Development of Wearable Heart Disease Monitoring and Alerting System associated with Smartphone

Hyuma Watanabe, Masatoshi Kawarasaki
Faculty of Library, Information and Media Science
University of Tsukuba
Tsukuba, Japan
{hyuma, mkawa}@slis.tsukuba.ac.jp

Akira Sato, Kentaro Yoshida
Faculty of Medicine
University of Tsukuba
Tsukuba, Japan
asato@md.tsukuba.ac.jp, kentaroyo@nifty.com

Abstract—Heart disease has the second high mortality rate behind cancer in Japan, and requires quick treatment. To take a part in emerging mHealth, we developed a wearable heart disease monitoring and alerting system “Dentan”. Dentan continuously monitors patient’s ECG in his/her daily activities and issues an alert to the patient as well as surrounding people if it detects abnormal heart behavior. Dentan consists of a wireless ECG sensor and a smartphone to achieve light-weighted, low-cost system that does not degrade the patient’s Quality of Life. In parallel, we developed ECG analysis algorithm to detect R-wave as well as arrhythmia and performed demonstration experiments to validate its effectiveness. We implemented these algorithms in wireless ECG sensor rather than in smartphone to save power consumption of ECG sensor caused by radio communication.

Keywords- mHealth; ECG; Telemedical service; Wearable Computing; Smartphone

I. INTRODUCTION

Mobile Health (mHealth) is a mechanism or a service that supports medical treatment and/or health-care by the use of mobile devices. The market of m-Health is expanding rapidly worldwide along with the penetration of mobile phones. Applications of m-Health include telemedicine, home healthcare and welfare services and are expected to improve patient QoL (Quality of Life), resolve the uneven distribution of doctors and reduce ever-growing healthcare cost. Continuous monitoring and analysis of patient vital signs is a typical example of m-Health application. This paper presents a wearable heart monitoring and alerting system associated with smartphone that we developed to take a part in m-Health.

Heart disease is a general term to represent disease of a heart such as heart failure, myocardial infarct, angina, atrial fibrillation and ventricular fibrillation. According to the demographics reported by the Health, Labor and Welfare Ministry of Japan in 2011, heart disease has the second high mortality rate behind cancer in Japan. Furthermore, heart disease is characterized by its need of emergency treatment. For example, acute myocardial infarction requires treatment within several hours to three days after its occurrence. When it comes to the ventricular fibrillation, survival rate diminishes approximately 10% by every one minute after its occurrence. In this way, heart disease is familiar but fatal disease that requires immediate action and treatment.

A. Necessity of ECG Monitoring System

Regarding the method of diagnosis for heart disease, there are traditionally two ways; the one is cardiograph monitoring performed at a hospital for the duration of several minutes, and the other is wearing a Holter monitor for 24 hours to record cardiograph data and analyze it later at a hospital. Actually, however, heart disease such as arrhythmia or angina cannot always be detected. They may appear only several times per week. In such cases, it’s not possible to detect it by conventional methods. Furthermore, if a fatal symptom comes up after hospital visit or outside the hospital, immediate action can be taken neither by the patient nor by hospital staff. This also makes the patient uneasy.

As for the stage of heart disease treatment, there still remain some problems in existing medical devices. Although there are implantable devices for fibrillation removal, not a small number of patients feel repulsion in implanting foreign substances into the body.

For above reasons, there is a evident need for Electrocardiogram (ECG) monitoring and alerting system that meets following requirements: (1) endure long time wearing up to about a week, (2) need not be implanted into the body, (3) not expensive compared with other medical devices, and (4) does not debase QoL of patient.

So we developed the “Dentan” as a Wearable Heart Disease Monitoring and Alerting System associated with Smart-phone that continuously monitors and analyses the patient’s ECG, raises an alert automatically if it detects abnormal heart behavior, and further shows the coping strategy and/or emergency action request on the smartphone screen to the patient and surrounding people.

