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A Mobile Phone Based Telemonitoring Concept for the Simultanous Acquisition of Biosignals and Physiological Parameters

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Abstract

Congestive Heart Failure (CHF) is a common chronic heart disease with high socioeconomic impact. Conventional treatment of CHF is often ineffective and inefficient, since self-management is complex and patients are insufficiently involved in therapy management. With telemedical concepts, continuous monitoring of the health status can be ensured, and consequently therapy management can be adapted to the individual requirements of every individual patient. Therefore, a mobile phone based patient terminal for the concurrent acquisition of biosignals (e.g. ECG) and bioparameters (e.g. blood pressure) for patients with CHF has been developed and prototypically implemented. Usability and interoperability aspects were especially considered by using Bluetooth and Near Field Communication (NFC) technology for data acquisition and standardized data formats for transmission of the data to a central monitoring centre. Results indicated that even complicated measurements like the acquisition of ECG signals could be accomplished autonomously by the patients in an intuitive and easy-to-use way. Through the usage of IHE conform HL7 messages, self-measured data could easily be integrated into a higher-ranking eHealth infrastructure.

Keywords:

Near field communication, eHealth, Telemedicine, Mobile communication, ECG, Congestive heart failure, Interoperability

Introduction

Motivation for Telemonitoring of Congestive Heart Failure

Congestive Heart Failure (CHF) is defined as *"a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood."* Since self-management of CHF is complex and since patients are insufficiently involved in the state-of-the-art therapy process, patients' compliance to the given therapy management is often poor – resulting in a high rate of re-hospitalizations within six months after discharge and in poor quality of life [1].

Telemonitoring for patients with CHF provides advantages for not only the patients but also the healthcare system. The attending physician can carefully watch the overall health status of his patients by the monitoring of various health parameters, namely ECG, weight, blood pressure, heart rate, medication, and well-being. This enables the physician to adapt the therapy in due time – avoiding readmissions to the hospital, emergency cases and extraordinary treatment costs [1].

State of the art

In the last years, several systematic reviews concerning the benefit of telemonitoring in the management of CHF have been conducted. Chaudhry et al. state that telemonitoring may be an effective strategy for disease management in high-risk CHF patients [2]. Clark et al. conclude that telemonitoring programs have a positive effect on clinical outcomes in community dwelling patients with CHF [3]. Louis et al. [4] conclude that telemonitoring might have an important role as part of a strategy for effective CHF management. Seto et al. [5] deal with the cost-effectiveness of telemonitoring in the management of CHF. The results of the aforementioned systematic review suggest that although CHF telemonitoring will require an initial financial investment it will reduce costs in the long run. The cost reduction is particularly caused by the decrease in readmissions and travel costs.

Most of the aforementioned studies used rather complex patient terminals, which could not be used intuitively or were too expensive for a widespread usage. A success factor for the implementation of telemonitoring in the healthcare system is to provide the patients with an easy to use patient terminal for intuitive data acquisition at low cost.

The mobile phone as patient terminal

Mobile phones have already been used as patient terminals in several existing telemonitoring systems for the management of e.g. obesity [6], psoriasis [7], diabetes [8], asthma [9], and CHF [1]. Most of the mentioned systems have used mobile phones with numeric keypads for data entry and mobile Internet technology for the transmission of the data to a central monitoring centre. However, manual data entry often overburdens (elderly) patients, especially if they are not familiar with handling mobile phones.

While the acquisition of an ECG could be helpful in CHF therapy management, it also opens new challenges for the development of a mobile phone based patient terminal. In [10-13], systems for the acquisition of ECG signals in a telemonitoring scenario were introduced. All systems used mobile phones as patient terminals and Bluetooth for the communication between the ECG recorder and the mobile phone. None of these solutions has been evaluated in the course of a clinical study with respect to usability for the given group of patients. Most of the systems required the application of adhesive electrodes to the chest in order to record an ECG. The quality of the ECG strongly depended on the ability of the patients to apply the electrodes correctly, which may pose a problem for daily usage in a telemonitoring scenario. Furthermore, the presented ECG recorders seemed to be too complicated to be used by the patients autonomously.

