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User Interaction Design and Development of a Heart Failure Management System based on Wearable and Information Technologies

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Abstract- **In the Western World, Cardiovascular Diseases (CVD) are the leading source of death. Only in Europe, they cause 45% of all deaths. Besides Heart Failure, the paradigm of CVD, affects mainly people older than 65. Facing this reality, the European Union has 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 the User Interaction for a Heart Failure Management System. This system consists on wearable and mobile technologies which monitors the Vital Body Signals in a daily basis, providing a continuous assessment of this chronic disease.**

I. 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 a decrease in the quality of life of the aging population.

Within this context, a Heart Failure Management System (HFMS) was designed to gather all vital information from the population suffering from HF. To then process this information to obtain feedback on the type of assistance that the patient may need. HFMS also provides professionals with selected information, permitting the evaluation of symptoms, such as arrhythmic and ischemic risk, with the aim of preventing possible re-hospitalizations.

HFMS makes use of the latest technologies to monitor heart condition, both wearable garments (for measuring ECG, Respiration, Activity and Cardiac Impedance); and portable devices (such as Weight Scale and Blood Pressure Cuff) with Bluetooth capabilities.

HFMS aims to decrease 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.

All the daily data are processed and used in the detection of functional capacity, worsening and ischemia 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.

Two are the main stakeholders of the system: a) HF chronic disease management service providers, such as cardiologists and nurses; and b) patients with HF. Our research activity, which is the design and development of the system for the user interaction, focuses on the second target group.

Fig. 1 sketches the global system, which consists of three main elements, as explained below [2, 4, and 5]:

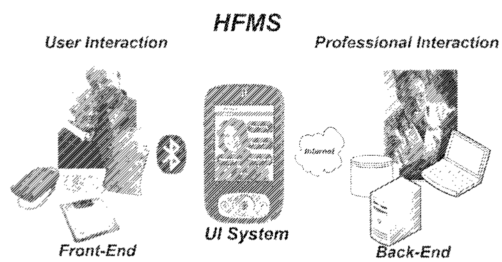

Fig. 1: HFMS overview

- The **Front-end** is composed of different garments, textile sensors and electronics to record vital signals. These signals are ECG, respiration and activity which are required by the application.
- The **User Interaction System (UIS)** is based on a personal digital assistance device that receives data from the monitoring sensors. These data are processed to send feedback to the patients and encourage the daily care of their heart. Besides, it enables the communication and the synchronization with the Back-end.
- The **Back-end** consists of the processing server and databases, which manage all patients' daily data. Professionals can visualize and manage all data through a web access provided by a portal, which is based on Cocoon technology [7].

Since the system collects personal and clinical data, security issues play a role of paramount importance.

The following sections explain the design process of the User Interaction and the later implementation of the solution.

II. METHODS

The design and development of the UIS was performed in three stages: the first stage is the system design, the second stage is the core components implementation and the third stage is the application customization.

A. *User Interaction Design Stage*

During this stage, the first step consisted of the definition of the target group characteristics. The target user 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.

In order to take the best approach for the user interaction and taking into account the results of a preliminary study (performed also within MyHeart [3]), the following requirements must be addressed:

Input methods: touch screen, since it is more intuitive for the target group of users.

Feedback methods: text, images, graphs and audio.

User interaction device requirements: it should be light weighted and should have a small size. 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 with sensors.

Data transmission requirements: vital data should be received from sensors following 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 protocols (e.g. HTTPS, SSL [8]). In addition, synchronization is needed to avoid data incongruities (e.g. messages, treatments or appointments).

Application requirements: the system needs to be highly user-friendly, intuitive and complying to usability requirements. Besides, it needs to implement workflows of different use cases such as: daily vital signals measurement, reminders, checking and displaying results, and automatic data transfer among others. Moreover, the application must support multiple languages: English by default, German and Spanish. Permitting also remote configuration, including firm-/software update.

Taking into account these requirements, a comparison amongst different devices available in the market was performed. Advantages and disadvantages of mobile phones and available PDAs were evaluated.

The most appropriated device is a PDA with touch screen and mobile communication capabilities: the QTek S-200 series.

After the definition of the requirements and the user terminal selection, modules specification was done. The application was divided into: Core modules, User Application (personalized for the needed functionality during the daily routine), and Graphical User interface.

B. *Core Implementation Stage*

The core modules were designed to be independently used from the use cases. These core modules deal with the system middleware, the transmission needs and the data management.

The User Interaction Core provides a set of libraries that deal with the main requirements of the patient's mobile station, making special emphasis on the communication and the data management capabilities of the architecture.

Regarding the communication requirements, HF Management holds the following two communication channels: a) the Front-end module which carries out the connection with the electronic garments of the patient; and b) the Back-end module which implements the communication to the servers.

With regards to the data management requirements, this core module provides with the appropriate means to store and retrieve all information, as well as pre-process raw data when needed.

C. *Personalization of the User Interaction System Stage*

Once the core components were defined, the System was customized to each particular use case. This customization was defined by medical experts in the field of long-term care of patients as well as in the field of Heart Failure disorder. During the first system implementation, each use case was defined in terms of the precise "*daily routine*" to be performed by each of the HF patients who had been enrolled in the system.

