

# Smart ECG Monitoring Patch with Built-in R-Peak Detection for Long-Term HRV Analysis

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**Abstract**—Since heart rate variability (HRV) analysis is widely used to evaluate the physiological status of the human body, devices specifically designed for such applications are needed. To this end, we developed a smart electrocardiography (ECG) patch. The smart patch measures ECG using three electrodes integrated into the patch, filters the measured signals to minimize noise, performs analog-to-digital conversion, and detects R-peaks. The measured raw ECG data and the interval between the detected R-peaks can be recorded to enable long-term HRV analysis. Experiments were performed to evaluate the performance of the built-in R-wave detection, robustness of the device under motion, and applicability to the evaluation of mental stress. The R-peak detection results obtained with the device exhibited a sensitivity of 99.29%, a positive predictive value of 100.00%, and an error of 0.71%. The device also exhibited less motional noise than conventional ECG recording, being stable up to a walking speed of 5 km/h. When applied to mental stress analysis, the device evaluated the variation in HRV parameters in the same way as a normal ECG, with very little difference. This device can help users better understand their state of health and provide physicians with more reliable data for objective diagnosis.

**Keywords**—Ubiquitous healthcare, Wearable sensor, Physiological measurement, Peak detection algorithm, Heart rate variability, Day-to-day activities, Stress assessment.

## INTRODUCTION

This study set out to develop a small and light electrocardiography (ECG) monitoring device with enhanced portability and wearability, software that contains a peak detection algorithm for analyzing

heart rate variability (HRV), and tasks to establish its credibility.

Health has become a constant concern for people in modern society, given their irregular lifestyles and high levels of stress. This has manifested itself in the shift from the technical trend of striving to diagnose and treat diseases as early as possible to the more recent trend of constantly keeping track of an individual's physiological information and helping to maintain their health so that they do not develop diseases.<sup>17</sup> Ubiquitous healthcare (U-healthcare) is a technique that responds to the needs of modern people. By integrating information technology and medical technology, U-healthcare provides healthcare and medical services without the limitations of time or space and helps improve and manage the health of people in modern society. Through the application of this technology, humans can constantly monitor their health and seek out appropriate medical care when needed.<sup>13</sup>

ECG monitoring is a typical form of U-healthcare. It records the electrical changes on the surface of the body by using the electric current that flows through the cardiac tissue. Clinically, it is most commonly used for diagnosing diseases related to cardiac activities and coronary vessels. Especially, heart rate variation analysis, which continuously measures the variation in the heart rate, is used as a non-invasive physiological indicator that can predict the risk of cardiovascular diseases and quantitatively measure the balance between the sympathetic and parasympathetic nervous systems.<sup>10</sup> The “standard limb leads” electrocardiographic method is commonly used in clinics. Although it can provide an accurate ECG that can be used for diagnosis, it requires the assistance of a specialist because of the cost, size, and weight of the equipment, and is thus inconvenient. Furthermore, cardiac disor-

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ders may not occur constantly but rather irregularly and sporadically. Therefore, there is a need for a convenient portable system that can continuously monitor the ECG and enable the management of the wearer's health status as he/she goes about his/her day-to-day life.<sup>12,30,32</sup>

Various studies are being conducted to develop a technique that can satisfy these needs. The Holter monitor is one of the most commonly used ambulatory ECG devices in the clinical field. In its early years, the device was large and heavy and usually caused discomfort to the patient, given that it required many electrodes be connected to their bodies, with wires. However, the device has since improved and now uses smaller recorders—although the size varies depending on the manufacturer—and uses relatively few leads, such that the patient remains comfortable during recording.<sup>2,35</sup> Other novel ECG monitoring devices that have been developed to provide portability include those which use only one or two leads<sup>20</sup> or devices based on capacitance-coupled sensing.<sup>9</sup> The capacitance-coupled sensing method assumes the patient's skin and an electrode to be two layers of a capacitor, such that bio-potentials can be measured without any direct contact with the surface of the patient's body.<sup>14</sup> Its application has been extended to unobtrusive wearable devices with measuring modules integrated or embedded into clothes or accessories.<sup>32</sup>

