35th Annual International Conference of the IEEE EMBS
Osaka, Japan, 3 - 7 July, 2013

New Use Cases for Remote Control and Configuration of Interoperable Medical Devices

H.G. Barrón-González, *Student Member, IEEE,* M. Martínez-Espronceda, *Member, IEEE,*
S. Led, L. Serrano, *Senior Member, IEEE,*
Christoph Fischer *Member, IEEE*, M. Clarke, *Senior Member, IEEE*

***Abstract*—The newest branch of the ISO/IEEE 11073 (X73) standard for Personal Health Devices (X73PHD), allow the development of interoperable personal health ecosystems. At the moment of this writing, more than 11 specializations have been successfully published by the Personal Health Device (PHD) Working Group (PHD WG). Nevertheless, some recent specializations at draft stage show the need for a procedure to control configuration parameters. As a solution, some *ad-hoc* methods have been elaborated to deal with it, but, the aim of the PHD WG is to standardize a general procedure, valid for longer term. Then it is needed to identify use cases requiring remote configuration services.**

This work identifies and studies new use cases that employ remote configuration services. The resulting use cases, discussed within the PHD WG to get the maximum consensus, are within the scope of the Basic Electrocardiograph (X73-10406), the Sleep Apnea Breathing Therapy Equipment (X73-10424), and the Medication Monitor (X73-10472) specializations. In addition, a classification of the findings is proposed for each use case. These findings could be the basis for the new remote configuration extension.

***Keywords*— extension package, interoperability, ISO/IEEE 11073, personal health, remote configuration, remote control, specialization, standardization, use case.**

I. Introduction

Advances in home telemonitoring have been prompted by the constant development of new medical devices for use in intensive care units [1]. The heterogeneity of the initial healthcare paradigm propitiated the development of standards that allow interoperability between the medical device and monitoring system [2]. This leads to the development of the ISO/IEEE11073 (X73) standard [3-5]. Subsequently, technological advances induced an adaptation to this standard to a new branch known as X73 for Personal Health Devices (X73PHD) [6,7]. Developed to standardize PHD communications, this new branch is mainly specified in the Optimized Exchange Protocol (11073-20601) and device specializations (11073-104xx). Nowadays, it is necessary to increase the functionality provided in some use cases within specializations, in order to optimize solutions and services centered in the patient [8]. For example, medical devices may require personalizing parameters in order to obtain a correct visualization of the data sampled by the agent.

Thus, the more recent specializations being drafted at this moment show a need to control configuration parameters [9]. As a solution, some *ad-hoc* methods have been elaborated so far, which provide the desired functionality. Nevertheless this functionality cannot be extended to other specializations easily. Therefore, the aim of the PHD Working Group (PHD WG) is to standardize a general procedure that allows the inclusion of remote configuration in any specialization (an extension package within the 11073-20601 toolbox). In order to define this procedure, the first step is to gather and to analyze as many use cases as possible on remote control, including both real ones and hypothetical ones.

In view of the above, this work proposes the study of new use cases within the PHD WG, which could benefit from the extension of remote control functionality within standard. This paper is divided as follows. Section II shows the methodology used to get the use cases, analyzed in this research. The use cases, specializations that generated and the technical characteristics of each are discussed in Section III. Future lines are discussed in Section IV. Finally conclusions are drawn in section V.

II. Methodology

The PHD WG defines standards in collaboration with the IEEE-SA. It has more than 298 members, organized into companies and universities around the world. Therefore, the group mainly develops its work by its mailing list. In

Manuscript received September 28, 2012. This work was supported in part by the Government of Navarra (NAsisTIC project IIM14089.RI1).

The authors would like to thank to Personal Health Devices Working Group (PHD WG) members for their guidance.

H.G. Barrón González is with Department of Electronic and Comunications, Universidad Autónoma de Nuevo León, San Nicolas De Los Garza, – México, (corresponding autor to provide pone:+52 8112603366; e-mail: gilbertobarron@ieee.org).

M. Martínez-Espronceda, S. Led, L. Serrano, are with the Department of Electrical and Electronic Engineering, Public University of Navarre, Campus Arrosadía, Pamplona, 31006, Spain.

