Validation of Wireless Wearable Electrocardiogram System for Real-Time Ambulatory Cardiac Monitoring

Huy Cu, Tuan Nguyen, Tam Nguyen, Trung Le, and Toi Vo Van

Abstract

In our preliminary study, we proposed a wearable, power-proficient and multichannel ECG device, so-called wECG, aiming at real-time ambulatory cardiac monitoring. This paper targets the validation of wECG device using a reference system. The collected ECG signals from the developed device have been benchmarked with those from Polysomnography (PSG) system under exercising condition following a Bruce-based protocol. Compared to current ECG monitors, the proposed wearable ECG system can provide significant improvements in terms of device mobility, system inerrability, monitoring duration and signal quality. These improvements will enhance critically the home-based diagnosis and treatment of chronic cardiac disorders such as arrhythmia and atrial fibrillation.

Keywords

Ambulatory ECG • Cardiovascular diseases • Wireless wearable system • Stress test • Device validation

1 Introduction

Cardiovascular diseases have become social and economic burdens as it is among the primary sources of mortality in the world. The World Health Organization (WHO) assessed that 17.5 million individuals died of cardiovascular disorders in 2008 and the mortality rate is predicted to reach consistently 23 million in 2030 [1]. Fortunately, consequences caused by cardiorespiratory disorders are avertable thanks to early diagnosis, prediction and promptly intervention [2]. Ambulatory Electrocardiogram (ECG), so-called Holter ECG, have been considered as crucial tools for the long-term monitoring and detection of cardiovascular disorders [3, 4].

wECG is a new wireless wearable device, which targets long-term ambulatory ECG recording under various normal and exercising conditions. The device cooperates with a smartphone and allows the measurement of up to 7 ECG leads including 3 bipolar limb leads, 3 augmented unipolar limb leads and 1 unipolar chest lead. The recorded signals will be transmitted to the smartphone via the Bluetooth Low Energy (BLE) protocol and stored on the online database. The wECG device was designed to comply with the medical general standard IEC 60601-1.

The aim of this work was to verify the accuracy of the ECG signals from the wECG compared to the signals collected from an FDA approved system-ALICE 5 from Philips. Multiple ECG characteristic features corresponding to physiological parameters include QRS amplitude, QRS time delay, and the heart rate were estimated from ECG signals collected from a Bruce-based data collection protocol. Also, other designed characteristics including Bluetooth communication parameters (i.e., connection interval (CI), connection latency, and sending package size) and power consumption parameters (i.e., average power consumption and maximum battery life) were also tested.

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T. Vo Van et al. (eds.), *6th International Conference on the Development of Biomedical Engineering in Vietnam (BME6)*, IFMBE Proceedings 63, https://doi.org/10.1007/978-981-10-4361-1_131

2 Methodology

2.1 Form Factor Design

The electronic circuit is fabricated on a double-sided surface mounted on a printed circuit board (PCB). The main component of the device is the data acquisition board with the size of 6 cm in diameter and 0.8 mm in thickness. This board is also served as the right arm (RA) electrode among four electrodes of the device. The other three electrodes corresponding to left arm (LA), left leg (LL), right leg (RL) and chest (V1) are connected to the board for the multiple channels data collection via a pluggable connector (see Fig. 1—Left). Figure 1—Right shows the electrode configuration setup of the designed device over the patient's thorax.

2.2 Electrical Design

The electronic design consists of three main modules: (1) the analog front-end using ADS1293; (2) the BLE and microcontroller using CC2451; and (3) the power source circuit. The device can collect data with the sampling frequencies from 20 to 1000 Hz with the resolution of up to 24 bits. Other hardware specification is shown in Table 1.

2.3 Wireless Communication System

The wireless communication module includes two components: the connection between the wECG device and Android smartphones via BLE protocol and the connection between smartphones and servers via TCP/IP protocol. The complete flowchart of software program is represented in Fig. 2.

The device was programmed to send 6 notification packages every 14 ms. The package of the data represented in Table 2 contains an overhead of 12 bytes and a payload of 20 bytes. The complete structure of this patket is 32-byte in length. After every 17 ECG samples, a 20-byte error packet is sent to check whether the previous packages are corrected. This error checking package consists of 2 running counter bytes for counting, 3 starting indication bytes (0xFFFFFF) for marking, 7 error status bytes for error checking and 8 ending indication bytes (0xFFFFFFFFFFFFFFFF) for marking. The error status bytes include information of lead-off detecting, battery level warning, AFE out-of-range and lead out-of-range.

