

1 Publishable summary

1.1 Introduction

This publishable summary comprises a description of the HeartCycle project objectives, the progress of work, achieved results in the period March 2010 to February 2011, the expected final results and their potential impact and use within the Integrated Project FP7-216695 HeartCycle Compliance and effectiveness in HF and CAD closed-loop management.

1.2 Objectives

HeartCycle is aiming at researching, developing and validating innovations for the next generation of disease management systems. Therefore, HeartCycle starts from an application point of view.

We have investigated, analysed and validated the needs of patients and professionals for specific disease management solutions. Based on the identified needs, we investigated and developed specific HeartCycle concepts. These concepts are applications that are tailored to a specific patient group. There are three concepts in HeartCycle

- Guided Exercises (GEx) concept for coronary artery disease (CAD) patients
- Disease management concept (HFM) for heart failure (HF) patients including health maintenance and medication management
- Assessment procedures for both patients groups including innovative sensor measurements, personalized healthcare processes and risk stratification strategies

HeartCycle is developing, implementing and validating these concepts to a maturity level that allows operation in clinical test beds. Important aspects are testing the technical feasibility, the user acceptance in these groups and that the concepts present new ways to deliver improved healthcare to patients and reduce workflow for professionals.

The goal of the first year has been to establish a process allowing creating and further developing the concepts (use cases) in a way that the insights gained by the concept development are accepted by the stakeholders from both, medical community and business. The second year has been the time to focus on the final use cases, to develop requirements and specifications for the innovations used in the clinical validations and do further research on innovative sensors, advanced algorithms, decision support and user interaction including education, coaching and motivation. This research has been continued in year three. In addition the major focus in year three has been on the final development, implementation and testing of the HeartCycle systems to be used in the clinical studies running in year 4, the definition of the clinical study designs and preparation of all documents needed to pass ethics and competent authorities for getting the approval for the studies.

1.2.1 Project Objectives of the third year

In general the major objectives have been:

For the concept development:

Finalizing the development of the use cases. After the final use cases have been agreed and requirements and specifications have been developed, the technical work packages started with the implementations to provide prototypes that can be used for clinical trial testing. From the use case

point of view, a huge effort has been spent to design the validation and especially the final clinical studies. WP1 is working on the definition of the overall project validation strategy and definition and Medtronic is responsible of ensuring that all the activities related to validation are completed following the current legislation and normative. This includes the supervision of all pilot tests that involve the participation of human beings under test and the preparation of all the needed documentation to pass the Medical Ethical Committees if required. More concrete definitions of the final HeartCycle validation trials were developed. The development for HFM is led by WP1 and defined and supervised by Prof. John Cleland. For GEx, the medical team around Prof. Patrick Schauerte is responsible. HeartCycle put many efforts on defining the clinical study protocol and prepare all the necessary documents needed for passing ethics and competent authority submissions in the three countries.

For the technical project management:

After finalizing the requirements and specifications for the components needed for the clinical testing the third year is intended for implementing the innovations for the validations. Technical development from WP2-WP5 includes further sensors and parameter extraction research as well as the development of the final versions of the HeartCycle systems, including development of alarm and managing algorithms, decision support and continued evaluation of motivation and education. A major part of the efforts is spent in implementing the research results into prototypes for clinical trial testing.

For the business assessment:

Creating first business models and starting to look into economic simulations and outcome calculations. Together with empirica, WP1 identified the stakeholders for heart failure tele-monitoring in the UK, Spain and Germany and studied a number of existing market participants with regard to their value proposition and business model. Within this task Medtronic and ITACA have carried out the stakeholder analysis for Spanish companies and the Spanish NHS, studying the business models of those tele-monitoring / tele-medicine systems that are available in the market. Empirica, Hull and Philips D have done the same for the German and the English market. As part of the stakeholder analysis the (lack of) business models for telehealth were considered. WP1 drafted the value proposition of the HF concept as a first step towards a business case.

1.3 Performed Work

1.4 Work performed and results achieved

The progress has been according to the plan. The major milestones defined for securing the proper development in HeartCycle have been achieved and the preparation of the clinical studies is ongoing.

WP1 has continued driving the redefinition and refinement of the requirement of the three Use Cases that have been elaborated within the project. Special focus has been given to the redefinition of the Assessment use case, whereas the Heart failure management and the Guided Exercise developments were further detailed and the final trial designs have been finalized. The Sporthochschule Köln and the Rehabilitation-Clinic Rosenquelle, both with an outstanding expertise in rehabilitation are mainly contributing to the further improvement and final definition of the GEx concept. Within the business assessment activities, the partners have continued to carry out interviews with Healthcare stakeholders and studying the business models of those tele-monitoring / tele-medicine systems that are available in the market.

Technical development from WP2-WP5 includes further sensor and parameter extraction research. A number of improvements have been established for various sensors and intensive testing of the sensor solutions as well as the related algorithms has been done. Concerning regulations and preparation for the submission to ethic committees and regulatory authorities before the trials, the risk analysis documentation, safety assessment as well as a user manual and a start-up manual for the IMAGE device have been produced and delivered to WP1 and WP6 partners. Related to the HF vest, Clothing+ has continued the development work including studying several options for the electronics box position, updating the vest design, and prepared trials related to wire quality and length.

