

# HeartCycle: Compliance and Effectiveness in HF and CAD Closed-Loop Management

Harald Reiter, Nicos Maglaveras, *Senior Member IEEE*

**Abstract**—HeartCycle is an integrated project aiming to provide a disease management solution for cardiovascular disease patients. The project develops technologies and services to facilitate the 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 an overview of the technological challenges that are under research and development in the HeartCycle project shall be presented and their possible implications on the personalized health concept shall be addressed.

## I. INTRODUCTION

In the EU cardiovascular disease (CVD) kills around 1.9 million people every year, with associated annual health costs estimated at EUR 105 billion. Around half of these deaths occur in people who previously have had a heart attack. Most of them will develop heart failure before they die. There are currently around 10 million heart failure patients in the EU and it is one of the commonest medical reasons for hospitalization in adults.

Finding better ways to manage and treat coronary artery disease (CAD) and chronic heart failure (CHF) is therefore seen as one of the most effective ways of reducing the human cost and financial burden of these debilitating conditions.

### A. Telemonitoring

Telemonitoring for patients is one of the most promising applications and already a well-developed field of research. However, there is still room for future improvement and important challenges remain to be addressed. Using daily measurements by the patients that give reliable information of the health status, telemonitoring has the potential to detect upcoming events by trend analysis early in time and generate smart alerts. Being alerted, the treating physician can react

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H.Reiter is with Philips Research Europe, 52066 Aachen, Germany (e-mail: harald.reiter@philips.com).

N.Maglaveras is with the Lab of Medical Informatics, The Medical School, Aristotle University of Thessaloniki, 54124 Thessaoniki, Greece ( e-mail: nicmag@med.auth.gr).

accordingly and prevent a deterioration of the health status of heart failure patient and a possible hospitalisation.

### B. Situation today and problem of adherence

Current treatment of HF and CAD entails recommendations from clinicians on medication, diet and lifestyle. Patients only receive feedback at doctors visits, or when facing symptoms. Daily monitoring, close follow up, and help on treatment routine is lacking. Adherence (also called compliance) describes the extent to which a patient follows agreed recommendations from a physician, nurse or other health practitioner. Many people with chronic illnesses have difficulty adhering to their recommended regimes [1, 2]. Non-adherence to the treatment regime is a major cause of suboptimal clinical benefit. The National Pharmaceutical Council estimates that non-adherence with medication adds over 100 billion dollars annually to the U.S. health care system. Eleven percent (11%) of hospitalisations are estimated to result from poor adherence with prescribed medication [3]. Patients with or at risk for coronary artery disease or congestive heart failure and who were classified as non-adherent were twice as likely to die as those who were adherent [4].

## II. THE HEARTCYCLE PROJECT

### A. Consortium and project overview

The HeartCycle consortium involves 18 partners from 10 different countries. It is a balanced multidisciplinary consortium of industry (including Small and Medium Enterprises), research institutes, academia and medical hospitals. The project started in March 2008 and has a total duration of 48 months. It is one of the largest biomedical and healthcare research projects in the European Union with a budget of about 21 million €.

The project is structured in 9 work packages covering a number of complementary issues that are needed to be developed for the final system to be operational and tested. Thus the R&D work includes parts dealing with application concepts and business development including socio-economic analysis. Four technical work packages are dealing with the development of the necessary components for the application work package based on the application requirements. The four technical work packages are dealing with

- Sensors and Parameter Extraction
- Multi-parametric Analysis and Decision Support

- Patient Loop
- Professional Loop

Two other work packages are responsible for the clinical validation of the HeartCycle solutions and the knowledge management.

### B. The HeartCycle Approach

HeartCycle aims to develop a personalised disease management care system, integrating care at home with professional care in the hospital. The system aims to support heart failure patients and coronary artery disease patients. The approach will follow a closed-loop disease management concept that consists of two loops (Figure 1). An inner home-based loop directly interacts with the patient in his daily life, giving feedback, motivation, and tailored help. An outer loop involves medical professionals, maintaining a personalised care plan for optimal therapy.

