INTENSA: Heart Failure Patient's Follow-up System Using the ISO/IEEE11073 Standard

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***Abstract*— This paper presents a novel implementation methodology of ISO/IEEE11073 standards for use in real monitoring platforms based on patterns paradigm. These monitoring platforms include several medical devices based on low voltage-low power microprocessors. As a proof of the concept, INTENSA project which aims to develop and evaluate a heart failure follow-up interoperable system including weigh scale, blood pressure and HOLTIN devices, is briefly described.**

I. Introduction

THE fast development of Information and Communication Technologies (ICTs) is fostering the transformation of the traditional health systems into new patient-centered environments. The so-called Patient Empowerment [1] is changing the conventional role of patients and physicians into a novel layout where patients take care of their own health and well-being.

On the other hand, the monitoring of different vital constants, for instance, ECG, weight or blood pressure is a key issue in the follow-up of some diseases such as heart failure, Chronic Obstructive Pulmonary Disease (COPD), arterial hypertension (which is one of the main risk factors for heart diseases, strokes and also a prognostic indicator of renal failure), or the obesity, which increases the potential of suffering other illnesses such as diabetes, cholesterol, hypertension, joint diseases, gallbladder malfunction or coronary and respiratory complications, among others [2].

It is essential the availability of Medical Devices (MDs) that can help patients to self-manage the follow-up of their diseases. These MDs should be wireless and wearable in order to be practical and useful, and they have to integrate communication protocols that allow the transmission of biomedical data. As an example, one platform developed by our group is HOLTIN [3] which consist on a wearable Bluetooth INtelligent HOLTer device that sends cardiac events through a mobile phone gateway to a healthcare center. However, the majority of the MDs as well as the protocols used in the healthcare system are proprietary and thus difficult to extrapolate to other scenarios.

In this context, several protocols have arisen to cover the interoperability issue. One of the most widely known is the European standard ISO/IEEE11073 (X73). Initially designed for patient's Point-of-Care (X73PoC) [4], it has recently evolved to Personal Health Devices (X73PHD) [5], in order to consider the emerging of new transmission technologies (such as Bluetooth, WiFi, or ZigBee) and wearable devices with limited capabilities. The basic topology of an X73-based monitoring system comprises three operational subsystems: the MD, the Compute Engine (CE) and the Monitoring Server (MS). The MD (also called Agent) collect biomedical measurements and send them to the CE via X73; the CE (also called Manager) gathers the medical measurements that came from the MDs and transmit them to the MS; whilst the MS has the task of gathering these measurements, coordinating and managing the different CEs and diagnosing patient with an online follow-up.

However, there are some drawbacks in the implementation of the X73 standard: its inherent complexity, the time needed to learn and implement it, the integration with other standards, lack of tools for developers or the special hardware needed to run it. These among others are focus of our work, which is being carried out in collaboration with the European Committee of Standardization (CEN) and has produced its first results [6,7] used as basis for the rest of this paper.

The paper is organized as follows. Section II presents an explanation about an interoperable X73PHD standard-based pHealth platform proposal for heart failure patients' follow-up, showing its main characteristics and the handicaps encountered. Later Section III makes an introduction to X73PHD specially to state the basic concepts needed to be implemented it into microcontroller-based systems, and in Section IV we propose a methodology and an architecture that enables the implementation of the X73 standard into limited resources systems and microcontrollers. In Section V, a review of future trends is presented. Finally, conclusions are drawn in Section VI.

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II. Heart failure patient's follow-up systems

The work carried out during the last years in our research group with the X73PHD interoperability standard and its implementation into wearable MDs or pHealth devices, together with the development of the new healthcare service called HOLTIN, in collaboration with the cardiology service of the Hospital Dr. Negrín (Las Palmas de Gran Canaria, Canary Islands), which allows follow-up of patient with paroxistic arrhythmias and syncope for long periods of time, leads to the proposal of the implementation of a standard-based end-to-end pHealth platform for the specific scenario of heart failure patient's follow-up (See Fig 1).

The X73PHD platform is made up of several MDs which acquire the patient's health state information and send it to a CE device through wired and/or wireless technologies such as USB, IrDA, Bluetooth or ZigBee. The CE device can be a mobile phone, set-top box or Personal Computer, and it transmits the information received from the MDs to the MS by means of ADSL, GPRS or any other long range technology. All the information at the MS can be analyzed by medical staff and integrated in the Hospital Information System (HIS).