In the next sections some general descriptions of the HFM and the GEx systems and information on the progress of the different use cases are presented.

1.4.1 Heart Failure Management System (HFM)

1.4.1.1 The system

The HeartCycle Heart Failure Management system is based on the commercial platform Motiva ®, developed by Philips. Philips Motiva ® is an interactive healthcare platform that connects patients with chronic conditions (e.g. Chronic Heart Failure) 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 meet goals for improved patient compliance, telehealth program efficiency, and lower healthcare costs.

In addition to automated vital signs monitoring, patients are supported by:

- Educational material delivered as videos, with topics relevant to their individual healthcare needs.
- Actionable feedback about vital signs measurements to help patients' track progress toward personal goals.
- Motivational messages from caregivers to help encourage healthy lifestyle choices for diet and exercise.
- Health related surveys that evaluate patients' comprehension, motivation, and self-efficacy levels; and provide subjective information to the remote caregiver about their current health status.



Figure 1: Motiva Philips ® Functionalities

All members of the care team can access Motiva's clinical application to review the patient's guidelines-based care plan defined at enrolment, trended survey responses, and 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.

HeartCycle Heart Failure Management system has been designed based on Motiva Philips system taking advantage of the offered functionalities, adapting some of them, and adding new ones according to the requirements of the project depicted vision. This section focuses on describing the specific parts of this system that have been designed and developed for the Patient Loop within WP4. The main tasks of the HeartCycle 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 is reflected in the model of the HeartCycle system in the figure below (Figure 2).

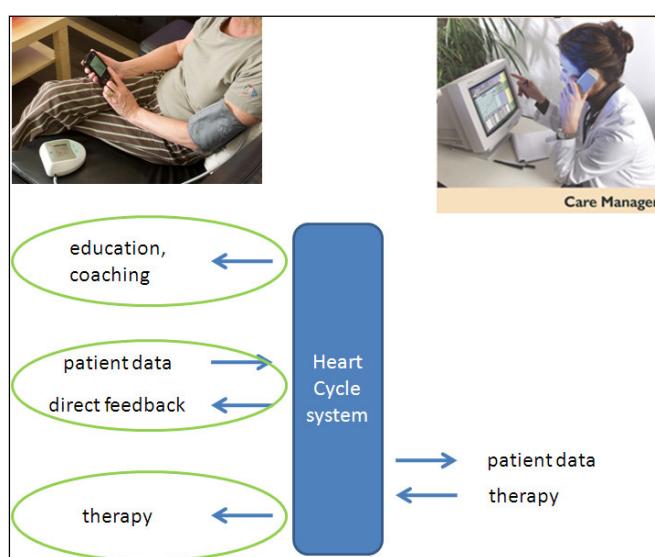


Figure 2: HeartCycle Heart Failure Monitoring Functionalities

To let the system and the care professional do their work (status) data about the patient is needed. These data are collected by letting the patient measure vital body signs and fill in questionnaires. Then, they are processed by the system locally at home, resulting in direct feedback messages. But patient data are also shown to the care professional, who interprets these data and may decide to change the therapy (e.g. reduce the Beta Blocker dose) or to advice particular education or coaching.

- The Education & Coaching part which defines how the Heart Cycle system educates and coaches heart failure patients on a variety of topics.
- The Patient Data Collection part which defines the symptoms questionnaires, the measurement of vital body signs, and the direct feedback.
- The Therapy Messages part which defines the detailed therapy-related messages to be given to the patient (e.g. reduce the Beta Blocker dose).

1.4.2 Guided Exercise System (GEx)

1.4.2.1 The system

The complete Guided Exercise system has the following architecture (Figure 3):

