A Long-Term, Portable ECG Patch Monitor Based on Flexible Dry Electrode

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Research Article

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Abstract

Purpose

Long-term electrocardiogram (ECG) monitoring is an essential approach for the early diagnosis of cardiovascular diseases. Flexible dry electrodes that contains electrolyte without water could be a potential substitution of wet electrodes for long-term ECG monitoring. Therefore, this paper developes a long-term, portable ECG patch based on flexible dry electrodes, namely SEUECG-100.

Method

A device consists of analog-front-end acquisition, data acquisition, and storage modules is developed and tested. An impedance test was conducted to compare the skin-electrode impedance of the flexible dry electrode and the Ag/AgCl wet electrode. The ECG signals were simutanously collected from the same subject using the SEUECG-100 and Shimmer device , which were then compared and analyzed from the perspective of ECG morphology, RR interval, and signal quality indices (SQI).

Results

The experimental results reveal that the flexible dry electrode has the characteristics of low skin-electrode impedance. SEUECG-100 could collect high-quality ECG signals. The ECG signals collected by the two devices have a high RR interval correlation (r=0.999). SQI results show that SEUECG-100 is better than the Shimmer device in overcoming baseline drift. Long-term ECG acquisition and storage experiments show that SEUECG-100 could collect ECG signals with good stability and high reliability.

Conclusion

The implementation of the proposed system design with dry electrodes could can effectively record long-term ECG monitoring with high quality in comparison to systems with wet electrodes from both impedance characteristics and signal morphology aspects.

1. Introduction

According to the death statistics recorded in 2015, 17.7 million people died of cardiovascular diseases worldwide. This number is equivalent to 31% of the total deaths[1, 2]. Heart diseases may have short-term and sudden symtoms. Conventional short-term ECG monitoring can easily miss abnormal ECG signals, prohibiting early and proper diagnoses and treatments for patients[3, 4]. Long-term dynamic ECG monitoring is an important approach for early evaluation of the cardiovascular risks[5, 6]. However, a conventional multi-lead Holter device is not only cumbersome but also has a great impact on the people's daily activities[7, 8]. Furthermore, the most common disposable silver/silver chloride (Ag/AgCl) electrodes contains wet gel-type eletrolytes, which could become dehydrated over long-term monitoring and result in degraded signal quality, partially due to a significant increase in the skin-electrode impedance and introducing noise and interference [9-11]. Is is also reported that some patients feel uncomfortable with the disposable Ag/AgCl wet electrodes using hydrogel because of skin irritation, allergies, redness and swelling [12].

In recent years, there have been reports on the development of different types of dry electrodes, such as microneedle electrodes, non-woven fabrics, metal dry electrodes, and fabric electrodes, which are expected to substitute disposable Ag/AgCl wet electrodes in some ECG monitoring scenarios [13-15]. It has been reported that dry electrodes are more comfortable to wear compared to wet gel-type electrodes. The challenges of unstable skin-electrode impedance and motion artifacts are still severe problems that restrict the clinical application of some types of dry electrodes[16-18]. Therefore, the evaluation of the electric characteristics and signal quality of ECG monitors with dry electrodes would be of interest to this research area, providing supporting evidence and guidance on the proper achievement of a solution with comparable or even better performance than systems with wet electrodes.

In this paper, we propose to develop a long-term, low-power ECG monitoring system based on flexible dry electrodes (SEUECG-100) and conduct experiments in both lab-bench and real-life scenarios. The system is in the form factof of a patch that could be connected to a peace of flexible dry electrode without any leads or wires.

Firstly, we conducted the skin-electrode impedance test of a flexible dry electrode and disposable Ag/AgCl wet electrode to analyze this essential characteristic that influence signal quality. A dehydration test is also performed to test the changes in skin electrode impedance. Secondly, to evaluate the signal differences and signal qualities of ECG signals from SEUECG-100 and Shimmer device (commercial wearable wireless sensor node, Shimmersensing, Ireland), we conducted experiments with two devices on the same subject from the aspects of the ECG morphology, RR interval correlation, and signal quality indices (SQI) parameters. The experiments were conducted under real-life simulation walking scenarios. Lastly, a long-term (more than 24 hours) ECG monitoring experiment was carried out for SEUECG-100.

2. Material And Methods

2.1 Flexible and Dry Electrodes

In this study, we cooperated with China Lucky Group Co. Ltd, to develop a flexible dry electrode. As shown in Figure. 1, the electrode is divided into four layers: substrate layer, adhesive layer, conductive layer and insulating layer. The conductive layer is formed by printing electrode paste on the polyurethane substrate through Screen-Printed technology. The printed part includes electrodes and leads. The electrode sensing area is covered with a stretchable ionic gel material whose thickness is within 0.1mm, which ensures the conductive performance and skin compatibility of the flexible dry electrode. All the lead surfaces except the electrode sensing area are covered with a layer of ultraviolet insulating ink, and finally the entire electrode assembly is realized by die-cutting composite technology. Compared with the disposable Ag/AgCl wet electrode conductive gel, the ionic gel does not contain volatile solvents and will not increase the skin-electrode impedance as the use time increases. When the electrode is connected to the device, there is no long metal wire, the electrode material can be bent and stretched, and the corresponding deformation occurs with the movement of the human body and the skin folds, and it closely fits the skin surface, thereby reducing the motion artifacts and noise in the ECG signal.

2.2 ECG Patch Design

The overall structure of the device is shown in Figure. 2. The device consists of a power control module, a microcontroller unit (MCU), a data acquisition module, and a user interface. The power control module supplies power to the various modules of the device, and the single-chip microcomputer controls the collection, processing, and transmission of ECG data, and it is finally stored in the TF card.

SEUECG-100 adopts a low-noise analog front end (AFE) circuit design and amplifies the original mV-level ECG signal amplitude to V-level through differential input. After the ECG signal is amplified, it is connected to a 0.05Hz high-pass filter and a 150Hz low-pass filter. Pass filter, filter baseline drift and EMG interference, design 50Hz notch filter to filter out power frequency interference in ECG signal. In order to shield the electromagnetic interference of electronic equipment in the environment, a metal film shielding layer on the periphery of the equipment is designed. Through the above design, the collected ECG signal has low noise and high accuracy. When the lithium battery is low, it can be charged via an external USB port. The LED indicator will be red in the charging state, and the LED indicator will automatically switch to blue when it is fully charged. We chose the STM32F103C8T6 microcontroller from STMicroelectronics because of its high performance, low power consumption, and low cost. The controller meets the system accuracy requirements and portable design.