There are several medical devices which are suitable in order to be used in a heart failure patient's follow up system: weigh scale, blood pressure, cardiac rhythm monitor, SpO2 and even thoracic impedance meter between others. The X73PHD pHealth platform proposal presented in this paper uses the following X73PHD compliant MDs:

- X73PHD compliant weigh scale [8]. The patient weighs oneself following the indications of the medical staff (measurement frequency and intervals), and the weigh information is sent to the CE device. If the transmission fails the information is temporarily stored in the weigh scale and sent later.
- X73PHD compliant blood pressure (BP) [9]. The patient takes the measurement (the device acquires systolic and diastolic BP, and calculates a mean) and the information is sent to the CE device.
- X73PHD compliant event cardiac Bluetooth monitor HOLTIN. The wearable medical device is placed at the patient's chest and carries out all the functionality related to the acquisition, processing of the ECG, detection, storage and transmission of cardiac events to the CE device (Smartphone) via Bluetooth technology. A fully X73PHD compliant specialization for ECG 1-3 lead devices is being drafted at the moment of this writing that will be adopted in the near future once completed.

Referring to interoperability in MDs, it is important emphasize the need of wireless transmission technologies such as Bluetooth and ZigBee, that provide specific profiles for eHealth applications and that make use of the X73PHD interoperability standard. In this way, ZigBee Alliance announced recently the beginning of the development of a new Health Care Profile (HCP), and Bluetooth Special Interest Group (SIG) published last year the new Health Device Profile (HDP) [10].

One important feature in a pHealth platform is that all the medical devices are going to be portable and/or wearable devices implemented with microcontroller platforms, and are characterized by strict power consumption requirements (most of these devices are supplied with batteries), reduced RAM/ROM memory resources and process capability. All these factors have an influence on the X73PHD implementation. However the manager functionalities are implemented in devices with more resources and process capabilities, such as Smartphone, set-top box or Personal Computer.

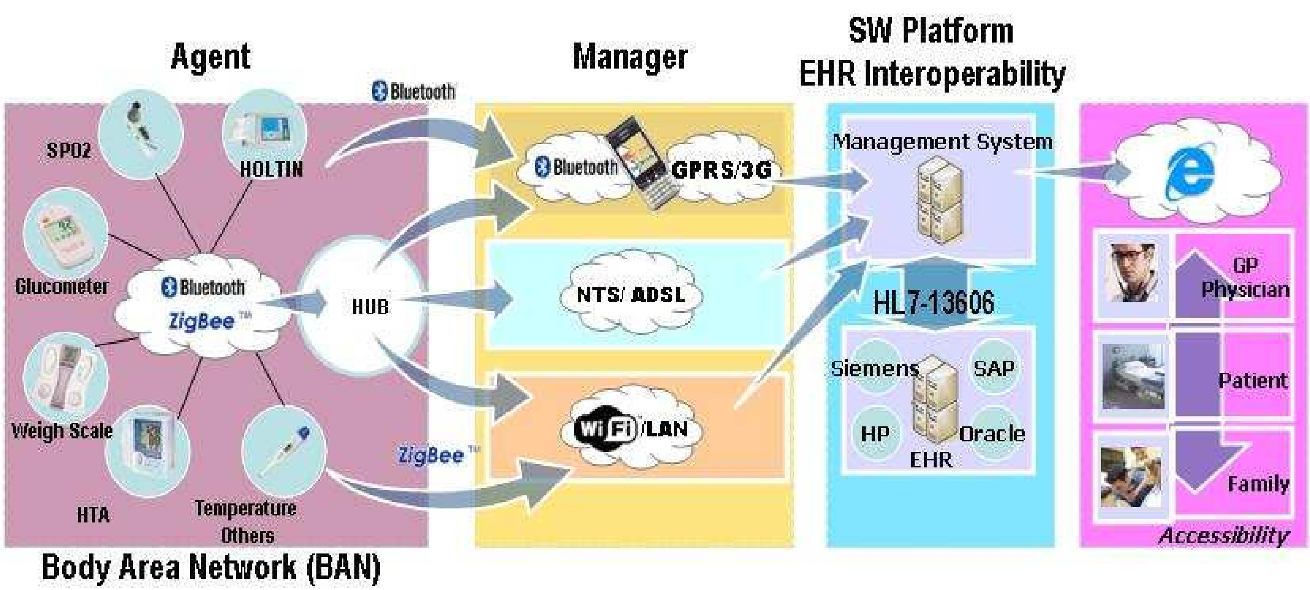

Fig. 1. Proposed X73 standard based p-Health platform for heart failure patients monitoring

