Personalisation of health in HF and CAD patients via closed loop systems
HeartCycle

- IST-e-health 7th framework
- Duration: 48 Months
- Budget: 20 M€
- Funding: 14 M€ (EU)
- Start: 01.03.2008
- Partner: 18
- Project coordination: Philips
Partners

- Philips (Project Coordination)
- Medtronic
- Communications
  - T-Systems
  - Vodafone
- Research organisations
  - VTT, ITACA CSEM
- Universities
  - Thessaloniki, Coimbra, Milano, Aachen, Madrid, Hong Kong
- Clinics
  - Madrid, Hull, Aachen
- SMEs
  - Clothing+, empirica
Target Applications

• Chronic Disease Management: Heart Failure
  – 10 million patients in the EU are treated for Heart Failure
  – Over € 3bln hospitalization cost in the EU
  – The cost of hospitalizations for HF is twice that for all forms of cancer and myocardial infarctions combined.
  → Proper closed-loop management can reduce mortality significantly and has a cost-savings potential of several billion Euros world-wide.

• Secondary Prevention: Coronary Heart Disease
  – Most common cause of death in Europe (~22%)
  – 18% of men and 35% of women have 2nd heart attack
  → Appropriate lifestyle and medication will significantly reduce the risk of such a secondary event
HeartCycle: Goal

• To improve the adherence to treatment regimes of HF and CAD patients
  • remotely monitor cardiovascular patients
  • show effectiveness of medication and lifestyle
  • motivate patients to follow treatment regimes and adopt beneficial lifestyles

• Strong evidence (WHO 2003) that
  – the effectiveness of adherence may have a far greater impact on the health than any improvement in specific medical treatments
  – adherence results in cost-savings
Current treatment regimes 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
- Non-adherence to the treatment regime is a major cause of suboptimal clinical benefit.
  - Over 100 billion dollars (US) annually due to non-adherence to medication
  - 11 percent of hospitalisations result from poor adherence with prescribed medication
  - 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.
HeartCycle Approach

• Closed-loop management of medication and lifestyle compliance by
  – Multi-parametric monitoring of vital signs and other parameters (questionnaires, context information, biochemical composites, cardiac performance, etc.)
  – Physiological and statistical modelling of medication and lifestyle effects
    ➔ An objective and personalised indicator of compliance, medication and lifestyle effectiveness
  – Motivating patients to adhere to treatment regime by feeding back the short- and long-term effects of their treatment
  – Decision support and care plan management for optimal treatment
    • Patient-loop
    • Professional loop
HeartCycle will provide a closed-loop disease management solution to serve both HF and CHD patients including:

- a **patient loop** interacting directly with the patient to support the daily treatment.
- a **professional loop** involving medical professionals, e.g. alerting to dynamically adopt the care plan.
# Scientific and Technical Objectives

<table>
<thead>
<tr>
<th>Scientific Objectives</th>
<th>Technical Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improve Disease Management in CV</td>
<td>Develop a system for assessing compliance</td>
</tr>
<tr>
<td>Compliance Management</td>
<td>Overcome limitations of skin-contact techniques for measuring vital body signs by contactless and ambient sensing technologies</td>
</tr>
<tr>
<td>Identification of parameters for trend analysis for health status assessment</td>
<td>Statistical and physiological models to assess effectiveness of lifestyle and medication</td>
</tr>
<tr>
<td>Medication and LifeStyle Effectiveness</td>
<td>Develop a decision support system for professionals and patients for improvement of disease management</td>
</tr>
<tr>
<td>Close Loop Management</td>
<td>Develop User Interaction techniques to improve compliance</td>
</tr>
<tr>
<td></td>
<td>Integrate Innovative Chronic Conditions Management</td>
</tr>
</tbody>
</table>
HeartCycle Logical Architecture
HeartCycle System Overview

Basic Telemonitoring system

HeartCycle telemonitoring platform

Standard Sensors
Transmission
Storage, Data model
User Interface, API
Administration
Certified

Advanced Sensors
Parameter Extraction

Analysis
Alarm
Feed-back professional
Feed-back patient
Assessment
Interface to HIS/EHR Datamodel

Dynamic titration
Uptitration
HF worsening

Guided Exercise
Exercise careplan
Anxiety management
Live feedback
Professional supervision
Motivational LS

Fly your future

Patient specific model
response
Motivational UI

Algorithms for the detection/alarms for the 3 cases
Decision Support for alert handling
Careplan adaptation for the 3 cases

Motivational strategies
Multi-role patient management

Compliance and Effectiveness in HF and CHD Closed-loop Management

pHealth 2009 Conference - Oslo
Approach for implementation

- Medical Devices
- Patient Station
- Medical Response Center
- Hospital EHR
- HC Integration Middleware
- HC Professional Tools Platform
- HC Data Analysis Platform