Figure. 3(a) shows the printed circuit board (PCB) of SEUECG-100's internal ECG signal collection front end, which integrates lithium battery rechargeable circuit, voltage regulator circuit, ECG signal acquisition circuit and data storage circuit. Figure. 3(b) shows the Shimmer device, which collects the subject’s ECG through a cable connected to a disposable Ag/AgCl wet electrode. Figure. 3(c) shows the subject wearing the SEUECG-100 based on flexible dry electrodes and using the disposable Ag/AgCl wet electrode Shimmer device at the same time. The ECG signals of the subjects collected by SEUECG-100 are stored in the TF card.

The SEUECG-100 and Shimmer device both operate at a supply voltage of 3.3V, and their operating currents are 25mA and 48mA respectively. The power consumption of SEUECG-100 is about 1/2 of that Shimmer device. With a 1500mAh rechargeable lithium battery and a 32GB TF card as a storage medium, the proposed system can continuously collect and record the subject's ECG data for more than two days.

The sampling rate of SEUECG-100 is adjustable, and its range is 200-2000Hz. The timer 1 (TIM1) of the master controller sets the sampling frequency of the ECG signal, and the timer 2 (TIM2) sets the time interval of the ECG data storage. After the ECG signal is processed by the front-end circuit, it is passed through the analog-to-digital converter (ADC) Is converted into a digital signal, and data is sent to the peripheral through the serial peripheral interface (SPI) method. In order to reduce the load of the MCU, the data is stored in the TF card in text format by the direct memory access (DMA) method.

3. Experimental Design

3.1 Electrode Impedance Tests

As shown in Figure. 4, a 0.5-1000Hz skin-electrode contact impedance experiment was performed using a low-frequency impedance analyzer (MFIA Impedance Analyzer, Zurich Instruments AG (ZI), Switzerland), by appling electrodes to the forearm skin of the same subject with a flexible dry electrode and a disposable Ag/AgCl wet electrode, to compare and analyze the contact impedance between the electrode and the skin. The peak-to-peak alternating current applied to the electrode is set to 50uA, and the subject's skin has not been pre-processed. The experimental data results are sent from the device to the computer through the data cable.

3.2 Electrode Dehydration Experiment

When the disposable Ag/AgCl wet electrode conductive gel is used for a long period of time, its gel moisture will gradually lose and the skin-electrode impedance will increase, causing noise and interference in the collected ECG signal and the signal quality will be greatly reduced. In order to simulate the skin-electrode impedance after the moisture of the electrode conductive gel attached to the skin evaporates and dries, we put the flexible dry electrode and the disposable Ag/AgCl wet electrode into the electrothermal constant temperature dryer at the same time and set the dryer temperature to 37 degrees Celsius. Carry out the experiment of water volatilization of electrode conductive gel. The dried flexible dry electrode and the disposable Ag/AgCl electrode were tested on the forearm skin of the same subject at a 0.5-1000Hz skin-electrode AC impedance test. The experimental equipment and experimental settings were consistent with the Electrode Impedance Tests before drying.

3.3 ECG collection in real-life scenarios

In order to verify the accuracy and reliability of the ECG signal collected by SEUECG-100, the performance of SEUECG-100 and Shimmer device were compared. We performed static and dynamic ECG synchronous acquisition experiments on the same subject on the SEUECG-100 based on flexible dry electrodes and the Shimmer device using disposable Ag/AgCl wet electrodes. The subject maintains a sitting posture in the static situation, and the subject walks on the treadmill at a constant speed (3km/h) in the dynamic situation. The purpose is to compare and verify that the SEUECG-100 device can accurately collect high-quality and low-noise ECG signals in the 2-electrode mode, especially to verify the anti-interference and noise suppression capabilities of the SEUECG-100 in dynamic scenarios. A 24-hour monitoring for the SEUECG-100 is to verify that the equipment can stably collect, record, and store long-term, high-quality ECG signal data. The skins of all test subjects were not subjected to any pretreatment.

In order to evaluate the quality of the ECG signals collected by the SEUECG-100 and the Shimmer device, the two types of device correspond to 20 subjects to synchronously collect and record 20 groups of ECG signal fragments. Based on the published work, six SQIs are extracted for each group of ECG signal segments. They are:

1) basSQI is the relative power in the 0-1Hz frequency band of the ECG signal, which represents the ECG signal. The baseline drift of the signal, its good quality parameter should be close to 1[19];

2) bsSQI is the baseline drift check of the ECG signal in the time domain, the larger the parameter, the better[20];

3) enSQI is the sample entropy of the ECG signal waveform, used for To evaluate the complexity of the ECG signal, the closer its parameter is to 0, the better[20];

4) kSQI is the fourth moment of the ECG signal distribution (kurtosis), and its good quality parameter should be greater than 5[21];

5) sSQI is the ECG signal The third-order moment (skewness) of the distribution, the larger the absolute value of the parameter, the better[22];

6) pSQI is the relative power of the QRS complex in the ECG signal, and its good quality parameter should be between 0.5-0.8[21].

4. Experimental Results

4.1 Flexible and Dry Electrode Characterization

The skin-electrode contact impedance spectra of the untreated flexible dry electrode and the disposable Ag/AgCl wet electrode in the frequency range of 0.5-1000Hz are shown in Figure. 5(a). The skin-electrode contact impedance of Our flexible dry electrode is generally close to disposable Ag/AgCl wet electrode in the frequency range of 0.5-1000Hz. The skin-electrode contact impedance of the two kinds of electrodes gradually decreases with the increase of the frequency of the alternating current applied to the two ends of the electrodes, and the decreasing trend of impedance changes from fast to slow. Fig. 5(b) shows the changing trend of the skin-electrode contact impedance of two kinds of electrodes after drying in the frequency range of 0.5-1000Hz. The disposable Ag/AgCl wet electrode skin-electrode contact impedance after drying in the range of 0.5-100Hz is higher than the flexible dry electrode, and the skin-electrode impedance of the flexible dry electrode and the disposable Ag/AgCl wet electrode at 1 Hz is 700 kOhm and 3475 kOhm, respectively. The impedance values of the flexible dry electrode and the disposable Ag/AgCl wet electrode at 1 Hz are 1.8 times and 8.7 times before drying, respectively. The experimental results show that the impedance of the dried disposable Ag/AgCl wet electrode is significantly increased in the 0.5-100Hz frequency band, and more than 90% of the spectral energy in the ECG signal is concentrated in this frequency band which seriously affects the collected heart Electrical signal quality. In summary, the flexible dry electrode based on the ionic gel material without volatile solvent is similar to the disposable Ag/AgCl wet electrode before the skin-electrode contact impedance is dried, and the degree of change in the skin-electrode contact impedance of the flexible dry electrode after drying Smaller.