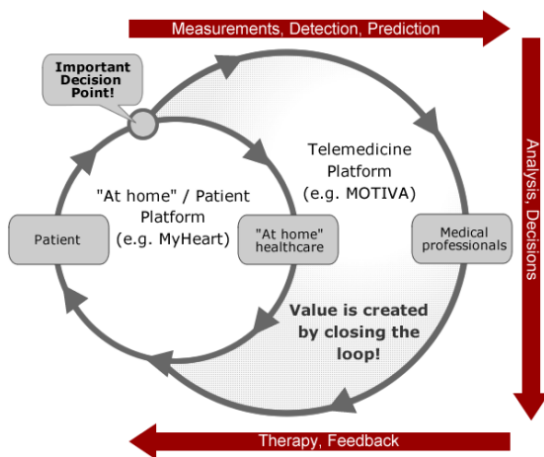


Figure 1. Patient and professional loop, allowing patients to be supported and motivated in their homes, and professionals to react timely in order to optimize therapy.

The overall concept is based on following elements:

- Vital body signs monitoring and multi-parametric analysis will be used to assess and track the health status of the patient and the impact of the current treatment.
- This daily analysis of the patient status by means of unobtrusive and easy-to-use wearable sensor technologies will allow for a much more frequent and earlier adaptation of the therapy than in the traditional care system.
- Appropriate feedback to both, patient and professionals on the current health status as well as on the modeled future health status will show the patients the importance of being compliant to the treatment, motivating them to improved treatment adherence and a more active role in their care.
- In case of unfavorable trends and by detecting upcoming health problems, adverse event alarms will

be generated for immediate professional attention and an automated decision support system will derive therapy recommendations from the information acquired.

The major objectives of the project are:

- Improve Disease Management in CVD
- Improve Compliance in CVD Treatment
- Develop a Health Status Assessment for Patients at Home
- Enable smart Vital Body Sign Sensing
- Measure Medication and Lifestyle Effectiveness
- Closing the Loop
- Model Cardiac State Prediction, Lifestyle and Medication Effectiveness
- Design a Decision Support System for Closed-Loop Management
- Improve User Interaction Techniques
- Develop the CVD Management Technical Platform

### C. Technical work overview

The four technical areas that are the project's backbone are the following:

#### 1) Sensors and Parameter Extraction

The Sensors and Parameter Extraction part of the project will provide the hardware and software that will be used for sensing and extracting the features needed for the patient and professional loops, addressing the requirements from the applications. To assess the health status the HeartCycle systems will use multi-parametric monitoring of vital signs and additional information from biochemical markers, questionnaires, and context information. It is one of the most challenging tasks to integrate the HeartCycle technology seamlessly into the patients' daily routine, therefore special solutions are needed e.g. unobtrusive sensors will be built into the patient's clothing or bed sheets. Some physiological signals will be measured using textile and wearable sensors, based on MyHeart and other EU projects outcome and experience. In this area we will also investigate new sensing technologies for parameters such as continuous blood pressure, oximetry, non-contact electrocardiogram and heart sounds. Some of the developed sensors will be prototyped for the clinical validation, while continued research will be pursued for more challenging sensors. It is important to note that patients don't have to wear the sensors for measurements 24 hours a day. To avoid bothering patients excessively, for the moment, and during the sensor development and adjustment phases the interactions with the HeartCycle system are limited. HeartCycle will optimize the number of needed measurements and interactions with the patients during day and only acquire data at e.g. 15 minutes for the morning and evening

measurements.

### 2) *Multi-parametric Analysis and Decision Support*

This technical part develops the models to derive medication and lifestyle effectiveness and a compliance indicator from the multitude of measured parameters (vital signs, symptom questionnaires, context information), which in combination reflect the current patient health status. One of the challenges is to find the appropriate choice of parameters as well as their combination for the purpose of the effectiveness analysis. In addition, we will also investigate and derive the conclusions/decision support from the parameter analysis, for use in the patient closed-loop system and in the professional system. One of the most innovative scientific issues of the project however is on modeling the patient-specific physiological effects of medication and lifestyle by combining information from different sensors in an appropriate way and drawing conclusions on patient compliance. These conclusions will be fed into a decision support system that will not only model the current medical guidelines for heart failure [5, 6, 7] and CAD management [8, 9, 10] but also new concepts for better lifestyle (activity, nutrition, stress, sleep) and medication management.

