Wearable Monitoring System for Heart Failure Assessment in a Mobile Environment

E Villalba[1], M Ottaviano[1], MT Arredondo[1], A Martinez[2], S Guillen[2]

[1]Life Supporting Technologies group, Technical University of Madrid, Spain
[2]Health and Wellbeing Technologies R&D group, ITACA Institute, Valencia, Spain

Abstract

In Europe, Cardiovascular Diseases (CVD) are the leading source of death, causing 45% of all deaths. Besides, Heart Failure, the paradigm of CVD, affects mainly people older than 65. In the current aging society, the European Union funded MyHeart Project, whose mission is empowering citizens to fight CVD by means of a preventive lifestyle and an early diagnosis. This paper presents the design and development of a Heart Failure Management System, based on daily monitoring of Vitals Body Signals, with wearable and mobile technologies, for the continuous assessment of this chronic disease.

1. Introduction

Heart Failure (HF) is a relatively common chronic disorder, mainly affecting people older than 65 (1). The increase on the life expectancy in the developed countries has resulted in an increase in the number of hospitalizations due to chronic diseases, as well as in a decrease in the quality of life of the aging population.

The Heart Failure Management System (HFMS) makes use of the latest technologies for monitoring heart condition, both wearable garments (for measuring ECG and Respiration); and portable devices (such as Weight Scale and Blood Pressure Cuff) with Bluetooth capabilities.

HFMS aims at decreasing the mortality and morbidity of the HF population. The system also focuses on improving the efficiency of the healthcare resources, maximizing the cost-benefit rate of the heart failure management.

The main users of the system are two: a) an HF chronic disease management service provider, with cardiologists and nurses; and b) patients with HF.

Heart Failure Management System consists of three main elements: a) The Front-end, b) the User Interaction System and c) the Back-end. The following figure sketches the global system:

Fig. 1: HFMS overview

The **Front-end** is composed of the different textile sensors and electronics for the recording of the vital signals that are required by the application (ECG, Respiration and Activity). Moreover some portable devices such as weight scale and blood pressure cuff are used.

The **User Interaction System** (UIS), which is based on a personal digital assistant device that receives data from the monitoring devices, processes it and encourages the patients in the daily care of their heart. Besides, it enables the communication and synchronization with the Back-end.

The **Back-end**, which includes the processing server and the databases, manages all patients' daily gathered data. Professionals can visualize and manage all data through a web access provided by a portal, which is based on Cocoon Framework (7). The system collects personal and clinical data. Therefore, security issues play a role of major importance.

All the daily data are processed and used in the detection of functional capacity, worsening and other complications. The timing tendency of data is automatically assessed in order to enable the early detection of: a) possible clinical decompensations (clinical destabilization warning signs), b) the continuous "out of hospital" arrhythmia risk stratification and, c) the evaluation of the HF progression. On the other hand, motivation strategies were taken into account in order to provide patients with pertinent and relevant information, according to their physical and psychological status.

2. Methods

The methodology applied is based on Goal-Directed Design (2), whose process can be divided into five phases: Research, Modeling, Requirement, Framework and Refinement.

During the **Research** phase, the field study technique applied was several interviews to the different stakeholders involved in such systems: heart failure population, medical specialists (cardiologists and nurses) and business managers related to the chronic disease management in hospitals. Within theses interviews a mock-up system was thoroughly validated during three months. The validation was based on personal interviews of open and close-ended questions followed by a system demonstration in order to allow the users to validate its usability and comfort. In total 26 people were interviewed: 10 end users (9 men and 1 woman, 80% of them above 60 years), 6 business managers and 10 cardiologists (3).

Once the Research phase was completed, the **Modeling** one generated both domain and user models, taking as input the results from the previous phase. Domain models included workflow diagrams. User models, or personas, are user archetypes that represent behavior patterns, goals and motivations.

The persona of HFMS is an elderly person aged about 65 years or more. He is aware of his heart condition and is proactive to take a better care of it. Furthermore, he is able to handle an electronic device, following a very intuitive system. Besides, he does not have special needs in terms of accessibility (e.g. blind people).

The user should be able to easily start/stop the application, view his daily tasks, be alerted of the previous uncompleted tasks, follow instructions to perform monitored sessions, view results, answer questionnaires (e.g. 5 questions in the assessment of his mood), and consult messages from professionals. On the other hand, the user interaction system should communicate with the Back-end and receive information from the Front-end through Bluetooth.