4.2 ECG Morphology

The ECG waveform fragments and power spectral densities (PSD) of the subjects collected in the real scene are shown in Figure. 6. In the sitting condition, the ECG waveforms collected by the two devices are very similar. The ECG P wave, QRS complex and T wave are clear, and the power frequency interference contained is small. The PSD numerical comparison is very close and the changing trend is consistent, and the peak power is concentrated in the range of 0.6-10 Hz.

The ECG signals of the subjects in the walking scene showed motion artifacts and noises introduced in the SEUECG-100 and Shimmer devices, and the ECG morphology changed. The PSD of the Shimmer device in the range of 7-25Hz is slightly higher than that of the SEUECG-100, which can be explained as the difference in the PSD value due to the different shape of the ECG waveform caused by the exercise state. The PSD of the ECG signals of the two devices showed a gradual weakening trend and the values gradually became consistent. The experimental results show that both the SEUECG-100 based on flexible dry electrodes and the Shimmer device using disposable Ag/AgCl wet electrodes can collect high-quality, low-noise ECG signals and have similar performance in overcoming motion artifacts.

4.3 RR Interval

The RR interval is calculated from 2 consecutive R waves detected. Figure. 7(a) shows the RR interval correlation of a segment of ECG signals collected by the SEUECG-100 and Shimmer device synchronously. The results show that the ECG signals collected by the two devices have a high RR interval correlation. (r=0.999). In order to further analyze the consistency of the RR interval between SEUECG-100 and Shimmer device, a Bland-Altman diagram as shown in Figure. 7(b) was generated. It can be observed that most of the RR interval errors are within ± 2ms, the maximum RR interval error is less than 5ms, and most of the measured values are within the 95% interval. The reason for the slight difference in the RR interval is that there are certain differences in the internal clocks of the two devices, resulting in a certain random error in the RR interval of the collected ECG signals of the subject, and this error is within an acceptable range. Therefore, we believe that SEUECG-100 can obtain a heart rate value comparable to that of the Shimmer device.

4.4 SQI Parameters

The SQI parameters of the ECG signal fragments of 20 subjects collected by SEUECG-100 and the Shimmer device are shown in Figure. 8. In the basSQI and bsSQI parameters, the SEUECG-100 has more good quality parameters than the Shimmer device, indicating that the SEUECG-100 has a smaller baseline drift. Among the enSQI parameters, most of the subject parameters of the two devices are relatively close, indicating that their ECG signal complexity is similar. The kSQI and sSQI parameters of 5 subjects in SEUECG-100 are better than those of Shimmer device, while the parameters of the remaining 15 subjects are relatively close, indicating that the third and fourth moments of the ECG signal distribution collected by SEUECG-100 are close. The pSQI parameters of the 20 subjects tended to be consistent overall, indicating that the relative power of the QRS complex in the ECG signals collected by the SEUECG-100 and the Shimmer device was relatively close. From the 6 SQIs parameters of 20 subjects, it can be found that the baseline drift of the Shimmer device's ECG signal is more than that of the SEUECG-100, and the power frequency interference noise is slightly higher than that of the SEUECG-100. In summary, the performance of SEUECG-100 in overcoming baseline drift is better than that of the Shimmer device, and the quality of the ECG signals collected by the two devices is generally close.

4.5 Long-term ECG acquisition

As shown in Figure. 9(a), SEUECG-100 collects and stores long-term ECG data (more than 24 hours) of subjects in real scenes. The ECG signal amplitude range is generally between 1-3mV, and the maximum noise amplitude is less than 4mV. The subjects' long-term ECG data does not have large data fluctuations and deviations, and the incidence of signal mutation events is low. The overall ECG signal Contains less noise. As shown in Figure. 9(b) and (c), the ECG fragments of the subject in static and motion state extracted from the 24-hour ECG data, the R peak detection algorithm is used to automatically identify the R peak and use the red circle to perform Label. SEUECG-100 collected and stored ECG data without significant interruption, the signal integrity was good, and the subjects had no obvious adverse events of skin irritation. The experimental results show that the ECG signal collected by SEUECG-100 long-term work is clear, stable and reliable.

5. Discussion And Conclusion

It is difficult to replace disposable Ag/AgCl wet electrodes with dry electrodes on wearable devices. Meziane et al. [13]studied dry electrodes of three materials: metal electrode sheets, soft material electrodes and fabric electrodes, and compared them with disposable Ag/AgCl wet electrodes. The results showed that high skin-electrode contact impedance is the main challenge of the application of a flexible dry electrode. The skin-electrode contact impedance of our flexible dry electrode is close to that of a disposable Ag/AgCl wet electrode, which provides supporting evidence of a proper impedance level compared to wet electrodes. The ionic gel of the flexible dry electrode does not contain volatile solvents, so the skin-electrode contact impedance of the flexible dry electrode after drying has a small degree of change. This report suggests that non-hydro-gel based gel-type dry electrodes could provide consistent and stable skin-electrode contact over time, which could potentially lead to a successful implementation for ECG monitoring.

Our further experiments show that the ECG waveform of SEUECG-100 in the sitting and walking situation is clear, does not show large power frequency interference, contains less noise and has high signal quality. SEUECG-100 did not show large baseline drift and motion artifacts in walking scenarios, and SEUECG-100 did not cause large power frequency interference due to the abandonment of the right leg drive electrode. The RR interval comparison results show that the ECG signal cycles collected by the SEUECG-100 and Shimmer device are highly consistent. The results of SQI parameters show that the baseline drift performance of the Shimmer device is better than that of the SEUECG-100. The Shimmer device is suspended on the subject in the form of a strap. In real life, the device will swing and shift. The electrodes of the Shimmer device are connected to the circuit board by cables. The cables will swing with the subject's limbs, causing the electrodes attached to the skin to vibrate, causing changes in the skin-electrode impedance, and the ECG signal introduces various noises. SEUECG-100 is directly attached to the skin of the subject's chest, and there is no cable connection between the peripheral interface of the device and the flexible dry electrode, thus avoiding the above problems.

Although this study has conducted a comprehensive comparison of various performance indicators between the developed portable ECG patch based on flexible dry electrodes and the Shimmer device, it lacks a large-scale population comparison experiment. Further work is to conduct a large number of clinical trials to verify the accuracy and reliability of the equipment. In future research, we can find more advanced materials and electrode design solutions for flexible dry electrodes.

In summary, we developed a long-term, portable ECG monitoring device based on flexible dry electrodes (SEUECG-100) and conducted experiments in various signal quality and electrode characteristic aspects. Firstly, the proposed design and experiments reveals that a system with dry electrodes could achieve consistent and stable impedance characteristics compared to wet electrodes and provides high-quality signals under real-life scenarios, with an acceptable power-consumption, cost, and system complexity. Secondly, the experimental results provides supporting evidence that non-hydro-gel type of dry electrodes could effectively record clinical grade ECG signals that morphologically comparable with those from wet-electrode-based devices. Lastly, the SEUECG-100 can easily and quickly realize long-term (24-hour) ECG monitoring in real-life scenarios, which is helpful for the early detection and treatment of heart diseases and has a good application prospect.