III. ABSTRACT MODEL OF THE ISO/IEEE11073-PHD IMPLEMENTATION

The X73PHD standard defines the reference model based on a well defined object oriented paradigm that guaranties extensibility and reusability with the definition of three different models: the Domain Information Model (DIM), the Service Model, and the Communication Model. Basic concepts and characteristics especially interesting for implementation purposes are given as follows:

- DIM. It describes an abstract model composed by a set of classes of objects which are instantiated and can be referenced in an X73PHD based communication. That includes their attributes and the methods and actions that can be executed on each of them. The DIM covers the definition of e.g. the Medical Device System (MDS) object (the root object in the MD modeling), scanner objects (for MD data reporting), different metrics (numeric, real time sample array and enumeration objects), and Permanent Metric (PM) store and segments (for data storing).
- Service model. It defines the means by which the manager can interact with the agent and distinguish two different types of services: association services and object access services. Association services provide methods to negotiate and agree a common configuration (association request and response), release associations and abort connections. Object access services provide methods that allow a manager interact with an agent by, remotely, executing actions and allowing access object attributes, thorough the link established. These services include *event reports* (often implemented by scanner objects and the MDS) that are initiated by the agent and used to send its configuration (during the association procedure) or medical or personal health data (once the association has been established), *get* and *set* methods that allow the manager access to object attributes, and *action* that allow the manager execute Remote Procedure Calls (RPCs) over the agent's objects. Whilst *event reports* are initiated by the agent's objects, *get, set* and *action* are executed over them and initiated by the manager.
- Communication model. It defines Finite State Machines (FSM) for both the agent and the manager that controls the communication state and transport mechanisms. All the transitions in the FSM are well defined and they involve the execution of some actions internally in the agent or the manager, the reception or the sending of a message, etc. The FSM determines the sequence diagrams in any X73 communication and an important key point is that it is transport agnostic that means that stack implementations can be shared among transport technologies (Blueooth, Zigbee, RS-232, etc.). It also defines different Encoding Rules (ER), such as Medical Device ER (MDER), those define the algorithms responsible of the marshaling of the messages generated by the DIM and allow to transform the abstract model given by the DIM into a stream of bytes.

IV. IMPLEMENTATION MODEL IN MICROCONTROLLER-BASED PLATFORMS

As it has been shown, agents and managers hardware differs strongly. Whilst agents are usually supplied by batteries and thus build into low-features hardware with low processor and memory capacities in order to reduce power consumption, managers are provided with higher capacity hardware such as a powerful 32-bit microcontroller and enough memory to run e.g. virtual machines (Java) and games. In fact it is difficult to carry out implementations in real agent devices as they are based on microcontroller-based platforms.

Previously proposed implementation solutions usually bring the X73PHD reference model into code in the way that each object in the abstract model is represented by an object into the targeted programming language (usually C++). They also use a buffer in RAM to generate the X73PHD messages what in sum requires a huge quantity of memory and processor usage. That finally forces the developer to modify the system's design in order to add a new microcontroller or a memory module to manage X73PHD communications.

Nevertheless, as X73PHD standard claims, peers can see each other as black boxes that execute actions internally conforming to the standard, which only defines how they must process incoming request messages and produce output result messages. A noticeable point is that typically messages of the same type do not differ ones from others strongly and their structure maintains invariant. That fact leads to the idea that messages used in a X73PHD communication can be obtained from linking a set of constant blocks of bytes (usually located at flash or ROM) and a few variables in RAM (see Fig 2). The blocks are called patterns and are grouped in a library called patterns library. This is similar to the idea of canned messages but uses a more generalized algorithm.

