Wearable and Mobile System to Manage Remotely Heart Failure

E. Villalba, D. Salvi, M. Ottaviano, I. Peinado, M. T. Arredondo, and A. Akay

Abstract—Cardiovascular diseases (CVDs) account for 45% of all deaths in the western world according to the 2004 World Health Organization statistics report. Heart failure (HF), CVD’s primary paradigm, mainly affects people older than 65. The European MyHeart Project’s mission is to empower citizens to fight CVD by leading a preventative lifestyle and allowing early diagnosis. This paper presents the iterative design and development of the HF management system, part of MyHeart Project. The system daily measures vital body signals to assess HF. The methodology applied herein has involved stakeholders in an iterative process: concept validation, feasibility, efficiency, patients’ experience, and patients’ acceptance. The final solution allows patient self-management of their chronic condition.

Index Terms—Goal-oriented design, heart failure (HF) patients, mobile systems, personalized applications, personalized health systems, wearable systems.

I. INTRODUCTION

The proportion of elderly people (aged 65 or over) in the European Union is predicted to rise from 16.4% in 2004 to 29.9% in 2050 [1]. This will increase the number of elderly suffering from chronic diseases such as cardiovascular disease (CVD) [e.g., heart failure (HF)] and significantly strain personal health care services with novel technologies, especially wearable and mobile systems [2], [3].

The research presented within this paper is based on the design and development of a solution that improves the quality of life in patients with heart disease: the HF management (HFM).

HFM aims to decrease the HF population’s mortality and morbidity. The system consists of a patient platform and a professional platform where patients are those people who suffer from heart disease, and professionals are both cardiologists and nurses.

The patient platform includes ad hoc and commercial devices, and a personal digital assistant (PDA). The ad hoc monitoring sensors measure ECG, respiration, and activity during exercise and at rest. They are wearable sensors embedded into a T-shirt, a bra, a harness, a bed sheet, and a pillow. All these sensors have been designed and developed within MyHeart Project. The commercial devices are a weight scale and a blood pressure cuff. The PDA receives data from all measuring sensors and devices via Bluetooth, processes it, and encourages patients in their daily healthcare. The professional platform includes the processing server (that analyzes all data), databases, and a Web portal that provides ubiquitous access to the professionals.

II. METHODOLOGY

The methodology used for this research has been ad hoc adapted by following the design principles of user-centred design [4] and goal-directed design [5] together in an iterative software design (ISD) process [6].

Following the Advisory Group form the European Commission, ISTAG, which boosted the involvement of users in all phases of the design and development beyond the validation in the latest phases, we co-design with patients and professionals [7].

We divided the process life cycle into three iterative phases (conceptualization, implementation, and deployment phases), each focusing on observing and interviewing stakeholders, (medical experts and patients) in all the stages of the process. Each phase comprises modeling, requirements elucidation, design, implementation, and validation. This way, the system is evaluated in different maturity stages.

Table I represents all validation performed along the three iterative phases. The validation was held in different countries in order to assure the internationalization of the solutions.

In total, 82 people took part in the validation: 56 HF patients, 6 final users without HF, and 20 professionals.

III. HFM CONCEPTUALIZATION

We modeled the solution during the conceptualization phase. We defined the system goals by reviewing existing similar solutions working together with technical experts, medical experts, and researchers. This multidisciplinary team stated the initial hypotheses for the system. The technicians created a non-functional prototype.

The prototype consists of an application running in a PDA and a Web portal. The patients used the PDA to perform some measurements, such as ECG, and to answer a short questionnaire to assess their condition. The professionals (cardiologists and nurses), via the Web portal, could see an overview of all their patients. Professionals have access to patients’ current health status and progression [8].

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The preliminary scenario was a short walk to promote exercise among HF patients. This controlled walk required a prepwalk phase to measure the heart condition and to state the activity’s maximum duration (5–10 min). We monitored the patient’s heart rate (HR) using a T-shirt with embedded wearable sensors and an accelerometer to measure activity (both developed within MyHeart Project). Next, the patient filled in a short symptoms’ questionnaire and all data were sent to the cardiologists and nurses for further assessment.

The standard patient was aged 65 or older and he/she suffered HF without additional disabilities. The professionals were both cardiologists and nurses.

