Prototype X73-PHD 3-Lead ECG Device for Personal Healthcare[1]

I.N. Korsakov, S.M. Kuptsov, D.A. Raznometov, V.V. Feklistov, and M.A. Sumskoy
National Research University Higher School of Economics, Russia,
ikorsakov@hse.ru, skuptsov@hse.ru, draznometov@hse.ru, vfeklist@mail.ru, maxim.sumskoy@gmail.ru

Abstract

This prototype development explains the challenges encountered during the ISO/IEEE 11073 standard implementation process. The complexity of the standard and the consequent heavy requirements, which have not encouraged software engineers to adopt the standard. The developing complexity evaluation drives us to propose two possible implementation strategies that cover almost all possible use cases and eases handling the standard by non-expert users. The first one is focused on medical devices (MD) and proposes a low-memory and low-processor usage technique. It is based on message patterns that allow simple functions to generate ISO/IEEE 11073 messages and to process them easily. MD act as X73 agent. Second one is focused on more powerful device X73 manager, which do not have the MDs' memory and processor usage constraints. The protocol between Agent and Manager is point-to-point and we can distribute the functionality between devices. Developed both implementation X73 Agent and Manager will cut developing time for applications based on ISO/EEE 11073.

Keys words: *ISO/EEE 11073, ECG, home monitoring system, personal distance healthcare*

1. Introduction

Electrocardiography has been used for many years as a key, non-invasive method in the diagnosis and early detection of coronary heart disease. For interoperability standard in healthcare systems usually used ISO/EEE 11073(X73) Medical / Health Device Communication Standards is a family of ISO, IEEE, and CEN joint standards addressing the interoperability of medical devices. The ISO/IEEE 11073 standard family defines parts of a system, with which it is possible, to exchange and evaluate vital signs data between different medical devices, as well as remote control these devices. The 11073 family is partitioned into a set of standards that cover the communication of medical data between devices and managing applications. This standard defines a common core of communication functionality for personal ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the

[1] The work was carried out with the financial support of the Ministry of education and science of the Russian Federation (the contract № 02. G 25.31.0033)

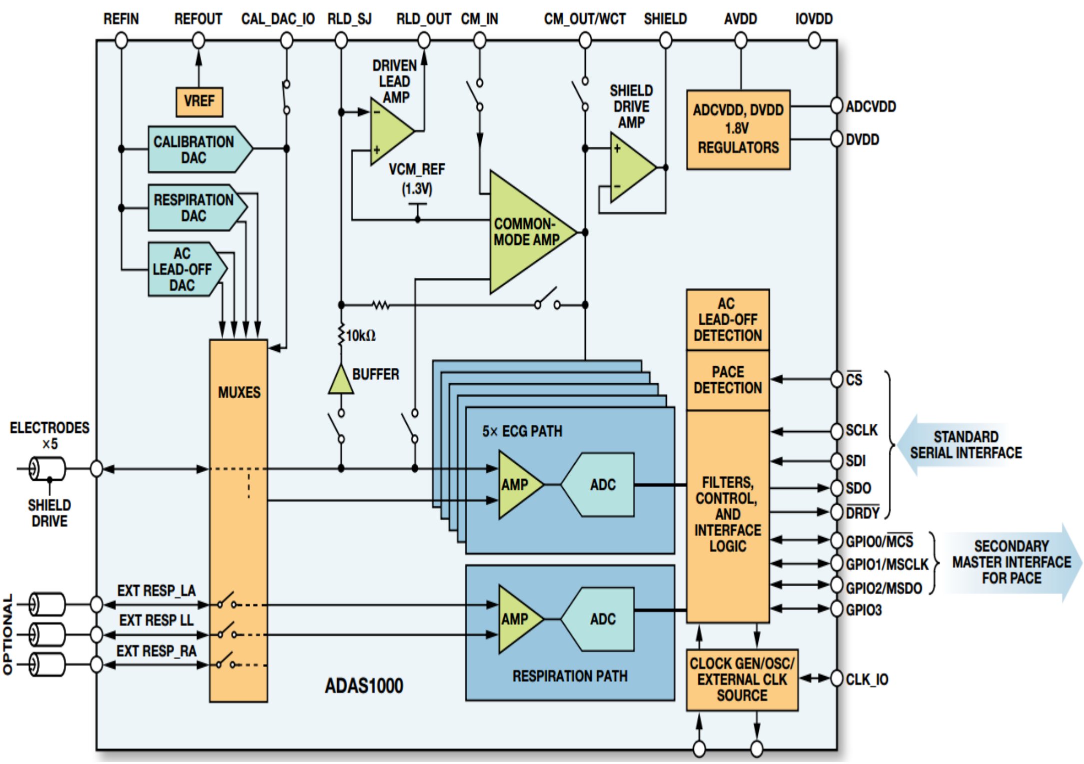
capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena.

