Enabling technologies for the in-house monitoring of vital signs in chronic patients

Massimiliano Donati[1,2], Alessio Celli[1], Alessandro Benini[1], Luca Fanucci[1,2]
Sergio Saponara[1,2]

[1] University of Pisa, Dept. of Information Engineering, via G.Caruso 16, 56122 Pisa, Italy
[2] IngeniArs srl, via Ponte a Piglieri 8, 56122 Pisa, Italy
massimiliano.donati@for.unipi.it

Abstract. The in-house monitoring of vital signs represents a real opportunity to improve the effectiveness of the healthcare of chronic patients, integrating the traditional in-hospital healthcare model with a new out-of-hospital follow-up based on frequent monitoring of the clinical status. It allows clinicians and practitioners to realize and act promptly suspect aggravations, before they become irreversible and lead to hospitalization. This model relies on ICT, in particular biomedical sensors and concentrator devices (i.e. gateway) that enable to acquire vital signs at patient's home and to transmit collected data in secure way, making them remotely available for medical personnel. This paper presents two gateway devices enabling the in-house monitoring of vital signs according to the kind and severity of the diseases, being the first conceived to be used by the patient while the second studied for professional caregivers. Moreover, it presents a novel sensor for the self-acquisition of the ECG signal.

1 Introduction

The management of chronic diseases represents an important challenge for the National Health System (NHS) in any developed countries, especially due to the large amount of resources required for the healthcare of the patients. Chronic Heart Failure (CHF) and Chronic Obstructive Pulmonary Disease (COPD) are today the main causes of hospitalization in the older adult segment. Additionally, they show a very high re-hospitalization rate (i.e. subsequent hospitalizations after the first acute episode) that affects considerably the healthcare costs sustained by the NHS, the congestion of the specialized resource and the patient's quality of life.

CHF affects approximately 15 million European citizens [1] and more than 5 million Americans [2], with a prevalence of 2% and an incidence of 3.6 million and 550.000 of respectively in Europe and in U.S [3]. It represents the 5% of all hospitalizations [1] and it is the main reason of admission in people aged 65 years or older, accounting for the 2% of the total healthcare expenditure [3]. Instead, more than 15 million Americans and approximately 210 million worldwide suffer from some forms of COPD [4], corresponding to a prevalence close to 8% [5].

The traditional model of care, based on periodic visits provided by specialized centers or practitioners, does not allow an early detection and reaction to the signs of decompensation, and often they become irreversible. This dramatically causes a high hospitalization rate, posing an important societal and economical problem to the NHS. Moreover, considering that according to the World Health Organization (WHO) the number of people affected by chronic diseases is expected to double before 2030, new cost-effective models of treatment are required.

The ICT technologies have a key role in the implementation of new multi-disciplinary and integrated management models, in which the in-house monitoring of vital signs (i.e. ECG, blood pressure, oxygen saturation, pulmonary capacity, weight, etc.) and lifestyle information are the central points. The in-house monitoring of patients with telemedicine systems integrating all actors involved in the healthcare of chronic patients results in a reduction of the mortality, hospitalizations, length of hospital stay [6]-[8] and consequently benefits both the patients and the NHS.

This paper presents two gateway devices that allow the in-house acquisition of vital signs from Bluetooth sensors and the transmission of data towards remote platforms by which medical personnel can monitor the patients at distance. Moreover, it presents a novel sensor aiming at the self-acquisition of the ECG signal for telemedicine purposes. Hereafter, Section II gives an overview of the in-house monitoring model. Section III and Section IV present the gateway and ECG devices respectively. Finally, conclusions are drawn in Section V.

2 The in-house monitoring

The general architecture for the provisioning of in-house monitoring of vital signs during the out-of-hospital follow-up is shown in Fig.1. The platform relies on the modern ICT that allows the acquisition, the storage and the secure circulation of the clinical information among all caregivers involved in the healthcare of chronic patients [9]. In this way, the medical personnel can monitor at distance the status of many patients though dedicated repository or the direct integration with the Hospital Information Systems, and they can take timely actions in case of aggravation.

