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Doctor's Degree Thesis

A Study of Wearable Heart Monitoring and Analysis System

Graduate School of Chosun University

Department of IT Fusion Technology

Jaehyo Jung

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웨어러블 심장 모니터링 및 분석 시스템 개발

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Jaehyo Jung

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Advisor: Prof. Youn Tae Kim

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Department of IT Fusion Technology

Jaehyo Jung

This is to certify that the Doctor's Thesis of
Jaehyo Jung

has been approved by the Examining Committee for the thesis requirement for the Doctor's degree in IT Fusion Technology.

Committee Chairperson
Prof. Sung Bum Pan _____ (Sign)

Committee Member
Dr. Myung-Ae Chung _____ (Sign)

Committee Member
Prof. Tai Won Um _____ (Sign)

Committee Member
Prof. Hyun-Sik Choi _____ (Sign)

Committee Member
Prof. Youn Tae Kim _____ (Sign)

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Acronyms

CNT	Carbon nanotube
ECG	Electrocardiogram
EMG	Electromyogram
PDMS	Polydimethylsiloxane
AMI	Acute Myocardial Infarction
PHD	Personal Health Device
SQL	Structured Query Language
ECG	Electrocardiography
POCT	Point-Of-Care Testing
DIM	Domain Information Model
SM	Service Model

요 약

웨어러블 심장 모니터링 및 분석 시스템 개발

정재효
지도교수: 김윤태 교수, Ph. D.
조선대학교 대학원 IT융합학과

본 연구에서는 심장 근육 상태를 실시간 모니터링하고 데이터를 지속적으로 수집하여 질병의 조기 진단이 가능한 휴대용 전기화학 분석기와 무선 심전도 측정 시스템을 개발하였다. 블루투스 통신을 통해 PC 또는 태블릿으로 데이터를 전송할 수 있는 휴대용 3 working 전극 전기 화학 분석기를 개발하였으며, 분석기의 성능과 신뢰성을 확인하기 위해 인듐 주석 산화 기반 패턴화 된 전극을 사용하여 혈액의 농도에 따른 전하 및 전류의 변화 실험을 수행하였다. 또한, 본 시스템은 ISO/IEEE 11073 프로토콜을 기반으로 구성되었으며, 측정된 데이터는 블루투스 모듈과 어플리케이션을 사용하여 실시간 모니터링 및 확인이 가능하다.

이와 더불어 심장의 전기적 신호를 실시간으로 측정하기 위해 무선 통신이 적용된 ECG 시스템을 개발하였다. 이를 위해 탄소나노튜브 및 접착성 폴리 디메틸실록산이 혼합된 건식 자가 부착형 전극을 개발하였다. 기존의 습식타입 전극은 장기간의 심전도 및 근전도 등의 생체 신호 취득 시 전도성 젤이 건조되어 신호 왜곡과 성능 저하를 일으키고, 피부 발진 문제를 야기할 수 있다. 개발된 건식 자가 부착형 전극은 표피와 전극 표면 사이에 진공 상태를 유지시켜 접착제 없이 피부에 접착 할 수 있으며 피부 자극, 가려움, 생체 신호의 검출 손실 없이 장기간 생체 신호를 기록할 수 있었다. 또한, 상용화된 Ag/AgCl 전극과 비교하여 ECG 및 EMG 신호는 약 94% 신호 유사도의 성능을 보였다. 기존의 심전도 측정 시스템은 신호 측정을 위해 물리적 전선이 필요하기 때문에 측정 중 활동에 제한을 받고 잡음을 발생시키는 문제점이 있다. 개발된 시계형

무선 심전도 측정 시스템은 BLE 통신을 사용하여 메인과 서브 모듈 간의 전위차 값을 동기화함으로써 무선 측정이 가능하다. 상용화된 유선 심전도 시스템과 비교하여 73.95%의 신호 유사도를 얻을 수 있었다.