This paper describes the architecture and behavior of Dentan, ECG analysis algorithm and its evaluation through experiment regarding the detection of arrhythmia.

B. Related Works

As for continuous health status monitoring, Brones et al. [1] propose a framework of context-aware m-health applications by illustrating a wearable m-health system to issue a warning to a wearing person and care givers about the acute symptom taking the epilepsy patient for instance. But neither
implementation nor validation of the proposed framework is performed in this work. Otto et al. [2] present hardware architecture and communication protocols of wireless body area network (WBAN) system for ambulatory health status monitoring (e.g., body motion and heart activity), focusing on time synchronization, power management and event management. Fensli et al. [3] propose wearable ECG recording system for arrhythmia monitoring system that works under the patient’s daily activity including physical exercise, body wash and normal work.

The automatic ECG analysis has been widely studied over 40 years. Two main groups of algorithms can be distinguished: QRS detection and wave delineation. The QRS complex is the most typical waveform of the ECG signal and easier to detect than the other waveforms. Various algorithms have been proposed for QRS detection. An extensive overview can be found in [4]. A generalized scheme has a two-stage structure: a preprocessing stage, usually including linear filtering followed by a nonlinear transformation, and the detection rule(s). Pan and Tompkins [5] proposed a real-time algorithm for the detection of QRS complexes and evaluated its correctness by the standard MIT/BIH arrhythmia database. In the preprocessing stage, they used a digital band-pass filter to reduce false detection caused by the various types of interference present in ECG signals, such as artifacts due to electrode motion, power-line interference, baseline wander, and T waves with high-frequency characteristics similar to QRS complexes. This filtering permits the use of low thresholds in QRS detection, thereby increasing detection sensitivity. They report that their algorithm correctly detects 99.3% of the QRS complexes. Concerning delineation (determination of peaks and limits of the individual QRS waves, P and T waves), Martinez et al. [6] developed a robust single-lead ECG delineation system based on the wavelet transform (WT). In a first step, QRS complexes are detected. Then, each QRS is delineated by detecting and identifying the peaks of the individual waves, as well as the complex onset and end. Finally, the determination of P and T wave peaks, onsets and ends is performed. They evaluated the algorithm on standard MIT/BIH arrhythmia database to attain over 99.8% of Se (sensitivity) and P+ (positive predictivity). Other algorithms that apply pattern recognition and morphology can be found in [8] and [9].

The rest of this paper is structured as follows; Section II describes the system configuration and behavior of “Dentan”. Alert types are also discussed in this section. In section III, we propose the ECG analysis algorithm for R-wave detection and subsequent arrhythmia detection. Section IV provides experiment results and evaluation of these algorithms through actual patient data. Section V provides future issues and section VI concludes this paper.

II. SYSTEM OVERVIEW

In “Dentan”, wireless ECG sensor monitors and analyses patient’s ECG data and smartphone raises an alert as needed based on the analysis results. This section overviews the Dentan system configuration and its behavior. The ECG analysis algorithm and its evaluation are described in section III and IV, respectively.

A. System Architecture

“Dentan” consists mainly of wireless ECG sensor and smartphone, which communicate each other by Bluetooth. Fig. 1 shows the system configuration of “Dentan”.

1) Wireless ECG sensor:

Wireless ECG sensor obtains ECG signals from electrodes that are placed on the body surface of a patient through lead wires. It then analyzes ECG data internally to detect the presence of abnormal heart behavior. If some abnormality is detected, it sends ECG data and relevant information to smartphone using Bluetooth.

Combined with above mentioned functions, requirements to ECG sensor are as follows: (1) light-weighted and small size that are easy enough for patients to wear for a long time, (2) power saving which stands up long time operation, (3) close-range wireless communication (e.g., Bluetooth) capability, (4) ECG sampling frequency over than 100Hz, (5) ECG data handling capability, and (6) storage capacity around 100kB.