Two kinds of in-house monitoring exist, depending on the disease and the severity of the clinical condition. The first is performed directly by the patient while the second envisages the involvement of professional caregivers during the domiciliary visits. In both cases, the main enabling element to implement the in-house monitoring

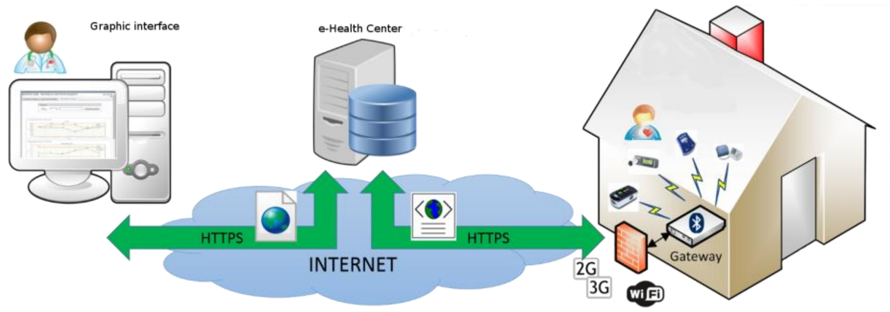

Fig. 1. In-house monitoring infrastructure

is a wireless sensor network (e.g. Bluetooth). It is composed of biomedical sensors for non-invasive measurement of the main vital signs under the coordination of a gateway device that contains all the computation and communication resources. The role of this part of the monitoring chain is to provide the rest of the platform with frequent (i.e. daily) and updated high-quality vital signs information collected at home.

3 The gateway system

The gateway is the central node of the wireless sensor network, being in charge of collecting, storing and transmitting in secure way the data coming from the biomedical sensors. Depending on the target user, patient or caregiver, it has different features and user interfaces that allow to maximize its effectiveness. The following sections describe in details two kinds of gateway specialized for their applications. They are implemented for Android ≥ 4.3 devices (i.e. tablet, smartphone, set-top-box) equipped with Bluetooth and at least an Internet connection (e.g. WiFi, 3G, etc.).

3.1 Gateway for patients

This model of gateway is usually delivered directly to the patient when enrolled in the telemedicine service, along with the set of sensors selected by the clinician. The gateway is conceived to minimize the impact on the patient and to maximize the usability. It enables the patient to follow autonomously the personalized treatment agenda (defined on the E-Health Center) exploiting reminder messages and audio-visual helps, while data acquisition and transmission are completely transparent.

Fig. 2 shows the typical lifecycle of the gateway permanently assigned to a chronic patient. During the idle phase the device shows, on the left, the last value of each collected parameter (e.g. hearth-rate, systolic and diastolic pressure, etc.) while, on the right, the current time is shown. The upper green bar reminds the time of the next activity, if exist, or shows that no more interactions are requested for the current day. When the time of an activity is reached, the gateway switches to reminder phase. The

Fig. 2. Example of lifecycle in case of a blood pressure measure

upper bar changes to yellow (user interaction request) and indicates the scheduled activity, the right part of the screen displays the graphical helper that explains how to use the sensor and, on the left, the deadline is shown. Now the patient has the time to complete the activity before the deadline. Once executed successfully the activity, the gateway provides an immediate audio-visual feedback, then it returns in idle phase. Meanwhile, it tries to transmit the collected data to the E-Health Center. In case of failure during the acquisition, the gateway requests again the same activity while if transmission fails, it store temporarily the data that will be added in future transmission retries. Additionally, the gateway is also able to receive out-of-agenda activities: once received, the only additional interaction required to the patient is to confirm the acquisition through an acknowledgment dialog.

3.2 Gateway for caregivers

This model of gateway is part of a specialized kit provided to professional caregiver to support their routinely domiciliary visits of chronic patients. It allows the management of the large list of assisted patients, specifying for each of them the personalized agenda of activities defined by the clinicians. The gateway derives from the previous version and maintains its basic functionality, but it includes more sophisticated data visualizations and interaction modes suitable for professional users.

Fig.3 shows the typical use case of the gateway during a domiciliary visit. The first step consists of the selection of the patient from the list, previously downloaded from the e-Health center, by textual search or by scanning the sanitary ID card. For each patient, personal data, information about the chronic diseases he/she is affected and expected activities are provided. Once selected the patient, the gateway switches to a specific screen with a series of in horizontal tabs that support the caregiver to perform all the requested activities. Each tab is related to a vital sign and indicates in the upper bar if the activity is requested or not through a message with yellow or gray background respectively. Moreover, it shows on the left the information about the last collected measure, if exists, while the area on the right it provides a graphical

Fig. 3. Example of lifecycle in case of domiciliary visit including the ECG

representation of the vital sign and the possibility to browse stored data. In particular, if the tab concerns scalar physiological measures (e.g. blood pressure, glycaemia, etc.), the graph represents the historical trend, otherwise for complex physiological measures (e.g. ECG, spirometry, etc.) the graph is related to the last wave collected. Now the caregiver can use the sensor to measure the requested vital signs, receiving immediately at the end of each activity an audio-visual feedback. Additionally, out-of-agenda activities can be always performed, activating manually the specific tab. At the end of the visit, the gateway sends all data to the E-Health center confirming the successful transmission. A failure in data acquisition results in a request to repeat the activity while a temporary storage of the data ensures to avoid loss in case of failure in transmission, allowing for deferred attempts.