Declarations

Acknowledgement

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Figures

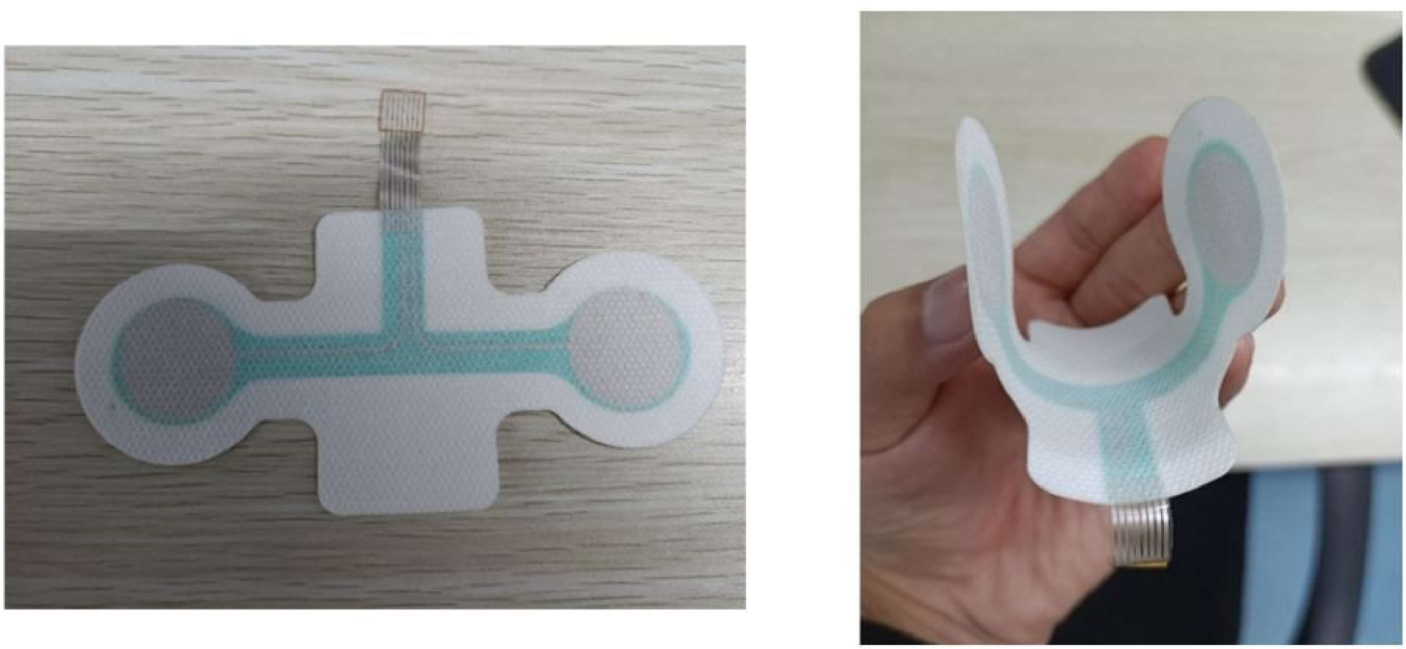

Figure 1

Exterior and structure of flexible dry electrode.

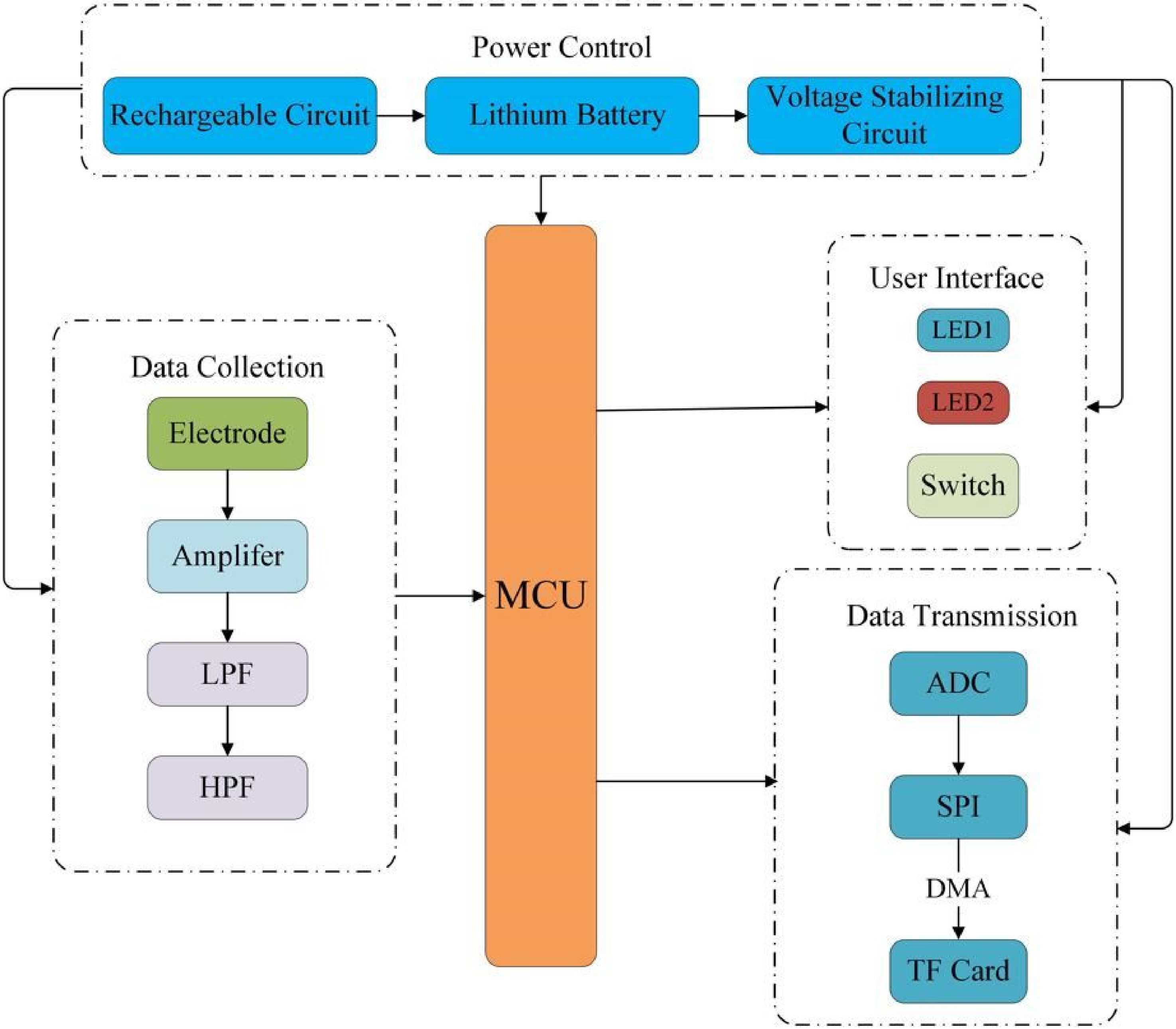

Figure 2

Block diagram of the hardware structure for collecting ECG signals.