Aim of the present work

It has been the aim of the present work to develop a patient terminal, which supports

1. an easy-to-use interface for acquiring bioparameters (e.g. blood pressure) and biosignals (e.g. ECG) and
2. the smooth integration of the patient terminal into existing eHealth platforms and hospital information systems.

The patient terminal should prototypically be implemented for the acquisition of home-monitoring data acquired by the patients themselves in the course of CHF therapy.

Materials and Methods

Wherever possible, standards were used for developing a prototype implementation of a telemonitoring system for CHF. These standards are shortly described in the following.

Communication protocols

One way for sending data from a measurement device to the mobile phone is Bluetooth. Therefore, prior to transmitting data in between the devices, the devices need to be paired using a PIN the user has to enter to the mobile phone. Bluetooth pairing is not an intuitive procedure and it may overstrain especially elderly patients. Therefore, an alternative easy-to-use method was demanded.

Near Field Communication (NFC) is an intuitive communication technique, allowing wireless data transmission over short distances. In the case of mobile phones, the maximum distance in between sender and receiver is about 1 cm. Data can either be exchanged between two active devices or in between an active device and a passive NFC tag. In the second case, information can be written on a tag (e.g. an identification number) and later on be read out by an active NFC device (e.g. mobile phone). Unfortunately, communication via NFC is rather slow and it is disconnected as soon as the devices are separated by more than about 1 cm. Therefore, transmission of large data such as a whole ECG file from a measurement device to a mobile phone via NFC is not possible in a reliable way.

Device Enterprise Communication (DEC)

The *Device Enterprise Communication* (DEC) profile as described in the IHE *Patient Care Device Technical Framework* [14] was used for developing the prototype. The DEC profile describes three actors: The *"Device Observation Reporter"* receives the data from the measurement devices, including these based on proprietary formats, and maps the received data into an HL7 *"Observation Result"* message. The reporter forwards the HL7 result message to the *"Device Observation Consumer"*. Additionally, a *"Device Observation Filter"* can be put in between the reporter and the consumer, transmitting only data that the consumer is expecting to receive [15].

Annotated ECG

ECG signals were encoded using the *annotated ECG* (aECG) data format. aECG is an HL7v3 message that has been developed by the HL7 Regulated Clinical Research Information Management Technical Committee. It is intended for the submission of annotated ECG waveforms by the sponsor of a clinical trial to the United States Food and Drug Administration (FDA) [16]. Like the DEC profile, aECG is based on the "Point of Care medical device communication (MDC) Nomenclature" of the ISO/IEEE X73 standard [17].

Backend server

All data acquired with the developed patient terminal were sent to an existing backend infrastructure including identity management, database, web-server, feedback service, interfaces to hospital information services etc.

Results

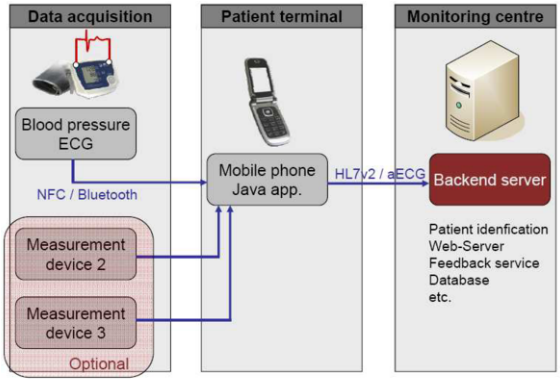

Figure 1- System architecture. A mobile phone based patient terminal collects data of several data acquisition devices and transfers them to a backend server via a standardized interface based on HL7v2 and annotated ECG (aECG).

A framework for acquiring bioparameters (e.g. blood pressure) and biosignals (e.g. ECG) has been prototypically implemented and integrated into an existing eHealth infrastructure.

A schematic representation of the system architecture is shown in Figure 1. The architecture is based on the *Device Enterprise Communication* (DEC). A J2ME based software application running on the patient terminal served as *Device Observation Reporter*. The backend server was used as *Device Observation Consumer.* As the *Device Observation Filter* is an optional part of the DEC profile, it has been omitted for the prototypical implementation.