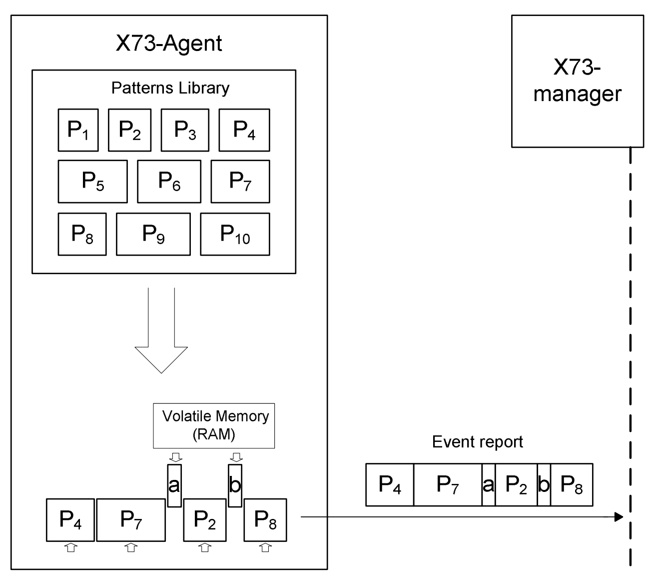

Fig. 2. X73 messages synthesis from pattern-based design

This idea can lead to a highly optimized implementation when applied to X73PHD agents. Once the device's specialization to be implemented has been selected, the range of patterns than the device needs to process X73 messages is reduced drastically. The architecture proposed for the generic agent is depicted in Fig 3. The basic components are: the patterns library (above mentioned) and the X73-kernel. The X73-kernel is the task that copes with pattern assembling, processing, comparison and transmission. It also manages the state of the FSM, the state of objects in the DIM, and some system signals which include data sent or data received signals, connection established, connection lost, timer signals for scanners (such as PeriCfgScanner), etc. There are also other two important components in this architecture: the MD specialization dependent drivers, those provide basic functions that allow the X73-kernel to manipulate the hardware, and the adaptation layer, that provides services that allow the X73-kernel to manage the transport stack. X73- kernel is transport independent thus the implementation can be shared between different devices and different wireless or wired transport technologies (Blueooth, ZigBee, IrDA, USB, etc.). The most complex component in the architecture is the X73-kernel since it is in charge of the correct operation of the whole X73PHD stack.

As a proof of concept an implementation has been successfully implemented on a blood pressure. To simplify its development has been used Free Real Time Operating System (FreeRTOS), as it provides common programming utilities (task, inter task communication mechanisms, etc.) that fosters the development process and allows the implementation to be portable to numerous hardware platforms with minor modifications.

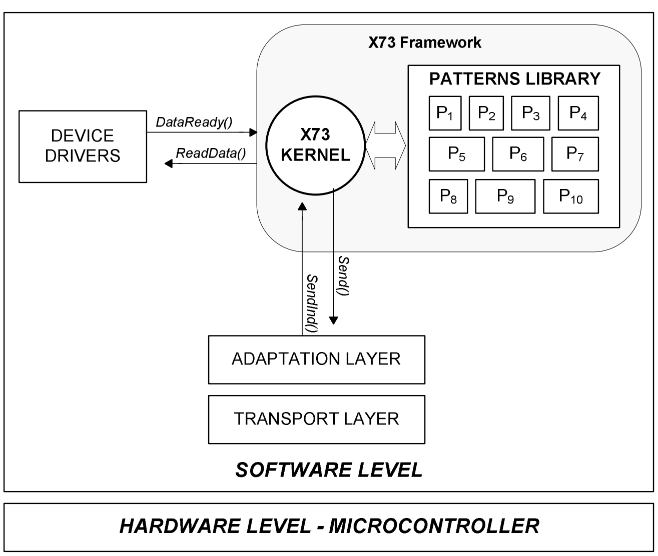

Fig. 3. Architecture proposed for MDs implementation supported by pattern-based design and X73-compliant

V. Discussion And Future Trends

Several points keep open and very active in INTENSA at the moment of the writing of this paper. In the line of implementation methodologies for microcontroller-based platforms we are studying alternatives to the use RTOS that will possibly reduce hardware resource needs and foster the source code's portability. These alternatives include the use of virtual machines in combination with finite state automatons. Moreover, given that the methodology exposed in this paper seems to be prone to automation, some algorithms to generate automatically the device's source code firmware from a machine understandable version of the standard are being studied.

VI. Conclusions

INTENSA aims to develop a real heart-failure patient follow-up system based on ISO/IEEE11073 in order to test and evaluate interoperability in personal health environments. In the way some challenges appear such as implementation into microcontrollers, remote control, new specializations (Simple ECG specialization for HOLTIN devices), integration with other standards and electronic health records, etc. All of these lines are being worked on by our group. In the case of implementation into microcontrollers, a first experience (a blood pressure) has been achieved using a novel methodology based on patterns. This methodology allows implementing the standard into systems with reduced hardware resources. The first results have been successful and encourage us to continue.

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