In addition to these, ECG sensor needs to be a programmable device so that a developer can program its behavior. We used “Wireless ECG sensor” produced by Shimmer Research of the Republic of Ireland. [10] Fig. 2 shows its appearance and Table 1 shows its specifications. This sensor device is built upon Tiny OS, a widely used open-source operating system for embedded sensor networks, and is a programmable device as well.

![Figure 1. Dentan system overview](image1)

![Figure 2. Shimmer Wireless ECG Sensor](image2)

![Figure 3. Wearing Dentan](image3)

In Dentan system, we made the ECG sensor device to have following roles: (1) continuous acquisition of patient’s ECG data with 100Hz sampling frequency, (2) analysis of ECG data to detect abnormal heart behavior, (3) sending out ECG data...
Table 1. Shimmer Wireless ECG Sensor Specification

<table>
<thead>
<tr>
<th>CPU</th>
<th>MSP430F1611</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage</td>
<td>microSD card slot</td>
</tr>
<tr>
<td>Size</td>
<td>35mm x 32mm x 23mm</td>
</tr>
<tr>
<td>Weight</td>
<td>15g</td>
</tr>
<tr>
<td>Radios</td>
<td>Bluetooth2.1+EDR, 802.15.4(ZigBee)</td>
</tr>
<tr>
<td>Sensors</td>
<td>ECG, 3 Axis Accelerometer, Tilt/Vibration switch</td>
</tr>
<tr>
<td>ECG Freq. Range</td>
<td>0.5 – 150 Hz</td>
</tr>
<tr>
<td>Battery</td>
<td>450mAh Li-ion Battery</td>
</tr>
</tbody>
</table>

and relevant information to the smartphone using Bluetooth only when abnormal behavior is detected, and (4) detecting intense movement and rubbing of clothing of a patient by using tri-axial acceleration sensor, so that misdetection in ECG data analysis is prevented.

As for electrode, we used “Clearode” of Fukuda Denshi Co., Ltd. [11] that is tolerant enough to patient’s movement.

2) Smartphone:

Smartphones are rapidly penetrating to our daily life. Many of them are easy to acquire and not so expensive, while being equipped with sufficient computing and storage resources, capabilities of verbal and data communication by a cellular phone network, close-range communication using Bluetooth and location measurement using GPS. It also has a large-size screen for information display, and can emit sound, light and vibration. Although our system is smartphone-OS independent, we implemented our applications on top of Google’s Android based smartphone.

In our system, the roles of smartphone are as follows: (1) provide a graphical user interface for the whole system, (2) set-up wireless ECG sensor remotely by using Bluetooth, (3) receive information about abnormal heart behavior from the wireless ECG sensor by Bluetooth, (4) issue an alert to the patient (i.e., the person who is wearing ECG sensor) and surrounding people by sound or vibration, (5) pop up on the screen the method of dealing with abnormal heart behavior at its occurrence, (6) measure the patient’s current location using GPS, (7) call the patient’s primary doctor or dial to #911 (#119 in Japan) automatically, and (8) record ECG data at the time of abnormal heart behavior.

B. Inter Device Communication

As described above, the communications between the wireless ECG sensor and the smartphone is performed on Bluetooth. Regarding the close-range radio communication method, ZigBee (IEEE 802.15.4) is less power consuming but it’s not widely adopted in commercially available smartphones. Accordingly, we excluded ZigBee from the viewpoint of cost and limited availability.

Otto et al. reports in [2] that 95% of power consumption in wireless sensor device is for wireless communication. As they used ZigBee, the experiment environment is not same as Bluetooth, the fact that radio communication consumes the majority of battery power would remain true. Accordingly, we designed Dentan so that it doesn’t communicate anytime but time when some abnormality is detected. This is why the wireless ECG sensor performs ECG data handling internally.