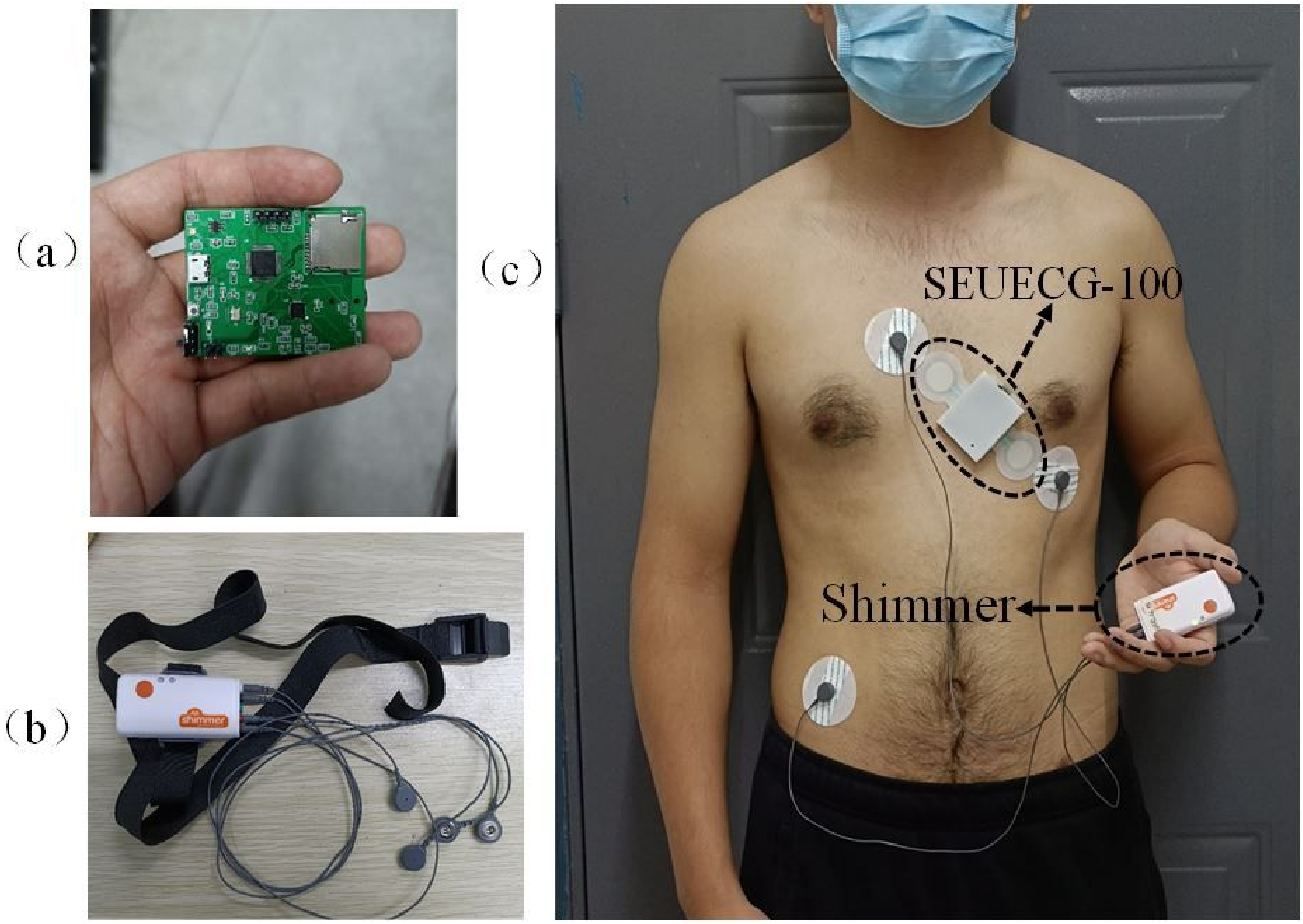

Figure 3

(a) SEUECG-100 internal collection of ECG signal front-end PCB, (b) Shimmer device for collecting ECG signals, (c) The subject wore SEUECG-100 and used a disposable Ag/AgCl wet electrode Shimmer device at the same time.