본 연구를 통해 개발된 전기화학 분석기와 심전도 측정 시스템은 심장질환 관련 만성 질환 환자의 건강상태를 실시간으로 제공함으로써 생존율에 크게 기여할 수 있을 것으로 기대한다.

I. Introduction

1.1 Background

1.1.1 Introduction of healthcare systems

Healthcare is a medical service that allows users to diagnose, prevent, treat, and follow up disease anytime, anywhere. As ICT technology develops, wearable devices of various sizes and shapes are being developed. As the interest in health has increased recently, the medical environment is also shifting from medical care to preventive care. Also, there is an increasing population to manage their lifestyle and health.

The wearable healthcare system has been developed as a mobile healthcare service using smartphones and wearable devices through the ubiquitous telemedicine platform in the early 2000s. With the miniaturization of the hardware, the weight reduction, and the variety of functions, the wearable healthcare industry market has been formed which can be worn on the body.

According to statistics released by Allied Market Research, the market size of the global digital healthcare industry is estimated at $ 96 billion in 2016, with an annual average growth rate of 21.1% and an estimated 206 billion dollars in 2020. Transparency Market Research estimated that the global smart health care products market will grow from $ 31.7 billion in 2016 to $ 57.8 billion in 2013 and 8.84% CAGR(Compound Annual Growth Rate) from 2015 to 2023 [1].

1.1.2 The need for a heart monitoring system

The smart healthcare industry has been attracting attention as an alternative to fast-paced aging, a rapidly growing medical demand for patients and health care expenditures. In particular, people with heart disease can die (sudden death) within an hour of sudden cardiac outbreaks without prior

warning. Myocardial infarction is caused by the bursting of impurities that have stuck to the inside of narrowed blood vessels. When the impurities inside the blood vessels are blown, the components inside the blood vessel wall are exposed to the blood components and cause a clotting reaction and make a blood clot. This thrombus interferes with blood flow and completely blocks blood circulation. This myocardial infarction may occur suddenly, even to people who had no common heart disease or received standard ECG, electrocardiogram, results during health diagnosis.

ECG is a graphical representation of the electrical signals that occur during cardiac activity and is a crucial indicator of the diagnosis and health status of heart disease. Heart disease, such as arrhythmia, is a cause of stroke and acute heart attack, so prevention and diagnosis are important, and continuous monitoring of ECG should be possible to detect abnormalities.

This paper has developed a wearable heart monitoring device capable of measuring and analyzing myocardial infarction and ECG. When the proposed cardiac monitoring healthcare device is activated, it is expected that personalized medical services will be available through continuous monitoring of health conditions.

1.2 Objectives

This paper consists of three chapters. Chapter 1 describes the necessity and purpose of this paper.

In Chapter 2, a wearable monitoring system for acute myocardial infarction was developed and analyzed. Outline of acute myocardial infarction, the design of acute myocardial infarction monitoring system, amperometric device and ITO glass sensor were developed, and the results were analyzed. A smartphone application and client software based on the IEEE 11073 communication protocol was also presented.

In Chapter 3, a wearable ECG monitoring system was developed and analyzed. The material and fabrication of the CNT / aPDMS capable of ECG

measurement were described and analyzed in comparison with the commercially available Ag / AgCl electrode. Also, a wireless communication system capable of ECG monitoring and a noise canceling filter have been developed and described.