There are also some unobtrusive sensing methods and wearable devices based on other principles such as ballistocardiogram (BCG), seismocardiogram (SCG), and photoplethysmogram (PPG). BCG measures the reaction forces of the body resulting from ventricular blood ejection, whereas SCG involves the measurement of the local fluctuations of the chest that are caused by a heartbeat. Wearable BCG and SCG units rely on attachable accelerometers integrated into the support device.<sup>5,7</sup> PPG sensing devices use light-emitting diodes to illuminate the skin and photo-detectors to measure changes in the light absorption. To achieve unobtrusive measurement, PPG measuring modules can be integrated into clothing, such as gloves or hats, or accessories, in the form of rings or ear-worn sensors.<sup>20,21,32</sup>

This study set out to design a new ECG monitoring system that integrates many of the advantages of the devices described above, based on recent studies, as well as the characteristics of various portable monitoring devices. We devised a small, lightweight ECG monitoring device that can be attached to the patient's torso. This device implements a modified lead arrangement, minimizing the distance between the electrodes required to measure the biologic signals. This allows all the electrodes to be on a single patch, which is easy to attach and detach to and from the

measuring device by using a snap button. Also, we developed software including an algorithm that detects important ECG peaks and which is essential for HRV analysis. We verified the performance and reliability of both the hardware and the software. For verification, we obtained ECG signals for 41 subjects over an extended period to evaluate the efficacy of the algorithm in the detection of peaks. We also compared the results obtained with our device with those obtained with a commercial device for common day-to-day activities such as laying down, sitting, and walking. Lastly, we analyzed the HRV under stressful situations and evaluated its practicality.

## MATERIALS AND METHODS

### *ECG Monitoring Device Using a Patch Electrode*

We developed a portable ECG monitoring device that can easily measure the ECG by connecting the measuring module to a patch with a minimized electrode array using a snap button. The measuring module, which is illustrated in Fig. 1(a), is small (38 mm wide, 38 mm long, and 7 mm thick), such that it can be held in the palm of one's hand. The weight of the module, including the battery, is 10 g.

Considering the minimum required potential difference, the electrodes were arrayed over a patch (patch electrode), which is illustrated in Fig. 1(b), with a width of 150 mm and a length of 60 mm, weighing 4 g. The material used for the patch is non-woven fabric with hydrogel and adhesive. We verified the biocompatibility of the two components (hydrogel, adhesive) that are in contact with the skin and they were found to have passed all the test requirements including cytotoxicity and skin irritation as proposed by the FDA and ISO 10993-1 for materials to be in contact with uncompromised skin. An Ag-/AgCl-

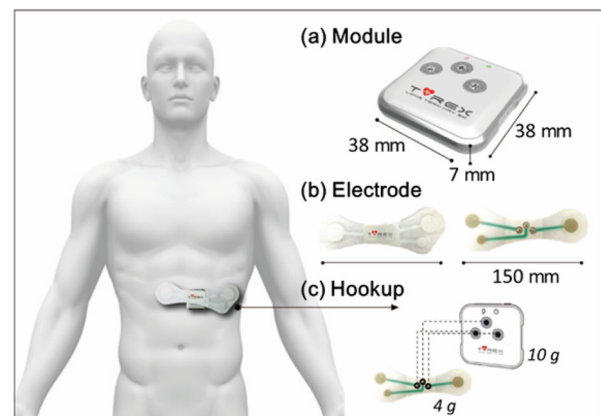


FIGURE 1. Smart ECG monitoring patch device.

based electrode array is printed into the patch and protected by an insulation coating. As a result of the effect of the insulation coating, the patch electrode exhibits a uniform impedance and stable performance even when subjected to sweat and moisture.

Attaching and detaching the patch to and from the measuring module by using a snap button (as illustrated in Fig. 1(c)) not only reduces the burden of attaching multiple lead electrodes to the body, but also reduces the noise emanating from the cables, allowing the measurement of more stable signals. When using the device, the user connects the measuring module to the patch electrode, attaches it to his or her torso (near the celiac plexus), and then presses the power button for about two seconds. A blue LED blinks to indicate whether the ECG signals are being detected normally. Because it is highly portable, convenient, and easy to use, ECG monitoring is possible at any time of the day or night, even while the subject is asleep.

