Proposal of an ISO/IEEE11073 Platform for Healthcare Telemonitoring: Plug-and-Play Solution with new Use Cases

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***Abstract*—Healthcare telemonitoring solutions demand standardization to be competitive and to take advantage of all the technological possibilities. In that context, new scenarios and needs arise while the ISO/IEEE11073 (X73) standards are adapting and changing in order to face the challenge. This work describes a proposal of some new use cases developed by three research groups in Spain. These use cases are compliant with the X73 standards. The aim of the proposal is to explore the advantages of standard compliant scenarios and to detect integration and implementation difficulties using these standards. In this way, the three research groups have started to extract and implement some needed functionalities that can provide an added value to the platform where the different systems from the proposed use cases could communicate in a standard format.**

I. INTRODUCTION

E-Health offers a wide range of solutions in patient telemonitoring where scenarios are built up with several device combinations for vital signal acquisition [1]. New Personal Area Network (PAN) and Body Area Network (BAN) are emerging as wireless communications advance. Nevertheless, some of these solutions become unpractical without the use of standardization [2]-[4].

ISO/IEEE11073 standards (X73) were designed to address Intensive Care Unit (ICU) scenarios [5] and thus, e-Health telemonitoring scenarios were not considered in the set of the above mentioned standards. However, the authors propose that, with the appropriate changes, X73 standards can be adapted to include these telemonitoring scenarios [6]. The proposed Use Cases (UC) are the start point to the analysis of the needs of these new scenarios, and a contribution to the evolution of the standards with the acquired *know-how*.

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Unlike ICU scenarios, these new emerging situations involve very strict communications restrictions due to particular electronic features as low voltage-lowpower sensors and processors included in wearable Medical Devices (MD), or even wired or wireless technologies not yet supported by X73. This means that the communication protocols need to be lighter, avoiding long time communications and being efficient in terms of overhead, bandwidth and use of CPU [7]. With today's means, this leads to the conclusion that the most of intelligence of the systems has not to be located near from the MDs or sensors that are monitoring the patient. In this way, these new features of the above scenarios are driving a deep review of the X73 standards, envisioning a new profile for Personal Health Devices (PHD) communications [8].

UCs proposal implementations are probably the best way of testing X73 and detecting handicaps and difficulties in such a task. It also allows foreseeing some possible ideal-standard future scenarios; a picture that is far from today's state of the art in telemonitoring. These scenarios should include devices and systems using the X73 standard protocol, where each module of the system can be replaced by a similar standard-one, taking advantages of Plug-and-Play (P&P) capabilities and making the systems' configuration easy. Furthermore, these can be scenarios where the data can flow seamlessly from a sensor in the patient's home to a hospital, with the possibility of interacting with the Electronic Healthcare Record (EHR) of the patient. In short, scenarios that bring up advantages in interoperability, costs, comfort and system usability for the patients.

This paper proposes a platform to integrate these UCs with new functionalities and modules that may provide P&P capabilities. This implementation experience is compliant with X73 and other standards (EN13606 or HL7). It permits to include (with minor modifications) items not yet supported by these standards, as wireless communications, but being ready to adopt the upcoming changes for telemonitoring scenarios. UC features are detailed in Section II. A brief description of the proposal of the X73 integration platform for a P&P solution is covered in Section III. New functionalities and improvements based on the Ambient Intelligence (AmI) paradigm, and included in the integrated platform are described in Section IV. Finally, conclusions of the work are drawn in Section V.