C. Method of Wearing ECG Sensor

As shown in Fig. 3, Dentan ECG sensor is worn by attaching four seal-shaped electrodes on the skin and connecting them to the wireless ECG sensor by using lead wires. The ECG sensor is tied up to the body by a belt as shown in the figure. Owing to the range of Bluetooth, smartphone needs to be carried within 10 meters from ECG sensor.

D. Alert Types

ECG abnormality ranges from something fatal that needs immediate action to something that needs only to record so that a doctor can check later. If the system always sends out loud alert, it would have a bad influence upon daily life of a wearing person, thus it’s necessary to control the volume of the alerting sound.

So we defined the following four alerting types so that Dentan can issue an appropriate warning according to the importance and the urgency of ECG abnormality.

a) Urgent Level (Class A): The patient is in impending and deadly situation (e.g.; ventricular fibrillation is detected)
   i. Show countermeasures on the smartphone screen.
   ii. Smartphone beeps or vibrates at the maximum level
   iii. Smartphone makes an emergency call if no action is taken

b) Alert Level (Class B): Urge the patient to take some action.
   i. Show countermeasures on the smartphone screen.
   ii. Smartphone beeps or vibrates at the maximum level

c) Caution Level (Class C): Notify the patient of the situation. The patient needs no action. (e.g.; atrial fibrillation is detected)
   i. Show countermeasures on the smartphone screen.
   ii. Smartphone beeps or vibrates at the ring alert level.

d) Record Level (Class D): Just record the situation. (e.g.; extrasystolic beat)

All the alerts are recorded with relevant ECG data so that the patient’s primary doctor can examine them later.

An indication example to a display of smart phone is shown in Fig. 1. In case of ventricular fibrillation detection, a message that urges the use of AED appears on the screen with a button that links to AED map all over Japan as well as a button that makes an emergency call automatically.

E. Patient’s Motion Detection by Accelerometer

As we suppose that a patient wears Dentan in daily activities, patient’s physical exercises or touching of wireless sensor with clothes may affect the monitored ECG data thus may invite errors in ECG analysis and consequent false alert. To prevent such adverse effects, we used the tri-axial accelerometer installed in wireless ECG sensor to monitor the patient’s motion and exclude ECG data that are suspected to be recorded during the time of motion. More specifically, by sending data of an accelerometer together with ECG data to the
smartphone, we allowed a doctor who reviews the ECG data at the issue of alert to know about the motion of the patient so that the doctor can judge whether the alert is a result of patient’s motion.

For the case when the system issues an alert that requires quick actions (e.g., Class A or B) under the environment where the accelerometer is detecting a sudden motion of the patient, we are investigating a method to urge the patient to keep a rest and restart monitoring.

III. ECG ANALYSIS ALGORITHM

The basic ECG wave profile can be categorized in P, Q, R, S and T-waves as shown in Fig. 4. The objectives of ECG analysis are to extract the features of each wave from ECG data (e.g.: presence or absence of a particular wave, wave size and wave frequency) and then to detect abnormal heart behavior of the patient based on the extracted features.

We developed two kinds of ECG analysis algorithms: R wave detection algorithm which is the basis of ECG analysis, and arrhythmia detection algorithm which uses detected R waves. These algorithms have been implemented to Dentan. The outline of them is described in this section.

A. R-wave Detection Algorithm

As shown in Fig. 4, R-wave is a distinctive positive wave that can be observed in ECG. The R-wave exhibits the largest variation range and is easy to detect. Considering the limitations of wireless ECG sensor in data handling capability as well as memory size and battery life, the calculation amount of R-wave detection algorithm needs to be small enough. The algorithm should also be robust against various noise and/or baseline fluctuation because the ECG sensor is worn in daily life. Using the specific features of R-wave such as large amplitude and high frequency within 0.12sec, we developed the R-wave detection algorithm as shown in Fig 5.

B. Arrhythmia Detection

Arrhythmia is the state that the rhythm of heartbeat becomes erratic. Atrial fibrillation and extrasystole are envisaged as the cause of the arrhythmia.