The measuring module is composed of amplifying and filtering circuits which can detect ECG signals from the leads attached to the wearer's body, an accelerometer for detecting movement and the body's posture, and a processor that performs functions such as signal processing and data transmission. An instrumentation amplifier (AD8235, Analog Devices Inc., USA), which has a high common-mode rejection ratio (CMRR = 100 dB) was used to amplify only the differential of the obtained signal. In addition, in an attempt to reduce the effect of noise and improve the R peaks of the ECG, we designed band-pass (5.9- to 48-Hz) and notch (60-Hz) filtering circuits by using quad op amps (LT6005, Linear Technology, USA) with a CMRR of 100 dB. The acceleration transducer was configured using a digital output motion sensor with a 3-axis acceleration indicator (LIS3DH, ST Microelectronics, Switzerland).

We used a microcontroller (STM32F103, STMicroelectronics) with a Cortex-M3 core, to build the main processor. The main control unit, operating at a 72-MHz clock speed, not only includes a variety of peripheral devices such as 512 KB of flash memory, 64 KB of SRAM, and a 12-bit analog to digital converter (ADC), but also supports communication

interfaces such as a serial peripheral interface, universal serial bus (USB), and universal asynchronous receiver & transmitter. To enable the connection of the measuring equipment to the computer, the data transfer part conforms to the communication device class of the USB interface; a diagram of the device is shown in Fig. 2.

Our device supports the collection of an ECG signal with a 12-bit resolution and a 256-Hz sampling frequency, as well as an acceleration signal with a 16-bit resolution and 1-Hz sampling frequency. The collected data is saved to a 32-MB serial flash memory block, from which the ECG and acceleration signal for the last 24 h can be reviewed (the reviewable duration can be extended by increasing the capacity of the memory up to 128-MB). Since the ECG signals of each individual have different amplitudes, the equipment automatically examines the waveform of the ECG saved in the memory and controls the gain of the amplifier to amplify the ECG signal to attain a consistent amplitude. The equipment uses a 3.7-V lithium polymer battery as its power source, which enables it to operate for around 90 h when fully charged. To enable longer monitoring, the equipment maximizes its use of the limited energy in the battery by entering energy-saving mode (disabling the peripherals) when the system is not operating.

### RS-Based Peak Detection

A QRS complex in an ECG signal indicates the depolarization state of a ventricle. The first positive signal is defined as the *R*-wave and the following negative signal is defined as the *S*-wave. We designed an algorithm to detect the QRS complex by detecting the *R* and *S* waves, using the information on their amplitude and the temporal interval between waves; a diagram of this process is shown in Fig. 3.

(1) Up-peak detection: In an ECG signal, up-peaks are detected by determining the point at which the slope changes from positive to negative, as well as the point of a local maximum. In our peak-detection algorithm, the *R*-peak and *S*-wave are determined from the following criteria.

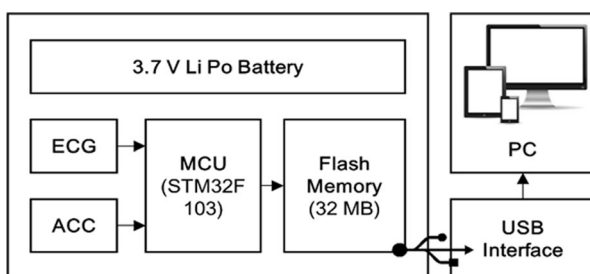


FIGURE 2. Architecture of developed device.

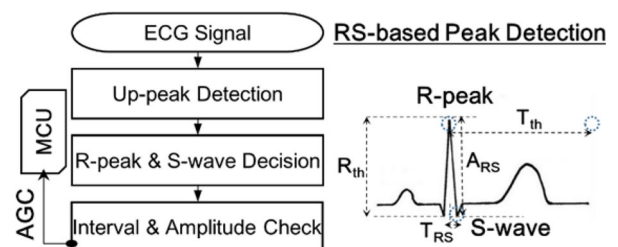


FIGURE 3. Flowchart of RS-based peak detection algorithm.

(2) *R*-peak amplitude ( $R_{th}$ ): The ECG measurement device we developed in this study includes an auto gain control (AGC) function. The AGC function periodically analyzes the morphologic shape of the ECG signals and automatically adjusts the rate of amplification so that the amplitude of the *R*-peak exceeds a constant value. Letting  $V_{lim}$  ( $V_{lim} = -2048$  to  $2048$ ) be the maximum range of the ADC value that can be expressed using the hardware, the amplitude of the *R*-peak must always satisfy Eq. (1).

$$R_{th} > \frac{V_{lim}}{2} \times 0.51 = A_{th} \quad (1)$$

(3) Temporal interval between *R*-peaks considering refractory period: Considering the refractory period of the heart, at least 200 ms is required for the successive generation of *R*-peaks. Therefore, the algorithm calculates the temporal interval between up-peaks with an amplitude in excess of  $A_{th}$ , detected as explained in (2). If the interval is less than 49 samples (= 191 ms), the peak is considered to be an abnormal peak due to noise, and is discarded.

