changes in his/her medication treatment or other therapy-related topics (e.g. blood tests).

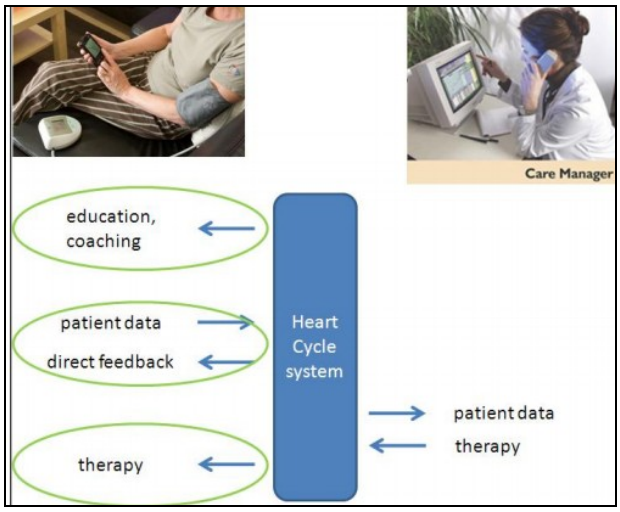


Fig. 1. HeartCycle Heart Failure Monitoring Functionalities.

### B. *The Guided Exercise System*

In the patient loop side [4], the patient is equipped with an exercise shirt that contains the IMAGE sensor, which collects patient's vitals during the exercise. The vitals are transmitted in real-time to the Portable Station (i.e. a PDA) that patient is carrying with him. This Portable Station contains the algorithms that are able to process the vitals collected from the sensor and, based on the patient exercise plan, provides feedback to the patient during the exercise. The transmission of data from the IMAGE sensor to the PDA is done via Bluetooth, while the synchronization of the PDA after exercise with a Patient Station (i.e. a PC) is done using wired synchronization (traditional PDA-PC synchronization using a USB cable). The Patient Station contains algorithms for trend analysis and exercise plan management (within boundaries defined by the medical professional). Moreover, the patient station also contains motivational and educational content that patient can access (which is authored by the medical professionals).

The Guided Exercise system architecture at the patient's side is divided into two main parts: software that runs on the user's personal computer (i.e. the Patient Station) and software that runs on the PDA that connects to the IMAGE

sensor (i.e. the Portable Station). The IMAGE sensor is depicted in Fig. 2.

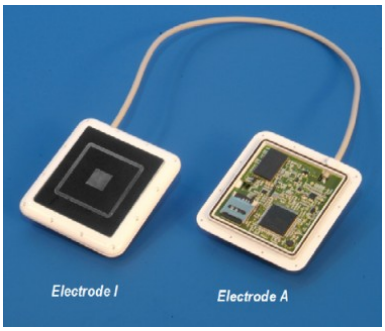


Fig. 2. The IMAGE sensor used in the Guided Exercise system.

The features offered by the algorithms encapsulated in the Guided Exercise system are targeting at: (a) *Pre-exercise testing of signal quality*, so as to check the signal quality before an exercise session and verify that the ECG signal is of acceptable quality for analysis; (b) *Online guidance*, aiming to guide the patient during an exercise session so that exercising is safe and beneficial for his health (Fig. 3); (c) *Post-exercise analysis*, aiming to address aspects such as arrhythmia detection, compliance to exercise plan (frequency and sessions), etc.

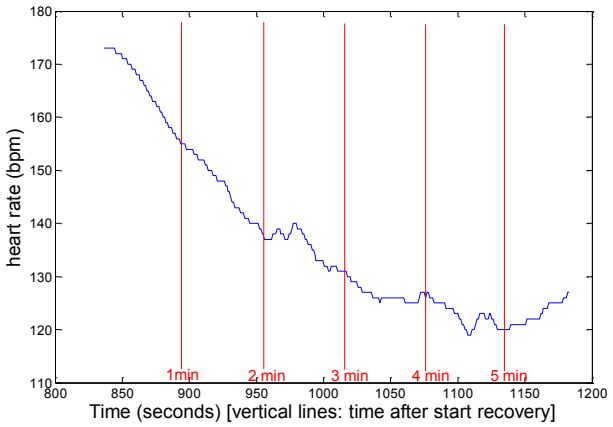


Fig. 3. Detection of adverse events using heart rate (HR) decline for a CAD patient during the Exercise Recovery phase.

The Graphical User Interface of the Patient Station has been intuitively implemented following an iterative process and consists of the following sections:

(a) *Messages* area, i.e. including mails from the physicians and reminders for activities, like filling questionnaires or reading educational content;

(b) the *Calendar*, allowing patients to check their compliance to the scheduled plan, and comprises a monthly view or a daily view;

(c) the *Exercise*, allows patients to have an overview of their exercise plan, as well as to personalize the plan. They may also track their progress per week or overall;

(d) the *Learning*, through which the patient is provided with a manual with educational material divided into chapters (Fig. 4).