### 3) *Patient Loop*

This technical task models, designs and develops the patient loop, which is the home platform to provide the users with a system to self-manage their health status and to educate them to adopt a healthy lifestyle. The system will be personalised for real users, adjusting the protocols to their personal daily routine according to their capabilities and needs. The system will show the health development of the patient, including parameters for which a clear correlation with the patient's treatment adherence and effectiveness is visible. Vital body signs (e.g. ECG, weight, blood pressure, bio-impedance) will contribute to medication and lifestyle (nutrition, activity, stress and sleep) management. Motivated by seeing the affects of his actions, and aided in following the complex treatment program, the patient compliance will increase, and health status will improve. Appropriate motivation strategies will therefore play a crucial role for addressing the compliance. The patient platform enables the integration among all actors and modules, gathering all information from the sensors, monitor the health status, provide feedback to the patient and enable the communication with the professional platform.

### 4) *Professional Loop*

The HeartCycle system will investigate requirements of the professional loop involving the medical professionals, alerting them of the need to revisit the patient's care plan, and of possible adverse events. The professional loop connects with existing hospital information systems, in order to ensure

optimal and personalised patient care. Thus within this technical area we will develop a scalable open standard technological platform, which enables the implementation and time to market deployment of remote management services such as the ones defined and specified by the users' requirements. The design of the professional loop will be based on the concepts of the WHO for the Management of the Chronic Condition [13].

### D. *Current R&D status*

#### 1) *Application research – Generating and validating insights by stakeholder feedback*

To ensure demand and applicability of the project results in real health care systems, the consortium has tested the proposed HeartCycle solutions in interview rounds with patients and professionals. The interview results have been used as input for two 3-days workshops, one on patient needs, the other on professional needs and expectations. HeartCycle-internal and external medical experts (nurses, treating physicians, cardiologists) have been invited to start with a detailed analysis of the requirements of a new and more intelligent generation tele-monitoring system from a patient as well as from a professional point of view.

#### 2) *Information and Communication research*

The technical work has continued to investigate the technical approaches, the technologies to be developed and to prepare the specifications based on the requirements delivered by the application experts. The initial goal is to define and select the sensors and parameters needed for the assessment of the patient's health status and trend analysis, as well as to research and test parameter measurements and methods for assessing medication effectiveness and compliance, and to develop concepts for their realization.

At this moment, the IMAGE sensor is already developed and it is a wearable textile patch capable of embedding measurement devices such as ECG recorders and other vital signs and signals micro sensors. The IMAGE sensor is expected to be distributed and tested within the clinical pilot sites within the next few months for issues of useability and accuracy of measurements. Further, according to the user requirements a lot of research and development is devoted into the issue of the development of sensors that measure bioimpedance as well as PTT based blood pressure measures.

In the multiparametric decision support system, at the moment new methods of modeling of trends of vital signs and signals (such as e.g. body weight and blood pressure for heart failure patients) and exploring alarming mechanisms as well as combination of new sources of information dealing for example with worsening heart failure patients are currently under active development and testing, for further use into the new generation of more intelligent telemonitoring systems.

### E. Expected outcome and Impact

HeartCycle aims in principle to research and develop innovative improvements for the next generation of more intelligent telemonitoring systems and will conduct validations via test beds implementing the proposed solutions in real patients' homes. Besides showing effectiveness of the proposed innovations, we aim at demonstrating that the technical monitoring and user interaction solutions can be used by patients with minimal medical assistance in their homes, not compromising quality of health care delivery. It will be of upmost importance that the HeartCycle solutions deliver reliable measurement results and health status assessments where medical professionals can base their decisions on. This is a prerequisite for closing the loop and enabling efficient healthcare and cost effective disease management. Furthermore strategies to motivate patients to be compliant will be tested against control groups. In addition, the HeartCycle system will allow closer monitoring of the effects of medication and lifestyle, making more personalised treatment plans possible.

The project will thereby contribute to abolish one of the main obstacles that are still hampering the success of current tele-medical disease management systems: insufficient patient compliance. Previous studies like e.g. the TEN-HMS study [14] have shown that such disease management systems, if accepted by the patients, can reduce mortality by up to 30% and can save billions of Euros for the European healthcare system.

It is also very important for this project to show how the new generation of personal health systems (PHS) is going to evolve. The HeartCycle PHS aims to affect the whole concept of intelligent telemonitoring and health delivery by introducing quality control of clinical care plans among others, that could have a profound effect on the Medical Device Industry and the Information and Communication Technologies (ICT) for health industry and related regulatory and industrial bodies such as IEEE and CONTINUA for example.

Regarding the time frame of the project, the first three years are dedicated to the research and development of the ICT and medical devices components, which would be integrated to compose the overall HeartCycle technical system solution which would be tested in small focused clinical pilots, while year four is preserved for the larger scale technical and clinical validation of the achieved results.

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