Three groups were tailored to validate the HFM concept: HF patients, medical specialists (cardiologists and nurses), and hospital business managers involved in administrative “chronic disease treatment” related tasks. The objective was to understand their vision, constraints, needs, goals, and behaviors to validate our initial hypotheses.

We based the conceptual validation on personal interviews with open- and close-ended questions followed by a system demonstration to allow the interviewees to evaluate the prototype’s usability and comfort. Twenty-six people were interviewed: ten patients (nine men and one woman, 80% of them were above 60 years), six business managers, and ten cardiologists. Philips Design, Eindhoven, The Netherlands, designed the interviews in the remit of the My Heart Project.

Each interview consisted of five sections: introduction, storyboard, demonstration, conclusion, and closure. The interviewer explained the interview’s purpose during the introduction, offering the interviewee a confidential agreement to sign. The interviewer posed some general questions probing positions toward technology and health status.

The interviewer presented the global system and asked the interviewee open questions about their impressions and doubts within the storyboard section. Once they grasped the system basics, the demonstration section started, wherein we presented the wearable garments (i.e., a T-shirt with embedded ECG sensors and respiration sensor) together with the electronics connected to the T-shirt to filter the signals and to send them to the PDA by Bluetooth. The PDA had a nonfunctional prototype (an application with GUIs without integration to the sensors or to the server) to guide the patients along the measurements. For cardiologists and business managers, there was a nonfunctional Web portal to see all data from patients.

During the conclusion section, the interviewer asked for their overall impression. Additionally, the interviewee completed a scoring sheet with ten closed questions rating from 1 to 5, which provides a quantitative result. Each interview’s time varied from 60 min for the professionals to about 120 min for the patients.

As an example, Fig. 1 shows the quantitative results out of the scoring sheet for the patients.

Among the patients, there was a positive attitude toward the concept. Most interviewees answered that they would use the system, but they did not trust the medical value. They asked for medical evidence (question 10).

The business people and cardiologists answered similar scoring sheets. Both groups had similar answers. They see the concept as a good solution to assess HF. However, they also asked for clinical evidence of the sensors and algorithms used. The business people stated the necessity of changing the current business model in Europe, based on social health care, and to create specific units to surveillance theses chronic diseases.

Although the concept represents a useful and adequate solution for long-term treatment of chronic disease, issues remain: the system requires user interaction with a technical device, thus reducing the number of people who could be incorporated to the program, necessitating a user-centered design.

Furthermore, the concept forces the users to follow a fixed routine that is potentially a burden in their lifestyles. Thus, the system should incorporate a higher modularity, offering different solutions to a diverse range of users. Therefore, the final solution implements many services and allows personalization. Besides, the system runs in a PDA with mobile capabilities to boost mobility and the professionals have a ubiquitous access via Internet.

Next, the final solution HFM was designed and further, completely developed and integrated.

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**TABLE I**

<table>
<thead>
<tr>
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<tr>
<td>Total</td>
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**Fig. 1.** Patients’ scoring sheet.
IV. HFM DESIGN

This section describes the design and requirements of the final implemented solution, an intermediate version is explained in [9].

In the final scenarios, the patients are prompted to follow a personalized daily routine consisting of a set of activities (i.e., symptoms questionnaires, measurements using wearable garments, and portable devices). The health data assessed are ECG, heart rate, respiration, blood pressure, and weight. To complete the information about their health status, patients fill in symptoms questionnaires twice a day.

We used a textile garment (a vest or T-shirt) to measure the daily ECG and respiration. The ECG measurement used a 256 samples/s sample rate. We used the information to obtain HR and HR variability (HRV). We also measured the respiration using a 256 samples/s sample rate. We used it to obtain the amplitude and respiration rate.

We used a three-dimension accelerometer that was placed in the on-body electronics box to obtain the activity. The box also takes signals from the garment, filters, and then, amplifies them. They also extract the HR from the ECG, and the respiration rate and amplitude. The device is also Bluetooth-compatible.

We used a piezofoil under bed sheets for night measurement. The raw data goes into a stationary bed-side monitor that obtains: 1) the HR; 2) the respiration frequency and amplitude; and 3) the activity level as outputs by applying algorithms to the raw data measured with the piezofoil.