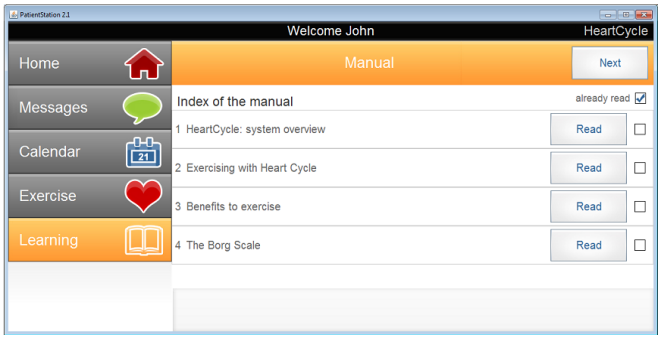


Fig. 4. Mock-up screen of the patient interface as regards available educational categories in the Guided Exercise system.

## C. *The Assessment System*

The Assessment System has been designed to reflect the innovative aspects of the many components developed in HeartCycle and aims at illustrating what the future generation of closed-loop systems may look like, from when the patient is enrolled in the telemonitoring system at the hospital, to the regular telemonitoring routine a patient will follow.

This has been done by defining a number of interesting and relevant clinical applications for HF patients, which are in the process of being developed into a clinical decision support system using both data from innovative sensors developed in HeartCycle, as well as data from other sources such as electronic health records. The output of the decision support system will provide advanced health assessments and thereafter advanced, clinically sound and reliable therapeutic recommendations (i.e. for treatment adaptations or further health status investigations) for the user of the telemonitoring system (mainly the healthcare professional), focusing on cardiac conditions and comorbidities.

Fig. 5. Bio-impedance sensor embedded in the HF vest.

In addition to the innovative sensors (such as the bio-impedance sensor [5], depicted in Fig. 5) and the advanced algorithms [6-7] embodied in the decision support system, the integrated system includes components in both the personalized patient loop and the advanced professional loop, as illustrated in Fig. 6. This includes clinical applications based on haemodynamic assessment, analysis of

sleep heart rate for the assessment of adverse events and comorbidities. In parallel, efforts will focus on innovative approaches for cardiovascular risk and status assessment, modeling of treatment effect, and the assessment of compliance and effectiveness of past treatment plan, related to 'Patient passport' concept, accompanied by attempts to incorporate context information, personalization and learning in the background intelligence.

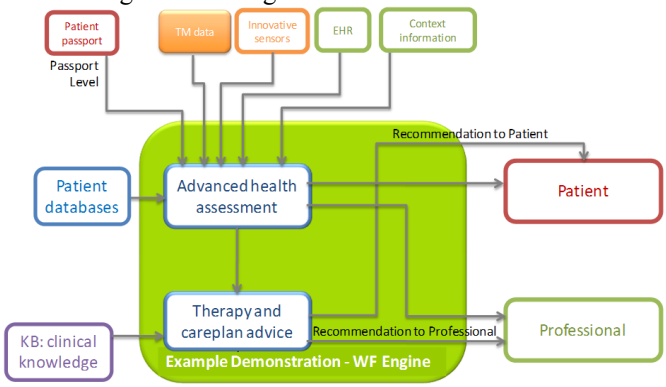


Fig. 6. High-level architecture of the HeartCycle Assessment system.

Unlike the Heart Failure Management and Guided Exercise systems, the Assessment system will be presented and explored together with patients and professionals in a controlled environment to obtain extensive and formalized quantitative and qualitative feedback.

In the course of shaping an advanced decision support system, various clinical applications, centred on the needs of HF patients, were identified as having potential for combining the information from the innovative sensors and requiring advanced algorithms, as well as having clinical relevance for Hf patients. Among these applications are arrhythmias, sleep disorders [8-9], haemodynamic tailoring, etc.

## III. Conclusion & Future Work

Clinical trials of the Heart Failure Management and Guided Exercise systems are about to start. Most of the algorithmic work for these trials has been completed. Final tuning and validation of algorithms will be carried out when the results of the trials become available. As the Assessment system has been relatively recently defined, a number of its components are still in the development stage. The validation of its components will be two-fold, i.e. individual validation of each component/block as deemed appropriate and possible for each task, and integrated prototype validation in two clinical centres. The integrated Assessment system will be presented and explored together with patients and professionals in a controlled environment to obtain extensive and formalized quantitative and qualitative feedback.

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