Patient terminal – Mobile phone

A commercial mobile phone featuring wireless communication via Bluetooth and NFC (Nokia 6212 Classic, Nokia, Espoo, Finland) served as a patient terminal. A Java 2 Micro Edition (J2ME) based software application was implemented on the mobile phone. We used the Java Specification Request (JSR) 82 for implementing the Bluetooth protocol and the JSR 257 for NFC communication implementation.

Data acquisition – Measurement device

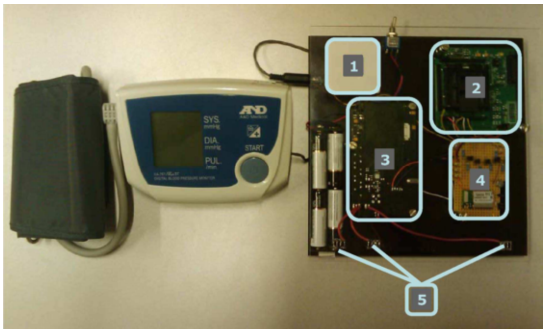

Figure 2- Prototype of the adapted blood pressure meter. 1) NFC Tag, 2) controller unit, 3) ECG module,4) Bluetooth module, 5) electrodes

In order to simultaneously acquire the ECG (Einthoven I), systolic and diastolic blood pressure, mean arterial pressure, and heart rate, an off-the-shelf blood pressure meter (UA-767 Plus BT, A&D, Tokyo, Japan) was used and extended.

An 8-bit single-channel 125 Hz ECG recording module (AIT Austrian Institute of Technology GmbH, Vienna, Austria) was added. For the prototype, the additional hardware was installed on a separate device connected to the blood pressure meter via cables. Three metal electrodes (left arm, right arm, driven right leg) were attached to the casing. These electrodes were to be touched by the fingers of the left and right hand.

Finally, a controller unit (MSP430F2410, Texas Instruments, Dallas, Texas, USA) was installed.

The system was equipped with an NFC tag (Mifare Standard 1K, NXP Semiconductors, Eindhoven, Netherlands) and a Bluetooth module (BNC4, Amber Wireless, Köln, Germany) enabling communication with the mobile phone. Figure 2 shows the hardware prototype of the adapted blood pressure meter.

Data transfer from measurement device to patient terminal

We combined the advantages of NFC and Bluetooth to develop an easy-to-use and reliable interface in between measurement device and mobile phone. The service ID of the Bluetooth module was written on the NFC tag on the adapted blood pressure meter and the Bluetooth connection was established by reading out this ID – without the need of any manual pairing procedure.

Data transmission from the blood pressure meter to the mobile phone was done in a proprietary data format. On the mobile phone, measured values were converted using an extensible mapping scheme. Every value and the corresponding unit were coded according to the MDC nomenclature of the ISO/IEEE X73 standard. For sending the data from the mobile phone to the backend server, the HL7v2 and the aECG standard were used.

Workflow

For data acquisition, the NFC tag on the blood pressure meter had to be touched with the mobile phone. The J2ME application started automatically read out the Bluetooth service ID from the tag and asked the user to take on the cuff of the blood pressure meter and to touch the ECG electrodes with his fingers. Next, the J2ME application sent a trigger impulse to the blood pressure meter, starting the inflation of the cuff. Thereafter, blood pressure measurement and ECG recording were done simultaneously.

The data were transmitted to the mobile phone via Bluetooth – using the service id stored on the NFC tag. The J2ME application analyzed the ECG signal and displayed a graphical representation of the current signal quality.

As soon as blood pressure data and ECG signals were available in sufficient quality, the data were automatically transmitted to the backend-system via UMTS. A device ID was added to the request, which was used to map the transmitted data to the patient.

The J2ME application guided the patient through this workflow, using a visual and acoustic interface – telling the patient, which step he had to take next.

Several measurements and processing cycles were performed successfully in various healthy volunteers.

Discussion

Usability

Effective and efficient treatment of CHF is one of the major challenges for healthcare systems and telemonitoring has been shown to be a useful tool for patients and physicians, increasing the overall therapy outcome. For telemonitoring, it is essential to provide the patient with an easy-to-use patient terminal for intuitive data acquisition. The advantage of mobile phones compared to other patient terminal technologies are their ubiquitous availability at low costs and their mobility. Limited resources concerning memory capacity and processing power, as well the small keypad and display are the main disadvantages of mobile phones. In the present work, the usage of NFC and Bluetooth technology completely eliminates the need to use the mobile phone's keypad for data entry. However, the limitation concerning the small display still is valid, even though much (but not all) information was provided to the patients visually and acoustically.