4 The ECG sensor

Among all the vital signs, the heart activity is one of the most important in chronic patients management. Heart activity can be monitored via electrocardiographic devices. Many devices exist on the market able to forward the recorded ECG to a telemedicine gateway. Unfortunately, they are often hard to be set and operated autonomously by the patient (e.g. complex interfaces, adhesive electrodes to be placed, etc.). Instead, these devices are mostly conceived for professional users.

In order to allow patients that suffers of chronic diseases to record their own ECG signal autonomously, a new user-friendly and ergonomic ECG sensor is proposed. The device consists of two pairs of dry metal electrodes placed on a plastic body having approximated dimensions of 30x5x3 cm. It works by placing each hand in contact with a pair of electrodes, measuring for 30 seconds the first lead of the ECG signal. The sensor provides real-time forwarding of the recorded data to a gateway exploiting a SPP Bluetooth connection. Moreover, it presents a minimal user interface consisting of a power button, a LCD display and a couple of LEDs. Once powered, the device displays a message inviting the patient to put the hands in contact with the electrodes. When contact is detected, the calculated HR is shown, a bar indicates the progress of the acquisition and a red LED blinks in correspondence of the R peaks (see Fig. 4).

A study about the shape of the device, the position of the electrodes and the arrangement of the contact with the hands was made. By placing the hands in contact

Fig. 4. User interface of the device while recording an ECG

with the defibrillation paddles of a professional ECG monitor, different hands-electrodes configurations were investigated and the quality of the signals detected were compared. Afterwards, several different shapes and ways to handle them were proposed to 7 elder people, in order to select the best configuration. In conclusion, the study shown that the best solution is a device with a parallelepiped shape having approximated dimensions of 30 x 5 x 3 cm and with the electrodes placed at the extremities of the wider face. Since the contact of the hands with dry electrodes could be a critical element, a characterization of the skin-electrode contact impedance was made in the 0-150 Hz frequency range. Results shown that the maximum magnitude of the contact impedance reaches the value of 11 KΩ at low frequencies and is negligible in respect to input impedance of the first stage amplifiers.

In order to record the electrocardiogram of the patients, a couple of dry steel electrodes is used to collect the differential ECG signal, while a second couple act as the reference contact. The analog front-end consists of a differential amplifier with a gain of about 100 and a bandwidth ranging from 0.5 Hz and 50 Hz. The amplified signal is then sampled by the internal ADC of a ARM Cortex-M4 microcontroller with a sample rate of 500 Hz and a resolution of 12 bit, for further processing. The firmware implements a highly selective digital FIR filter with a bandwidth between 0.67 Hz and 37 Hz, which is suitable for ECG monitoring purposes, and an algorithm for the real time calculation of the heart rate. When a valid heart rate is detected the device starts to record the ECG signal and sends it, along with the heart rate, to the paired gateway exploiting a Bluetooth connection and a proprietary communication protocol.

A prototype of the proposed ECG device was realized and a test was made involving seven people older than 75 years. Each tester were asked to use the device and to give a feedback. The results of the testing phase, using Matlab to receive data and plot the signal, demonstrate the quality and the usability of the device. All the testers were able to use the device without any help and the position of the hands is comfortable and easy to keep. The signals are clean and free of artifact due to muscular activity. Furthermore, a comparison of the first lead of the ECG signal recorded using simultaneously the prototype (i.e. by placing the hands on its electrodes) and a professional Lifepak 15 ECG monitor (i.e. by attaching wet electrodes on the chest) confirms that the signals are very similar and can be overlapped almost perfectly, as shown in Fig. 5.

Fig. 5. Comparison of the ECG acquired using Lifepak and the prototype

5 Conclusions

The presented devices enable the implementation of the in-house monitoring of chronic patients integrated with the traditional in-hospital care. The gateway ensures data collection and transmission from a wide range of sensors adapting to the target user, while the ECG device enables high-quality self-acquisition of the ECG. All devices have been successfully tested in validation pilots with real patients and have been recently transferred to the spin-off IngeniArs that will take care of the CE certification and the commercialization of the final products.

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