2.4 Comparing Features

Three criteria related to peak amplitude, peak time delay, and heart rate error are used to compare the developed device to the benchmarked system [5]. The descriptions of the comparing parameters are described as:

$$QRS\,ratio = \left|\frac{V_{QRS_{Alice5}}}{V_{QRS_{wECG}}}\right| \tag{1}$$

$$QRS\,delay = \left|i_{QRS_{Alice5}} - i_{QRS_{wECG}}\right| \tag{2}$$

$$relative\,error\,(\%) = \left|\frac{HR_{Alice5} - HR_{wECG}}{HR_{Alice5}}\right| * 100\% \tag{3}$$

where V_{QRS_Alice5} and V_{QRS_wECG} are QRS amplitude in (mV) of ECG from Alice 5 and from wECG; $i_{QRS_{Alice5}}$ and $i_{QRS_{Alice5}}$ are the sample order of R peaks from Alice 5 and from wECG; and HR_{Alice5} and HR_{wECG} are the heart rates in beats/min estimated from Alice 5 and from wECG.

The relationship between sampling rate, packet rate and the Bluetooth connection interval are described as:

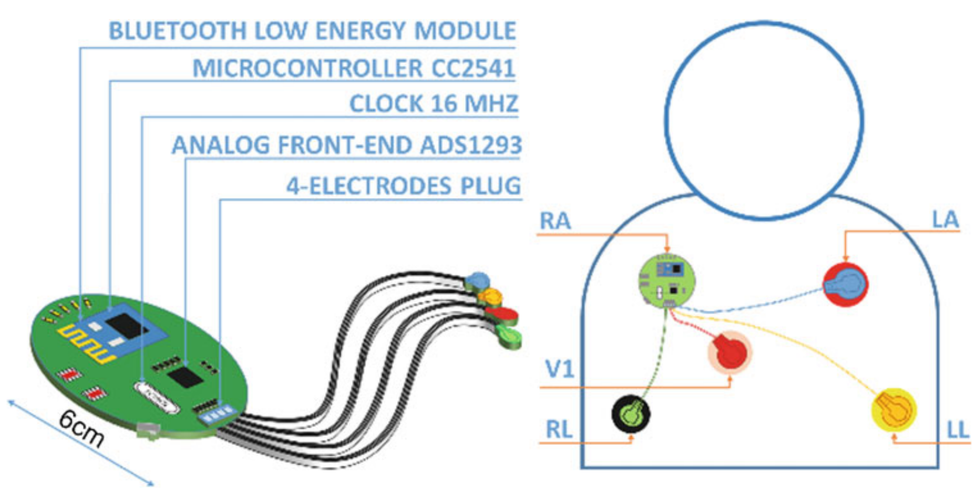

Fig. 1 *Left* Hardware design of the ECG circuit, *right* front size of the thorax with the full electrode configuration

Table 1 wECG hardware specification

Parameter	Value
Electrode quantity	5
Number of direct channels	3
Total number of channels	7
Bandwidth	0–80 Hz
Output data rate	20–1000 Hz
Supply voltage	3.3 V
Common-mode rejection ratio	100 dB
ADC resolution	24 bits
Gain	3.5 V/V