II. Wearable AMI Monitoring System

2.1 Introduction

Modern medical services are rapidly transformed from a hospital-based system requiring personal visit by patients to Ubiquitous Healthcare (U-Healthcare) system using telemedicine. U-Healthcare enables patients to access relevant medical services in order to diagnose, treat, and prevent diseases regardless of the time or their location by utilizing sensors and smart devices. The accessibility and usability of U-Healthcare service have increased with the advancement and convergence of medical information and technologies. In the pursuit of a healthier life, there has been growing interest in and demand for U-Healthcare services [2]. The use of high-performance smartphones has become widespread worldwide and, consequently, numerous proposals related to mobile healthcare services have recently been made in the literature [3-5]. Mobile healthcare consists of technology of digital communication over cellular networks. With regard to chronic diseases, U-Healthcare systems are required to provide status monitoring and effective treatment options to mitigate and even resolve emergencies. The widespread availability of smartphones renders these devices such as POCT suitable for implementing U-Healthcare systems. Patients with multiple chronic diseases may require additional emergency measures to prevent sudden and unexpected fatalities during emergencies. For this reason, real-time monitoring and well-timed treatment are essential for patients. Acute myocardial infarction (AMI) is among the most critical diseases worldwide [6, 7], and requires treatment within an hour from its onset in order to provide the patient with a reasonable chance of survival. Real-time monitoring and diagnostic systems are significantly more critical for AMI than for other chronic diseases, such as obesity, diabetes, and high blood pressure. In general, diagnosing AMI requires two to three days of hospitalization [8], which is problematic if a sudden

attack occurs, and patients spend a considerable amount of money to get their health status checked using expensive and large-scale medical instrument in hospitals. Although most AMI patients receive proper treatment, many encounter significant difficulties afterwards, such as aftereffects as well as living in constant fear of unpredictable heart failure. However, the AMI detection device developed in this study can detect AMI in any location up to 12min after the event. Persistent care and early treatment are vital components of AMI management, hence rendering patients with smartphones suitable candidates for the implementation of U-Healthcare. In this study, we design and develop a ubiquitous monitoring and management system for AMI. This system provides AMI disease management services regardless of the time or place for patients. We propose a Personal Health Device (PHD) based on the ISO/IEEE 11073 standard protocol suited to AMI. Using the PHD agent and PHD management methods, a patient's AMI symptoms can be remotely monitored by medical personnel and proper medical treatment can be provided. If a patient requires emergency treatment, his/her location can be determined using the Global Positioning System (GPS) sensor of their smartphone in order to promptly transfer them to a hospital for further observation.

2.2 Design of AMI monitoring systems

2.2.1 Acute myocardial infarction (AMI)

The human heart is supplied with oxygen and nutrients from three coronary arteries. If any one of these arteries is blocked, oxygen and nutrient supply to part or all of the cardiac muscle cells can be interrupted, causing these cells to die. This is known as AMI, or a heart attack. The most common cause of the blockage of the coronary artery is the accumulation of degenerative material (atheroma), such as cholesterol and fat, in the artery wall. When this material dislodges, a portion of the interior arterial wall is

damaged, and a blood clot is formed at that location. The blood clot may completely block blood flow. AMI may be the cause when a patient experiences chest pain for more than 30-min cardiac enzymes are more than twice their normal range, or an electrocardiogram (ECG) reading indicates myocardial injury pattern in the STsegment and T-wave abnormality, or a new Q-wave. At least two of the above symptoms are required for AMI to be declared [9]. AMI has a high mortality rate worldwide [10]. Moreover, it is well-known that mortality rate because of AMI increases dramatically if timely treatment is not provided. The most important factor in treating AMI is the prompt stabilization of blood flow in the coronary artery. Treatment must be initiated within 2 to 3h of the onset of AMI [11]. In case of an onset, the most critical factor delaying a hospital visit is the time taken by the patient to realize the cause of their symptoms [12]. AMI detection device that can detect and analyze the symptoms of AMI and transmit a patient's medical status to medical personnel can automatically alleviate the problem. The convergence of information technology (IT) and medical technology facilitates medical diagnosis service using biomarkers. Common biomarker devices are blood pressure monitors, body thermometers, and blood sugar level monitors. With the aid of biomarker devices, treatmentfocused medical systems have transitioned to preventative medicine by detecting and monitoring patients' physiological information. Efficient and inexpensive blood sampling biomarker devices have been developed for AMI diagnosis. ECG pattern analysis and cardiac marker detection in blood samples are typical methods for an effective AMI detection and treatment scheme. Cardiac muscle movements generate electrical signals that can be detected by a set of pads applied to the patient's skin. The signal pattern can be carefully analyzed by a cardiovascular specialist to detect evidence of AMI. An ECG device requires 12 to 15 electrodes, which are attached to the patient's body, is generally less accurate than AMI detection using cardiac markers. Any physical movement by the patient, such as fi dgeting, talking, or shivering, may distort test results. For these reasons, ECG is not suitable for a U-Healthcare system. Furthermore, it cannot be used for

early diagnosis of AMI [13]

