DEVICE ENTERPRISE COMMUNICATION FOR A SELF-DEVELOPED MOBILE ECG DEVICE WITHIN THE SCOPE OF IEEE X73

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Abstract

According to the WHO, cardiovascular diseases cause the highest numbers of deaths worldwide. [1] The current disease management focus is on the acute condition of cardiovascular diseases. In this paper a home-care approach is presented were the focus is on the regular monitoring of the patient through a mobile ECG device. The observed data is transmitted via Bluetooth to an Android smart phone in the scope of IEEE's x73 and passed on to a tele-health service centre for storage, review and reporting.

***Keywords** – mECG, IEEE x73, Interoperability, IHE-PCD*

1. Introduction

Worldwide cardiovascular diseases (CVD) and chronic heart conditions are the number one cause of fatalities according to WHO's CVD fact sheet [1]. An early detection system could significantly reduce the cases of deaths caused by heart failure. The presented proof of concept prototype system consists of a three lead self-developed mobile ECG device for home care use that is connected to a smart phone which transfers the observation reports to a tele-health service centre for persistent storage and report generation. Currently hospitals only have the capability to react to an aggravation of the heart condition in cases of a cardiac event. An early warning system incorporating mobile ECGs and tele monitoring would help to manage and monitor the course of the disease as shown in previous works [2] . However, systems that are currently used do not follow interoperability design paradigms and rely on proprietary solutions. Healthcare providers and health care systems rely on standardized communication and standardized interfaces for cross enterprise communication. The system presented in this paper shows a standardized approach to chronic disease monitoring from the patients home to generated reports collected in a Health Reporting Network (HRN). The mobile ECG system allows a standardized interoperable overall approach to disease course monitoring, starting with the waveform recording, displaying data on the smart phone, transmitting the data to the tele-health service centre and generating monthly reports for the assessment by physician. In order to present the physician at the hospital an informative monthly

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report generated from the weekly observation results the mobile ECG system implements CDA reports which are stored and retrieved from a HRN. The mobile ECG system utilizes standards designed for use in health care systems aimed at interoperability, ranging from Continua guidelines, through IHE technical frameworks to IEEE x73 standards and the new x73 ECG device specialization [3]. The ECG device specialization offers a way to integrate ECGs into the family of standardized personal health care devices which in the past had only non standardized communication pathways [4]. IEEE's 11073-10406 is newly applicable standard with only some functioning approaches that are currently developed, like a wearable ECG recorder by Led et al. [5]. The presented mECG solution shows an overall approach of integrating an ECG in an interoperable communication chain linking patients to tele-health service centres.

2. Material and Methods

2. 1. Printed Circuit Board

The first prototype of the mobile ECG device used a PIC32-Pinguino-OGT Olimex development board [6] for the signal acquisition, digital filtering, signal processing and sending the data via a Bluetooth chip. The Olimex board was used because it offers a schematic file in Eagle format which can be used for the design of a self-designed PCB. The onboard Bluetooth chip for the device communication, the Stollmann BlueMod+P24/P25/G2 [7], uses the Health Device Profile (HDP) which is needed within the specifications of the IEEE 11073 standards family. The data processing preformed on the PIC32 microcontroller is based on preliminary tests, which were done in MATLAB for identifying the right filter for the specific needs, which showed that the implementation of a Direct-Form-FIR would fit best. The communication with the Android application is performed via Bluetooth's HDP using the abstract syntax notation one (ASN.1) and medical device encoding rules (MDER) found in ISO/IEE 11073-20601:2010 Annex A (p. 98-129) and F (p. 151-162) respectively. [8]

2. 2. Application Hosting Device and Enterprise Communication

The Android application functions as Device Observation Reporter (DOR) Actor as defined in the Device Enterprise Communication (DEC) Profile of IHE's Patient Care Device Technical Framework [9]. The mobile ECG's PCB is paired via Bluetooth with the Android application and transmits the observations via HDP. The data transmission uses the standardized approach from ISO/IEE 11073-20601:2010 - optimized exchange protocol [8] and additional constraints gathered from ISO/IEE 10406:2012 - Device specialization Basic electrocardiograph. [3]

