2 Publishable summary

2.1 *Introduction*

This publishable summary comprises a description of the HeartCycle project objectives, the progress of work, achieved results in the period March 2011 to February 2012, 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.

2.2 *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.

2.2.1 Project Objectives of the fourth year

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. The approval procedure in all three countries took more time than expected as this is an interactive process and competent authorities and ethics separately are asking for more and more information to be provided. In addition new legislation (Medical device directive due March 2011) has to be taken into account and reacted to. Clinical trials started in January 2012 in Hull first therefore the HeartCycle consortium has asked the Commission for a project prolongation to be able to finalize clinical studies and respective analysis and reporting.

2.3 *Performed Work*

In the last 12 months work has been continued to get approvals for the clinical studies, to extensively test the final systems for the trials and to further perform research on the Assessment Use Case. The

start of the clinical trials has been delayed until January 2012. In addition the consortium defined a work plan taking into account the recommendations given by the last review.
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.
All partners have fulfilled their tasks according to the DOW, have actively supported the further development of the applications and have participated in the daily work routine of the project.
As an example, more details on the textile research are reported in this summary.
A key component of HeartCycle is the regular monitoring of vital signs by the patient himself. This patient self-management provides the basic information for physicians to detect trends and worsening of patients' health status and to make medical decisions. Consequently, self-measurement needs to be accurate, reliable and easy-to-use for the patients. Starting in MyHeart and continued in HeartCycle, a novel sensing method based on bio-impedance measurement in combination with a textile vest has been explored.
Our new approach foresees a wearable system with textile electrodes in combination with a textile vest. The vest allows a reliable self-positioning of the electrodes on the thorax day by day. The measurement which is not supervised by medical staff is taken by patients themselves at home and takes about 10 minutes each day.
Appropriate textile design requires, besides classical criteria for a textile like comfort and fashion that the design also ensures the new functionality in the design process for the specific group of patients. Aspects like the placement of electrodes on the body with an appropriate contact pressure, the integration of electrical components like cables and connectors and finding a suitable position of the electronic components have to be taken into account form the very beginning. Extensive user interviews and user tests bring essential insights in needs and wishes of the patients balanced by current textile technologies available for later mass production.
Chronic Heart Failure patients are typically 75+ years old. They show all sorts of different body shapes from thin to tick as well as disease specific issues. Elderly people have their own requirements for clothing, where special emphasis has to be paid to sensitive skin, comfortability and dressing easiness of the cloths [5, 6]. In contrast to sport applications, medical textiles dedicated for elderly do not allow the use of shirts and bra solutions since dressing is a major problem in particular to pull a textile over the head and fasten small hooks. Easy-to-dress is necessary to allow accurate and repeatable positioning of the textile sensors on the body. The figure below summarizes the design issues with some examples.

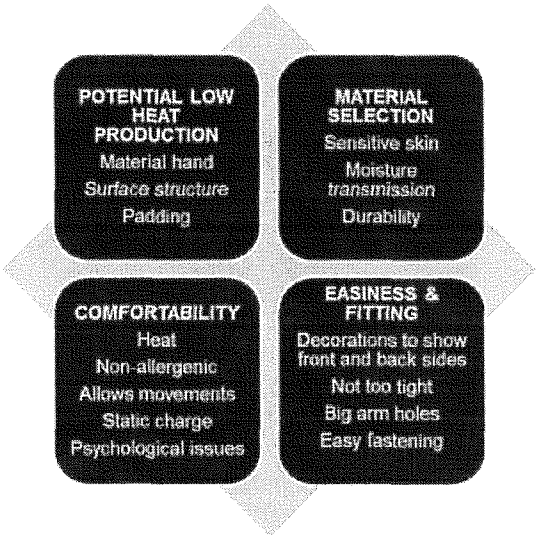

Figure 1: Identified design issues related to the clothing of disabled and elderly people

The figure below shows different realized prototypes. We confronted patients with alternative concepts close to the first version as well as more cloth-like designs.