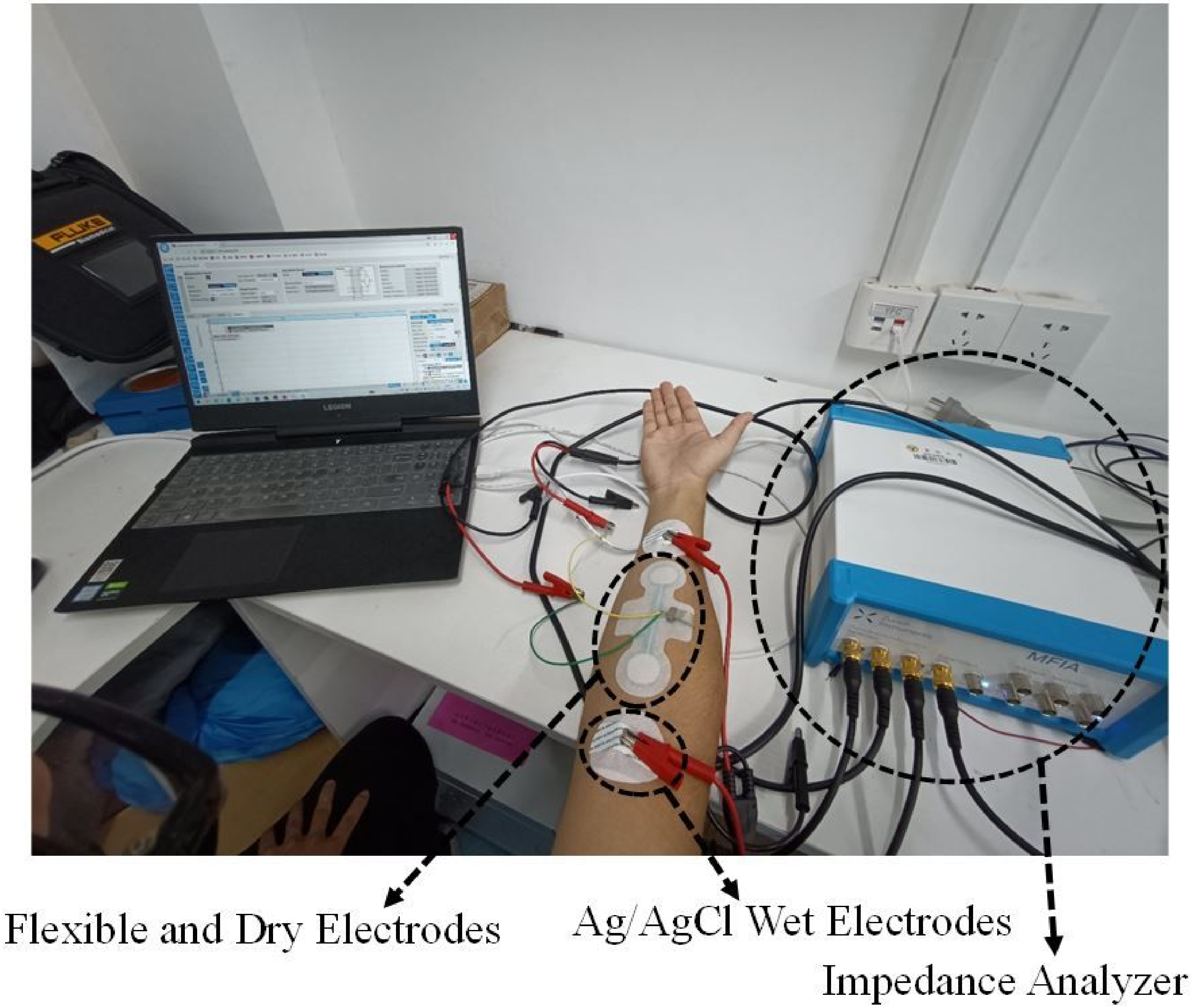

Figure 4

The skin-electrode AC impedance test was performed on the skin of the forearm of the same subject with the flexible dry electrode and the disposable Ag/AgCl wet electrode.

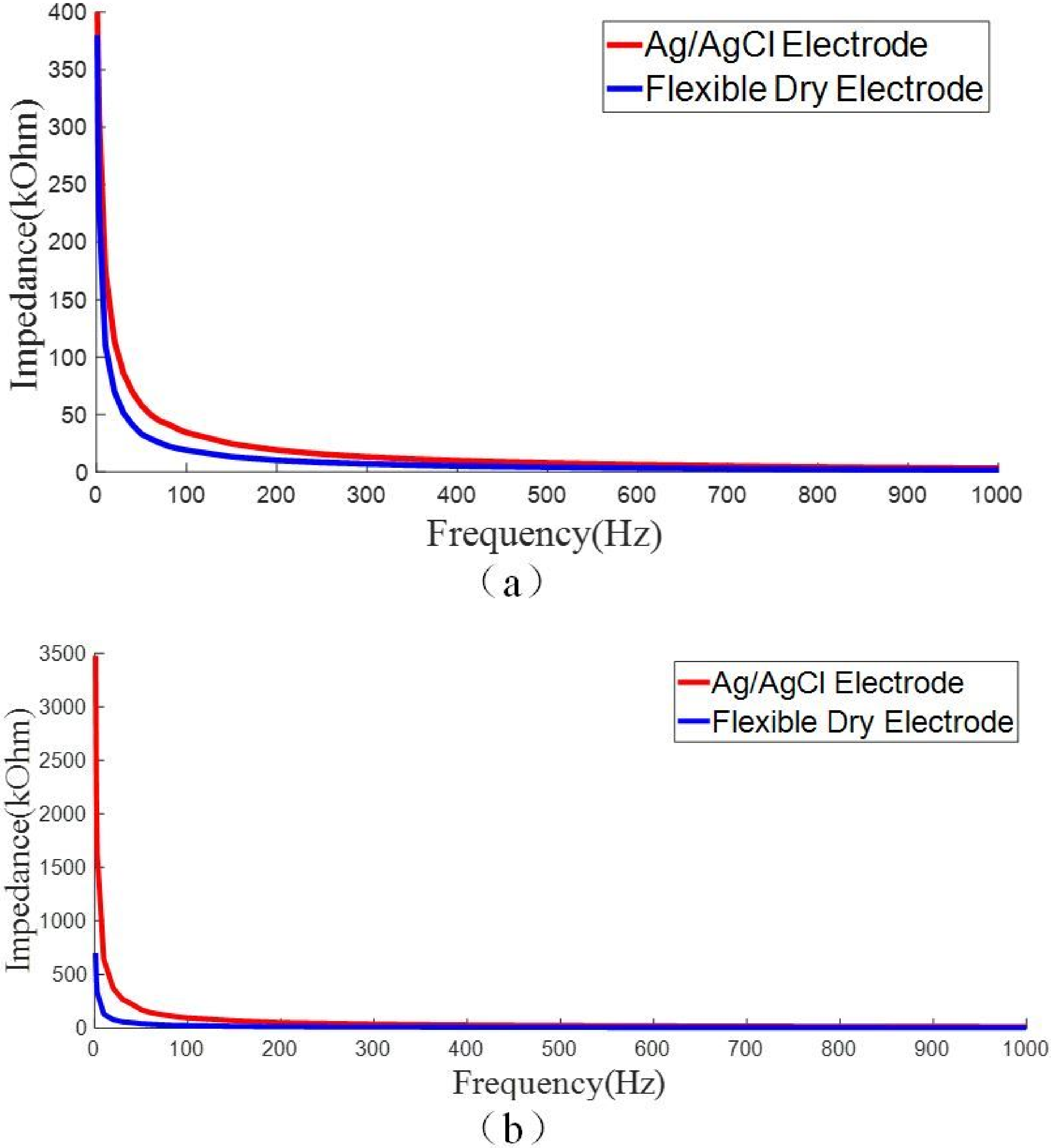

Figure 5

(a) Untreated flexible dry electrode and disposable Ag/AgCl wet electrode in the frequency range of 0.5-1000 Hz skin-electrode contact impedance spectra, (b) Skin-electrode contact impedance spectroscopy between the dried flexible dry electrode and the dried disposable Ag/AgCl wet electrode in the frequency range of 0.5-1000 Hz.

