Proceedings of the 28th IEEE
EMBS Annual International Conference
New York City, USA, Aug 30-Sept 3, 2006

Innovative Concepts for Prevention and Disease Management of Cardiovascular Diseases

Sergio G. Guillén, Pilar Sala, Joerg Habetha, Ralf Schmidt, Maria-Teresa Arredondo

Abstract—**.Innovative concepts for prevention and disease management of cardio-vascular disease are being developed in the framework of MyHeart project. After a successful first phase where 16 different concepts were tested, four of them where selected on the basis of user acceptance, technical feasibility and foreseen impact. The present paper gives an overview of such product-concepts that are being implemented and will be extensively tested in the next phase of the project.**

I. Introduction

THE individual lifestyle plays the most important role to prevent cardio-vascular diseases. Primary and secondary prevention and early diagnosis will automatically reduce the individual risk factors for acute events of each citizen and effectively prevents the reoccurrence of cardio-vascular events and improve the quality of life of chronically ill patients [1],[2]. Although prevention is believed to be a very efficient approach to fight cardio-vascular diseases, it has yet not been successfully implemented and innovative ways to involve citizens and patients in their own health management should remain under research. In that sense, the four product-concepts selected at the end of MyHeart project phase I cover the whole lifelong cycle of health care delivery process, from healthy people to chronically ill patients, providing easy to use solutions that motivate people to adapt their lifestyle and improve their quality of life.

In the first 6 months of phase II of the MyHeart project, the applications of the four product-concepts were defined in detail; customers, users and stakeholders were identified and business propositions were elaborated. An important contribution to the technical development of the product-concepts was the definition of the requirement specifications that are the basis for the development of test systems that will be used in the third phase of the project.

In the following sections, an overview of the four product-concepts will be given [3],[4].

Manuscript received May 15, 2006. This work was supported in part by the IST-2002-507816 My Heart Project.

S. G. Guillén is with the Institute ITACA, Valencia, SPAIN (phone: +34963877606, fax: +34963877279, e-mail: sguillen@itaca.upv.es).

P. Sala, is with the Institute ITACA, Valencia, SPAIN.

J. Habetha, R. Schmidt are with Philips GmbH Forschungslaboratorien, Aachen, GERMANY

M.T.Arredondo is with LST Research Group, Polytechnic University of Madrid, Madrid SPAIN

II. Activity Coach

A. Value proposition

The value proposition for the Activity Coach product-concept is the "Continuity of Care", and is defined as: *"Empowering and making the end-user enjoy the most of the regular exercise sessions, both in terms of pleasure and health impact, anywhere, anytime through personalized training programs and guidance in a motivating (rewarding and incentive-rich) context"*

The product concept provides the end-user with:

- Entertaining and challenging context where the exercise takes place making the user feel a pleasurable, memorable and immersive experience of use,
- Easy to understand, but professional coaching that helps the user reaching his fitness goals, by means of:
  - Tailored training programs built taken into account user profile, preferences and goals, [5]
  - Automated real-time coaching, based on personal performance
- Personalized entertainment (esp. personalized music) to enhance motivation during exercise,
- Clear feedback on performance vs. goals,
- Possibility of using the system both in a fitness studio environment (indoors), and in the own environment (outdoors), which gives flexibility in place and time: 'Continuity of Care'

B. Users

Main target group foreseen for the product is **people exercising for fitness & fun**. This group has as distinctive characteristics an extrinsic motivation to do physical activity, seeking for optimal exercise result at the lowest effort, highest convenience, and in the shortest possible time. Also, they are health concerned, prepared to take action to take care of their fitness level, or already doing that

The product concept could also be interesting for more "advanced" exercisers, e.g. training for a race. This user group is looking for an improvement of their performance or reaching a specific goal in a determined period of time.

C. System architecture and personalized algorithms

The product consists of four main components:

- **Body Signal Sensor (BSS)**, responsible for monitoring the required vital signals, it is integrated into garment. The acquired data are sent to the interaction device

using Bluetooth.

- **Fitness Coach Bike (FCB)**, it is an integrated product for indoor scenario. It includes exercises related sensors, a processing and communication unit and the user interaction device.
- **Personal Mobile Coach (PMC)**, it is the device for outdoor scenario. It receives the data from sensors, generates the appropriate feedback and interacts with the user and the service centre.
- **Fitness Coach Service Centre (FCSC)**, it is the professional platform that provides the online services to the users. Receives all the information from the session, process it by means of algorithms for fitness status assessment and performance analysis and stores all the results. Also provides a web-based interface through which professional and users are able to access different functionalities such as session results visualization, messaging services or training program schedule.