2.2.2 AMI detection device

In this study, developed a point-of-care testing (POCT) device using a microneedle [14], a flow-through-hole (FTH) thin multilayer film, a 3D electrochemical immune biosensor [15], and highly sensitive signal processing circuitry. The wristwatch-shaped AMI detection device is easy to operate and requires pushing a button once to complete AMI biomarker analysis. The bio-chemical and electronic layers of the sensor module are located in the body of the unit. Signal processor and radio frequency (RF) modules are located in its top cover. For multiple readouts, three individual test modules are supplied in the system. Hence, three AMI tests can be performed with a single patch. The dimensions of the device are 60mm×47mm×23mm. A patient wishing to test their AMI biomarkers opens the cover of the device and pushes one of three test buttons for approximately 10 s. Upon the onset of an AMI, four types of proteins will be found in the blood stream and are identified as cardiac markers. These are troponin I, troponin T, CK-MB, and myoglobin. A blood sample is extracted using a single hollow microneedle. The sample is then passed over the FTH thin multilayer film for pre-filtering. The filtered serum is processed by a reduction-oxidation operation on electrodes to detect the cardiac markers. The marker data is interpreted as electrical current on electrodes and passed to the main board through a flexible printed circuit (FPC) cable. The CPU is PSoC5 of Cypress, and Bluetooth is HBG2X3N of Chipsen. Lithium polymer battery (401235-120mAh), which continuously keeps the device active for 2h 40min, is used in AMI detection device and can be recharged via micro 5-pin for smartphone charger. In this case, this device can be operated three times a day for five days. Figure 2.1(b) shows a prototype of the test module with the microneedle. The microneedle (2000μm long, with an internal hole diameter of 60μm, an external diameter of 120μm,

and a tip angle of 15°) and a vacuum polydimethylsiloxane (PDMS) chamber are utilized to extract blood with a single push, a single step for operation. The module is 7mm long and 7mm wide. When it is pressed with a finger, the needle penetrates the patient's skin and approximately 20μl of blood is extracted through an internal vacuum effect. The pressed state must be maintained for 10s [14]. The electrochemical immune biosensor can detect four types of cardiac markers. The constant rate of serum flow is possible to facilitate the efficient reaction of the blood sample on the electrode channel for the optimization by the sensors. The cardiac markers in the blood are detectedbya chemical reaction with specific antibodies coated onto the electrodes. The current is filtered and amplified for further processing. The entire process is significantly faster and more accurate than ECG analysis.