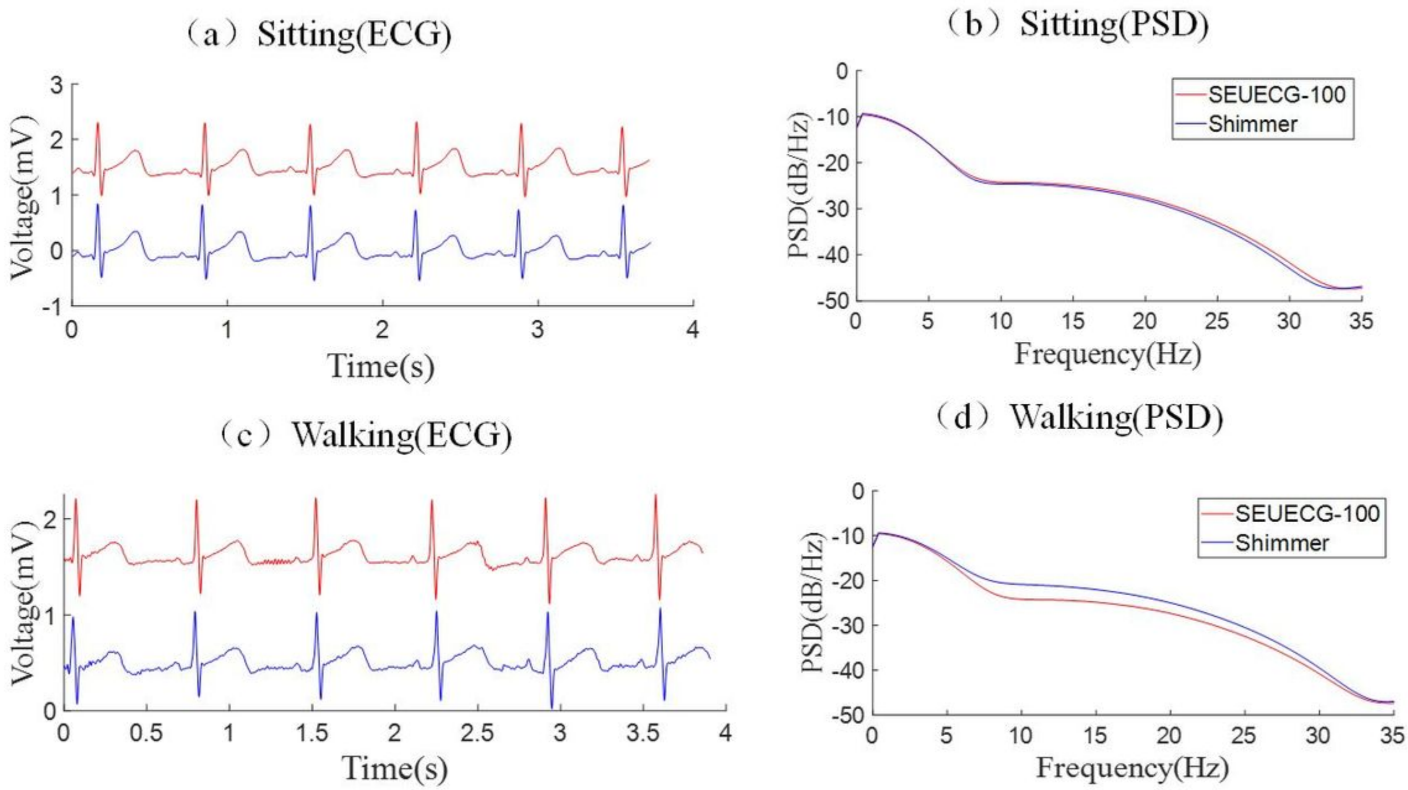

Figure 6

ECG waveform fragments from subject collected synchronously in a real-life scenario: Use SEUECG-100 (red line) and Shimmer device (blue line) to collect ECG waveform fragments and PSD in sitting condition in (a) and (b), Use SEUECG-100 (red line) and Shimmer device (blue line) to collect ECG waveform fragments and PSD in walking condition in (a) and (b).

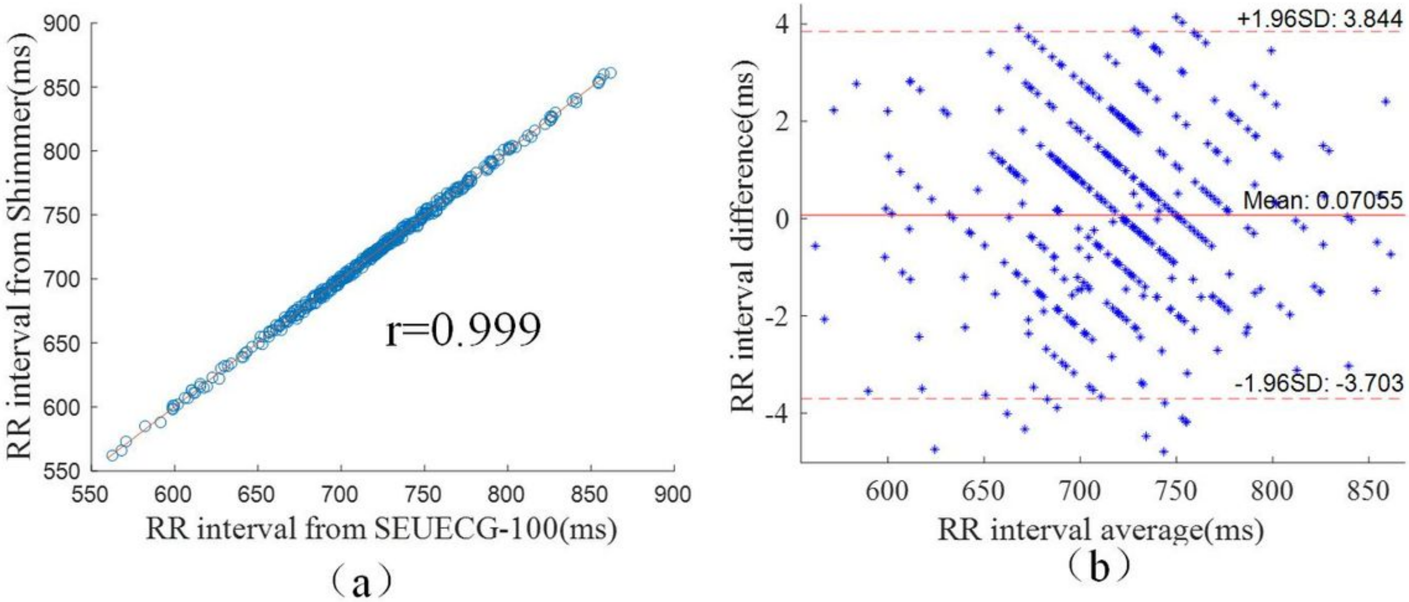

Figure 7

(a) RR interval correlation analysis between SEUECG-100 and Shimmer device, (b) Bland-Altman plot between SEUECG-100 and Shimmer device of their RR intervals.