The **Requirement** phase employed scenario-based design methods. The scenarios detected within this system are three. The end user is prompted to follow a daily routine divided into morning, exercise and before sleeping context. The first and third consist of a set of measurements, making use of the wearable garments and portable devices at home. Besides, the user answers two questionnaires defined by the medical team. These two contexts form the indoors scenario. The exercise context proposes a short walk to promote a healthy lifestyle and to improve cardiovascular capacity, which composes the outdoors scenario.

Finally, the third scenario sketches the professional interaction to assess the health status of their patients. The persona which describes the professional is a very busy specialist which needs to visualize the most significant information.

The analysis of the different scenarios is carried through an iterative refined context scenario from the study of "day in the life" of the persona during the **Framework** phase.

Thereafter, the **Refinement** phase culminated in a detailed documentation with all the requirements and specifications. From these detailed information some requirements should be emphasized, as follows.

The selected input method for end users is a touch screen, since it is more intuitive. The professionals will interact through a web-based application that allows ubiquity.

As feedback methods text, images, graphs and audio are addressed.

The user interaction device should be light weighted. However, it must have enough memory capacity to store the gathered data (at least 512 MB). Furthermore, a mobile connection is needed to communicate with the server through the Internet (i.e. GPRS or UMTS). Likewise, Bluetooth is necessary to connect to sensors.

Vital data should be received from sensors following a specific Bluetooth protocol, both for wearable and portable sensors. After the reception, processing and management of the data, results are sent to the back-end through secure channels (e.g. HTTPS, SSL (8)). In addition, synchronization is needed to avoid data inconsistencies (e.g. messages, treatments or appointments).

The user application needs to be highly user-friendly, intuitive and compliant to usability requirements. Besides, it needs to implement different use cases workflows such as: daily vital signals measurement, reminders, checking and displaying results, and automatic data transfer among others.

Moreover, the whole system must support multiple languages: English by default, German and Spanish.

Taking into account these requirements, a comparison amongst different available devices in the market was performed. The most suitable device is a PDA with touch screen and mobile communication capabilities: the QTek S-200 series.

All gathered data should be stored in a robust system with high level security and remote access from the server.

The server supports all business logic, workflows and error handling. Furthermore it delivers all information to the portal, to be consulted by the professional team.

Once all requirements and specifications are addressed, the HFMS is divided into 2 systems to be developed: the User Interaction System and the Back-end System.

3. Results

The resultant HFMS is composed of 2 sub-systems: the User Interaction System, implemented in a QTeK s200 as a device; and the Back-end, which includes the server, the data management module and the Cocoon based portal

After the design of the **User Interaction System** three core modules were implemented: the Front-end Communication Module, the Back-End Communication Module and the Data Management Module.

The user application lies above the former modules. It executes a set of workflows for measuring contexts, questionnaires, calendars, messages and GUI screens. Figure 2 below sketches the architecture of the UI System.

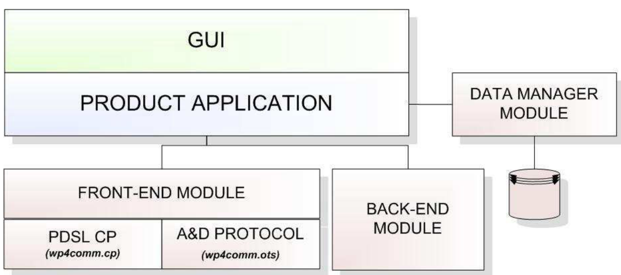

Fig. 2: HFMS Modules

In order to provide a good portability among different mobile device, the application has been developed in Microsoft .NET (9**,** 10) framework which is widely compatible with many Pocket-PC compliant devices.

The Front-end module provides a standard interface for each devices, i.e. electronic scale, pressure cuff and t-shirt sensors. The aim of this module is to isolate the complexity of each communication protocol from the modules used to get the data.

This module provides with an interface to abstract the complexity of lower layers: the PDSL protocol for the t-shirt (defined by Philips (PDSL) for this project), and the A&D proprietary protocol for the so called off-the-shell electronics (commercial devices not developed within MyHeart Project), i.e. the scale and the blood pressure cuff.

There is a device layer which isolates the complexity and provides the system with a clear interface, based on methods and signal retrieval events which make the system more general, portable and reliable to use.

The Back-end module deals with the communication between the UI system and the server that controls the data storage and management. The Back-end also provides with a secure channel for data transmission. The communication has been developed using Web Services (6) over a secure channel which has been implemented under the SSL protocol. The SSL is a "de facto" secure transport protocol which is used by financial institutions to ensure the security of their transactions over the Internet. The Web Services technology is a standard communication framework that provides reliable connection between sources. It has been selected among others due to its portability and level of standardization.