Atrial fibrillation is a state of the heart where the atrium wiggles to make the constriction of ventricle irregular, thus brings arrhythmia. Atrial fibrillation itself is not a fatal disease; it may cause blackout or cerebral infarction, or may induce myocardial or heart failure.

Atrial fibrillation has two features in ECG signals: the one is irregular R-wave interval and the other is absence of P-wave. By analyzing either or both of these features, we can detect atrial fibrillation. Larburu et al. [7] compared the accuracy of several atrial fibrillation detection algorithms, and concluded that R-R interval (interval between successive two R-waves) based algorithm is robust and preferable under the condition where the patients subject for ECG monitoring walk around.

So we decided to measure R-R interval and to judge the existence of arrhythmia when the variation in the number of heartbeats surpasses the given threshold level. The calculation is lightweight in this method.

Extrasystole is a kind of arrhythmia where a heartbeat deviates from original timing and shrinks. Under the extrasystole, blood cannot be sent out normally, and there is a possibility which causes dizziness and a faint. We judged it to be an extrasystole when either of the following two events occurred: (1) R-wave was detected at the timing deviated from normal R-wave position and (2) R-wave was missing. The reason of adopting the second event is that R-wave under extrasystole is smaller than a normal R-wave and is not judged as R-wave by the algorithm mentioned above in many cases.

IV. EXPERIMENT AND EVALUATION

To validate the accuracy of ECG analysis algorithms as proposed in section III, we performed some demonstration experiments. Experiment environment and result are described below.

A. Validation of R-wave detection algorithm (Part I)

In Part I, we validated the R-wave detection algorithm by targeting a healthy person.

The subject wears the Dentan and records ECG data. To the recorded data, we performed the R-wave detection algorithm that is exactly the same as that implemented in Dentan, on a computer and compared the R-wave detection by algorithm with R-wave check by watch.

1) Experiment Environment:

As we assume that wearable device is used in all environment of the daily life, ECG data was acquired in the following three environments:

```
 valleyWave(ECGdata[12], Threshold)
 Threshold // Predefined threshold
 ECGdata[D1...D12] //ECG Data for 0.12sec, 100Hz
 max = subscript of max(D1...D12)
 min = subscript of min(D1...D12)
 if( (Dmax - Dmin) > Threshold)
   and
   ( Di < (Dmax - Threshold) | i < max)
   and
   ( Dj < (Dmax - Threshold) | j > max)
 then R-wave
```

Figure 5. R-wave detection algorithm
a) Calm State: Standing, sitting and walking within 10 meters, indoors (for 10 min., 722 R-Waves).

b) Active State: Walking, running and going up and down the stairs, outdoors (for 10 min., 981 R-Waves).

c) Touching State: Changing clothes (for 40 sec., 67 R-Waves).

2) Experimental Results:
   a) Calm State: When the subject wasn't involved in intense movement, there was no disorder in ECG and R-wave was detected rightly by 100%. (Fig. 6)

   b) Active State: In this case, detection accuracy of R-wave was 99% (978/981). When a subject was running or going up and down the stairs, myoelectric potential was added to ECG, and a baseline fluctuation was observed that was caused by change in resistance of a electrode by skin stretch. (Fig. 7). But our algorithm was not affected by such noise and detected high-frequency components of R-wave which fluctuate significantly. A detection error was caused by high frequency and high fluctuation noise really akin to R Wave. Such mis-detection could be handled by the review of a doctor in attendance, in actual operation.

c) Touching State: Detection accuracy was 84% (56/67), which was the worst among three experiment environments. As shown in Fig. 8, ECG wave profiles are disturbed to the extent that the original form cannot be recognized. This is because clothes have touched the lead line, sensor and electrode of Dentan to grind against each other.