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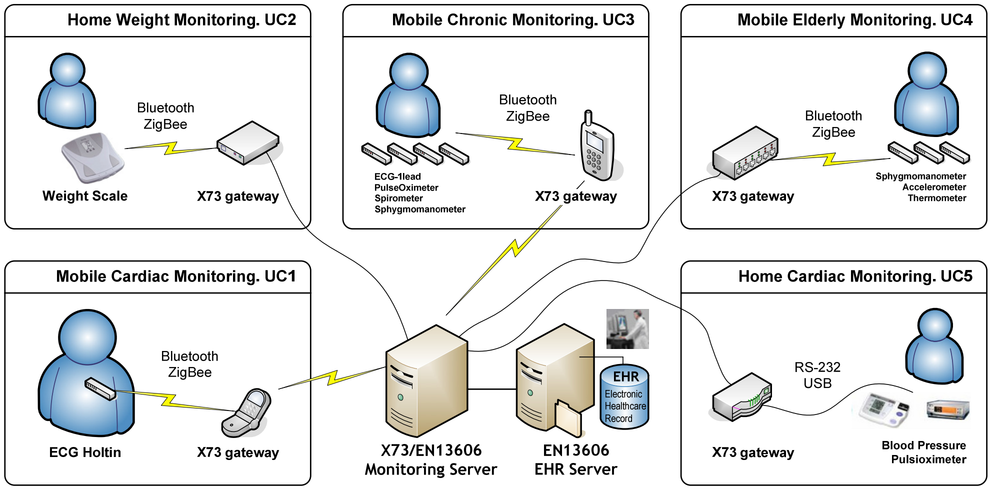

Fig. 1. UCs generic scheme

II. PROPOSAL OF NEW USE CASES

The proposed integrated solution that includes all these UCs is shown in Fig.1. The data from the different X73 MDs (according to each UC) is fetched in their X73 gateways, transmitted and managed by the X73/EN13606 Monitoring Server (MS), and stored in the EN13606 EHR server. The specific characteristics of each UC are following detailed:

A. UC1 – Mobile cardiac monitoring

A patient that suffers syncope or sporadic non perceptible symptoms of cardiovascular diseases could use the HOLTIN monitoring service [9]. The system is based on a native X73 wearable Holter device which controls the patient's ECG signal for long time periods in order to detect possible cardiac events. These events are transmitted, with Store-and-Forward (SF) scheme, to a X73-compatible mobile phone via Bluetooth and retransmitted to the MS by means of General Packet Radio Service (GPRS) technology, see Fig.1.

A front-end device located at the patient's chest performs both the acquisition of a modified ECG lead II (with a sampling rate of 200 samples/s) and the automatic detection of several cardiac events (tachycardia, bradycardia and asystolia) based on a QRS-detection algorithm. Moreover, a hand-triggered event is also possible if the patient notices he/she is having a specific symptom or suffers some syncope. Detected events are temporally stored in the device (up to 80 min.) for a later transmission to the gateway.

Setting of specific HOLTIN features as gain, cardiac event threshold values, signal store time for both automatic or hand-triggered event detection and patient data, can be configured by health professionals based on patient pathology. Likewise alarms and warnings are run on both front-end and X73 gateway informing about power supply, limit of memory, number of events, etc.

B. UC2 – Home weight monitoring.

A healthcare professional prescribes this use case when he/she is concerned about the patient's weight (situation very common in cardiac arrest patients). The connectivity between the X73-compatible weigh scale and the X73-gateway is achieved via Bluetooth or ZigBee, see Fig.1. Each time the patient follows the weighing protocol, her/his weight is transmitted to the X73-gateway and then to the MS via Internet. Once there, a specialist can access the MS to inspect the recorded data. The weigh scale is P&P and the patient only needs controlling the battery status.

C. UC3 – Chronic respiratory patient management

A patient with a chronic respiratory condition (typically COPD [10]) self-monitors her/his status, usually once a day. Monitoring results are: spirometry (main values and flow volume curve), oxygen saturation (pulse-oximeter), and answers to a symptoms questionnaire. In case the patient has a co-morbidity, typically coronary disease or diabetes, monitoring may as well include ECG, non-invasive blood pressure, and weight (cardiac) or blood glucose levels (diabetes). The service is prescribed for chronic respiratory patients and it may be used during an exacerbation episode or for longer periods. The case manager, with technical staff support, provides the patient with a cellular phone (see Fig.1) prepared with the monitoring application, as well as the spirometer and pulse-oximeter. The information is transmitted to the MS once the different data have been gathered (immediately after), and patient is warned if the transmission is not ok. The X73-gateway takes care of retransmission if necessary. Transmission is SF and is not time critical, provided that it is sent within the same day. Case manager checks patient's status daily and receives alarms triggered by the system. The service is supervised by the technical staff from the service provider which takes care of the equipment. The gateway informs the patient if the monitoring MDs are not working properly (no batteries, device not connected or not working). Finally, warnings (SMS message, beeper call, email, web page) are issued if values are outside normal levels (personalized to the patient), if no data are received after a pre-established period, etc. Case manager or social worker may call the patient or pay a visit if needed.