For X73 certificated medical devices there is a database [2], where you can find already certified medical devices, but you cannot find any ECG devices (on a time of writing). According to X73 for ECG medical device we just need analog front end (AFE) , multiplex and 16-24 bit analog to digital converter (ADC), all of this function you can find even on one chip solution from **Texas Instruments, Analog Devices & Freescale.** For rest of X73 functionality we need just regular 8-32 bit microprocessor with USB2.0 and/or Bluetooth 4.0. For rapid development all company offer evaluation modules : complete 3-5 lead ECG medical device.

Chip selection

Analog Devices

ADAS1000 Functional Block Diagram



The ADAS1000 [3] 5-electrode electrocardiography (ECG) analog front end (AFE) addresses the challenges facing designers of next generation, low power, low noise, high performance, tethered and portable ECG systems. The ADAS1000 chip consists of five electrode inputs and a dedicated right leg drive (RLD) output reference electrode and has been designed for both monitor and diagnostic quality ECG measurements.

In addition to supporting the essential elements of monitoring ECG signals, the ADAS1000 is equipped with functionality such as respiration measurement (thoracic impedance measurement), pace artifact detection, lead/electrode connection status, and internal calibration features.

One single ADAS1000 supports five electrode inputs, easily enabling a traditional 6-lead ECG measurement. Cascading a second ADAS1000 device allows scaling of the system to a true 12-lead measurement, while cascading multiple devices (three and above) scales the system to a 15-lead measurement and beyond.

Respiration

The ADAS1000 has an integrated DAC respiration drive at a programmable frequency (46 kHz to 64 kHz) and an ADC measure circuit that simplifies this difficult measurement. The measurement is demodulated and provided to the user as magnitude and phase from which they can determine the corresponding respiration, given their specific cable parameters. The circuit is capable of detecting down to 200 mΩ resolution using the internal capacitor and to lower resolutions using an external capacitor and has a flexible switching scheme allowing measurement on one of three leads (I, II, III).

Pace Detection Algorithm

The pace detection algorithm runs three instances of a digital algorithm on three of four possible leads (I, II, III, aVF). It runs on the high frequency ECG data in parallel with the internal decimation and filtering. It’s been designed to detect and measure pacing artifacts of widths ranging from 100 μs to2 ms and amplitudes of 400 μV to 1000 mV. The ADAS1000 returns a flag that indicates pace was detected on one or more of the leads, as well as the measured height and width of the detected signal. In the event that a user wishes to run their own digital pace algorithm, the ADAS1000 provides a high speed pace interface providing the ECG data at a fast data rate (128 kHz), with the filtered and decimated ECG data remaining on the standard interface

Low Power

Designed for low power, the ADAS1000 operates five ECG electrode measurements from as little as 21 mW. To further minimize overall power dissipation in applications such as battery-operated Holter and telemetry, any unused channels or features can be conveniently disabled to further minimize power to as low as 11 mW for one lead.

Low Noise

Low noise performance is critical for appropriate diagnosis of different conditions. The ADAS1000 noise performance is 10 μV p-p over 0.05 Hz to 150 Hz to support end equipment regulatory standards. The ADAS1000 offers methods of trading off noise performance, power, and data rate—making it suitable to a wide variety of end products. In line-powered ECG systems, where power isn’t a major concern, the ADAS1000 performance excels. Device noise performance can be improved using the high performance mode (where the sample rate of on-board SAR ADCs increases to reduce noise).Flexible Configurations for Expansion While the ADAS1000 has been designed for five electrode inputs, it readily expands to systems with larger electrode/lead counts. Cascading multiple ADAS1000 devices allows scaling of the system to a true 12-lead or 15-lead measurement or beyond.