Besides the wearable, and wearable sensors and electronics (both wearable and stationary), there are two other additional off-the-shelf electronics: a blood pressure cuff and a weight scale. We used the IEM’s StabilOGraph Blood Pressure Monitor to measure blood pressure. We used the Philips Motiva as a weight scale. Both are validated in accordance with organizations such as the Association of the Advancement of Medical Instrumentation (AAMI) and certified.

The sensors and electronic communicate via wires. The devices communicate with electronics wirelessly using Bluetooth with a serial port profile.

The blood pressure cuff and weight scale follow proprietary protocols. The MyHeart electronics protocol is defined within the project’s remit.

The patient can perform a light exercise of 5–6 min, several days a week to improve their health.

The daily routine must be personalized for each patient despite the light constraints. Specifically, each patient will have a different daily health schedule according to particular health status, preferences, mental status, and recommended medical protocol.

The patient application must be intuitive, user-friendly, and must allow natural interaction. The PDA with a touch screen allows these requirements. The high-tension cable (HTC) series with mobile capabilities were selected as patient interaction device.

Adaptability to user preferences and routines within HFM is achieved via dynamic workflow execution (which depends on the context information). First, we defined taxonomy: the session/context/activity model. A session is a day using HFM, a day is divided into contexts (morning, exercise, evening, and night). Each context comprises a set of activities requiring user participation at the same temporary term (i.e., a task or activity is the measurement of blood pressure). It is done while measuring the subject’s weight and the morning questionnaire. Thus, we have the morning context. Each context is defined by a beginning and ending time that sets the validity period, restricts the context execution, sets activity performances, and describes the current context state. The state can be inactive, active, performed, aborted, and incomplete. Following this scheme, after the application is turned off, all contexts are inactive.

Different rules govern context activation (i.e., they are performed between starting and ending time). They also have restrictions in the medical protocol (i.e., exercise must be finished 2 h after medication).

Following context activation, the alarm is launched and executed with the user acknowledgement. The context execution equates the activity execution in the list. Each manager controls each activity, thus allowing modularity. The manager invokes all necessary software (SW) and hardware (HW) modules (e.g., sensors).

Restrictions are events-based occurring in real time. They are triggered either by the user via direct interaction (user voluntarily stops an activity) or by the system. The system launches events coupled to the health status from the study of vital information or the environmental status (patient location, etc.).

The activities execution dynamically occurs depending on the current context: period status, user dialogue, and the health status, together with other contextual information.

All gathered data, raw processed raw signals, and notifications are sent to the back end for further processing and management. Back-end communication requires the user device to have general packet radio service (GPRS) or universal mobile telecommunications system (UMTS) connection to enable a client for a Web service in the server side via secure channels (e.g., hyper-text transfer protocol secure (HTTPS) and secure sockets layer (SSL) [10]).

The professionals access all data via the portal. The first available information is an outline of every user highlighting crucial events. The professionals can also consult and edit the information for specific uses, and they can adjust the thresholds and/or questionnaires.

V. HFM IMPLEMENTATION

The resulted system contains two main subsystems: 1) the user platform and 2) the professional platform (see Fig. 2).

A. Patient Platform

The final user platform is a modular architecture running on Microsoft’s .NET Framework [11], [12]. The session context engine is the core element that provides flexibility in the protocol that users follow. We based it on the workflow engine that invokes the tasks the user performs according to a workflow that varies with every patient. The varied tasks are organized in contexts.
Fig. 2. Modular architecture of the user platform.

Fig. 3. Modular architecture of the user platform.

Fig. 3 illustrates the user platform’s architecture whose modules are further explained shortly.

The system is divided in four main areas: 1) the front-end module; 2) the workflows; 3) the engine; and 4) the back-end module. The PDA also comprises the postprocessing algorithms and the GUI forms that allow the patients’ interaction.

The front-end module provides a standard interface to the sensors. The module isolates the complexity of the communication protocols toward the different sensors.

The module is structured into the following subunits: 1) the Bluetooth manager; 2) the sensor manager; and 3) the device managers. It also includes the integrated measuring devices’ drivers.

The Bluetooth manager discovers and connects to Bluetooth devices with the serial port emulation profile, and sends and receives raw data.