The daily routine is divided into the morning routine, the exercise routine and the before sleeping routine.

During the morning routine, the patient starts the application just after waking up wakes up. Immediately if there are new updates in the patient profile, these are downloaded into the UI system. Then the patient is prompted with the questionnaire. Some examples of questions defined by the medical team are:

Did you sleep well last night?

Did you wake up breathless during the night?

How is your mood today?

Then UI system indicates to the user how to measure the following vital information: a) the blood pressure (diastolic and systolic), b) the ECG and respiration, measured by the T-shirt, and finally c) his weight by using the Bluetooth Weight Scale.

If no anomaly is detected during the morning routine and no contraindication is indicated by the back-end, then the exercise routine is commenced. This routine consists of five minutes of monitored walk

The system is not required during the rest of the day, unless the patient wishes to use it. Thus, the UIS is minimally invasive in the HF population life.

Just before going to bed, the before sleeping routine starts. The patient checks the UIS for any update and answers a simple questionnaire about how he felt during the day.

The Graphical User Interface (GUI) is accordingly designed to the common *Look & Feel* recommendations, which have been developed within the MyHeart project. Issues such as the font, the colors, the logo and questionnaires have been pre-defined.

Thus, the Verdana font, 36pt, has been selected in this application for its readability. The GUI settings were also taken into account, with a light-colored background which permits the dark-colored font to be easily visible. Also, a *traffic light metaphor* is applied. For instance, good health improvement indicators are displayed in green. For simplicity, questionnaires are direct admitting only close answers, when possible yes/no; or just five scoring buttons when more concrete information is needed.

III. RESULTS

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 then, with controlling modules to measure sessions, tasks calendar, messages and GUI screens. Figure 2 below sketches the architecture of the UI System.

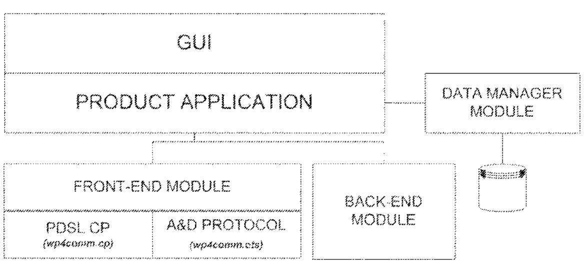

Fig. 2: HFMS Modules

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

The following subsections explain in detail each module and the product application that incorporates the GUI.

A. *Front-End Communication Module*

This 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 protocols 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 the aim of the project), and the A&D proprietary protocol for the so called *off-the-sheel electronics* (commercial devices not developed within MyHeart Project), i.e. the scale and the blood pressure cuff.

The PDSL protocol is based on a stack of layers whose communication is based on interfaces. Thus, this protocol is meant to be a general purpose communication protocol. It can send different signals and algorithm results using different communication channels which are defined in the protocol. The A&D is a protocol based on fixed frames of data and it is used for limited purposes and for devices with limited capabilities. 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.

B. *Back-End Communication Module*

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 transportation. 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" security 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.

C. *Data Management Module*

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. This functionality is achieved via a portable database provided by the architecture framework, and is covered by an abstraction layer for portability issues.

On the other hand, the data management has to solve the coupling between the application and algorithms that need to be executed in order to pre-process raw body signals. These algorithms demand high computational and memory hardware requirements because of the amount of data under management. 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 activity supervision algorithm has been used in the HF management application. This algorithm computes the level of exercise executed by the patient providing feedback on the quality of the exercise. This algorithm does not demand high performance requirements. Therefore it has been codified directly using the .NET Framework C# programming language [10], which relies on a light-weighted database developed by Microsoft, the

SqlCE server [10]. Nevertheless, the abstraction layer has been developed to ease the portability to other light databases.

D. Product Application and Graphical User Interface

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. Figure 3 shows the resulted GUI.

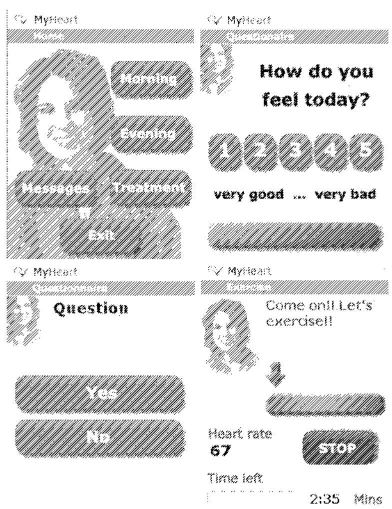

Fig. 3: Screen of the HFMS GUI

IV. CONCLUSION

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

There are still further improvements to be developed using the Bluetooth communication technology, which will provide a greater transparency of the system connectivity. In future projects, more algorithms will be integrated into the system, for instance Atrial Fibrilation detection and Heart Rate Variability.

The most immediate challenge is the creation of a completely dedicated device which will keep the user away from any interaction with the operating system, being aware only of the HFMS.

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

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 treat chronic diseases.

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