Christoph Fischer is with Institute of Assistance Systems and Qualification at the SRH University of Applied Science Heidelberg, Heidelberg, Germany (christoph.fischer@ieee.org)

M. Clarke is with Brunel University, Uxbridge, Middlesex, UB8 3PH, UK (phone: +44-1895-265053; fax: +44-1895-251686; e-mail: malcolm.clarke@brunel.ac.uk).

addition, the group holds online weekly meetings and face-to-face (F2F) working sessions (2 to 4 calls per year).

PHD WG has developed the optimized exchange protocol (2008, 2010 versions) and more than 10 specializations. It is working on the development of new specializations and the improvement of existing ones.

This work has elaborated a methodology to determine and analyze remote control and configuration use cases. This methodology is break down into several steps. First, a call of proposals is issued within the PHD WG. Once the members have proposed their use cases, the new use cases are deeply discussed within the PHD WG. The results obtained are then analyzed to determine main common features. Taking the common features into account, specific parameters are determined for each use case. Then, the results are discussed and agreed within the PHD WG.

The information presented by the agents follows a methodology based on grouping the data into the function of which they are part.

- Operational modes: This classification groups the different operating modes that can be implement in an agent. It is important to know it because the ability to change parameters could not be present in all operation modes.
- Equipment, user data and settings: These are the data that identify and characterize both the device and the user. These can be classified into several categories such as device data (e.g. device type, serial number, software version), device state (e.g. stand-by, drying, therapy), maintenance data (e.g. hours of flow generation, hours of filter use), technical alerts (e.g. delivered pressure out of specification, empty humidifier), and patient preferences (e.g. patient user interface language) among others.
- Therapy data and operational settings: This group represents two types of data, which provide service to the most important functional characteristics of the case studies. First, the therapy parameters include all the parameters needed to implement personalized therapies in the case that the agent has enabled this special operation mode. This operational mode is present in one of the new specializations presented in this analysis. (e.g. CPAP/hPa, Min APAP/hPa, Max APAP/hPa). And second, operational settings are related to the correct acquisition of medical information. These settings are present in therapy devices but are more related to monitoring devices that though lack the ability to apply some therapy. These parameters are required to develop its main functions (e.g. Taqui-Lim, Asist-Lim, Alarm-duration).

The use cases proposed by PHD WG are associated to the following specializations:

- Part 10406 Basic Electrocardiograph (1 to 3 lead ECG) [10, 11]. This specialization is intended for ECG monitoring devices acquiring and recording 1 to 3 channel (leads) electrocardiographic waveforms or analyzing the acquired signals to measure heart rate.
- Part 10424 Sleep Apnea Breathing Therapy Equipment [12]. This specialization is still in drafting state. This specialization is intended for sleep apnea therapy devices that gather multiple parameters during sleep.
- Part 10472 Medication Monitor [13]. This specialization is intended for simple *medication monitor that provides a record of the people usage of medication.* It does not include the composition of medication.

III. RESULTS

In the third column will only show the most representative parameters of each use case as the number of elements cannot be all included.

The results obtained are summarized in Tables I and II. The use cases are shown in Table 1. Within this table, the operation modes proposed for these new use cases are shown in the first column. The use case A is based on a monitoring device with two operational modes. The use case B is a Medication Monitor that has only one operational mode. These two agents have configuration parameters, which are shown in the third column. The use case C has several operation modes implicitly within the capabilities of the application of therapies available to the agent, which are shown in the third column. This table shows that the use cases share the requirement of a configuration service for its operational parameters.

The settings found in these use cases are summarized in Table II. The name of the setting and the use cases where it is needed are show in the first and the second columns, respectively. The third column shows data types associated to that setting.

TABLE I. Use Cases

Use Case	Operational modes	Settings Parameters
(A)ECG Recorder	Store-and-forward Realtime	Operational-Mode, Taqui-Lim, Brady-Lim Asist-Lim QRS-Number T-Wave-Time Search-Back
(B)Medication Monitor	_____	Operational-Mode, Time-Dose-Available Alarm-duration Event-Dosage-Number
(C) Sleep Apnea Breathing Therapy Equipment.	Standby, Therapy, Drying, Mask-Test	Therapy-Selector, CPAP/hPa, IPAP/hPa, EPAP/hPa, Inspiration-Trigger-Sensitivity/%, Expiration-Trigger-Sensitivity, Minimum-Respiratory-Frequency/bpm, Ramp-Start-Pressure /hPa, Ramp-Duration/min

TABLE II. Setting classification.