(4) Down-wave detection: Beyond the peak that satisfies the criteria of (2) and (3), a window of 49 samples is applied. Among the data within the window, a down wave is determined by determining that point at which the slope transitions from negative to positive and has a local minimum value.

(5) Final decision: The temporal interval ( $T_{RS}$ ) and the amplitude ( $A_{RS}$ ) between the up-peak and the down-wave determined using the methods described in (2)–(4) are measured. Using the developed device, we collected and analyzed ECG signals from over 30 subjects. As a result, we could set up an empirical threshold that normal ECG signals satisfy. Equation (2), below, shows the empirical threshold of  $T_{RS}$  and  $A_{RS}$ .

$$T_{RS} \leq 78.125 \text{ ms}, A_{RS} \geq \frac{V_{lim}}{2} \times 0.87 \quad (2)$$

Through an analysis of the up-peak and down-wave information selected using this equation, *R*-peak was ultimately determined.

#### *Auto Gain Control (AGC)*

Some criteria included in the *RS*-based peak detection algorithm described in previous section are derived from the maximum range of the ADC value of the hardware ( $V_{lim}$ ). We designed the algorithm to periodically analyze the morphologic form of the ECG to maintain a constant amplitude of the QRS complex so that the algorithm can function continuously. Through the application of the AGC, the amplification rate of ECG signals was periodically adjusted so that

the *R*-peak is positioned at approximately 1000 ( $V_{lim} = -2048$  to  $2048$ ).

#### *HRV Analysis*

The HRV analysis methods can be divided into time and frequency domains. All of the HRV parameters presented in this paper were obtained by following the guidelines laid down by the Task Force of the ESC and NASPE. The intervals between the *R*-peaks (RRI) were derived from the detected *R*-peaks. The HRV parameters for the period were calculated directly from these original RR interval time series. They include the mean HR (mean of the heart rate, in bpm), SDNN (standard deviation of all NN intervals, in ms), and RMSSD (the square root of the mean of the sum of the squares of the differences between adjacent NN intervals, in ms).<sup>27</sup>

Subsequently, after resampling at 4 Hz *via* piecewise cubic Hermite interpolation, the HRV parameter for the frequency was calculated. Irregularly time-sampled signals should be produced as an even sample time series prior to spectrum estimation to prevent the generation of additional harmonic components in the spectrum.<sup>18</sup> While a standard rule of the RR interval resampling frequency is not defined, 4 Hz has generally been adopted in most HRV reports.<sup>22,23</sup> The resampling rate needs to be chosen according to the Nyquist criterion; thus, 4 Hz is acceptable for the case when the RR tachogram remains below 120 bpm (i.e., 2 Hz).<sup>4</sup> According to Singh *et al.*, “this is an appropriate resampling rate for the study of autonomic regulation, since it enables the computation of reliable spectral estimates between DC and 1 Hz, which represents the frequency band within which the autonomic nervous system has a significant response.”<sup>22</sup> The PSD results from the fast Fourier transform were divided by the frequency range. The LF and HF components were indicated as frequency ranges of 0.04–0.15 Hz, and 0.15–0.4 Hz, respectively. The sum of each component was normalized and indicated as norm LF and norm HF. The ratio of the normalized component was expressed as LF/HF.<sup>25</sup> The HF component mainly reflects the activity of the vagus nerve. Some investigators claim that the LF component indicates the quantitative activity of the sympathetic nerve while others argue that it reflects the activity of both the sympathetic and parasympathetic nerves. Regardless, the LF/HF ratio is commonly used as an index for the vagal balance, reflected according to the activity of sympathetic nerve.<sup>3,25</sup>

#### *Experiment 1: Evaluating the Performance of the R-Peak Detection*

To evaluate the efficacy of the algorithm at detecting peaks, 829 h of ECG data obtained from 41 subjects

(about 20 h per subject) were obtained. The subjects went about their day-to-day activities after attaching the ECG monitoring device developed in this study to their torso.