2. 3. Tele-health service centre

The tele-health service centre personal can access the stored Observation Reports through a web access interface. Through the web service the tele-health service centre personal can create documents based on the data acquired from the mobile ECG device. The created documents are implemented following HL7's Clinical Document Architecture (CDA). The generated report uses the Design Guidelines (Allgemeiner CDA-Implementierungsleitfaden Version 2.01 [10]) outlined by the ELGA GmbH, a body responsible for the implementation of the electronic health record (EHR) in Austria. The Design Guidelines define further constraints on the Domain Information Model of the CDA, specific for the legal situation and requirements for the use in Austria. Within the scope of Austria's implementation of an EHR in the coming years the last step of the presented system solution is the implementation of the Cross-Enterprise Document Sharing (XDS.b) as defined in IHE's IT Infrastructure Technical Framework. [11]

3. Results

3. 1. Printed Circuit Board

The mECG circuit consists of three electrode inputs (left arm, right arm, left foot) and one ground electrode (right foot). The first channel measures changes in the voltage between left and right hand, the second between left hand and left foot and the third between right hand and left foot, every time measuring against the ground electrode. Each channel passes through an active 4th order low pass filter for noise reduction. Over an analogue-digital converter the acquired signal is then processed by the microcontroller via digital 10th order direct FIR-filter. The FIR-filter implements cut-off frequencies of 1 Hz (high-pass) and 40 Hz (low-pass), which removes movement artefacts and noise that passed the analogue filter. The microcontroller holds two detection algorithms. One algorithm detects the heart rate and the other one has been designed for asystole detection. The heart rate detection algorithm is designed as an on-the-fly single threshold R-peak detector, whereas the asystole detection algorithm checks the mean amplitude of the ECG waveform. The microcontroller transmits the waveform data via the Bluetooth's HDP. For a functional agent-manager communication, e.g., between the mobile ECG device and the Android smart phone, the implementation of the needed Protocol Data Units (PDU) follows the metric object instance as shown in the basic ECG profile [3] and ASN.1 and MDER. The extended configuration, based on the domain information model holds three waveform objects (Lead I-III), one heart rate object, one R-R interval object and one device status object for information about the lead connectivity.

3. 2. Application Hosting Device and Enterprise Communication

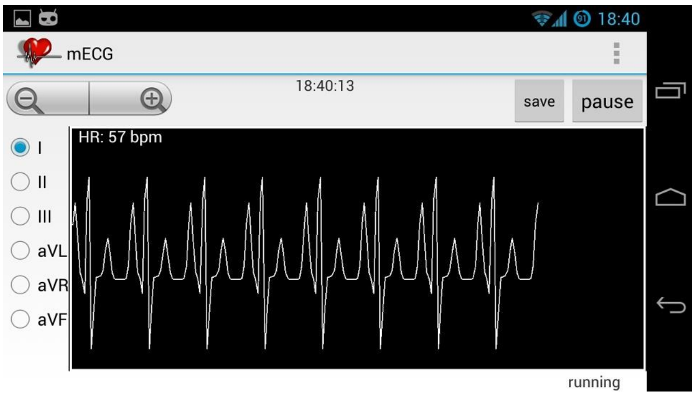

Figure 1: User interface of the mECG Android Application

The Android application acts as manager for the mobile ECG within the scope of IEEE's 11073 standards family. The application receives the data every second via agent-initiated communication. The waveform data is presented as moving graph on the UI (user interface) and the currently displayed waveform can be chosen through buttons (*Figure 1*). The ECG data, waveform information, heart rate and R-R interval, are read from the protocol data units and stored for further use. The Android application processes the gathered information from the mobile ECG into an Observation Report defined by a HL7 ORU^R01^ORU_R01 message based on Patient Care Device Technical Framework Volume 2 [9]. The required information is translated into a HL 7 message by the Android application and prepared for transfer to the server, e.g. the Device Observation Consumer. The HL 7 message is generated by matching the data fields from the mobile ECG to the corresponding parts of the HL 7 message via a translation module within the Android application. The Enterprise server is realized as tomcat server hosting a MySQL database. The transmitted Observation Reports are only accepted if they pass the validation process on the server side. The secure communication over the WAN interface between the AHD and the tele-health service centre is achieved via Simple Object Access Protocol (SOAP) and HTTPS transfer. The Android application takes the generated HL 7 message and puts it into a SOAP envelope which is then processed by the web service on the tele-health service centre side.