Manual inspection and automated detection of the ECG signals transmitted to the backend indicated that the signal quality would be sufficient for QRS detection and ventricular rhythm analysis. However, up to now no clinical validation of the system has been done. In a future study the usability of the system for CHF patients and the clinical benefit of recording ECG signals (additional to bioparameters as used for up-to-date CHF telemonitoring) will be evaluated.

Standardization and expandability

Initially, standardized data transmission throughout the whole system was intended. However, the adapted blood pressure meter used a proprietary data format. Therefore, standardizing the communication from the device to the mobile phone according to the (currently developing) Continua Health Alliance interoperability standard [18] is planned for the future.

In the management of CHF, it is important to monitor different parameters (ECG, weight, blood pressure, heart rate, medication, and wellbeing) in order to get a complete view on the health status of the patients. The DEC profile only supports physiological parameters (weight, blood pressure, heart rate). Parameters like medication or well-being are not in the scope of the current version of the profile. Additionally, as the current version of the profile does not define the standardized handling of biosignals like ECG, a concept for additional integration of biosignals was needed and has been implemented on the basis of the aECG standard.

Currently, the use case described only supports the acquisition of ECG and blood pressure data (systolic, diastolic and mean blood pressure, heart rate). For clinical usage, additional parameters (weight, medication, subjective parameters) have to be included in order to get a complete view on the health status of the patients. However, because of the modular architecture of the software and due to the use of standards, modules for the acquisition of further parameters could easily be integrated into the developed software.

Safety and security considerations

Up to now, the Bluetooth connection in between measurement device and mobile phone established via NFC by the use of the device's Bluetooth service address is un-authenticated and unencrypted. Therefore, in a clinical setting, an alternative way of establishing the Bluetooth connection via NFC may be required.

In 2007, the Bluetooth Special Interest Group (SIG) announced the new version of the Bluetooth core specification, namely Bluetooth 2.1. Among others, with Bluetooth 2.1 and through the usage of NFC, the initiation of this simplified pairing process can be automated. The only user action required for pairing is holding one device closely to the other. NFC handles the initiation of the pairing without further user interaction.

Unfortunately, Bluetooth pairing via NFC is an optional feature of Bluetooth 2.1, and mobile phones currently available only support this feature for sending images to electronic picture frames or printers. However, it is expected that in future devices this feature will be implemented for all Bluetooth devices.

Security issues are explicitly excluded from the DEC profile. As it is primarily intended for the usage in an encapsulated network (e.g. within a hospital network) data security methods are disregarded. For the use in a telemonitoring scenario, the profile has to be embedded into an additional "Security Framework" in order to ensure a secure end-to-end transmission of the acquired data and to be compliant with data protection regulations. For the development of the prototype, security aspects were also disregarded in the first step. Hence, further developments of the software will focus on the development of a security layer including an encrypted Bluetooth connection form the device to the patient terminal and encrypted data transmission over the Internet form the patient terminal to the backend server using HTTPs.

Identity management of personalized data (i.e. the assignment of a data set to a patient) is one of the big opportunities in future telemonitoring scenarios. Today entering username and password is the golden standard for personalizing data on the Internet. For elderly patients it may be hard to keep the username and password in mind and additionally entering data using the alphanumeric keypad is rather difficult. Identity management issues are also disregarded by the DEC profile. We chose to use a device ID, which was explicitly mapped to a patient ID, for assigning the data received from the patient terminal to a patient. Alternatively, NFC smart cards with personal patient IDs could be handed out to the patients and identification could be made by simply touching this ID whenever transmitting data.

Conclusion

An interoperable mobile phone based patient terminal for the intuitive acquisition of biosignals and physiological parameters was developed and implemented prototypically. Via the use of Bluetooth combined with NFC technology, an easy-to-use interface in between measurement device and mobile phone could be developed. Due to standardized transmission protocols, architectures and data formats, smooth integration of the patient terminal into existing eHealth structures was achieved.

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