Researchers with at least four years of experience labeled the peak information of the ECG signals. Two or more researchers analyzed the data as a team to maintain caution and objectivity in the labeling of the peak annotation. We used an internally developed MATLAB-based software tool that features manual R-peak marking or correction functions for ECG analysis.

Using the indicators of sensitivity ( $Se$ ), the positive predictive value ( $PPV$ ), and error ( $Er$ ), the efficiency of the algorithm was statistically evaluated. These indicators were calculated by the methods defined by Eqs. (3)–(5).<sup>34</sup>

$$Se = \frac{TP}{TP + FN} \times 100 (\%) \quad (3)$$

$$PPV = \frac{TP}{TP + FP} \times 100 (\%) \quad (4)$$

$$Er = \frac{FP + FN}{TP + FN} \times 100 (\%) \quad (5)$$

$TP$ ,  $FP$ , and  $FN$  indicate the following situations ( $TP$ : detected peak is a valid  $R$ -peak,  $FP$ : detected peak is not a valid  $R$ -peak,  $FN$ : failure to detect an existing  $R$ -peak).  $Se$ ,  $PPV$ , and  $Er$  are statistical indexes used to evaluate the following performances ( $Se$ : detection of  $R$ -peaks from a valid ECG,  $PPV$ : differentiation of peaks that are  $R$ -peaks and those that are not  $R$ -peaks from a valid ECG,  $Er$ : accuracy of the algorithm).<sup>15</sup>

#### *Experiment 2: ECG Monitoring During Day-to-Day Activities*

We set out to compare and evaluate the ECG data obtained using both a commercial device and the newly developed device. For this comparison, we planned to validate the accuracy of the new ECG device when applied to day-to-day activities. Twelve adult males and females [average age 26.8 ( $\pm 3.1$ )] without any history of cardiovascular disorders enrolled in this study. Lying in bed, sitting on a chair, and walking were selected as day-to-day activities. After attaching an ECG monitoring patch to a subject's torso, the ECG was measured while he/she laid in bed for 10 min, sat on a chair for 10 min, and walked on a treadmill at a speed of 1, 3, and 5 km/h, respectively, for 5 min. The total ECG data duration was 35 min per subject.

To compare the data obtained with the developed device with that obtained with a conventional device, another ECG was obtained simultaneously using a data-acquisition system (MP150, BIOPAC System, Inc., USA) with a sampling rate of 1000 Hz. Commercial devices utilize Ag–AgCl electrodes to detect ECG signals in the Lead-II position. The electrodes are connected to the measuring devices using wires. Wires are attached to the body with tape to reduce the noise generated by movement. In a conventional Holter system, the Holter device is fixed to the waist, with the wires connected to the machine and the electrodes attached to the body with tape. We mimicked this wire/device array.

In addition to evaluating the quality of the signals according to the amount of noise, the estimated signal-to-noise ratios (SNRs) of the ECG signals obtained simultaneously from both the commercial and developed devices were compared. The details of the SNR estimation were conducted following procedures from literature.<sup>6,31</sup> This estimation methodology accounts for all sources of noise and interference that affect the signal quality, including electronic noise and motion artifacts.<sup>8</sup> The  $R$ -peak detection and SNR calculation were done using software (MATLAB R2014b, The Math Works, Inc., USA).

#### *Experiment 3: Stress Assessment Using HRV Parameters*

To verify the performance and practicality of the new device, we compared the HRV analysis results. This experiment was undertaken with 17 subjects [average age 27.8 ( $\pm 3.1$ )], obtaining the ECG from both a commercial device and the newly developed device in a mentally stressful situation. The test consisted of a resting state (5 min)—Stroop test (5 min)—mental arithmetic test (5 min) sequence. The Stroop test assesses color–word interference. Test participants are asked to respond with the name of a color that is different from the meaning of a colored word. In the mental arithmetic task, subjects were asked to repeatedly subtract 13 from 1079. Subjects were not allowed to use their fingers or pens, and were only allowed to perform the calculations in their heads.

ECG signals from both a commercial device and the newly developed device were measured simultaneously (i.e., concurrent data acquisition) for all mental stress states to prevent debate regarding confounding effects like learning. After obtaining the ECG from both devices, the HRV of the time and frequency domain was analyzed in a similar manner as described in the previous section (HRV analysis). The reliability of the new device was evaluated by comparing the results obtained with the two devices.