Flexible Data Rates

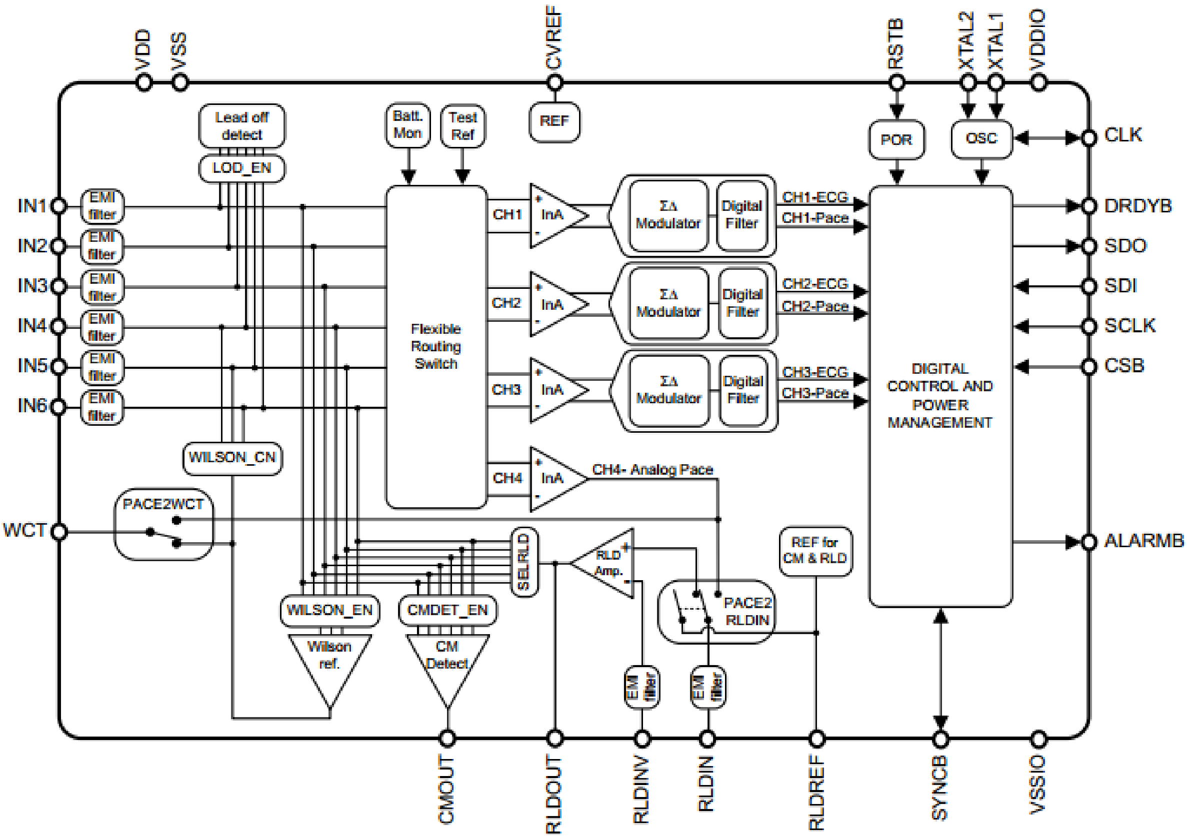
The standard serial interface outputs all the information related to the ECG, including LEADS OFF status, pace, respiration, and other auxiliary functions. The large number of 32-bit or 16-bit data words, collectively known as a packet or frame, is put onto the serial SDO pin of the data bus. Different data frame rates (2 kHz, 16 kHz, 128 kHz) are available to ensure ultimate ease in data capture. The slowest data rate of 2 kHz allows for more decimation and is the premium frame data rate for low noise performance. It's also possible to read data in "skip" mode, which reads the packet or frame from the device only every second or third word. The slowest data rate is 500 Hz.