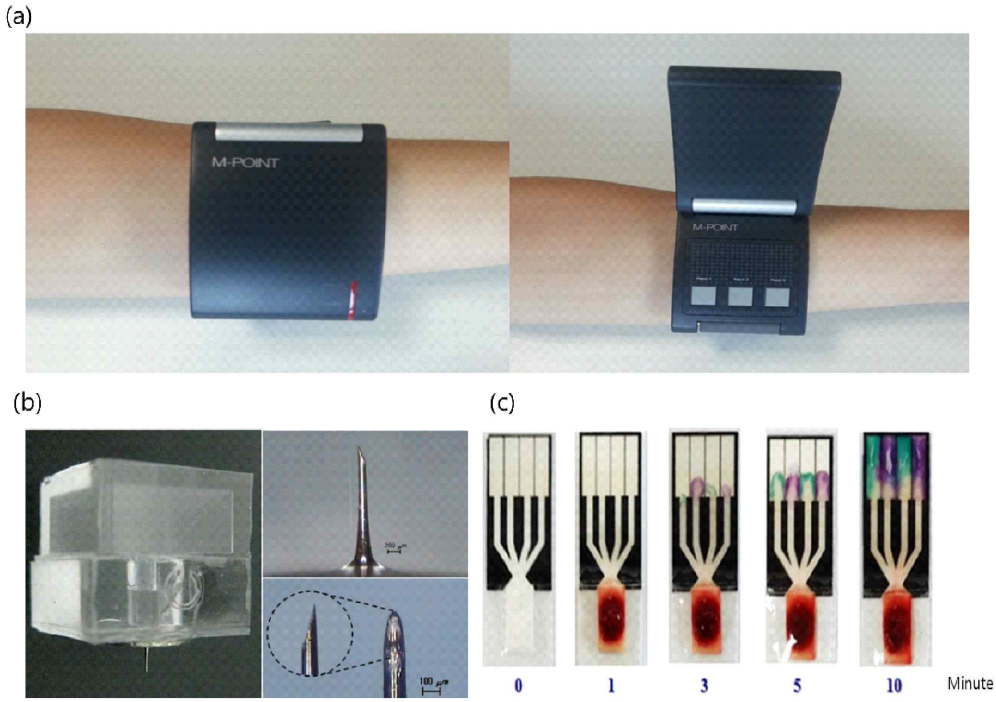


Figure 2.1. Wearable AMI detection device. (a) AMI detection device worn on the wrist. (b) Blood sampling using hollow microneedle. (c) Electrochemical immune biosensor.

2.2.3 ISO/IEEE 11073

The ISO/IEEE 11073 PHD protocol is a standard for the transmission format of a health profile. It defines data exchange sequences and methods between telemedicine (Agent) and managing (Manager) devices. The ISO/IEEE 11073-20601 protocol aims to optimize communication and minimize the data size transferred between an agent and a manager. The ISO/IEEE 11073-104xx protocol includes an interoperable communication format used to communicate between agent and manager using Wi-Fi, Bluetooth, ZigBee, or a Universal Serial Bus (USB) [16, 17]. Moreover, it defines communication standards for medical devices, such as thermometers, weight scales, blood pressure meters, electrocardiography, and several other personal health devices. In this research, we used a logical point-to-point communication channel between the agent and the manager. An agent device communicates to only one manager. A manager can communicate with a number of agents [18]. As shown in Figure 2.2(a), the structure of the ISO/IEEE 11073 PHD standard model is composed of three sub-models: a Domain Information Model (DIM), a Service Model (SM), and a Communication Model (CM). The DIM is composed of several subclasses specified by the type of health device [19]. Each subclass of the DIM further consists of one or more classes. The classes represent the measured data and the function of the personal health device. Subclasses are identified by their nomenclature code defined in the ISO/IEEE 11073-10101 specification. The SM defines data access methods between the PHD and the manager. Data access based on the SM must comply with the format defined by the DIM. Service commands for accessing data include Event Report, Get, Set, and Action. The CM provides that it is data communication network protocol between the PHD and the manager. To provide interoperability with various devices, the DIM model supports data coding specification [20–22]. Figure 2.2(b) shows a model for the message exchange sequence between the PHD agent and the PHD manager [20–22]. Rapid analysis of data transferred

from wearable AMI detection devices to a smartphone can be achieved by complying with ISO/IEEE 11073 PHD protocols. The data transfer process is carried out in the following four phases:

i) Association phase

In this step, the agent sends an association request message to establish a session with the manager. The message includes necessary information, such as the system ID or the configuration ID. The manager analyzes the request message andverifies the composition of the agent, such as the communication method and procedure. If the manager approves the component, it sends an 'accept' message to the agent. Otherwise, the manager responds with an 'accepted-unknown-config' message to refuse the connection.

ii) Configuration phase

In this phase, the agent transmits the required information, including measurement results, transmission methods, sequences, and data types, to the manager. If the message is confirmed, the manager stores the relevant organization's information in the user's smartphone and immediately sends an 'accept' response. Otherwise, the manager sends an 'accept-unknown-config' message to refuse the session.