**TABLE 1. Performance evaluation of proposed RS-based peak-detection method.**

Record	Duration (hh:mm)	Number of beats			<i>Se</i> (%)	<i>PPV</i> (%)	<i>Er</i> (%)
		<i>TP</i>	<i>FP</i>	<i>FN</i>			
01	21:15	104434	0	1430	98.65	100.00	1.35
02	21:18	90943	29	559	99.39	99.97	0.64
03	20:18	91140	1	980	98.94	100.00	1.06
04	21:18	91681	7	1727	98.15	99.99	1.86
05	21:11	103308	6	913	99.12	99.99	0.88
06	21:15	96683	0	33	99.97	100.00	0.03
07	21:16	100495	2	587	99.42	100.00	0.58
08	11:09	35462	3	2048	94.54	99.99	5.47
09	21:04	83070	5	544	99.35	99.99	0.66
10	21:20	78796	0	77	99.90	100.00	0.10
11	21:15	90257	1	150	99.83	100.00	0.17
12	21:16	89732	0	26	99.97	100.00	0.03
13	21:17	98157	0	82	99.92	100.00	0.08
14	21:17	107640	2	447	99.59	100.00	0.42
15	19:00	81298	1	90	99.89	100.00	0.11
16	20:53	92921	0	184	99.80	100.00	0.20
17	21:19	90909	0	149	99.84	100.00	0.16
18	21:19	81901	2	17	99.98	100.00	0.02
19	20:49	91445	0	47	99.95	100.00	0.05
20	21:14	102752	0	230	99.78	100.00	0.22
21	21:19	89649	3	943	98.96	100.00	1.04
22	21:17	96444	0	18	99.98	100.00	0.02
23	21:19	93870	0	115	99.88	100.00	0.12
24	21:18	86049	3	16	99.98	100.00	0.02
25	21:19	75546	3	3485	95.59	100.00	4.41
26	20:54	89701	0	61	99.93	100.00	0.07
27	21:14	90903	1	100	99.89	100.00	0.11
28	21:17	82640	16	4503	94.83	99.98	5.19
29	21:18	102140	0	71	99.93	100.00	0.07
30	21:16	93663	2	145	99.85	100.00	0.16
31	21:18	89173	0	19	99.98	100.00	0.02
32	17:18	45682	0	3	99.99	100.00	0.01
33	21:17	94379	2	135	99.86	100.00	0.14
34	21:16	98500	2	342	99.65	100.00	0.35
35	21:19	87497	0	9	99.99	100.00	0.01
36	21:18	102595	1	284	99.72	100.00	0.28
37	16:55	65885	0	17	99.97	100.00	0.03
38	21:15	99498	2	1262	98.75	100.00	1.25
39	21:16	92162	0	199	99.78	100.00	0.22
40	20:45	69753	7	630	99.10	99.99	0.91
41	21:18	85688	21	3239	96.36	99.98	3.67
Total ( <i>TP</i> , <i>FP</i> , <i>FN</i> ) or average ( <i>Se</i> , <i>PPV</i> , <i>Er</i> )		3634451	122	25916	99.29	100.00	0.71

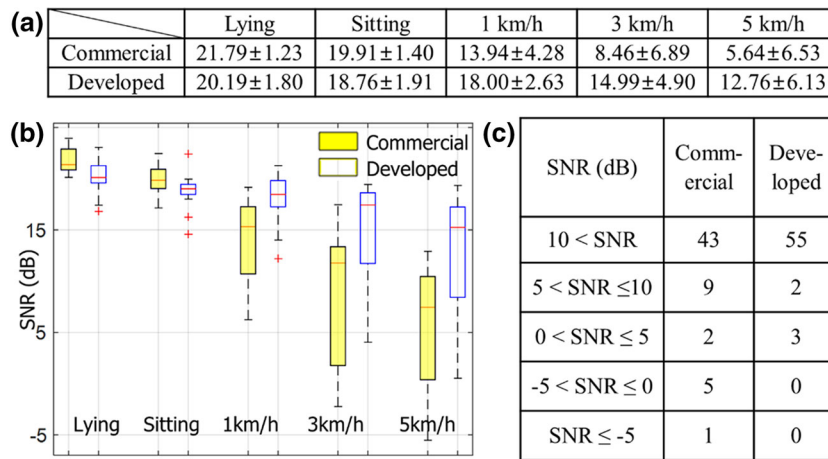
## RESULTS

We evaluated the performance of the peak-detecting algorithm using the ECG data obtained with the patch ECG monitoring system developed as part of this study (data are provided in Table 1). The algorithm shows the statistical results for  $Se = 99.29\%$ ,  $PPV = 100.00\%$ , and  $Er = 0.71\%$ , in comparison with the annotated work done manually by investigators on 829 h of ECG data. Additionally, the results of the other related algorithms cited in literature are summarized in Table 2 and compared to our results.