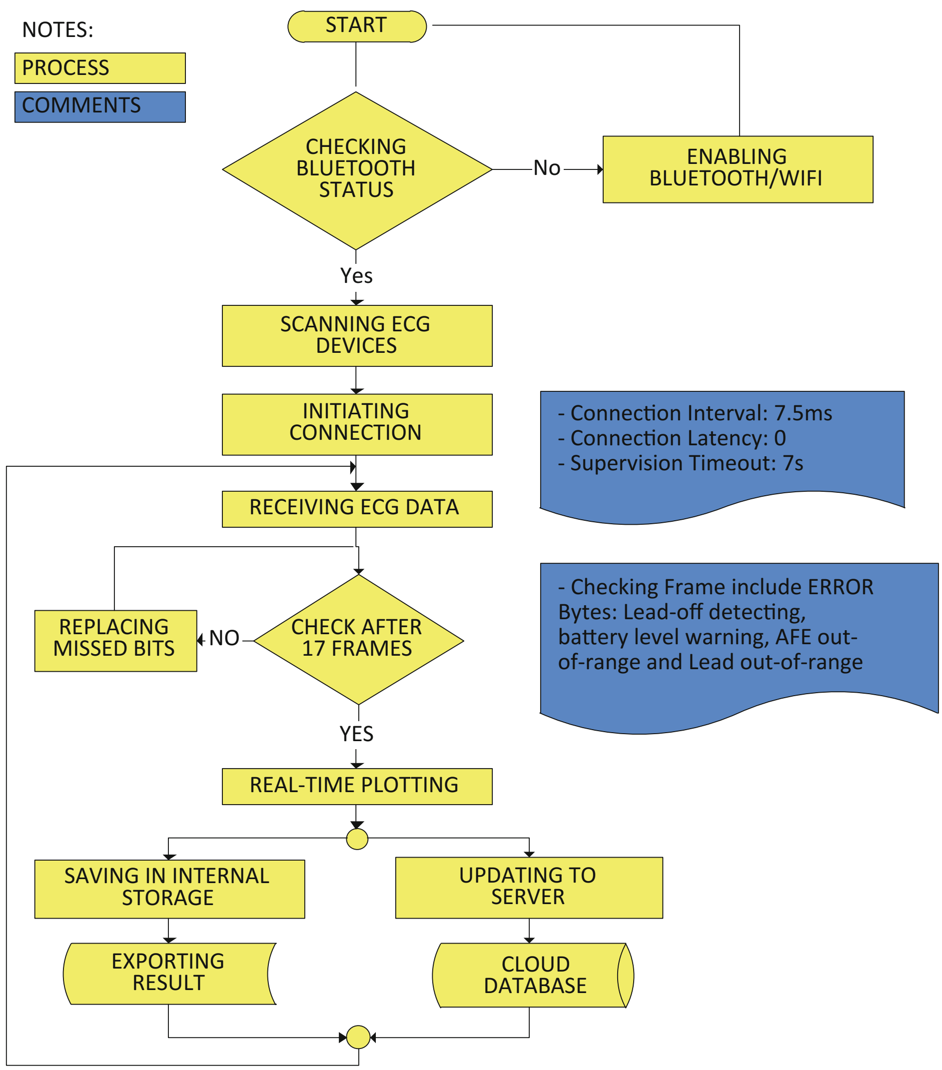

Fig. 2 BLE transmission flow chart

Table 2 Data byte structure in one package

Byte order	Description
0, 1st	Counter byte
2, 3, 4th	ECG sample 1, channel 1
5, 6, 7th	ECG sample 1, channel 2
8, 9, 10th	ECG sample 1, channel 3
11, 12, 13th	ECG sample 2, channel 1
14, 15, 16th	ECG sample 2, channel 2
17, 18, 19th	ECG sample 2, channel 3

Table 3 The modified Bruce-based protocol for stress test

Stage/level	Speed (mph)	Grade (%)	Duration (min)
Warm-up	2	0	5
Level 1	1	1	3
Level 2	2	2	3
Level 3	3	3	3
Level 4	4	4	3
Level 5	5	5	3
Level 6	6	6	3
Level 7	7	7	3
Relax	3	0	7

$$Sampling\ rate = \frac{1}{Packet\ rate} * D * Fr \tag{4}$$

$$Packet\ rate = \frac{1000}{Connection\ Interval\ (ms)} * N \tag{5}$$

where $D = 2$ is the number of samples per packet, $Fr = 17/18$ is the frame scale, and $N = 4$ is the number of packets sent per connection event.

3 Experiment Design

The designed wECG device is validated at the Clinical Engineering lab of International University under different simulated and in vivo conditions. The diagnostic cardiorespiratory sleep system ALICE 5 of Philips was selected as the benchmarked. The signals collected from both the device and the benchmarked system are sampled equally at the highest frequency of 200 Hz.