During the exercise, body and exercise sensor data signals are acquired (heart rate, respiration rate, temperature, and rpm or pace). This data are used in the personalized algorithms on the FCB and the PMC to influence the behavior of the specific device, in order to guide the user through the exercise [6]. They coach and motivate the user to keep on with the training program, and to create the immersive environment.

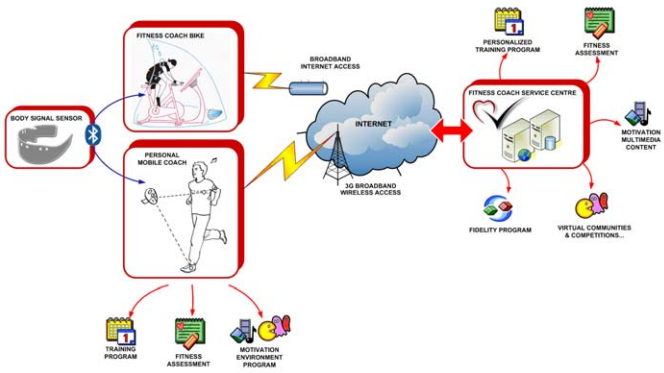

Fig. 1. Architectural view of the components and communication links.

III. TAKE CARE

A. Value Proposition

The value proposition for TakeCare product-concept is the "Self-management of CVD risk in daily life" and is defined as: "*Empowering user to change lifestyle by assessing CVD risk factors and providing appropriate improvement plans and personalized recommendations*".

The product-concept provides the user with:

- Reliable and trustful measurements, analysis and support to overcome CVD risks. [7][8][9]
- Personal guide that shows user's current health status and gives indication on how successful the efforts to change lifestyle are.

TakeCare concentrates on education, monitoring and coaching in order to provide the best chance of lifestyle improvement. The concept especially supports people to learn to listen to their own body, which is a very important factor in the whole process of managing health (taking care).

B. Users

TakeCare is a consumer device for healthy people at risk (age +40) who are interested in their health and are willing to spend money out of their own pocket (health activists) to adopt a healthier lifestyle.

TakeCare addresses especially following customers:

- People with difficulties to create own improvement plans
  - People trying to be more active
  - People trying for long time to loose weight.
- People with sleep and stress related problems.
- People who quickly resign from following lifestyle adoptions due to lack of self motivation

C. System Architecture and Personalized Algorithms

Figure 2 sketches an overview of the overall system diagram of TakeCare. The monitoring devices consist of a wearable shirt/vest with integrated textile sensors and on-body electronics (SEW) for recording of vital body signs (HR, respiration, activity) at day. Additionally, for sleep quality assessment, piezo sensors and textile electrodes are integrated into the bed. The sensor signals are processed and stored on the SEW on-body electronics. Data are sent via Bluetooth (BT) to the TakeCare user interaction device. The TakeCare UI device represents the central location of the personalized algorithms for sleep, respiration and coaching and in addition acts as the platform for information, motivation, and feedback to the customer. On demand of the customer data can be forwarded to a professional center via the MyHeart platform.

Figure 2: Overall architecture of the TakeCare concept

A weight scale, a blood pressure meter, and a cholesterol meter are devices that contribute to the assessment of the risk profile. In a first step information from those devices is entered via manual input to the user interaction device.

The specific algorithms developed in TakeCare can be categorized as follows:

- Quality of Sleep related algorithms
- Coaching algorithms
- Stress management algorithms
- Activity management algorithms

- Weight management algorithms

IV. Neurological Rehabilitation

A. Value Proposition

The product-concept aims at:

- Ensuring early intensive rehabilitation for more patients with neurological morbidities [10],[11] (mainly caused by cerebrovascular events), both inpatients and outpatients
- Improving care by innovative treatments, able to quantify rehabilitation outcomes
- Optimizing the therapeutic process inside and outside of the clinic
- Producing new scientific results

Also, from the point of view of cost/effectiveness and efficiency of the services:

- The introduction of MyHeart Neurological Rehab service will trigger a series of positive events: the rehabilitation unit will discharge patients earlier, so improving bed turnover and shortening waiting lists. Early intensive rehabilitation is known to improve the final outcome. The service will allow treating more patients without increasing the number of beds and personnel, such as physiotherapists and logopedists.
- MyHeart Neurological Rehab service will increase the efficiency of all the wards devoted to cerebrum-vascular events treatment; it will decrease the costs of post-acute rehabilitation and will facilitate treatment for patients living in rural zones, decreasing the needs for expensive home visits.
- Huge economic impact is expected also, through earlier re-integration to job occupation.