The data management module deals with two main functionalities. On the one hand, it provides means to store and retrieve all information that needs to be shared with the Back-end. On the other hand, the data management module also solves the coupling between the application and future algorithms that need to be executed in order to pre-process raw signals. These algorithms demand high computational and memory requirements because of the large amount of data under study. To improve the system performance, these algorithms are developed in low level programming languages like C++ and C. Thus, the core provides a layer that supplies compatibility with them and the rest of the application.

The Graphical User Interface follows the MyHeart Project common Look & Feel. Furthermore, it is user-friendly and intuitive, with clear indications of the necessary steps to follow during the monitoring sessions. Following figure shows the resulted GUI.

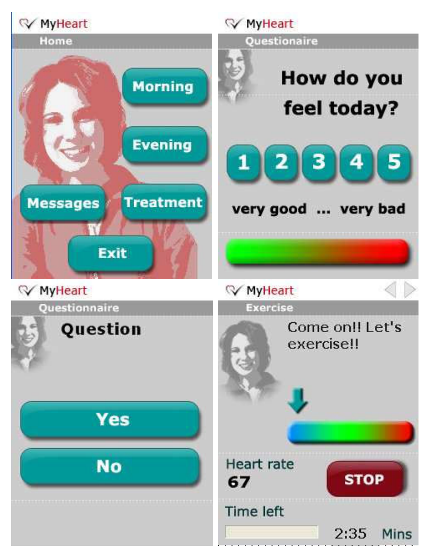

Fig. 3: Screen of the HFMS GUI

The **Back-end** includes the server, the data storage and the portal. It has four different functionalities:

- Processing module for data received from the UI system in which the ECG and the patient data (i.e. Questionnaires) are processed.
- Data storage module, which includes the

monitoring session data, the Patient data and the Clinical History, treatments, etc. The database access is based on Hibernate Technology in order to isolate the data model from the underlying database implementation.

- Notifications both to inform technical staff about errors, and medical professionals about improvement or worsening of their patients' health status.
- Web access for the professional interaction, which allows managing patient related data, monitoring session's schedule, notifications from the processing algorithms (according to a medical protocol); and visualizing of recorded and processed data.

Besides, it must also grant a secure access, User Login Administration and Data Privacy and Confidentiality.

The Server architecture was designed by the HF Management Team as a well integrated system based on Web Services, with a secure access, user login administration (based on LDAP technology), data privacy and confidentiality and communication services (e.g. SMS sending).

The Professional interaction is based on a web access through the Cocoon Framework and a CFORM based visualization, as shown in the following figure:

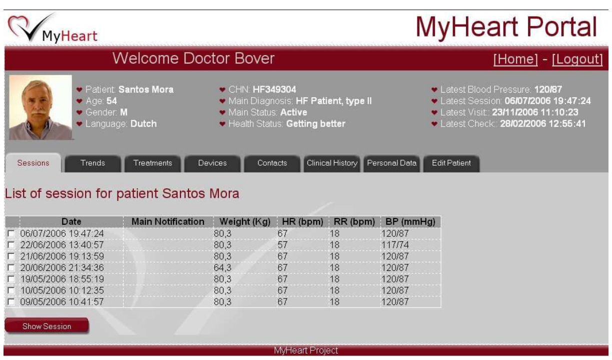

Fig. 4: Professional Interaction

4. Discussion and conclusions

As far as the system has been validated, these positive technical results encourage us to continue with our work and development. In particular, it has been proved that connectivity through the Internet and Web Services works as planned. Compared to previous versions, the user interaction with the current system has been widely improved (the look and feel of the user interface, etc).

Nevertheless, more studies about security issues need to be carried out, since those are a critical part of the system. In order to create a strongly consistent system, an error handling protocol during the interchange of data will be also developed.

Hence, future work encompasses the complete technical revision, clinical validation and a complete integration of data algorithms.

Finally, in the new paradigm of Ambient Intelligent, we strongly believe that in the future this kind of systems will represent an important part of the daily activity of this kind of patients, supporting a better quality of life and helping to prevent and to treat chronic diseases.

Acknowledgements

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Address for correspondence

Elena Villalba Mora
Life Supporting Technologies
ETSI Telecomunicación.D-204
Ciudad Universitaria s/n. Madrid 28040.
e-mail: evmora@lst.tfo.upm.es
Tel. +34913366834 / Fax: +34913366828