A Wearable ECG Apperatus for Ubiquitous Health Care

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Abstract—**The goal of this research is to develop a wearable electrocardiogram (ECG) apparatus with Bluetooth 4.0 function which can detect the heart beats, mental index and physical activity in real time. It measured one lead ECG signal. Its specification follows the standard of International Electrotechnical Commission (IEC) for medical electrical equipment and ambulatory electrocardiographic systems (Holter ECG system). Moreover, its ingress protection rating has IP 68 degree. Thus, the user could wear it all day and to do any exercise including swimming. In order to let patients feeling comfortable, its weight is light and it could full run above 24 hours. The data was stored in a 4G flash memory. We also proposed a method to detect the heart beats and frequency parameters of heart rate variability (HRV) in real time. This algorithm can be embedded in a single chip microcontroller. We used the MIT-BIH Arrhythmia Database to evaluate the performance of our designed system. The sensitivity and positive predictivity arrives 99.7% and 99.0%. The results show our designed Bluetooth wearable ECG apparatus can record the ECG signal and detect the heart beats, HRV and step counts in real time. It is very suitable to be applied in the ubiquitous healthcare.**

Keywords—Bluetooth, Electrocardiogram, Holter, Ubiquitous.

I. INTRODUCTION

The commercial wearable devices for health care have been widely used in recent years. They almost use the electrocardiograph (ECG) or photo-plethymograph (PPG) to detect the heart rate (HR) in real time. However, these devices all belong to the commercial 3C or exercise products that don't follow the standards of medical equipment [1]. Thus, only the normal heart beats could be detected and showed. The arrhythmic beats will be ignored and not be showed.

In the medical device, Holter ECG wore in the user is used to record ECG signals within twenty-four hours. A software classified the heart beats as the arrhythmic or normal beats from the recorded ECG signal on off-line process. Because the weight of Holter ECG device is very heavy, its size is large, and it doesn't have the higher ingress protection rating, users always be suggested not to do any violent exercise and shower.

In order to classify the types of heart beats, the first step is to detect the heart beats. However, the challenge is how to classify the arrhythmic wave and the noise wave. Several researches have addressed problems of heart rate (HR) detection and classification of cardiac rhythms. Pan and Tompkins proposed an algorithm to detect the heart beats in real time process [2]. Liu et al. proposed the neural network method to automatically detect the heart beats and classify their types [3]. The classification of cardiac rhythms is based on the detection of the different types of arrhythmia from the ECG waveforms [4,5].

The accelerometer has been used to detect the physical activity including the falling down [6], gate number [7] and sleeping time [8]. The commercial products such as i-watch and Garmmi watch all have the functions of HR and physical activity. But these products could not continuously detect the HR in 24 hours.

The heart rate variability (HRV) is an optional test in IEC 60601-2-47. HRV have been approved that it can evaluate the condition of autonomic nervous system [9]. Authors have studied the HRV application to the mental work load [10] and aromatherapy [11].

The goal of this study is to design a wearable ECG apparatus with Bluetooth 4.0 function which not only measured one lead ECG, but also detected the physical activities such as step counts. In the hardware, this apparatus was designed following the standards of International Electrotechnical Commission (IEC) for medical electrical equipment and ambulatory electrocardiographic systems. Its ingress protection rating has IP 68 degree. A novel method to detect the HR in real time was developed which can be embedded in a single chip microcontroller (MCU). The HRV also is calculated in real time. We wrote an APP algorithm to show the ECG signal, HR, psychology stress by HRV, and the gate number in one day. It also records the data in a 4G flash memory over 24 hours.