iii) Operation phase

A user 's measured data and diagnostic information is sent to the manager by the agent either regularly or on demand. The manager must validate the agent by sending a 'Get-function' message. The information obtained by the diagnostic instrument is sent at the request of the manager. Once the agent is verified by the manager, the agent transmits the measured data to the manager.

iv) Release phase

In this phase, data communication between the agent and the manager is

no longer required. The release phase session is performed to terminate communication. The request and response configuration information between the two actors is released. The agent sends an 'Association Release Request' message to terminate the current session. The manager responds with an 'Association Release Response' message to terminate the session.

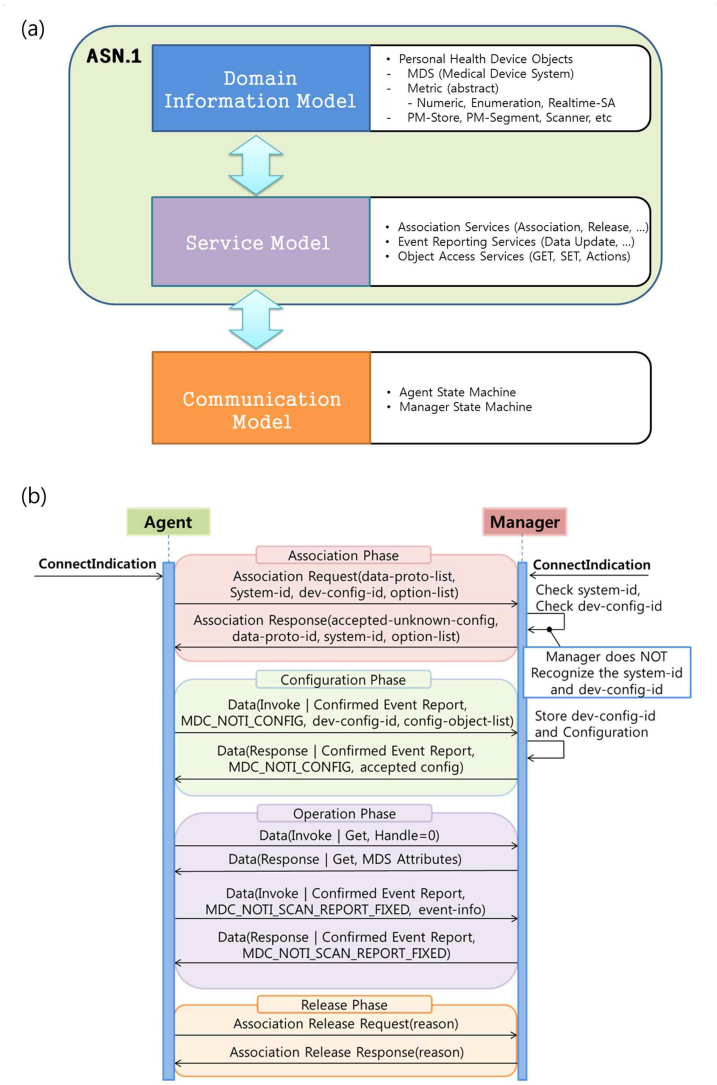
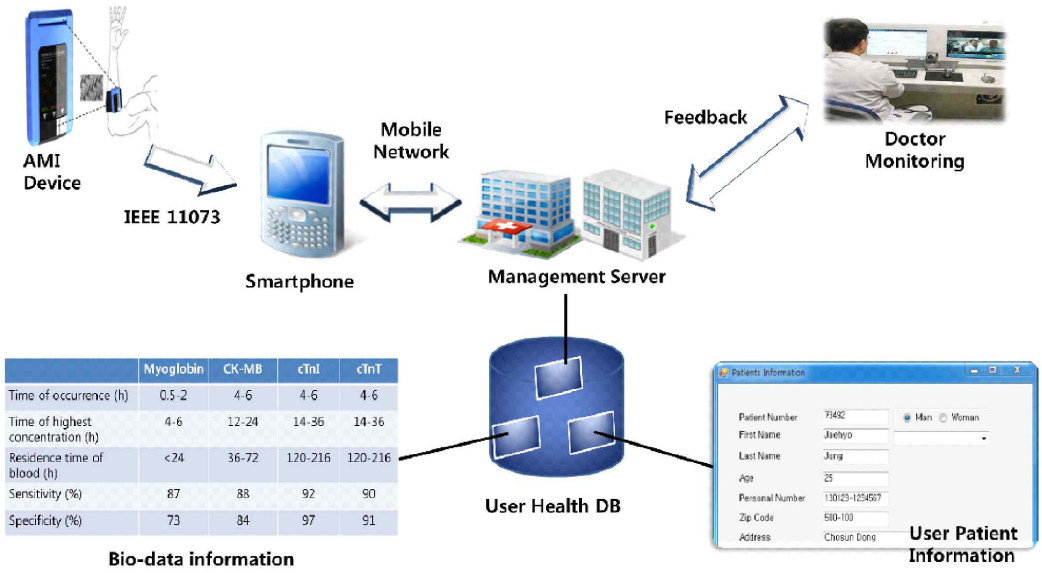