Small Form Factor

This 5-electrode device is available in a RoHS-compliant 9 mm × 9 mm LFCSP or 12 mm × 12 mm LQFP package.

Picture 2. Lead I,II,II,V1,V2 from ADAS1000

Solution from Texas Instruments



Picture 3. ADS1293 [4]

The ADS1293 incorporates all features commonly required in portable, low-power medical, sports, and fitness electrocardiogram (ECG) applications. With high levels of integration and exceptional performance, the ADS1293 enables the creation of scalable medical instrumentation systems at significantly reduced size, power, and overall cost.

The ADS1293 features three high-resolution channels capable of operating up to 25.6ksps. Each channel can be independently programmed for a specific sample rate and bandwidth allowing users to optimize the configuration for performance and power. All input pins incorporate an EMI filter and can be routed to any channel via a flexible routing switch. Flexible routing also allows independent **lead-off detection**, **right leg drive**, and **Wilson/Goldberger reference** terminal generation without the need to reconnect leads externally. A fourth channel allows external analog pace detection for applications that do not utilize digital pace detection. The ADS1293 incorporates a self-diagnostics alarm system to detect when the system is out of the operating conditions range. Such events are reported to error flags. The overall status of the error flags is available as a signal on a dedicated ALARMB pin. The device is packaged in a 5-mm × 5-mm × 0.8-mm, 28-pin LLP. Operating temperature ranges from –20°C to 85°C.

Picture 4. Lead I, II, III from ADS1293

MSP430 Medical Platform [6]

When you start to developed device from scratches , you can use any of this chip, but in our case we use EVM module , the TI module have additional feature – 8 Gb flash memory chip, than is very important to store the result of measurements.

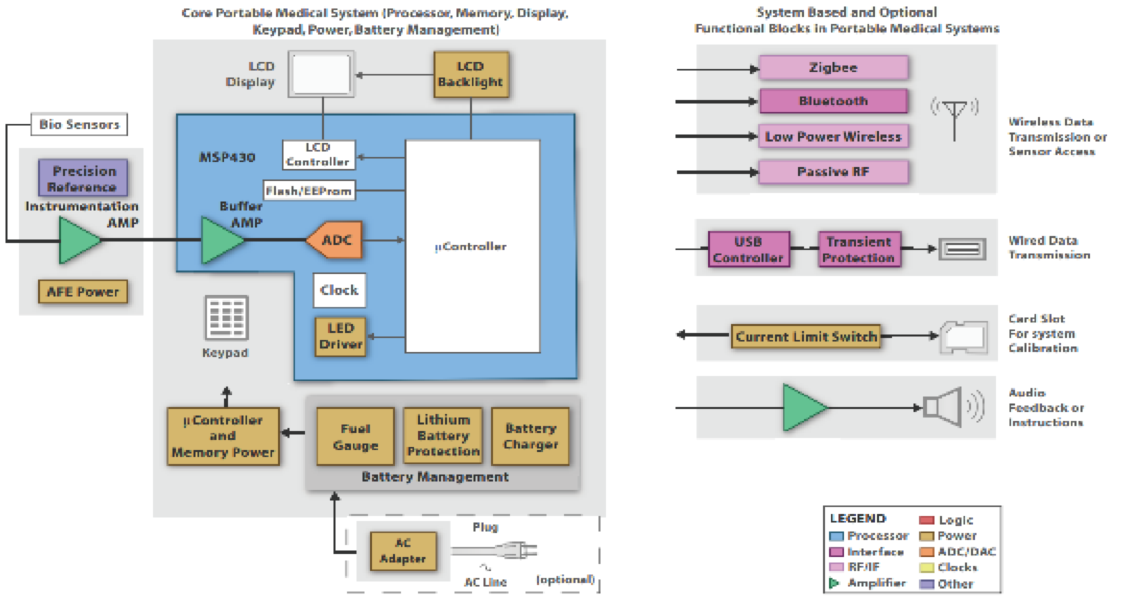


Fig.1. Basic Medical platform from Texas Instruments

TI provides this platform to enable original equipment manufacturers (OEMs) to bring personal health devices to market quicker and to simplify the design of USB-enabled consumer medical products such as blood glucose meters, digital thermometers, pulse oximeters, weight scales, and blood pressure monitors.

