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Reliability and Validity of TIPS Wireless ECG Prototypes

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Abstract. The aims of the present study are to examine the reliability and validity of the Heart Rate signal registered using two self-made wireless ECG systems, R-Tips and TipsShirt, and to compare them with another commercial ECG device typically used in psychophysiology studies. An ECG simulator was used to artificially generate signals corresponding to different cardiac frequencies. Results of the reliability study showed that the signal acquisition, signal processing and signal transmission were reliable and valid for R-Tips and TipsShirt. Consequently, these wireless ECG prototypes could be used for studies where the freedom of movements of the participants is fundamental without any loss of quality in the registered signals.

Keywords. ECG wireless, R-Tips, TipShirt, ECG100C, Biopac, Heart rate, Cronbach's alpha

Introduction

Ambient Intelligence (AmI) refers to electronic environments that are sensitive and responsive to the presence of people. Users must notice that the surrounding is redesigned in an intelligent way to adapt to their needs.

The new technological advances are allowing the implementation of wireless intelligent sensor networks to acquire and select the necessary variables for the decision making of the motor of inference in each case [1-2].

Regarding the specific fields of therapy and the clinical treatment, a sensorial structure is required to contribute to design activities that interact with the physiological response of the patient.

Referring to the patient´s monitoring in free-living conditions, there is a need of translating determined physiological and contextual information variables about the physical and/or mental status of the patient without altering his perception of the environment [3-4]. One approach to obtain non-invasive monitoring technologies has been the use of smart fabrics, which allow the monitoring of patients over extended

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periods of time, in a natural context, in biomedicine, as well as in several health-focused disciplines [5].

One of the most important parameters to detect in these situations could be instantaneous Heart Rate, which can be applied for the measurement of energy expenditure, physical activity and exercise, emotional states and cardiac monitoring between others purposes [6-8]. Regarding emotional and psychological detection, heart rate variability (HRV), which is calculated from the ECG, can be used as an indicator [9]. In a continuous electrocardiographic (ECG) record, each QRS complex is detected, and the so-called normal-to-normal (NN) intervals (that is, all intervals between adjacent QRS complexes resulting from sinus node depolarizations), or the instantaneous heart rate is determined. A cardiac signal could be acquired from the current smart fabric sensors with a quality similar to standard 12 lead ECG.

The aim of this study is to test the feasibility and validity of a new platform called TIPS (Therapy Intelligent Personal Sensor). For this reason, two different versions of TIPS, R-Tips (RT) and TipsShirt (TSh, Nuubo Wearable Medical Technologies), will be evaluated and compared with a clinical validated sensor (ECG100C; Biopac System,Inc) using for this purpose a cardiac waveform simulator (Fluke Biomedical, medSim 300B).

1. Methods

The different TIPS platforms were designed to capture ECG information of the subject in real time. The main components of the TIPS platforms are an acquisition and transmission system of the ECG signal (hardware part) and a processor of the received signal (software part). The ECG signal is captured by different sensors, depending of the version of TIPS that is being used. The captured signals are preprocessed to remove noise and are transmitted to a PC with TIPs property software using a Bluetooth transmitter. The HR is calculated with the property software in real time.

1.1. R-Tips

RT (Figure 1a) is one of the first versions of TIPS platform. This system allows monitoring of the cardiac signal remotely and wirelessly [10]. The sensors used are in the same way as in any commercial ECG. The sensors are connected to the transmitter system through several cables. This system can only transmit the data using Bluetooth wireless technology.

1.2. TipsShirt

TSh (Figure 1b) is a new version of TIPS, smaller and more portable than RT. This device allows monitoring the heart signal remotely and wirelessly, through a system based in biomedical textiles [11]. This system can transmit the data using Bluetooth wireless technology or save it in an internal memory.

Figure 1. a) R-Tips; b) TipsShirt c) ECG100C Biopac

1.3. Protocol of study

RT, TSh and ECG100C (Figure 1c) were tested [12] with simulated R-waves, Fluke Biomedical, medSim 300B (Figure2) with and without noise for different frequencies, for 1 minute and 30 seconds at each frequency, so no subjects were required for the experiment.

Figure 2 Fluke Biomedical, medSim 300B

The frequencies and conditions that were simulated and programmed in the simulated R-waves were 30 bpm, 30 bpm with 50Hz noise, 60 bpm, 60 bpm with muscular noise, 80 bpm, 80 bpm with 60 Hz noise, 120 bpm, 120 bpm with baseline noise, 160 bpm, 160 bpm with 50Hz noise and 200 bpm with muscular noise. This study lasted 16 minutes and 30 seconds for each device.

1.4. Statistical Analysis

Statistical Package for the Social Sciences (SPSS v.17.0) was used to conduct the statistical analysis.

Coefficients of variations and reliability analysis were applied to analyze the differences between real value and the calculated value by our systems. Cronbach's alpha Intraclass correlation coefficients (ICC) of reliability between the real values and the values obtained for each device were calculated.

2. Results

The descriptive statistics of coefficients of variations, with respect to the original signal, for the different apparatus are shown in Table1. In this table, small mean values

in coefficients of variation can be observed in all devices. The commercial system, ECG100C, has the lowest coefficient of variation, 0.0307(0.330), but similar values are obtained for all the systems.

Table 1. Mean (standard error of the mean) values of coefficients of variation with respect to the original signal (ECG simulator)

Rtips	TipsShirt	ECG100C
0.0367(0.477)	0.0428(0.510)	0.0307(0.330)

Cronbach's alpha Intraclass correlation coefficients (ICC) of reliability, with respect to the original signal generated by the ECG simulator, were also calculated (Table 2). In this statistical study, the most reliable device was the ECG100C, 0.998, followed by RT, 0.997, and TSh, 0.996, with similar values as can be observed. All results were significant ($p<0.001$).

Table 2. Cronbach's alpha Intraclass correlation coefficients of reliability with respect to the original signal (ECG simulator)

Apparatus	Cronbach's Alpha	Significance
Rtips	0.997	$p<0.001$
TipsShirt	0.996	$p<0.001$
ECG100C	0.998	$p<0.001$

3. Discussion

This paper presents the feasibility and validity of two different versions of a new non-invasive platform of cardiac monitoring called TIPS. The main conclusions and their implications for future studies are discussed below.

The obtained results show that both RT and TSh are a technically reliable and valid system for ECG measurement, 0.997 ($p<0.001$) and 0.996 ($p<0.001$) respectively. In fact, if we compare these results with results obtained by the commercial system (ECG100C), 0.998 ($p<0.001$), we can appreciate that the difference between the results is very small. This shows that signal acquisition and signal transmission is reliable and valid in our wireless ECG prototypes.

In our opinion, the results confirm that our TIPS systems can register correctly the cardiac output of any subject and in any situation. For this reason, we think that TIPS systems can be used in studies where the subject has to execute physical activities to record data from every day, for example, in a study with virtual reality where the subject is introduced in a CAVE system or a study of emotional engineering. These studies will need to have a system less invasive and more comfortable that traditional or clinical apparatus. Moreover, in these studies it is especially important to have reliable and feasible recorders. All these, our systems would be able to offer them.

The next step is to validate the TIPS version with human subjects in different daily situations. In this way, we will check that the systems remain robust and reliable in extreme conditions. For this, the recorders ECG data will be compared with other obtained through a commercial system in future studies.

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