B. Users

Main user group are patients with stroke symptoms (people that had a stroke or have a neurological disease with similar symptoms) and to physicians, physiotherapists or occupational therapists. Patients are provided with upper-limb wearable technology, and speech therapy tools, learning tools and communication tools. This allows patients to have an immediate feedback about their performance, and therapists either tele-monitoring the patient rehabilitation exercises, or controlling the exercises off-line. Therapists could send suggestions to patients and also send a modified exercise protocol on the patient console.

A patient may be assisted by a caregiver, usually a family member, who also becomes a final system user.

Healthcare personnel are users, even if at a different level with respect to the patient. He will benefit from the system because it allows a better organization of the hospital work and an opportunity to perform adequate follow-up to patients that would be otherwise lost.

C. System Architecture and Personalized Algorithms

The final system will be made by three main stations, located at different sites, plus the communication infrastructure between them. Of course the "patient Site" is not only one, but it is replicated for all patients.

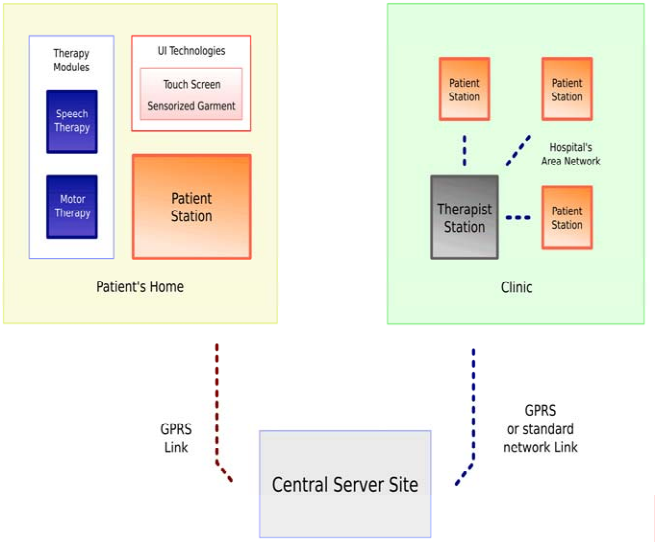

Figure 3: The final Neuro Rehab system, three sites, including the communication infrastructure between them

The three sites, as shown in the figure below, are

1. the Patient Site, physically located near the patient, who, in the case of a motor deficit, wears the sensitive garments. The Patient Site computer is connected both with the Server Site and with the electronics which interfaces to the garments.
2. the Therapist Site, from which the physician can monitor, the patient's exercises. In principle, the monitoring can happen both in real time (on-line) and on the stored sessions (off-line). For the next 12 months of the project only the latter solution will be implemented.
3. the Server Site, where a firewall-protected central server hosts a database of configurations, exercises, session recordings, demographic data, and all the necessary software to serve web pages dynamically generated to provide easy access to the system. The rehabilitation protocol itself is stored in this central server. The "therapist station" may access it and configure it for the specific patient. After each training sessions, outcomes are also transmitted and stored in the central server for therapists' review.

The specific algorithms developed in this product-concept are related to posture recognition and classification.

V. Heart Failure Management

A. Value Proposition

The main objective of the Heart Failure Management Product Concept is to improve the outcome of Heart Failure patients with respect to mortality, morbidity and quality of

life [12],[13],[14]. This objective will be achieved by monitoring vital body sign that are relevant for Heart Failure on a daily basis at the patients' homes. The data is automatically analysed in order to detect changes in the patients' state early enough, adjust therapy accordingly and thus avoid severe deterioration and hospitalization.

An additional objective is to improve the management of Heart Failure by the physicians and the patients. This implies to monitor and react on co-morbidities that may lead to a worsening of the patient state or impairs the prognosis like Atrial Fibrillation or depression.

B. Users

End-users of the system are patients with chronic failure and physicians or nurses that treat those patients. Using symptom oriented classification NYHA, patients that benefit from the Heart Failure Management Product Concept belong to classes 2-4.

Professionals are the second group of end-users. Typically the GP or a nurse is in charge of caring for the Heart Failure patient.