As personal healthcare devices become more ubiquitous, companies are developing products with connectivity that allow data to be exchanged easily . PHDC (Personal Healthcare Device Class), which is part of the USB standard, is designed for portable medical and wellness devices to be able to send measurements to USB hosts such as personal computers, cell phones, etc . The Continua Health Alliance has released guidelines for interoperability between various types of devices implementing the USB standard . Texas Instruments offers a hardware-software platform that has been certified by the Continua Health Alliance after having passed a rigorous testing procedure . Customers can use the software stacks of this platform to reduce development time for devices that will comply with the medical industry standards such as the Continua Health Alliance. These stacks are available for use on TI’s industry-leading, ultra-low-power MSP430™ MCUs.

Bluetooth LE Interface

In several key aspects, Bluetooth low energy technology is a totally new technology. For instance, the technology features very efficient discovery and connection set-up, short data packages, and asymmetric design for small devices. The new advertising functionality makes it possible for a slave to announce that it has something to transmit to other devices that are scanning. Advertising messages can also include an event or a measurement value. There are also differences in software structure. In Bluetooth low energy technology all parameters have a state that is accessed using the attribute protocol. Attributes are represented as characteristics that describe signal value, presentation format, client configuration, etc. The definitions of these attributes and characteristics along with their use make it possible to build numerous basic services and profiles like proximity, battery, automation I/O, building automation, lighting, fitness, and medical devices. All these nuances are needed to make the implementation seamless and compatible between devices from different manufacturers.

The key feature of Bluetooth low energy technology is its low power consumption that makes it possible to power a small device with a tiny coin cell battery—such as a CR2032 battery—for 5–10 years. Most important thing for choosing Bluetooth module is the HDP implementation and developing tools.

2. Implementation

Hardware ADS1x9xECG-FE board [7]

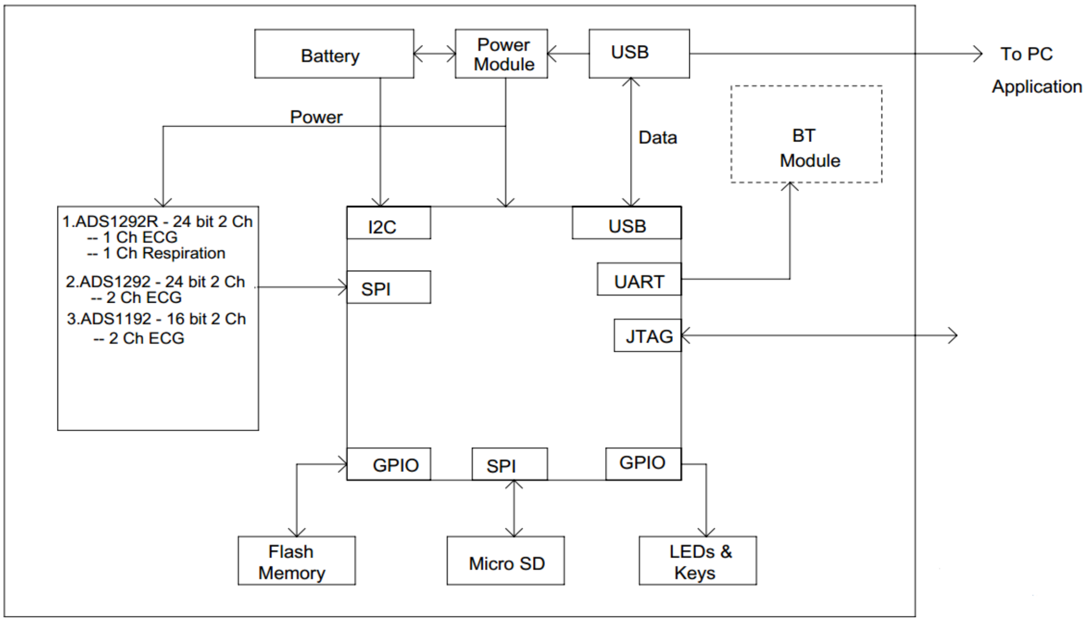


Fig 2. Block – scheme X73-PHD 1-3 Lead ECG Medical Device with Bluetooth LE

For proof-of-concept we need:

- To add Bluetooth LE module to ADS1x9xECG-FE board according the knowledge and basic soldering skills.
- Modify firmware ADS1x9xECG-FE to meet the requirements of ISO/IEEE11073-10406:2013 and ISO/FDIS 11073-91064
- Minimum functionality for x73/SCP-compliant ECG device: data acquisition, store data and sending storing data.

The communication path between agent and manager is assumed to be a logical point-to-point connection. Generally, an agent communicates with a single manager at any point in time. A manager may communicate with multiple agents simultaneously using separate point-to-point connections. The primary concentration is the interface and data exchange between the agents and manager. However, this interface cannot be created in isolation by ignoring the remainder of the solution space. Remaining cognizant of the entire system helps to ensure that data can reasonably move from the agents all the way to the remote support services when necessary. This path may include converting the data format, exchange protocols, and transport protocols across different interfaces.[12]

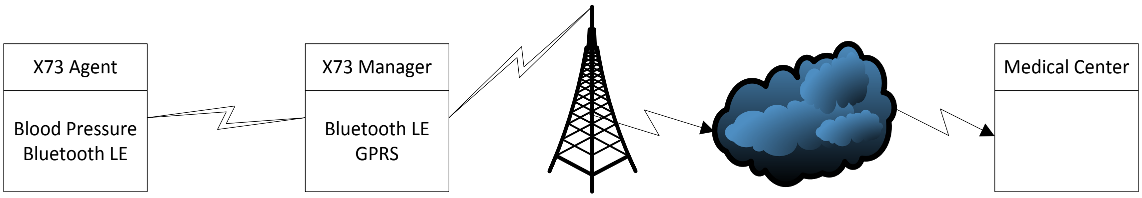
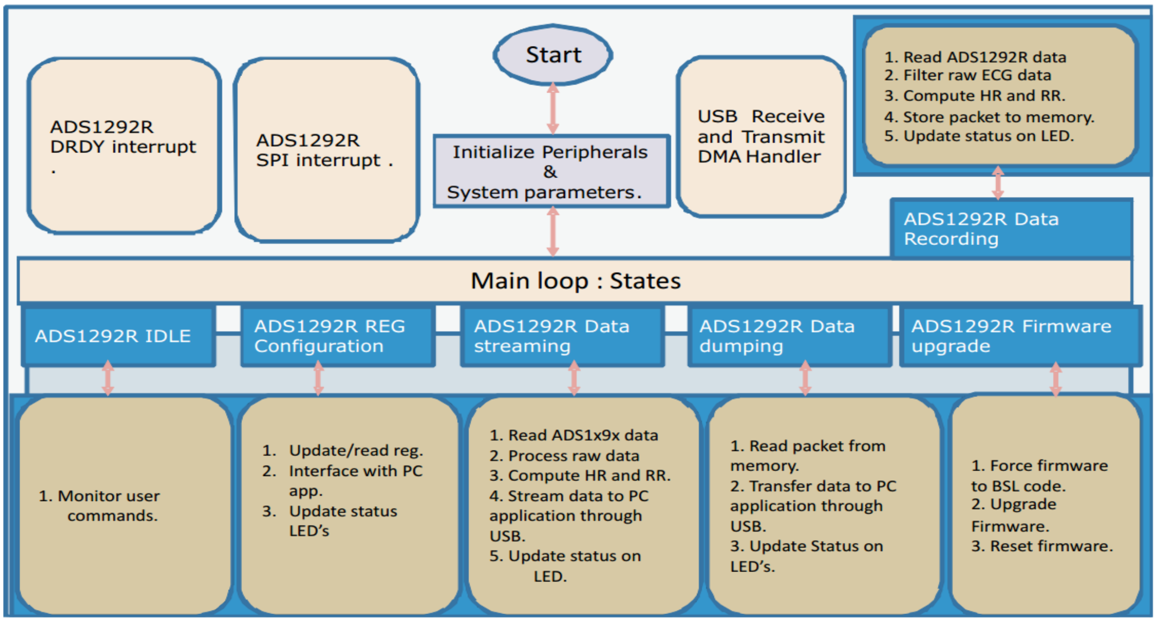