D. UC4 – Elderly patient follow-up.

Similarly to UC3, the patient's vital signs are controlled once a day using several sensors. There are two main differences between both use cases: 1) a wearable 3D accelerometer (that records patient movements during all day) is included to detect falls and/or to obtain a summary of her/his level of activity. 2) The gateway uses a fixed internet access to transmit data to the MS, as in UC1. As depicted in Fig. 1, note that data transmission between the X73-gateway and each of the sensors is wireless.

E. UC5 – Home cardiac monitoring.

A single patient concerned with his heart health at home wants his cardiac parameters to be controlled by a cardiologist. The patient has a weigh scale, a blood pressure and a pulse and oxygen saturation measurement equipments installed at home using a fixed connection via RS-232 or USB, see Fig.1. Following the doctor's advice, he has to use the equipment several times a day.

A summary of the technical characteristics required for every UC is detailed in Table I. From this new proposal, the following section presents the X73 integration methodology for a P&P solution.

TABLE I. TECHNICAL CHARACTERISTICS REQUIRED IN EVERY UC

	UC1	UC2	UC3	UC4	UC5
Communications					
X73-gateway possible inputs					
Wireless (Bluetooth, Zigbee, ...)	✓	✓	✓	✓	
Wired (RS-232/USB)			✓	✓	✓
X73-gateway possible outputs					
Wireless WAN	✓		✓		
Wired WAN		✓		✓	✓
Other features					
X73 sensor adapter–μcontroller				✓	
User warnings (SMS, e-mail, ...)			✓		
Battery status control	✓	✓		✓	
Faulty operation warnings	✓	✓	✓	✓	✓

III. X73 INTEGRATION FOR P&P SOLUTION

The UCs previously presented aim to be implemented end-to-end, following the X73 standard [2] and integrated in a homogeneous telemonitoring X73 platform, see Fig.1. The X73 standard enables this integration in a modular way by defining each Virtual MD (VMD), its specific Domain Information Model (DIM), its working mode (*baseline* or *polling*), its communication technologies, etc. However, the existence of X73 MDs is strongly conditioned to the vendors and manufacturers. Currently there are a high percentage of MDs that not implement the X73 standard. Moreover, although the proposed UCs will permit to integrate them when they become available, it is also difficult to find MDs with an X73-compatible physical output: at this moment, only RS-232 and IrDA are included in X73 standard (but most extended interfaces are not allowed the: USB or Bluetooth).Thus, in this development, proprietary MDs have been used with X73-adapters for the UCs proposed. These adapters implement the X73 standard on one side, and proprietary interfaces that can only be modified by knowing the vendor programming codes on the other side. The X73 MDs and adapters included in the proposed solution (see Fig. 2) are described as follows:

- *VMD1*. HOLTIN is a low voltage-low power customized wearable device supplied with a Li-Po rechargeable battery. An 8-bit microcontroller performs the main tasks (acquisition of ECG signal, detection and storage of cardiac events) and a Bluetooth chip enables the communication with the mobile phone (X73-gateway in UC1). Default working mode is baseline and an X73-adapter is no required. However, a native X73 implementation on HOLTIN is a handicap that has to be addressed, because it requires the standard to be lighter to avoid excessive power consumption due to overhead in data transmitted and excessive use of CPU. Moreover, the current version of the X73 standard does not include the use of wireless technologies as Bluetooth although this situation is moving.