No direct users of a Heart Failure Management System but payers are Disease Management Organisations (DMO) and health care insurances. DMOs have a choice of the tools they use to provide their service and are very much cost driven. Health care insurances are typically not free in choosing what service or therapy they pay for.

C. System Architecture and Personalized Algorithms

The monitoring devices consist of a wearable with integrated sensors and electronics for recording of vital body signs relevant for heart failure management. In addition one or more sensors are integrated in the bed. A weight scale and a blood pressure cuff complete the set of monitoring equipment.

The patient interaction device is a smartphone. It is the interface for the patient to the system, guides measurement procedures and provides feedback. At the same time it connects the sensors with the backend and performs data analyses. Communication with the sensors is realized via Bluetooth. Communication with the backend uses GPRS/UMTS connectivity.

The backend or professional platform consists of a gateway from GSM to the internet (Red Box) and servers that run the backend applications like databases and the web portal for professionals. All (pre-) processed patient data is sent to the central server. The server will provide a web-based interface through which health care professionals will be able to access application configuration and patients' data visualization functionality.

Several specific algorithms are being developed within this product-concept:

- ECG signal processing
- Respiration signal processing
- Activity supervision
- Decompensation prediction

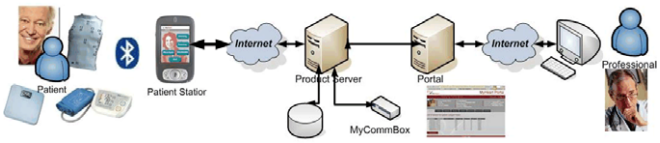

Figure 4: HFM system architecture

VI. CONCLUSIONS

All four product-concepts are being implemented in 2006 in order to be tested in 2007. Tests will address from technical properties to user acceptance aspects and the expected number of participants will be 300.

REFERENCES

[1] European Guidelines on Cardiovascular Disease Prevention in Clinical Practice. Executive summary: European Heart Journal 2003; 24(17): 1601-1610 and European Journal of Cardiovascular Prevention and Rehabilitation 2003; 10(4): S1-S11.

[2] MJ Stampfer et al., Primary prevention of coronary heart disease in woman through diet and lifestyle, *N Engl J Med* 2000; 343:16-22

[3] My Heart IST-2002-507816 project (2004). Information available in http://www.cordis.lu/ist

[4] Joerg Habetha editor (2005). *My Heart project Deliverable D14: Product Concept Definition*. Available on request to My Heart project coordinator.

[5] A. Dunn et al. Dunn AL, et al. (1999). Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness. *JAMA* 28:327.

[6] M. Romagnoli et al., "Sensitivity of heart rate recovery kinetics to changes in physical fitness", in 2005 *Proc. 4th European Sport Medicine Congress*

[7] Hans-Werner Duchna, Ludger Grote, Stefan Andreas et al. Sleep-Disordered Breathing and Cardio- and Cerebrovascular Diseases: 2003 Update of Clinical Significance and Future Perspectives. Somnologie 7: 101–121, 2003

[8] Lifestyle and risk factor management and use of drug therapies in coronary patients from 15 countries – Principal results from EUROASPIRE II – European Heart Journal (2001) 22, 554-572. EUROASPIRE Study Group. Clinical reality of coronary prevention guidelines: a comparison of EUROASPIRE I and II in nine countries. Lancet 2001; 357:995-1001.

[9] Gordon NF, Salmon RD, Saxon WE, et al. Getting risk factors to goal: Lifestyle intervention is worth the effort in patients with hypertension, hyperlipidemia and/or hyperglycemia. Paper presented at: 53rd annual scientific sessions of American College of Cardiology; March 7-10, 2004; New Orleans.

[10] Sulch D, Perez I, Melbourn A, Kalra L. Randomized controlled trial of integrated (managed) care pathway for stroke rehabilitation. Stroke 2001; 31:1929-34

[11] Micieli G, Cavallini A, Quaglini S; Guideline Application for Decision Making in Ischemic Stroke (GLADIS) Study Group. Guideline compliance improves stroke outcome: a preliminary study in 4 districts in the Italian region of Lombardia. Stroke. 2002 May;33(5):1341-7.

[12] K. Swedberg et al. Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005): The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology, Eur. Heart J., June 2005; 26: 1115 – 1140

[13] Recommendations for exercise testing in chronic heart failure patients, Eur. Heart J., January 2001; 22: 37 - 45.

[14] S. Stewart and Lynda Blue (Ed.), Improving Outcomes in Chronic Heart Failure, BMJ Books, 2001