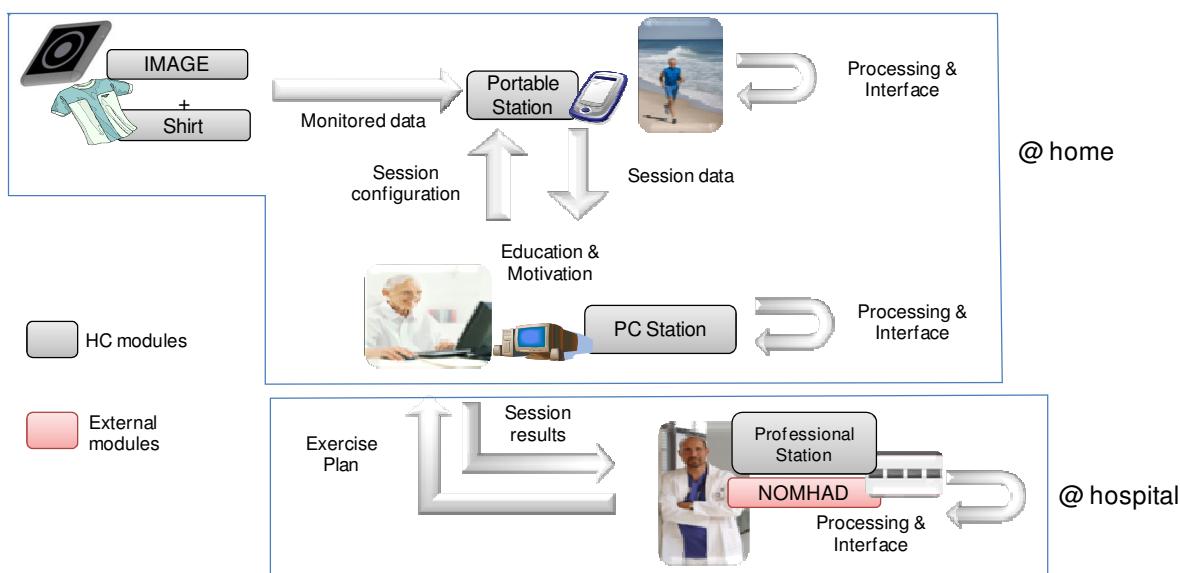


Figure 3: HeartCycle Guided Exercise system architecture.

The patient is equipped with an exercise shirt that holds the IMAGE sensor, which collects patients' vital signs during the exercise. The vital signs are transmitted in real-time to the Portable Station (PDA) that the patient is carrying with him on his upper arm.



Related to the GEx shirt shown in the picture on the left, one of the main activities has been changing the connection method between the shirt and the sensor box from Velcro to snaps. In addition, a design update was made to the male model in order to improve the skin contact of electrode S (located on the upper part of the sternum).

This Portable Station (PDA) 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 the Patient Station (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).

WP4 has focused in designing and developing most of the patient loop components of the previously described system (e.g. PDA Portable Station, PC Patient Station, communications between them and with the IMAGE sensor developed in WP2).

With the aim to raise awareness about the project in the clinical community, the HeartCycle consortium has participated and presented their work in many conferences around the world.



HeartCycle participated with its own session at the pHealth 2010 conference providing an excellent opportunity for disseminating the project to scientists from ICT, medical doctors, and policy makers from the healthcare and hospital administration professionals.



The HeartCycle Team, jointly with the European commission, Unit "ICT for Health", organized an exciting programme related to telemonitoring at the Heart Failure Congress 2010 in Berlin, the annual specialist meeting on this topic run by the European Society of Cardiology. A series of symposia dealt systematically with the complex issues surrounding the deployment of telehealth for patients with heart failure. These also informed cardiologists and other stakeholders about the HeartCycle project as well as advances in other devices and technologies for the management of HF.

1.5 Expected final results

HeartCycle will research, develop, and validate innovative improvements for the next generation of telemonitoring systems. To deliver accepted results, HeartCycle will conduct validations via test beds implementing the proposed solutions in real patients' homes and show the 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. To be accepted by the medical community, it is very important 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. In addition, HeartCycle will test strategies to motivate patients to be compliant with control groups. The HeartCycle system will allow closer monitoring of the effects of medication and lifestyle, making more personalised treatment plans possible. The time frame of the project foresees, that the first three years are dedicated to

research and development of the ICT and medical devices components, while year four is reserved for the larger scale technical and clinical validation of the achieved results

1.6 Impact and use

The cost and incidence of CVD is expected to rise with the aging of the European population. It is a significant challenge for the European health care systems to address these issues, providing the best affordable health care possible. HeartCycle will contribute to the stabilisation of the cost of the health delivery systems. Closed-loop management of HF and CHD patients will stabilise their condition, resulting in more efficient care, fewer or shorter hospitalisations and therefore less associated costs. As the European population ages, and chronic diseases become more prevalent a high quality, cost effective treatment system becomes more and more urgent. The HeartCycle system will be an example of the closed-loop disease management of the future. The savings for the health delivery system obtained in HF and CHD management will be exemplary for possible gains in other chronic disease management systems. Furthermore, HeartCycle will contribute to the improvement of the productivity of healthcare systems, because in HeartCycle, regular measurements of the patient health status are taken, enabling early reactions to potential problems before they develop into serious problems. This increase in (cheaper) preventative treatment results in a larger decrease in reactive (expensive) treatment, thus improving the productivity of the healthcare system. For the patients, HeartCycle will facilitate a more active participation of citizens in illness prevention and care processes. The HeartCycle project will achieve patient's attitude changes towards risk factor reduction and more active participation in the prevention and care process through its focus on a decision support system for patient motivation and treatment adherence. The HeartCycle system will provide the patients with access to medical expertise, which offers guidance through the appropriate risk reduction activities. In addition, the easy-to-use solutions developed in this project will motivate the citizens to keep up a healthy lifestyle over a long term.

1.6.1 Coordinator contact details

The following table shows the contact details of the Project Coordinator.

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Table 1 Coordinator contact details

1.6.2 Public Project Website

The Public Project Website can be found on: <http://www.HeartCycle.eu>