HeartCycle: Compliance and Effectiveness in HF and CHD Closed-loop Management
HeartCycle Platform – OPTION 1

Medical Devices

Patient Station

Medical Response Center

Hospital EHR

Raw sensor data exchange

Commercial, E2E Certified Solution

EHR Interface

HC Integration Middleware

HC Special Devices

HC Patient Interaction Platform

HC Professional Tools Platform

HeartCycle Platform – OPTION 1

HeartCycle

Compliance and Effectiveness in HF and CHD Closed-loop Management

pHealth 2009 Conference - Oslo
Compliance and Effectiveness in HF and CHD Closed-loop Management

HeartCycle Platform – OPTION 4

- Medical Devices
- Patient Station
- Medical Response Center
- Hospital EHR
- EHR Interface
- Integrated/Embedded Patient User Interface
- Raw sensor data exchange
- HC Special Devices
- HC Patient Interaction Platform
- Integration of services
- Progressive integration
- Joint Work for Adaptation

Commercial, E2E Certified Solution
HeartCycle Platform

Basic Telemonitoring Platform
- Innovation in clinical usage
- Certified (external)

Basic Business Services
- Innovation in clinical & business usage
- Certified via risk analysis / external

HeartCycle ‘Smart’ Services
- Innovation in intelligence
- Certified via risk analysis (internal)

HeartCycle Research Services
- Innovation in research
- Quality control of research

Clinical Validation Trial
Research Validation
Research in new monitoring systems and devices

**IMAGE modules for CAD concept:** Three multifunction electrodes inserted in an ergonomic double layer T-shirt.
- A and I electrodes for ECG and respiration signals
- S electrode for activity and SpO2 signals
- Sensor data transmission based on 802.15.4

**BISCUIT module for CHF concept**
- Bio-impedance Spectroscopy for CHF patients
- Impedance cardiography
Research in new monitoring systems and devices

- BS for Bed side monitor
  - 8-channel sensor
  - USB data transfer and processing in PC
  - Data interface with HeartCycle protocol

- COMPRE module for Blood pressure
  - Feasibility Studies of BP and BPV surrogates based on signals easy to measure

- Heart sound
  - Continuous non-invasive BP surrogate
  - Cardiac reserve parameters (PEP, LVET, CO, Contractility, ...)

A/D conversion board and USB controller box
8-channel Emfit foil in a cushion bag
Multiparametric Analysis and Decision Support

- To provide patients and professionals with the **essential information and personalised decision support for an optimal management** of the disease

- To **create a personal model** incorporating the factors influencing compliance and medication and lifestyle effectiveness

- To **extract health trends and statistically significant factors from multi-parameter analysis** of available data as well as semantic mining from existing WWW resources (MyHeart study, knowledge databases, new trials)

- To **validate the proposed analysis and model** with data from the HeartCycle final clinical study
Multiparametric Analysis and Decision Support

- A model to represent the **effects of the treatment on the patient**, which learns and is updated using information from past measurements.
- A model to **estimate the adherence** to the treatment from the patient.
- Different models to **estimate the status of the patient** in different categories (CV, mental status, stress levels…) and an overall health status indicator.
- A **tool for the professional** to estimate which intervention can have better impact in the patient, thus giving valuable input to the physician when she plans adaptations to the careplan.
- A **tool for the patient** to represent his estimated outcome if his compliance to the treatment changes, or remains the same.
A typical work flow for the system is as follows.

1. Take the new health related parameter data.
2. Update intervention effectiveness and patient compliance parameters, given the new health related parameters.
3. Compare different intervention options for the physician.
4. Compare different adherence outcomes for the patient.
HC Professional Tools Platform

External Systems

Health Care Services' Broker

Central Ontology

Care Plans
Dynamic management

Proactive Agenda

Active Processes

Templates

Manage Proactive Agenda

Care Plan Management

Process management

Patient Data Management

General Business Models' Container

Graphical User Interface

Profesional User

Access to Patient Data

Provide Data

Access to public data

Provide Monitoring

Provide Care Plan actions

Access to active Processes

Provide to Action List

PublicData

Subscribed Events

Show Data

WP3

WP4/WP2
Compliance and Effectiveness in HF and CHD Closed-loop Management

HC Professional Tools Platform
HC Professional Tools Platform

Compliance and Effectiveness in HF and CHD Closed-loop Management
Example of Guided Exercise

Aim of the HeartCycle Guided Exercise features

- To help the **patient** (mainly the CAD patient), who is in rehabilitation phase, to follow the prescribed exercise regimen in a safe and beneficial manner, to become cardiovascularly fit again, and to keep this fitness level in normal daily life.