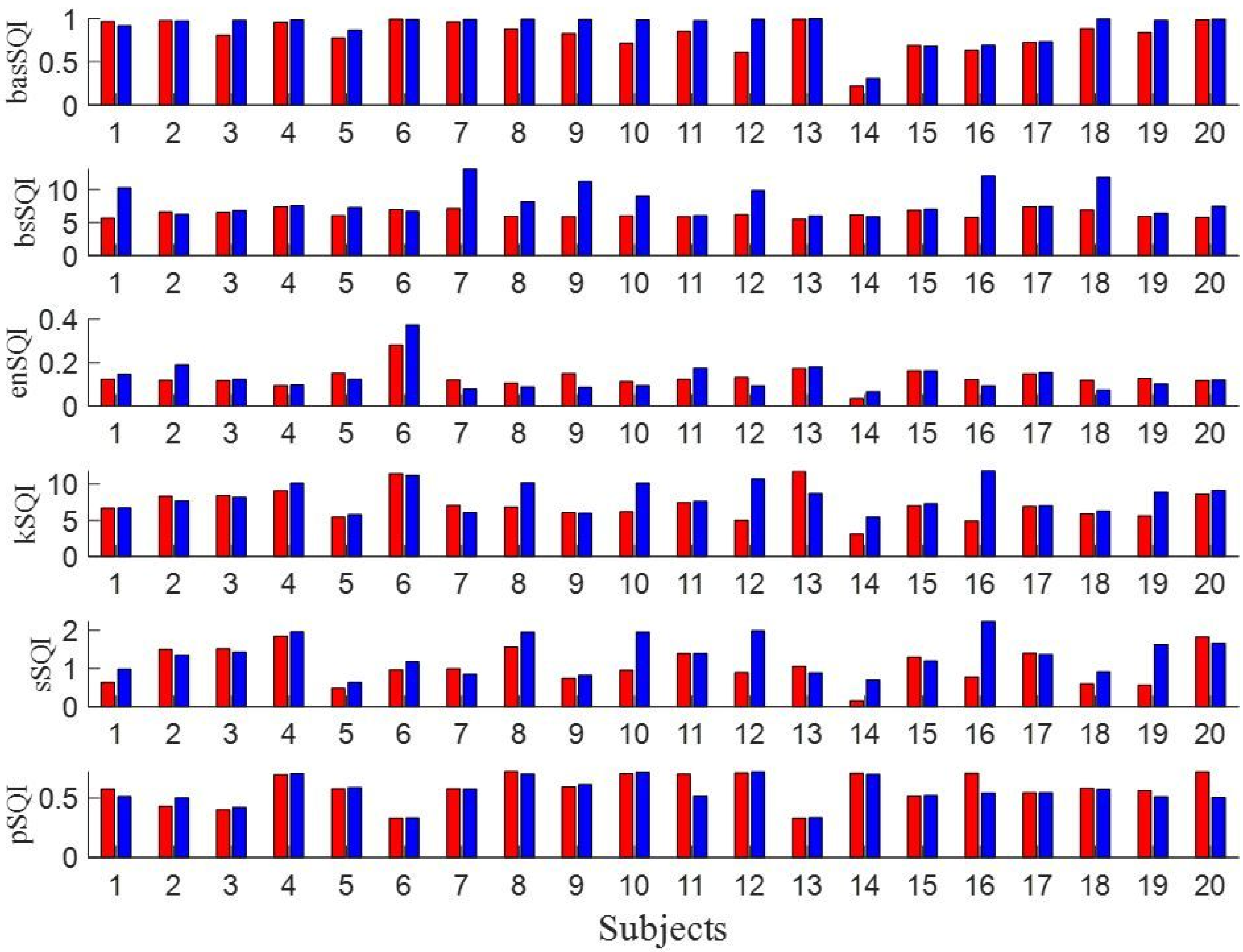

Figure 8

SQI parameters of 20 subjects' ECG signal fragments collected by SEUECG-100(blue pillars) and Shimmer device (red pillars) synchronously.

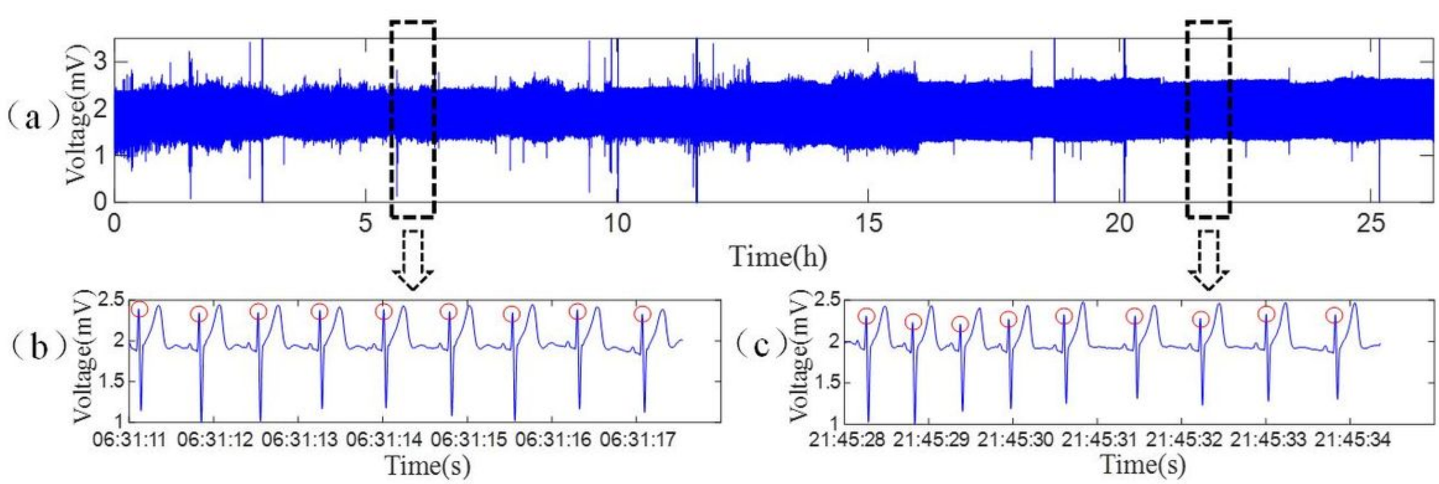

Figure 9

(a) Long-term (more than 24 hours) ECG data of subject collected and stored using SEUECG-100 in a real-life scenario, (b) An ECG segment of the subject in a stationary state, (c) An ECG segment of the subject in a movement state. The automatically detected R peaks are marked with red circles in (b) and (c).