We used Bruce-based protocol for ECG stress test with the modified level of speed and grade shown in Table 3. A group of 5 different healthy male subjects whose ages range from 20 to 23 volunteered for this experiment. Each data recording session lasted about 42 min. The time on the treadmill was varied depending on the endurance of the subjects with the maximum duration of 21 min. The collected data is truncated into epochs corresponding to 7 exercising levels with the length of 3 min per epoch as shown in Fig. 3. In each epoch, heart rate variability was estimated using Pan-Tompkins algorithm. The pair-wise comparisons were performed between the data epochs of two mentioned devices.

Three Android platforms with predefined configurations were chosen to test the quality of BLE transmission between devices and smartphones. Bluetooth communication process was captured using “Bluetooth HCI snoop log” function of smartphone and then analyzed with Wireshark software. The BLE connection parameters of each device was configurated as shown in Table 4.

4 Results

Figure 4 shows a snapshot of the recorded ECG signals from Alice 5 and the developed device. In the figure, the left colum indicates the representative 5-second frame of signals and the right column indicates one ECG cycle. The x-axis shows the signal amplitude in uV and y-axis the time in seconds. It been shown that the amplitudes and the durations of the signals are comparable in both long segment and individual heart beat. In particular, the average amplitude ratios of P-wave, QRS complex, and T-wave are 0.83, 1.12 and 0.92, respectively.

There are significantly similarities between the amplitude of two devices, especially in QRS complex. The average QRSratio are 1.10 ± 0.48 and 1.02 ± 0.18 for lead 1 and lead 2, respectively. For time delay, lead 1 varies about 38 samples (0.19 s) from the benchmarked one; meanwhile this

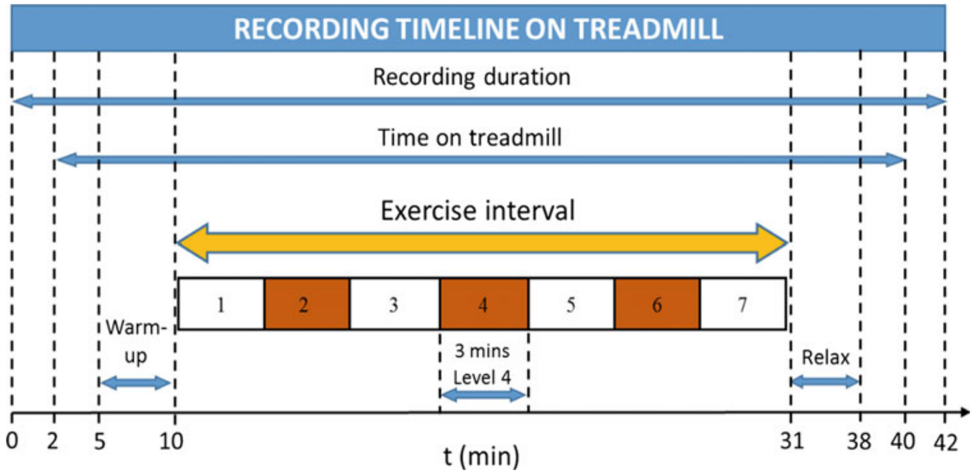

Fig. 3 Time profile of the data recording procedure on treadmill

Table 4 BLE connection parameter configuration

Parameters	Device A	Device B	Device C
Android version	4.4.2	5.1.1	5.1.1
Min/max CI (ms)	7.5/7.5	30/50	30/50
Desired CI (ms)	7.5	30	48.75
Connection latency	0	0	0
Supervision timeout (s)	7	7	20
Packets sent per connection event	4	4	4