   It is difficult to detect R wave even by human eye from the ECG wave profile. To resolve this issue, hardware that is robust enough against rubbing of clothes needs to be developed.

Although it was not possible to remove noisy factors for R wave detection, we prevented a mis-detection by using a built-in accelerometer to detect contact of clothes and electrodes in this case.

Fig. 9 shows a simultaneous data of accelerometer and ECG. A big fluctuation of the accelerometer data is recognized at the part where a lot of noise generates in ECG. By detecting and recording this, we can reduce the burden of doctor's review and can suggest the patient of re-measurement in rest.

B. Validation of R-wave detection algorithm (Part II)

In Part II, we validated the R-wave detection algorithm by targeting a patient of atrial fibrillation during the resting state.

1) Experiment Environment:

   We used ECG database stored in the hospital. These data were collected from 20 of atrial fibrillation patients who were placed at bed rest.

2) Experimental Results:

   Our algorithm achieved 100% of R-wave detection accuracy in all of the 20 patients' ECG data. Based on that, it further detected stationary arrhythmia and gave a diagnosis of arrhythmia.

   The ECG data of the atrial fibrillation patient in above experiment is shown in Fig.10. By this result, it revealed that our algorithm is applicable not only to a healthy person but also to atrial fibrillation patients.
C. Experiment of Extrasystole Detection

Through the above-mentioned experiment, we could confirm that Dentan achieves a quite high R-wave detection accuracy if there is no intensive touch to the body of Dentan. The next stage is the experiment of the extrasystole detection through the detection of arrhythmia.

1) Experiment Environment:
A person who experiences ventricular extrasystole approximately three times in two minutes was made the target for a subject. He wore Dentan for 30 minutes to collect ECG data. Along with the previous experiment, we performed the same arrhythmia detection algorithm using R-R interval as that of Dentan on the computer, and compared the result with a check by watch.

2) Experimental Result:
The ventricular extrasystole as shown in Fig.11 was not detected as R-wave. As it woke up disorder of the heart rate, all were recorded as arrhythmias.

![Figure 11. Detected Arrhythmia](image)

D. Battery Life

An element that makes Dentan a wearable device is that a battery lasts for at least one day. Dentan achieved continuous operation of 36 hours in an actual wearing experiment. Shimmer's Wireless ECG Sensor is equipped with Li-Ion battery of 450mAh, and if it is replaced by something high capacity, it's possible to extend the operation time.

V. FUTURE ISSUES

A. Support of Other Heart Diseases

At present, the algorithm mounted in Dentan can only detect non-fatal heart disease such as arrhythmia. Towards the next step, we are currently investigating the detection algorithm of cardiac infarction and other ischemic cardiac diseases through the detection of ST segment elevation.

B. Improvement of Device Wearing

As described in section II-C, there are some difficulties in wearing the wireless ECG sensor. There are a lot of problems in hardware such as ambiguity in locating the electrode, unfixed lead-wires and thick substance of wireless cardiograph. However, many of these problems come from the fact that we used general-purpose sensor for system development, and could be resolved if we adopt an exclusive design. For example, the problem of lead-wire would be resolved if we use a sheet of sticker-like electrode that integrates electrode and lead-wire. The problem of the thickness of wireless ECG sensor substance comes from the scalability design that uses a connector and a multiple substrate for multi-purpose development. This could also be resolved by exclusive design.

C. Demonstration Experiment

Initially, we planned to perform the experiment of Dentan to the patients in University Hospital. Actually, however, only authorized medical devices were permitted to be worn by patients. To verify the effectiveness of Dentan in clinical practice, we plan to implement our functions over authorized wearable sensor device and perform demonstration experiment.

VI. CONCLUSION

In this paper, we proposed Dentan as a wearable heart disease monitoring and alerting system associated with smartphone and validated its effectiveness through experiments. In emerging needs of m-Health, we believe that Dentan can respond to our expectations. We will continue developing a system, asking for medical expert's cooperation.

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