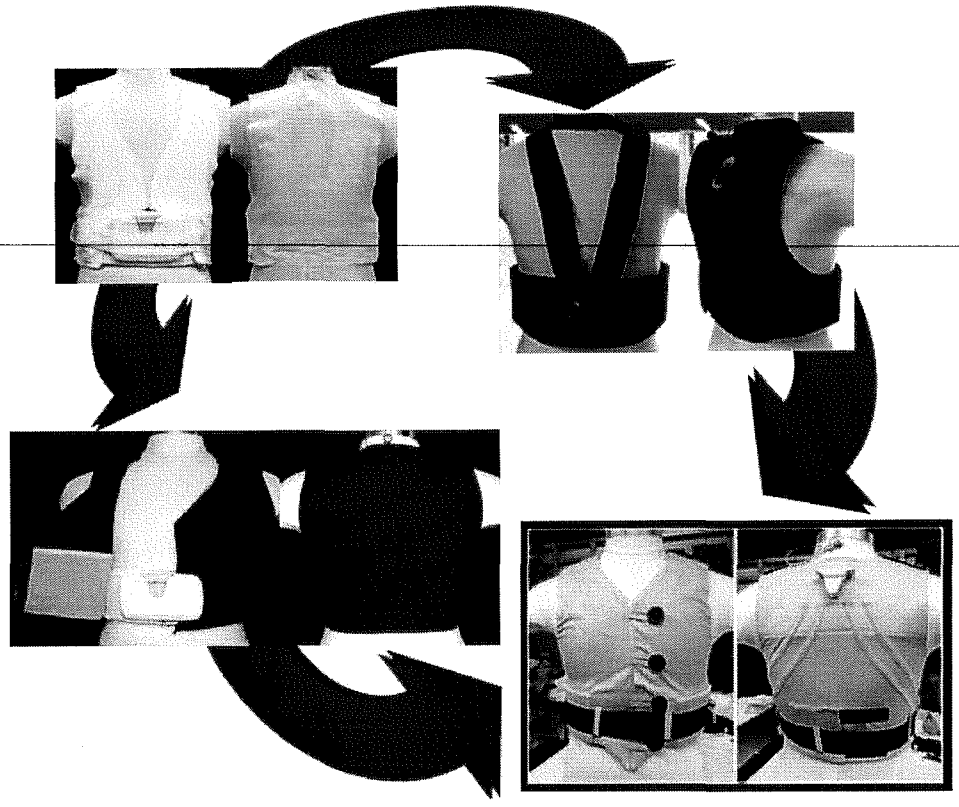

Figure 2! Different investigated design concepts for an improved new vest

Based on this design, significant improvements have been made in enhanced signal quality and usability aspects. This new vest is being tested in clinical studies.

2.4 *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 preserved for the larger scale technical and clinical validation of the achieved results.

2.5 *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 patients 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.

2.5.1 Coordinator contact details

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

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2.5.2 Public Project Website

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

HeartCycle is funded under the IST (Information Society Technologies) priority of the European Union's FP7 (Seventh Framework Programme)

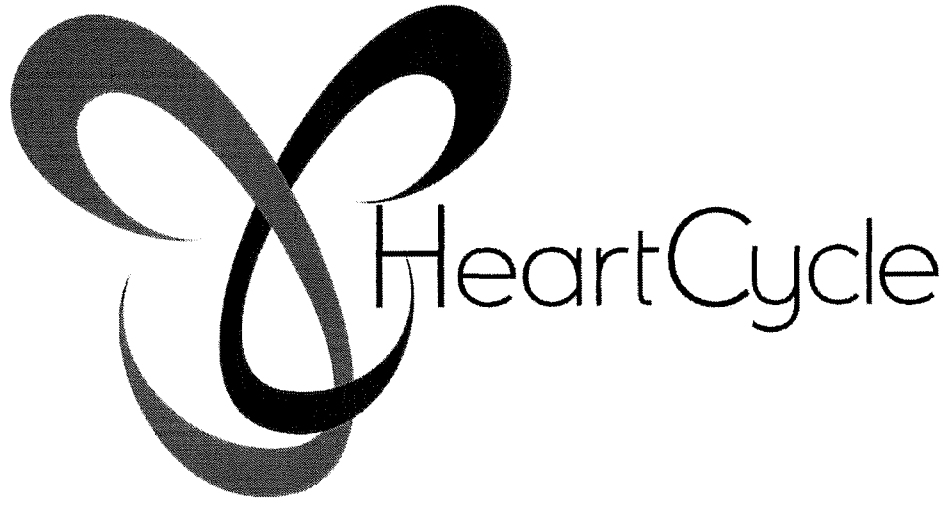

Figure 3: *Project logo*

3 Project objectives for the period

In this section we provide a short survey of the project objectives. For detailed information we refer to the description of work (DOW).

- Redefine the Assessment use case according to the recommendations of the review 2010 including validation
- GEx and HFM
  - The final version of all system components should be available.
  - The system integration should have been completed including intensive testing.
  - The planning of the clinical study (including study protocol, etc.) should be completed.
  - Approval by ethics and competent authorities should be obtained

- Progress
  - AUC:
    - New definition of AUC on request of review 2010 → big effort involving complete consortium leading after several iterations to a huge improvement for AUC.
    - Technical system development and integration ongoing
    - Validation scenarios worked out
      - Planned start March 2012
  - GEx:
    - Technical system ready for trial
    - Trial protocol finished and agreed; preparation ongoing.
    - Waiting for ethics and competent authority approval
      - Planned start March 2012
  - HFM:
    - Technical system ready for trial
    - Trial protocol finished and agreed; preparation ongoing.
    - Waiting for ethics and competent authority approval
      - Start January 2012

Conclusion from delay → We will ask for project prolongation

- The HeartCycle consortium is asking for an extension of the project duration until 30.06.2013 (16 months)
  - Clinical studies started in January 2012 with enrollment of patients in Hull for HFM
  - Proposed study duration: 6 months (GEx) , 12 months (HFM), several encounters (AUC)