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II. HARDWARE DESIGN

The apparatus used Li battery (300 mA/h), charging IC (TI BQ24072), regular IC (XC62FP, 3.3V). The apparatuses used the USB port to charge the batteries. In analogue circuit, we follow the standard of IEC 60601-2-47. The instrument amplifier is AD 8232 chip, input impedance is larger than 10M Ω, its band-width is 0.67 Hz to 40 Hz, the baseline response of rectangular pulse is lower than 0.1 mV (voltage), it resists ± 300 mV offset voltage, the noise is lower than 50 uV, and the common mode rejection is higher than 60 dB. The maximum voltage of MIT-BIH Arrhythmia Database is 5 mV, and the full range of the analog circuit is 0 to 3 V. Its baseline is 1.5 V. Thus, the gain is set 200. The three-axis accelerometer is ADXL 325 chip which rang is ±5G. Its X_{OUT}, Y_{OUT}, and Z_{OUT} frequency ranges are separately 0.5 Hz to 1600 Hz, and 0.5 Hz to 550 Hz by the different capacitor values. The MCU used ST M32L151RD which analogue to digital converter (ADC) has eight channels, and resolution is 12 bits. Its sampling rate is 500 Hz. The Bluetooth module is the CSR SBC2112 which used the long data mode to transmit data. The total weight of this ECG apparatus is only 36 g. The long and short axial lengths are 120 mm and 45 mm, respectively. The width is 8 mm.

III. HEART BEATS DETECTION

Although the ECG has been filtered by the analogue circuit, the filtered ECG also couples a lot of motion artifact and the power line artifact. The ECG signal was filtered by the stopband filter that used the butterworth filter, 4 orders and 59 to 61 Hz stop bandwidth, and the lowpass filter that used the finite impulse response filter, 20 orders and 20 Hz cutoff frequency. These discrete filters were designed in the MCU. We processed the heart beats detection within 3 seconds segment. In order to lose heart beat at the boundary of the segment, the overlap time is 0.25 second between two adjacent segments. Figure 1 shows the flowchart of the heart beat detection algorithm. The filtered ECG signal, F_ECG(n), was differential, D_ECG(n). Then, positive peaks (P_Peak) and negative peaks (N_Peak) were separated, respectively, and the principle P_Peaks and N_Peaks were determined. Then, P_Peak and N_Peak were paired (P_N_Pair). The paired rule was that the closest interval has the high priority, and the sequence is from left to right. Because, some P_Peaks or N_peaks was paired in the different P_N_Pair in the same time, we deleted the redundancy P_N_Pairs. The interval of P_N_Pair only has one zero crossing point. If there were above two zero crossing points, the values between two zero crossing points were set to zero. The R wave in the raw ECG signal was detected within the P_Peak and N_Peak interval. Figure 2 (a) shows the raw ECG signal, the differential signal is shown in Fig. 2 (b). Figure 2(c) and (d) show the positive signal and negative signal. The detected R waves are shown in Fig. 2 (e) by the red circles.

IV. HEART RATE VARIABILITY

HRV is derived from the R-R interval (RRI) time series with discrete time Fourier transform (DTFT). The RRI series were resample to 4 Hz by the quadratic interpolation. The window time of DTFT is one minute and overlapped time is 30 seconds. Hann window was used to eliminate the side lobes of DTFT. The points of DTFT are 256. Therefore, we padded 16 zero values in RRI series. The resolution of DTFT is 0.0156 Hz. In the frequency parameters of HRV, the integral value of the low frequency domain (LF: 0.04-0.15 Hz) represents the activation of sympathetic nervous, and the integral value of the high frequency domain (HF: 0.15-0.4 Hz) represents the activation of parasympathetic nervous [9]. Thus, the top 26 elements of DTFT are enough to calculate the LF and HF. Thus, we used the Goertzel method to get them, and the ratio of LF and HF (LF/HF) as the indicators of autonomic nervous activity, mental index.

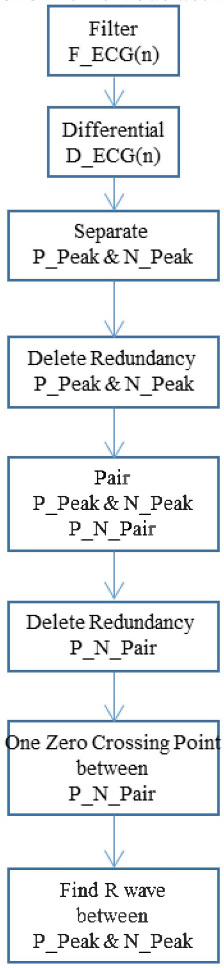
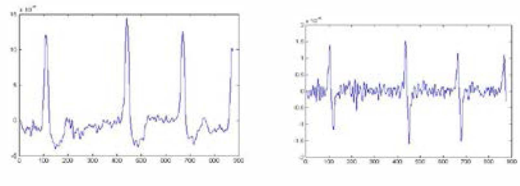


Figure 1. the flowchart of heart beat detection algorithm.