Operational Characteristics	Use case	Type	Value	Example
Operational-mode	(A), (B), (C)	Enumeration	MDC_DEV_PROFILE	Real Time, Store-and-forward
Therapy-Selector	(C)	Enumeration	MDC_<THERAPIE>_ENABLE	CPAP, Auto-CPAP, Bi-Level-PAP Auto-Bi-Level-PAP
Configuration Parameters	(A), (B), (C)	Enumeration,	Taqui-Lim	100-200 beat-per-minute
		Compound Numeric	Asist-Lim	2-4 seconds
		Numeric	Store-Time-Auto	30-120 seconds
		Numeric	Dosage-Number	30 dosages
		Numeric	Daily-Alarm-Times	1-24 times
		Compound Numeric	CPAP	4-20 cm3 H2O
		Compound Numeric	IPAP	4-30 cm3 H20

A. Basic Electrocardiograph (1 to 3 lead ECG)

This is an ECG event recorder. Events are automatically detected by this agent as well as automatically triggered by the patient (by pressing a button in the manager). Automatic detection is based on heart rate which is obtained by the agent thru analysis of ECG waveform. Given that the morphology of the ECG waveform can vary considerably in each patient, the configuration of this agent must be personalized for each study.

The following parameters are needed to be correctly configured by the physician:

- Bradi-Lim: It determines the minimum instantaneous heart rate value that will trigger bradycardia event in beats per minute
- Taqui-Limit and QRS Number: It determines the maximum instantaneous heart rate value and the number of consecutive values that will trigger a tachycardia event in beats per minute.
- Asist-Lim: It determines the maximum time without detecting QRS complexes that will trigger an asystolia event.
- Store-Time-Auto: It is the recording time for automatic event, in seconds. Similarly to automatic events, this time is distributed symmetrically to the instant when arrhythmia is detected.
- Store-Time-Manual: Recording time for manual event type in seconds. This time is distributed symmetrically with respect to the instant when the detection of arrhythmia occurs.
- T-wave-Time and Search-Back: They are used to define a blanking window. They represent the blanking time and sensitivity for adjustment of the QRS complex detection algorithm. The blanking window is established after detecting a valid QRS. Within this window, a new QRS is considered valid if only if its peak level is over a certain level of sensitivity determined by Search-Back.
- Operational-mode: It has two possible values, representing the two operation modes of this device. In the offline operation mode, the ECG waveform is stored in a PM-store and sent to the manager every 5-10 minutes in bulk transfer. In real time operation mode, the ECG recorder is always connected to the manager and the ECG waveform is sent in real time. The operational mode is selected by the technician.

The modification of these parameters must be transactional, meaning that this operation updates the parameters at once, or, on the contrary, fail if any of the parameter values is incorrect, doing no change to the configuration.

In addition, the agent publishes a remote control operation identified by Trigger-Manual-Event. When the patient feels arrhythmias, he/she presses a button in the manager, which automatically transmits to the agent. The agent then begin recording a manual event.

B. Medication Monitor

The medication monitor is made up by a carousel that is loaded with medication, and it is programmed to turn on at specific times to make the medication available to the patient.

At these times it flashes and/or beeps to remind to take medication. On tilting to remove the medication it generates an event. If the medication is not taken after a predefined interval it also generates an event.

It is required to be able to program the times and intervals through ISO / IEEE 11073- 20601. The following settings have been identified:

- Medication dosage settings: They are used to indicate the start and end time of an event during which the drug is available to the patient (Start and end time).
- Alarms: They are used to indicate the start and end time of duration of alarms. These alarms alert the patient about the disposition of the drug (Start and end time).

Again, the device presented in this use case requires transactional behavior. Settings that the manager requests to modify must be done at once.

C. Sleep Apnea Breathing Therapy Equipment

This is a new specialization being drafted within the X73PHD protocol stack. It was developed to be used for the treatment of various types of sleep related diseases by the application of continuous positive airway pressure to the patient's respiratory tract during the night. The agent requires a greater diversity set of parameters needed to support several functions, which are described as follows:

- Patient related configuration: It is used to store information concerning to the user, as their characteristics of the environment in which it is located (e.g. Patient User Interface Language).
- Therapy mode: It has four values representing the therapies that this device can apply to the patient: Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BPAP), and Adaptive Servo Ventilation (ASV).
- Therapy parameters: These bring together the needed values and ranges that allow the physician personalizing the therapy to a patient.
- Compliance data: It is used to store information about the therapies provided to the patient. (e.g. Hours of Patient Use, …).
- Continuous waveforms data: It is represents the evolution of the therapy (e.g. flow over time, pressure over time).
- Event data: It is used to register events that are related to the disease, and that have occurred during the use of the agent (e.g. apneas, hypopneas).
- Analysis data: statistics of therapy data, such as AHI, oAHI, cAHI.
- Therapy alerts: These represent values that allow to trigger alerts when there are problems in the operation of the device (e.g. Extended Leakage …).