We developed the module in .NET for the Windows CE operating system, which provides an abstraction layer for the basic functionality of the operating system that Bluetooth’s stack implementation offers.

The sensor manager module responsible for storing the information on sensors is available at the system during its operation. The module stores the sensor’s connection details (i.e., Bluetooth’s address and pin number) to use them when a sensor is needed.

The device managers implement the command flows to be sent to the devices when an activity must be performed. They abstract all the communications by providing exact measurement data and launching events when a critical activity step has been reached.

Workflows use device managers to separate the user interaction from the sensor management during the activities. They implement the activity’s basic steps using the lower modules of the front-end area and call the algorithm.

Workflows define the patient interaction via displayed messages and actions taken when the patient presses the button. Events from the scheduler trigger the workflows when a context requires performance; the related workflow starts showing the correct user interface. Activity workflow communicates with the device manager and receives the measured data plus events relating to activity status during the activity’s execution. The workflows use the GUI via opening and closing formularies, and setting their text fields. The workflows use a localization module that gathers the local language’s textual information from an XML file to provide internationalization into the application.

The engine implements and manages the session/context/activity model that was explained in the former section. This engine covers: 1) the application data meaning and storage; 2) a scheduler; 3) some modules for the application configuration; and 4) an error management module. The application runtime information is stored on tabloid, a data structure. A tabloid implements the table containing the list of actions the application performed and will perform during the day.

A scheduler persistently updates the tabloid. The scheduler checks the system clock and decides the actions that the user performs. It manages contexts, sends information, and launches events warning the user of pending action.

Context execution is managed on the tabloid. Each context is defined via starting and ending time that sets the validity period, a set of restrictions constraining the context situation, a set of activities the user will be performing, and a variable describing the current context state [9].

The context execution means the execution of activities included in the list. Activity managers control each activity: a questionnaire activity manager supervises the questionnaire’s extraction from a configuration file, fills the questionnaire data structure, and manages the answers.

The data model comprises the structure set that describes all possible data treated in the application and a module able to map this data into a database. The data model includes: 1) the SessionPlan data that represent the current daily activity routine planned by the professional; 2) Done data that represent the measurements sets taken by the user according to the daily routine planning; and 3) Tabloid data are used to manage real-time information regarding which activities must be executed or were already executed. Besides, common data contains datasets that are shared among all the application.

The configuration modules get the application’s general configuration from an XML-formatted file for generating the tabloid information starting from the session plan data. The error management module stores all error events encountered during the application’s execution. This module’s focus is to log adverse events to send this information to the professional platform for further analysis.
The back-end module focuses on communication between the user interaction platform and the back end. We developed this using Web services over HTTPS as the transport protocol. The module implements security measures (i.e., encrypted channel and authentication).

The back-end communication module works with two datasets: 1) data collected from daily routine performances and 2) the system configuration.

The protocol uses Web services to directly interchange objects. All the exchanged data are structured using the XML schema that are automatically converted to the platform-specific types by the SOAP libraries of the .NET Compact Framework (CF) [13].

Finally, the patient platform allows the computation of additional algorithms used for measurement’s postprocessing. These algorithms demand high computational and memory requirements because of the large data quantity that must be processed. These algorithms were developed using low-level programming languages (C++/C). Thus, the algorithms module provides a layer that supplies compatibility among algorithm libraries plus the entire application. The algorithms are precompiled libraries and must be integrated into the PDA software.

The graphical interfaces are the crucial part of the system, since people who will benefit from this application are not technically skilled.

Graphical patient interaction is provided as .NET formularies (forms). Each form represents an application screen, with static, graphic elements (text/pictures), and dynamic and interactive elements like buttons and slides. User interaction and workflows manage the forms via events.

We designed the GUIs according to heuristic rules for usability [13]–[15]. We carefully performed and validated the design for patients aged 65 years, experts, and nonpatients final users in various development stages (see Fig. 4).

B. Professional Platform

We developed the professional platform on JBoss AS v. 4.2.1 with a J2EE 5 Java virtual machine [16]

The database runs on MySQL Server v.5. Hibernate abstracts the lower level service of database [17]. The platform complies with all of the European legislation’s privacy protection security requirements. The European Commission gave the general guidelines in the Directive 95/46/EC “on the protection of individuals with regard to the processing of personal data and on the free movement of such data”1 and in Directive 97/66/EC “concerning the processing of personal data and the protection of privacy in the telecommunications sector”2.