(a) (b)

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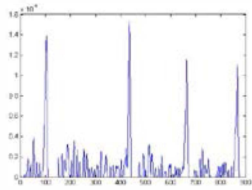
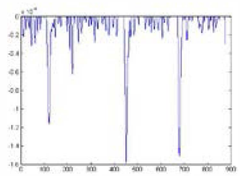
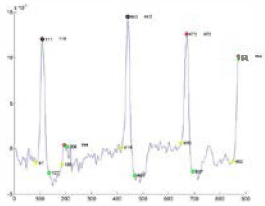


(c)



(d)



(e)

Figure 2. (a) the raw ECG signal, (b) the differential signal, (c) the positive signal, (d) the negative signal, (e) the detected R wave by the red circles.

V. RESULTS

Table I shows the specification of the proposed wearable ECG apparatus. As can be seen in Table I, the proposed apparatus has passed IEC standards including safety, home healthcare environment, electromagnetic compatibility (EMC), ingress protection rating, and radio frequency (RF) instruction. Figure 3 is the real photo of the wearable ECG apparatus which has an exercise cover. It uses the regular ECG electrode patch to fix it in the user's body. Figure 4 shows the wearing place. It also can use the exercise cover adding the chest girdle to fix it when user is exercising.

Table II shows the results of MIT-BIH Arrhythmia Database. According to the standard of IEC 60601-2-47, 4 files, 102, 104, 107, and 217 having the pacemaker beats, are excluded in the algorithm test. Thus, we only processed 44 files in this study. The total beats are 101464 beats. TP has 100448 beats, TN has 285 beats, and FP has 1016 beats. The sensitivity is 99.7%, and positive predictivity is 99.0%.

We also wrote an APP program for Android and ios system to show results of the wearable ECG apparatus in the real time as shown in Fig. 5. First, we search our device and contact with it. The Bluetooth name shows in the top button (SBC21120246). In the same time, APP program will update the real timer clock (RTC) of the wearable ECG apparatus. Then, the ECG apparatus will send some information to the APP device, such as HR, step counts in one day, the wasting calorie, and the mental index. The percentage of blue range in the circle ring represents the active degree of parasympathetic nervous, and the percentage of red range represents the active degree of sympathetic nervous. If the numbers of arrhythmic beats over the designed criterial, one minute ECG signal will be sent to the smarter phone or tablet and showed on the scream. Figure 6 shows the one minute ECG signal. We can change the time scale to look the ECG signal clearly.

TABLE I. THE CERTIFICATION.

Safety	(Test report) IEC 60601-1: 2005+A1: 2012 & EN 60601-1: 2006 + A1: 2013(3rd) & EN 60601-2-47
Home Healthcare Environment	(Test report) IEC 6060-1-11: 2010
EMC	(Test report & VoC) IEC/EN 60601-1-2 :2007
Ingress Protection Rating	IP68
RF Instruction CE R&TTE	(RF) (Test report) EN 300 328 +EN62479(MPE) (BT 4.0 signal mode)
	(EMC_RF) (Test report) EN 301 489-1 & EN 301 489-17

Fig. 3 The real photo of wearable ECG apparatus.

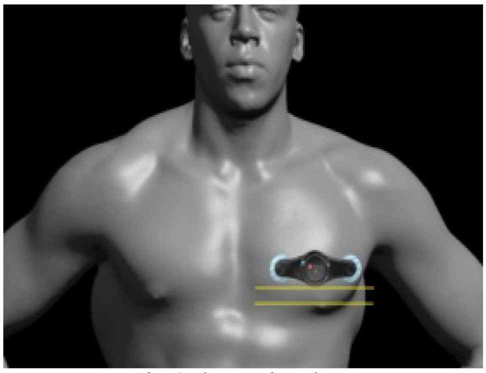


Fig. 4 The wearing place.