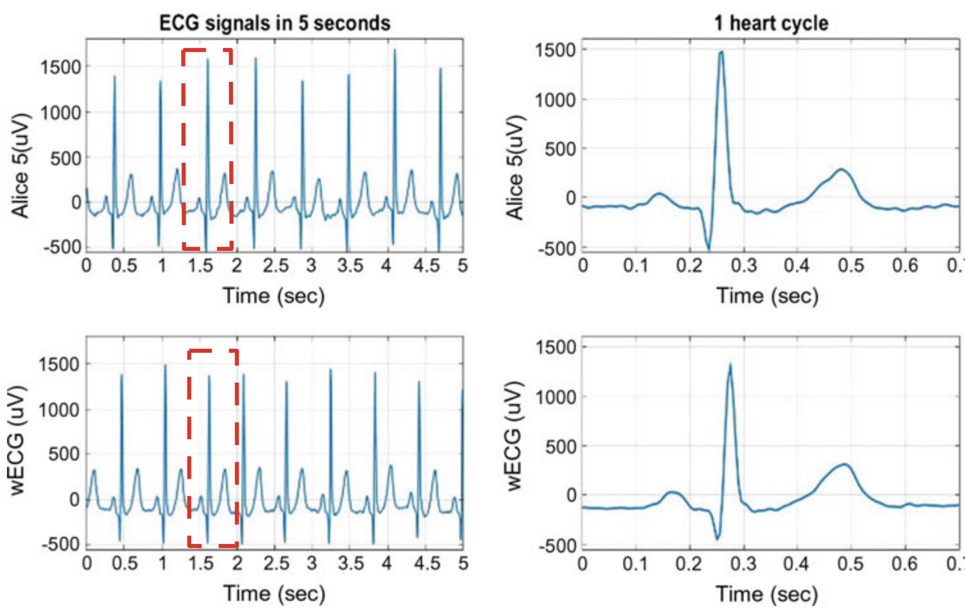

Fig. 4 Data comparing between the wECG device and Alice 5 system. The *left figures* show 5-second raw ECG signal acquired from lead 2 of a subject working at level 3 of the protocol. Visually, the result indicates that two signals are highly comparable between wECG and Alice 5 on a specific level of exercise. We used Pan-Tompkins algorithm [6] to estimate the heart rate

number in lead 2 is slightly lower, 29 samples (0.145 s). These delays affected the heart rate accuracy, of which the relative errors are 9.17% for lead 1 and 5.72% for lead 2. This result indicates better quality of lead 2 compared with lead 1. Table 5 summazies the comparison for each recording.

Table 6 summarizes the parameters of data transmission rate via BLE and power consumption of each smartphone platform. The overall performance was tested for an hour (running) in the airplane mode (Wifi and mobile data off) with the brightness of 20%. With Fs = 160 Hz, we estimated the packet rate of 84.7 packets/s and minimum CI (the time between two consecutive connection events) of 47 ms using Eqs. (4) and (5). For the first two devices, we configured the CIs were 7.5 and 30 ms. The result showed that the packet rate were 84.7 and 83.3 packets/s, respectively. Meanwhile,

Table 5 Performance comparison between the proposed wECG device and Alice 5 system in stress test

	Lv	$QRS_{ratio} \pm$ SD	QRS delay ± SD (samples)	Heart rate wECG	Heart rate Alice 5	RE (%)
DI	1	1.04 ± 0.32	38.06 ± 33.64	73.70	70.29	8.13
DII		1.05 ± 0.14	49.31 ± 47.19	74.80	71.51	6.62
DI	2	1.44 ± 0.55	50.03 ± 35.09	79.20	80.11	10.49
DII		1.10 ± 0.15	24.49 ± 26.95	79.54	77.77	6.14
DI	3	1.12 ± 0.48	60.69 ± 43.89	87.62	86.43	4.94
DII		1.30 ± 0.25	28.26 ± 26.26	86.56	84.29	4.10
DI	4	0.98 ± 0.45	31.34 ± 25.82	89.19	91.54	10.81
DII		0.97 ± 0.15	44.06 ± 32.43	93.64	89.43	6.75
DI	5	1.11 ± 0.52	34.11 ± 27.43	93.29	96.96	11.91
DII		0.87 ± 0.17	31.20 ± 21.50	109.49	104.26	5.40
DI	6	1.12 ± 0.59	38.34 ± 29.13	98.87	102.80	15.92
DII		0.92 ± 0.23	15.34 ± 10.19	125.00	103.90	8.11
DI	7	0.92 ± 0.47	15.80 ± 20.69	126.40	123.90	2.02
DII		0.95 ± 0.18	9.00 ± 7.65	126.80	123.20	2.92
DI	A	1.10 ± 0.48	38.34 ± 30.81	92.61	93.15	9.17
DII		1.02 ± 0.18	28.81 ± 24.60	99.40	93.48	5.72