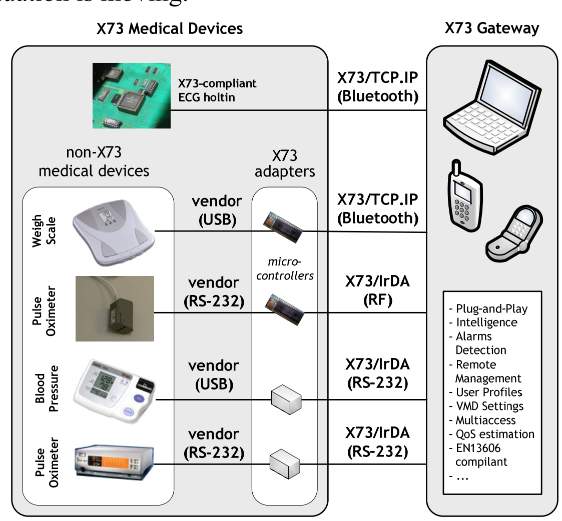

Figure 2. MDs and X73-adapters considered in the solution.

- *VMD2*. The PP1015B0 is a commercial weigh scale battery supplied showing the weight in a Light Controller Display (LCD). An *ad-hoc* adapter has been developed and integrated into the weigh scale for UC2. The adapter consists on a Peripheral Interface Controller (PIC), which taps data from the LCD, and a Bluetooth module, which manages the VMD communication in polling mode profile. The limited processing capacity and ultra-low power consumption required are the maximum challenges to be addressed.
- *VMD3.* It is based on a MEDLAB EG00302 OEM pulse oximeter which measures blood oxygen saturation (SpO2), heart rate and plethysmographic waveform and communicates through a RS-232 port. To configure the X73 VMD it is connected to a wireless module offering a Bluetooth/Zigbee interface as used in UC3 and UC4. Default working mode is baseline (UC3), although a polling profile can be added if combined with an extra microcontroller (UC4).
- *VMD4.* The OMRON 705IT measures asynchronously the blood-pressure and the pulse rate, with a 28 acquisitions memory. It provides a USB connection used in UC5.
- *VMD5.* The DATEX-Ohmeda 3900 is a pulse-oximeter with a serial-port output (RS-232) that measures blood oxygen saturation (SpO_2), heart rate values every 2s, and provides alarm support for UC5.

IV. New Ambient Intelligent functionalities

The proposed X73 integration platform contributes to a P&P solution taking advantage of the X73 features in MDs interoperability. In order to improve the reliability and usability of this telecare platform, new functionalities based on some Ambient Intelligence paradigms have been included in the development. These AmI functionalities are:

- Quality of Service (QoS) analyzer module for evaluating the status of each internet access technology. As the number of MDs increases depending on the complexity of the monitoring scenario, the internet access must be properly managed, sharing the resources for each transmission's quality requirements. This module provides the possibility to select the most suitable type of transmission.
- Although the X73 standard supports alarm reporting from MDs, some additional technical and human situations may have to be reported to MS where a healthcare professional is supervising the system. Absences of patient response or unexpected device behavior are some examples of these alarms that, in some cases, can be communicated to the patient directly from the gateway.
- Personalized graphical and sensorial interface that helps guiding the patient in her/his sampling procedure and ensures that the measurement data are within reasonable range. This information is gathered from the remote server that contains an up-to-date EHR file of the patient. This functionality is based in two configuration files: *settings* (with the VMD/X73-adapter proprietary technical characteristics, detailed in Table I) and *profiles* (with the user -patient, doctor- requirements, detailed in the UCs presented in Section II).

V. Conclusion

The work towards interoperable telemonitoring devices based on standards is mandatory to achieve mature e-Health solutions that are not dependent on a single vendor. It is interesting to approach this work from the perspective of different research groups, as interoperability problems arise faster than in proprietary developments. Ambient Intelligence platforms running on X73 *gateways* will also provide new functionalities with the aim to control the PAN status overall, interact with the patient through dedicated interfaces and report any hardware faulty operations or suspicious patient status to a remote control centre, among many other implementations. It is clear that the absence of medical device P&P standards is an unacceptable barrier to innovation for safety and efficiency.

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