TABLE II. THE RESULTS OF MIT-BIH DATABASE

File	TP	TN	FP	Sensitive	(+p)
100	2272	1	0	1.000	1.000
101	1864	1	5	0.999	0.997
103	2083	1	0	1.000	1.000
105	2540	32	85	0.988	0.968
106	2022	5	3	0.998	0.999

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108	1691	72	237	0.959	0.877
109	2530	2	4	0.999	0.998
111	2109	15	20	0.993	0.991
112	2538	1	11	1.000	0.996
113	1794	1	1	0.999	0.999
114	1879	0	1	1.000	0.999
115	1952	1	0	0.999	1.000
116	2394	18	8	0.993	0.997
117	1534	1	5	0.999	0.997
118	2277	1	16	1.000	0.993
119	1986	1	1	0.999	0.999
121	1861	2	17	0.999	0.991
122	2475	1	0	1.000	1.000
123	1518	0	0	1.000	1.000
124	1618	1	2	0.999	0.999
200	2599	2	42	0.999	0.984
201	1953	10	6	0.995	0.997
202	2132	4	4	0.998	0.998
203	2929	51	59	0.983	0.980
205	2650	6	1	0.998	1.000
207	1860	0	306	1.000	0.859
208	2941	14	5	0.995	0.998
209	3004	1	7	1.000	0.998
210	2646	4	7	0.998	0.997
212	2747	1	4	1.000	0.999
213	3249	2	0	0.999	1.000
214	2257	5	3	0.998	0.999
215	3361	2	1	0.999	1.000
219	2154	0	0	1.000	1.000
220	2047	1	0	1.000	1.000
221	2423	4	1	0.998	1.000
222	2480	3	10	0.999	0.996
223	2605	0	1	1.000	1.000
228	2044	9	80	0.996	0.962
230	2256	0	1	1.000	1.000
231	1571	0	0	1.000	1.000
232	1775	5	60	0.997	0.967
233	3075	4	2	0.999	0.999
234	2753	0	0	1.000	1.000
	100448	285	1016	0.997	0.990

Fig. 5 The APP program

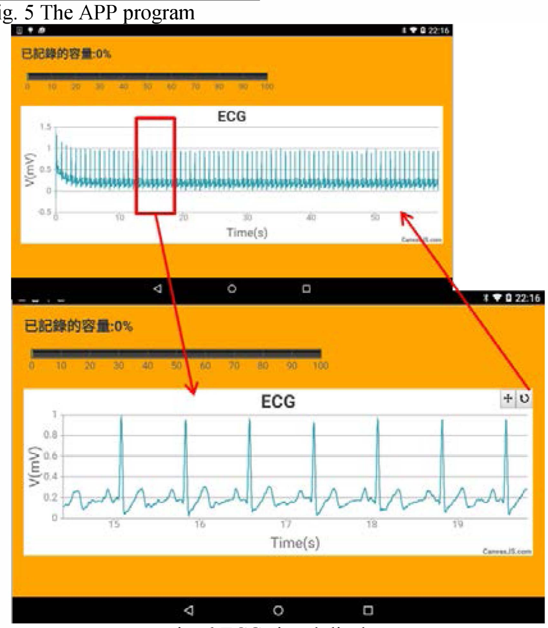

Fig. 6 ECG signal display.

VI. Disscusions and Conclusion

The commercial Holter system only records the ECG data in the SD card, and uses the lead wire to connect the ECG electrodes. Moreover, the weight of Holter system is very heavy. Thus, the user will feel unconfortable [12]. Because the Holter has to record data at last 24 hours, the power is a important issue. Now, there are many studies to study the wireless Holter system. How to design a apparatus with the light weight, small size, and low power dissipation is a challeng.

We have designed a wearable ECG apparatus which hardware was designed following the IEC standards for the medical electrical equipment and the ambulatory electrocardiographic system. They are importment issues that the degree of ingress protection rating of the designed apparatus is IP 68, a simple algorithm being ran in a MCU could detect the heart beats and frequency parameters of HRV was claculated to evaluate the psychological stress in real time. Moreover, this apparatus has the functions of step counts.

In the algorithm test for the MIT-BIH Arrhythmia Database, we let the TN beats decrease by our best.

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According to the IEC standard, the algorithm not only detects heart beats, but also classifies the different arrhythmic beats. Therefor, how to classify the normal and arrhythmic beats in real time will be studied in the future work.

In this paper, we designed a small size, light weight, and low power apparatus to measure one lead ECG signal, and body activities. Because this wearable ECG apparatus has the Bluetooth function and IP 68 standard, it is very suitable to apply in the ubiquitous healthcare in the future.

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