We measured the ECG using a conventional device and our device, in conditions representing day-to-day activities (i.e., lying position, sitting position, and walking at 1, 3, and 5 km/h). A total of 120 sets of ECG data were obtained (60 from the conventional device, 60 from our device). The quality of the signals was assessed according to the amount of noise estimated by the SNR methods. Figure 4(a) shows a comparison of the mean SNR estimation of our device to a conventional device for experiment 2. The values of the SNR analysis for the two data sets show similar results for small-movement conditions such as lying

**TABLE 2. Performance summary of other related works**

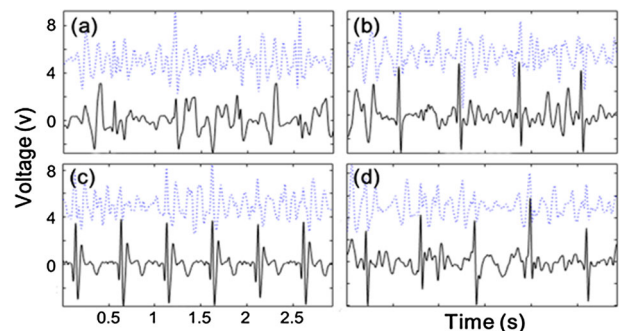
Total beats	TP	FP	FN	Se (%)	PPV (%)	Er (%)	Reference
(a) Performance comparison of algorithms tested by open source database (MITDB)							
109494	109401	91	93	99.92	99.92	0.17	33
109494	109398	103	96	99.91	99.91	0.18	24
108494	108323	97	171	99.84	99.91	0.25	34
109494	109241	393	253	99.77	99.64	0.59	1
116137	115860	507	277	99.76	99.56	0.68	19
(b) Performance comparison of algorithms tested by their own developed device							
27012	27001	40	11	99.96	99.85	0.19	26
7426	7253	138	173	97.67	98.13	4.19	11
67143	65116	1455	2027	96.98	97.81	5.19	1
7576	7103	37	473	93.76	99.48	6.73	1
(c) Performance results of algorithm for our developed device							
3660367	3634451	122	25916	99.29	100.00	0.71	–



**FIGURE 4. Comparison of SNR between commercial and developed devices under conditions representing daily activities: (a) mean data, (b) box-plot comparison, (c) frequency distribution table.**

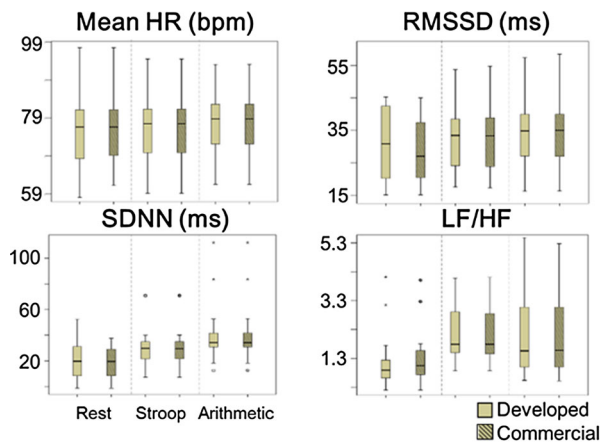
and sitting. However, for a walking speed of 1 km/h or more, a considerable amount of noise arose. Thus, there is a significant difference between the SNRs of the results obtained with the two devices. Our device, which is superior in terms of signal quality, shows a high SNR. Figure 4(b) and 4(c) are a box-plot comparison of the SNRs and a frequency distribution table of the SNRs, respectively. Among these, the 5 km/h data for subjects 4, 6, 10, and 12 were compared and shown in Fig. 5.