Fig. 5 sketches all three JBoss tiers’ components.

The Web services enable communication with the user platform. Two interfaces exist: one receiving session data from the patient’s device and the other uploading the session plan into the PDA. The authentication module provides full access control to the system that grants confidentiality and security. We applied different security policies for the Web Services’ two interfaces. We added another security layer via encrypted communication channels into this module.

The notification service module receives information generated that the system generates and either stores it in the data model or sends it to another service. The notification handler manages the notifications and reacts to significant events. It distinguishes three different notifications: communication problems, behavior, and medical.

The scheduler periodically executes the evolution analysis service. This module summons newly scheduled jobs to conclude a pending analysis.

The data model includes: 1) professional data; 2) patient data; 3) session planning; 4) medical data; 5) algorithms data; and 6) questionnaires data.

The context analysis service is the first analysis level of the patient’s data sent from the patient station. It evaluates the biosignal’s quality and the data’s medical coherence (e.g., checks to ensure that the weight is coherent with previous measurements or a basal data).

This service is executed whenever a patient’s device sends the session data. Data are analyzed and stored in the back-end model. A notification is generated if something goes wrong.

1Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
Fig. 6. Patient record in the medical portal.

The evolution analysis service analyses the entire data periodically to extract information. It accesses the entire data model for further data analysis along time. The module executes complex algorithms that estimate for instance the patient’s adherence to the session protocol or the worsening symptoms.

The graphical professional interface (presentation tier) uses portlets that use Web module (JSR168 specification).

The professional portal manages patients, devices, and visualizes the patient’s ongoing health status. Fig. 6 shows the medical portal GUI.

VI. HFM SYSTEM VALIDATION

During the implementation phase, we performed first a heuristic validation. The heuristic evaluation involved four experts in user interaction and people research took place in Eindhoven, The Netherlands, in November 2006. This validation detected an immoderation during the entire routine. We implemented the skip functionality plus more help functionalities, clarifying information for users.

Next, we did a usability test with five patients, also in Eindhoven. We performed the interviews in two rounds with three users each time. All users were over 65 years and had chronic illness related to cardiovascular pathologies or rheum. We interviewed a woman in both rounds, showing an improvement in our understanding of the interaction. The users had some problems in understanding instructions, especially with symbols, despite being able to handle the device. Thus, we refined the instructions in easily readable text.

Latterly, we carried a field test with four women with HF. They used the integrated system at their homes during a week in Basel, Switzerland, in July 2007.

Two cardiologists from Medgate (a clinic in Basel) played the role of professionals using the Web portal. The study’s primary objective was to validate the implemented and integrated system for HF’s assessment in a real environment with real users who will use the system in their homes.

Patients performed all tasks until technical problems occurred. The patients initially felt intimidated by the device. After the pilot, they felt more positive although they were still unsure how it will fit into their daily routines.

We fixed all technical bugs detected during the field test bringing out the final integrated solution in the deployment phase.

Finally, at the end of the deployment phase, a field test was done in Madrid, Spain, during February 2008.

The final HFM was validated with 37 patients in Madrid (mean age was 60.3 years and the standard deviation 5.75) together with Hospital Clínico. No usability or acceptability problems appeared and the system resulted robust and stable (see Fig. 7).

Further analysis, by separating different components and activities, showed that the PDA and the blood pressure were highly appreciated whereas the garment (vest or bra) was the least valued component (see Fig. 8).

VII. CONCLUSION AND FUTURE WORK

The final results were really promising. All people involved showed a high interest in the solution. A detailed analysis to enhance individual experience incorporating this system into the daily routine in a long-term basis requires further study. A study is underway on the behavior components toward e-health to create a communication framework plus increasing the patient’s interest in such systems. A future framework considers the analysis of different variables [18].

Likewise, we must evaluate the long-term impact in the quality of life of heart patients and their health status. To achieve that goal, an extensive validation will take place involving up to 200 patients using the solution during 1 year, in Germany and Spain in 2009.

We strongly believe that these systems will play an important role in the HFM patient’s daily lives, supporting a quality of life that will prevent and treat chronic diseases.
Acknowledgment

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References

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