3. 3. Tele-health service centre

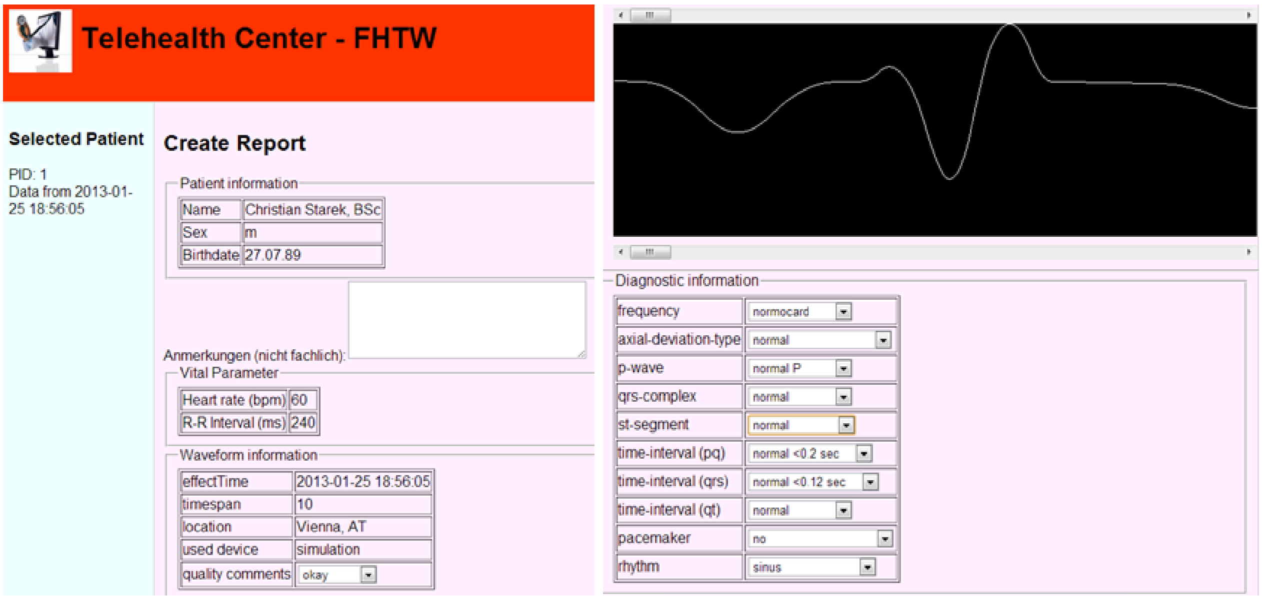

Figure 2: Overview of the tele-health service centre web application

The tele-health service centre generates documents based on the Observation Reports gathered from the mobile ECG which are transmitted by the AHD as HL 7 message. In order to stay within the focus of an interoperable data exchange and document generation a web based application enables the tele-healthcentre personal to access the Observation Reports and generate CDA documents (*Figure 2*). The design of the ECG report document follows the constraints gathered from ELGA's implementation guidelines (Allgemeiner CDA-Implementierungsleitfaden Version 2.01 [10]). The generated XML file representing the ECG report document is the basis for the CDA documents that are made available by the tele-health service centre within the scope of IHE's XDS.b profile [11]. In accordance to the XDS.b profile the tele-health service centre application implements the Document Source actor needed for the document registration within the registry.

4. Discussion

The presented prototype shows an overall approach to standardized communication within the eHealth field – starting at the signal acquisition of the electro potential of the human heart to the final clinical document. The mECG approach shows the interoperable integration of the ECG into the world of tele-monitoring relying on standards and guidelines. Previous systems following this paradigm were designed following a proprietary approach without incorporating IEEE's 11073-

10406 Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG) such as a wearable ECG-recording system in a tele-home-care setting [12]. The mECG project is implemented as a proof-of-concept approach showcasing the abilities of a standardized communication pathway from patient to assessing tele-health centre service personnel. For further assessment of this approach an actual test run in a tele-care setting has to be done in the future. Currently the main attention of the mECG is on the interoperability of the overall system. In the future when tests with the whole system in medical settings are done the attention will shift to improving the ECG's design as well as the android application's usability.

In conclusion the self-designed system is able to acquire a three lead ECG signal, filter and process it and send it via Bluetooth within the scope of IEEE's 11073 standard family to an Android smart phone which functions as a manager. The phone than forwards the information packed in a HL 7 message to the enterprise server and to the tele-health service centre.

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