Figure 6 compares an HRV analysis of the ECG signals as obtained with the conventional and newly developed device for the subjects undertaking experiment 3 (mental stress). When an individual is anxious or excited, the sympathetic nervous system is activated, increasing the LF value among the HRV indexes. Moreover, when an individual is angry, concerned, or afraid, the parasympathetic nerve system is deactivated, leading to a decrease in the HF value.<sup>3,28</sup> Therefore, our identification of the increased LF/HF ratio in stressed subjects is consistent with the general



**FIGURE 5. Examples of ECG signals recorded using a commercial device (blue dotted line) and the developed device (black line): 5 km/h data for (a) subject 4, (b) subject 6, (c) subject 10, (d) subject 12.**

physiological principles of autonomous nervous system imbalance. We found that, for subjects placed in stressful situations such as taking the Stroop test or a mental arithmetic test, the LF/HF ratio, which reflects the balance state of the ANS, increased significantly. Also, when differences in the HRV analysis results



**FIGURE 6. Comparison of HRV parameters under stressful conditions.**

obtained with the conventional and newly developed device were plotted as a box plot, equivalent results were obtained, confirming the measuring accuracy of the new device. Statistically, using linear regression to compare the results from both devices, the regression value was over 0.99 for every HRV parameter. This signifies that the measured results are identical in the two devices.

## DISCUSSION

In this study, we suggested a new system for measuring ECG, using a patch with minimized electrode arrays as an alternative to a conventional portable ECG measuring system in order to improve portability, wear comfort, and accuracy of measurement when the subject is moving.

In general, when evaluating the performance of an algorithm, open source data such as the MIT-BIH database are used to objectively evaluate its performance and relatively.<sup>16,19</sup> However, in this study, the algorithm we developed was based on the AGC and the indigenous threshold of the maximum amplitude that can be expressed on the developed hardware. Thus, this algorithm is optimized to process only data obtained with the newly developed device.

The results of the ECG measurements and peak detection tests performed as the subjects performed their day-to-day lives showed an acceptable level of performance, given a sufficient number of subjects. However, there are some limitations. The algorithm adopted for this study can analyze only the data acquired from our hardware. Although we summarize the performance comparison in Table 2, it was impossible to make an objective comparison with other algorithms that differ in their experimental circumstances.

The method in which we obtained an ECG using a commercial device is similar to the common use of the conventional Holter device. We connected the leads and the device with wires and anchored the wires to the body of the subject with tape. However, even with the wires firmly fixed, the ECG signal quality was often disturbed as the wires moved depending on the subject's body movements as he or she walked or performed other actions. According to one study, the ratio of motion peaks to normal peaks was estimated as being about 10% when the ECG was taken from a freely moving patient using the Holter system. For this reason, the ECGs obtained using Holters were limited, and algorithms used to eliminate noise from the data have been actively developed.<sup>29</sup> As important as it is to detect and exclude generated noise from the analysis, it is even more important to reduce the occurrence of noise itself.

We evaluated cardiac activities using the developed device and a conventional device under conditions that represent day-to-day activities and analyzed the SNRs of both ECGs to evaluate the amount of noise generation in the two devices. In circumstances involving little action, reasonable SNR estimation values were observed for both devices. When we increased the motion of the subjects, we found that the new device was relatively less affected by motion noise. It is obvious that the movement of the wire connecting the leads and the device add to the presence of noise in the conventional equipment. Generally, devices used to acquire ECG data during day-to-day activities are susceptible to diverse noise such as power noise, respiratory noise, and muscle noise.

From the results, we expect our device to be capable of obtaining more stable and simpler ECG measurements for day-to-day activities, including those with moderate amounts of movement, e.g., walking at 5 km/h. This improvement results from efforts to minimize noise artifacts from both the software pre-processing the signals and the hardware, which was achieved by incorporating the wires connecting the leads to the device into the integral patch. Therefore, we anticipate that the new device will be useful for ECG monitoring during real-life activities while still being able to measure stable and credible waves.

Moreover, we analyzed the activities of ANS while the subject was subjected to a stressful situation in order to examine the performance and practicality of the device designed in this study. The HRV parameters were significantly different between normal and stressful conditions. This was clearly distinguishable using the new device.

There is currently an increased demand for HRV analysis in a wide range of user environments. Therefore, technology using a patch electrode and a mea-



suring module to measure ECG is very well suited to application as a health monitoring system. Specifically, the target market for the developed device will likely be those related to sleep, chronic disease, or any applications that have a need for long-term ECG monitoring. Also, tests related to the adoption of Bluetooth low energy wireless communication are being undertaken to keep pace with the convergence of the Internet of Things and mobile health. The developed device has already been granted Korea Food & Drug Administration certification and will be granted CE and FDA 510(k) in the future.

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