Fig 3. Block – scheme X73-PHD 1-3 Lead ECG Medical Device with Bluetooth LE

The micro-controller receives the two-channel data from ADC through the SPI interface to send to the PC. The software is designed to handle the following activities:

- Data acquisition
- ADC Lead off detection
- DC signal removal
- Multi band pass filtering
- ECG lead formation
- QRS (HR) detection
- RR Detection
- USB communication
- Firmware upgrade through USB

Software (existence firmware)



The modification of firmware of x73/SCP compliant ECG and was implemented by HSE research group. It was developed using C++ and included all the required classes, attributes and specifications defined in X73-PHD. The first device implemented were: weighing scale. Later, a custom-defined specification was added. Within the project described in this paper, the simulated ECG device was used to record, store and later transmit an ECG by means of the PM-Store concept. Application:

- ***PM-Store***: It contains all the ECGs stored in the device. The attribute Number-Of-Segments specifies the number of stored ECGs.

- ***PM-Segment***: An ECG. The PM-Seg-Person-Id attribute identifies the patient/user.

- ***Entry:*** It encapsulates one lead (per Entry) in a RT-SA structure. Therefore, it contains the data itself but also the information related to this lead, such as Sample Size or Scale and Range specifications.

- ***Element***: One single ECG sample. The first elements in the entry correspond to the information related to this lead.

The data are stored in a device exactly in the order that the Manager would ask for them, so that it is quicker to create response messages or SegmentDataEvents. Thus, the x73-PHD standard is followed by an Agent to configure a ECG device, record and store an ECG signal and finally send it to the Manager using the PM-Store concept, classes and procedure. After that, the Manager generates a SCP-ECG file that can be sent to an EHR Server and included in the patient history.

3. Conclusion and future directions

The acquisitions of real data (from electrode),store in PM-Store and sending it to Manager has been investigated. The relationships between the different fields and messages of both standards have been described. This process has proved that the x73-PHD PM-Store concept is a well-defined idea to manage metric stored data, including ECGs. The main further research trend is the implementation of the Transcoder Server x73-SCP/PHD to EHR Server (EN 13606). It will be allowed to use this concept in REAL HEALTHCARE MONITORING, including Medical Center and Hospital Information Systems.

References

[1] Continua Alliance . http://www.continuaalliance.org/

[2] http://www.continuaalliance.org/node/77

[3] Freescale ADAS1000

[4] Texas Instruments ADS1293

[5] Bluetooth LE. BTE 112.

[6] MSP430 Medical Platform

[7] ADS1x9xECG-FE board

[8] SCP-ECG, Standard Communication Protocol for Computer-Assisted electrocardiography, EN1064:2005+A1:2007.

[9] ISO/IEEE11073. Health informatics Medical Devices communication [P11073-20601.Application profile-Optimized exchange protocol].http://standards.ieee.org/. First edition: 2006.

[10] ISO/FDIS 11073-91064 Health informatics. Standard communication protocol – Part 91064: Computer-assisted electrocardiography.

[11] ISO/IEEE11073-10406 Health informatics. Personal Health Devices communication. Device Specialization - Basic ECG (1-3 lead).

[12] J.D. Trigo, F. Chiarugi, Á. Alesanco, M. Martínez-Espronceda, C. E. Chronaki, J. Escayola, Ignacio M. and J. García, "Standard-Compliant Real-Time Transmission of ECGs: Harmonization of ISO/IEEE 11073-PHD and SCP-ECG", in *Int Conf IEEE Eng in Medicine and Biology Society*, 2009

[13] S. Led, L. Serrano, M. Galarraga. "Intelligent Holter: a new wearable device for ECG" European Medical and Biological Engineering Conference EMBEC, Prague, 2005 [HOLTIN project, in collaboration with Cardiology Dept. of Negrín Univ. Hospital, Canary Islands].