- To help the **professional** to monitor the patient’s progress and compliance and allow early intervention if necessary.

Approach

- The patient and the professional agree on an exercise plan.
- The system suggests exercises at the right intensity that the patient is able and willing to do.
- The patient’s progress is followed by the system (using the measured vital body signs), and the suggested exercise is updated accordingly.
- During exercise, vital body signs are monitored to ensure that the exercise is done at the right level: beneficial and safe.

Main Devices

- IMAGE shirt - provides measured data (ECG, respiration and movement)
- Portable Patient Station (PDA) - processing unit that extracts heart rate (HR), breathing rate (BR) and activity level in real-time. Provides: feedback on the development of measured signals, instructions for performing exercise, and motivational messages
### Example of Guided Exercise

#### EXERCISE PLAN 1: OUTPATIENTS

**Patient profile: Low – moderate risk level**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Order</th>
<th>Activity</th>
<th>Duration</th>
<th>Activity Level</th>
<th>HR_{min}</th>
<th>HR_{max}</th>
<th>SafeHR_{min}</th>
<th>SafeHR_{max}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warm-up</td>
<td>1</td>
<td>walk</td>
<td>10 min</td>
<td>light</td>
<td>20% HRR</td>
<td>30% HRR</td>
<td>50bpm</td>
<td>90% HR_{max}</td>
</tr>
<tr>
<td>Main</td>
<td>2</td>
<td>Aerobic Activity (e.g. brisk walking)</td>
<td>30 min</td>
<td>moderate</td>
<td>40% HRR</td>
<td>60% HRR</td>
<td>HR_{rest}</td>
<td>90% HR_{max}</td>
</tr>
<tr>
<td>Cool-down</td>
<td>3</td>
<td>walk</td>
<td>5 min</td>
<td>light</td>
<td>20% HRR</td>
<td>30% HRR</td>
<td>Bradycardia (50bpm)</td>
<td>90% HR_{max}</td>
</tr>
<tr>
<td>Passive recovery</td>
<td>4</td>
<td>Sit down</td>
<td>10 min</td>
<td>minimal</td>
<td>HR_{rest}</td>
<td>HR_{rest}</td>
<td>Bradycardia (50bpm)</td>
<td>90% HR_{max}</td>
</tr>
</tbody>
</table>

**Frequency per day**: 1  
**Frequency per week**: 5

**HRR**: Heart Rate Reserve  
**HR_{rest}**: the minimum HR recorded the morning of the same day.
Example rules of the system:

- IF HR is unsafely high THEN instruct to stop the exercise
- IF HR is moderately high THEN instruct to decrease WL substantially
- IF HR is slightly high AND WL is increasing THEN instruct to decrease WL slightly
- IF HR is ideal AND WL is steady THEN instruct to maintain pace
- IF HR is slightly low AND WL is decreasing THEN instruct to increase WL slightly
- IF HR is moderately low AND WL is not increasing THEN instruct to increase WL slightly
- IF HR is unsafely low THEN instruct to stop the exercise

During the exercise – Live Analysis example: Fuzzy control system for Live Analysis and Guidance
Example of Guided Exercise

Recovery phase – fitness assessment and summary feedback

example features

• **HRmax**: maximum HR during exercise
• **HR_{1min}**: HR (or HRmax-HR) at 1st minute of recovery
  - it is a predictor of cardiovascular mortality
  - usually if HRmax-HR_{(1min)}<12: high cardiovascular risk

Healthy subject: HRmax-HR_{(1min)} = 35.2 bpm
Cardiovascular patient: HRmax-HR_{(1min)} = 14.42 bpm
After exercise examples: long-term benefit analysis and adherence visualisation

HRmax during exercise

- HRmax during main exercise phase is a measure of exercise capacity
- For trends, an average value per week is calculated, showing the improvement in maxHR during 6 months

- upper graph: actual exercise (mins/day) compared to prescribed duration
- lower graph: cumulative adherence, \( C(n) \), calculated using the cusum method – it allows early detection of even small deviations from the plan

\( x_n: \text{actually realised} \)
\( T: \text{target} \)
Conclusions and Expected Outcome

- Builds on learnings from previous projects MyHeart, PIPS, SENSATION, CHS, INTERLIFE, PERSONA
- Step of closing the loop towards integrated disease management still to be made
  - Results of MyHeart clinical heart failure study will only be available at the end of MyHeart.
  - HeartCycle will use the results of the MyHeart project and especially the clinical study to develop a closed-loop disease management strategy.
- Patient study in last project year will assess improvement in patient health outcome and compliance against control group.