Table 6 Data transmission rate and power consumption by wECG

	Device 1 2100 mAh		Device 2 3200 mAh		Device 3 2900 mAh	
	Pacs/s	Bytes/s	Pacs/s	Bytes/s	Pacs/s	Bytes/s
Mean	84.7	2710.2	83.3	2664.4	54.8	1751.9
Variance	43.8	44835	44.6	45697	15.9	17140
SD	6.6	211.7	6.7	213.8	4.0	130.9
Connection interval (ms)	7.5		30		48.75	
Battery usage (%)	29		14		15	
Average power (mW)	2143		3383		2494	
Battery life	3 h 33 m		6 h 39 m		5 h 13 m	

the packet rate of the third device, with the higher minimum CI of 48.75 ms, was reduced to 54.8 packets/s which decreases the designated sampling frequency. In these experiments, the highest battery life was 6 h and 39 min from the device 2.

5 Discussions and Conclusions

A validation of the wireless wearable Holter ECG device has been presented in this paper. Such device can be integrated with machine learning algorithms to facilitate the Internet of Thing (IoT) applications in healhcare [7, 8]. The comparability in amplitude and duration indicates that wECG can be used as a multi-signal monitor for real time ECG monitoring. The wireless transceiver via BLE proved to be a potential altinative due to its compatibility with the Android smartphone, real-time, and low power consumption. The minimal CI allowed central devices to determine the maximum sampling rate of peripheral one (wECG device). Unfortunately, to the best of our knowledge, Bluetooth stack on Android is vendor-specific and varies on different devices. In our test, the minimum connection interval is 7.5 ms, which characterizes a maximum sampling frequency of 250 Hz according to our frame configuration. Another concern is that the battery life, which is proportional to connection interval, is of central device.

For future applications, wECG device with a wireless system is a potential solution for telemedicine, especially in sleep disorders and heart diseases [9, 10]. Also, this is a first step toward the development of the bio-signals data collection and cloud storage. Then, a full telemedicine healthcare system might well be established to manage data. Other algorithms, such as annotating, analyzing, alarming, and predicting can be developed and implemented in the real time.

Acknowledgements This work has been supported by British Council-Newton Fund and Vietnam National University HCM City under the grant No. 1161/QĐ-ĐHQG-KHCN.

References

1. Priori SG, Blomstrom-Lundqvist C et al (2015) 2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. Eur Heart J 36:2793–2867
2. Le TQ, Cheng C, Sangasoongsong A, Wongdhamma W, Bukkapatnam ST (2013) Wireless wearable multisensory suite and real-time prediction of obstructive sleep apnea episodes. IEEE J Trans Eng Health Med 1:2700109
3. Yusuf S, Pearson M, Sterry H, Parish S et al (1984) The entry ECG in the early diagnosis and prognostic stratification of patients with suspected acute myocardial infarction. Eur Heart J 5:690–696
4. Smith DW, Nowacki D, Li JK (2010) ECG T-wave monitor for potential early detection and diagnosis of cardiac arrhythmias. Cardiovasc Eng 10:201–206
5. Miao F, Cheng Y, He Y, He Q, Li Y (2015) A wearable context-aware ECG monitoring system integrated with built-in kinematic sensors of the smartphone. Sensors 15:11465–11484
6. Pan J, Tompkins WJ (1985) A real-time QRS detection algorithm. IEEE Trans Biomed Eng 32:230–236
7 Le TQ, Bukkapatnam ST (2016) Nonlinear dynamics forecasting of obstructive sleep apnea onsets. PloS One 11(11):e0164406
8 Le TQ, Bukkapatnam ST, Benjamin BA, Wilkins BA, Komanduri R (2013) Topology and random-walk network representation of cardiac dynamics for localization of myocardial infarction. IEEE Trans Biomed Eng 2013:2325–2331
9 Karandikar K, Le TQ, Sa-ngasoongsong A, Wongdhamma W, Bukkapatnam ST (2013) Detection of sleep apnea events via tracking nonlinear dynamic cardio-respiratory coupling from electrocardiogram signals. 6th International IEEE/EMBS Conference. pp 1358–1361
10 Yang H, Bukkapatnam ST, Le T, Komanduri R (2012) Identification of myocardial infarction (MI) using spatio-temporal heart dynamics. Med Eng Phys 34(4):485–497