IV. Discussion

The main goal of this work was the analysis of use cases for agents with monitoring functions. Nevertheless, as observed in the monitor medication and Sleep Apnea Breathing Therapy Equipment, functions that allow configured therapies from the administrator and executed by the service agent are also necessary.

It was also necessary to specify data for monitoring and configuration functions, due to the different types and amount of data required for these functions. It is also necessary to define the full potential of a specialization, for example in the case of Basic Electrocardiograph this acquired data samples whose size is important to get the most significant changes of the physiological signal, or in the case of the thermometer where samples intervals are essential to sense this variable correctly. Who will be allowed modifiying these settings, whether the service professional or health's care, must be studied more thoroughly.

It is noteworthy that there are more case studies within the standard specs, but mentioned here have similar characteristics to the other, so that the data can be obtained an overview of the new features and functionality that should be included within the standard.

V. Conclusion

Several use cases have been presented, studying their operational modes and main settings. Results are useful to define a generalized configuration and control service over the existing Optimized Exchange Protocol (ISO/IEEE 11073-20601). Some of the use cases shared some common settings and modes. Therefore, future lines of this research includes to extend this results to model a configuration and control service within the context of ISO/IEEE 11073 standard to meet the requirements of the new use cases presented in this paper.

References

[1] J. L. Monteagudo, O. Moreno, eHealth for Patient Empowerment in Europe, [Online]. Available: http://ec.europa.eu/informationsociety/newsroom/cf/itemdetail.cfm?item_id=3448. Last access: 09/12

[2] L. Kun, "Interoperability: The cure for what ails us (government affairs)" *IEEE Engineering in Medicine and Biology Magazine*, vol. 26, no. 1, pp. 87-90, 2007.

[3] "Health Informatics-Point of care, Part 10201: Domain Information Model" IEEE Std 11073-10201, 2004.

[4] "Health Informatics-Point of care, Part 20301: MDAP optional package, remote control" IEEE Draft 11073-20301.

[5] Continua Health Alliance. http://continuaalliance.org, Last visit: 9/12.

[6] IEEE Std 11073-20601™-2010. Application profile—Optimized Exchange Protocol. IEEE Std 11073-104xx. Part 104xx: Device specializations.

[7] M. Clarke, "Using IEEE 11073 Standards to Support Biomedical Engineering Research," in *34th Annual Int Conf of the IEEE Engineering in Medicine and Biology Society (EMBC2012),* San Diego, 2012, ISBN: 978-1-4244-4120-4

[8] M. Martínez-Espronceda, I. Martínez, L. Serrano, S. Led, J. Trigo, A. Marzo, J. Escayola, and J. García, "Implementation methodology for interoperable personal health devices with low-voltage low-power constrains" *IEEE Transactions on Information Technology in Biomedicine*, vol. 15, no. 3, pp. 398-408, 2011.

[9] Lasierra, N., Alesanco, Á., García, J. "An SNMP-based solution to enable remote ISO/IEEE 11073 technical management", *IEEE Transactions on Information Technology in Biomedicine*, 16 (4), art. no. 6178799, pp. 709-719. 2012.

[10] M. Martínez-Espronceda, S. Led, J. Redondo, A. Baquero, L. Serrano, "Adoption of ISO/IEEE 11073 in Electrocardiogram (ECG) Recorders: Lessons Learned," in *34th Annual Int Conf of the IEEE Engineering in Medicine and Biology Society (EMBC2012),* San Diego, 2012, ISBN: 978-1-4244-4120-4

[11] IEEE Std 11073-10406™-2011. Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).

[12] P11073-10424 - Standard for Health informatics - Personal health device communication - Device specialization - Sleep apnoea breathing therapy equipment [Online]. Available: http://standards.ieee.org/develop/project/11073-10424.html. Last access: 01/13.

[13] "Health Informatics-Personal health device communication Part 10421: Device specialization- peak expiratory flow monitor (peak flow)," IEEE Std 11073-10421-2010, pp. 1-63, 19, 2010.