Figure 2.2. ISO/IEEE 11073 PHD standard communication protocol. (a) ISO/IEEE 11073 PHD standard model structure. (b) Communication procedure.

2.3 System Configuration

Figure 2.3 shows the network structure of our proposed AMI U-Healthcare system. We apply the following technologies in the AMI detection system: (i) A microneedle for blood sample extraction [23], (ii) a flow-through hole layer and a microfluidic layer to separate serum in the blood sample, (iii) three-dimensional (3D) bio-electrical sensors to detect AMI cardiac markers (cardiac troponin T (cTnT) and I (cTnI), creatine kinase MB (CK-MB) isoenzyme, and myoglobin), and (iv) signal processing circuits [24, 25]. A smartphone is an ideal device for U-Healthcare communication for the following reasons: (i) Most people tend to keep their smartphone within an accessible distance; (ii) one can use smartphones to communicate practically anywhere, and (iii) smartphones are sufficiently powerful to perform a number of complex tasks. We designed an Android-based application to control our AMI detection device and collect AMI cardiac marker data. This application enables a patient, or a hospital that needs a patient's medical information, to review their personal information, AMI prognostic information, and information regarding the relevant medical personnel. The patient's cardiac marker data, along with their personal information and diagnostic history, are stored on a server. The data is accessed by medical personnel using a client software [26]. The application transmits the patient's cardiac marker data to a hospital server over third-generation (3G) or Wi-Fi infrastructure [27]. The AMI Detection Device is equipped with three sets of replaceable cardiac marker detection sensors [25, 28]. Cardiac marker data measured by these sensors can be transferred to a server at any scheduled time. Medical personnel can access marker data through a web application using Structured Query Language (SQL). Upon receipt and review of the patient's cardiac marker data (cTnT, cTnI, CK-MB, and myoglobin), diagnostic procedures can be carried out to determine the patient's medical condition. This technology allows medical personnel to monitor a patient's state in real-time and without hospitalization

[29, 30].



	Myoglobin	CK-MB	cTnI	cTnT
Time of occurrence (h)	0.5-2	4-6	4-6	4-6
Time of highest concentration (h)	4-6	12-24	14-36	14-36
Residence time of blood (h)	<24	36-72	120-216	120-216
Sensitivity (%)	87	88	92	90
Specificity (%)	73	84	97	91

Figure 2.3. Network structure of our proposed AMI U-Healthcare system.

2.4 Methods

2.4.1 Design of amperometric analyzer

AMI detection device includes amperometric analyzer. This developed a portable three-electrode electrochemical analyzer that measures the current generated using an electrochemical sensor based on amperometry and wirelessly communicates the result via Bluetooth. This electrochemical analyzer was developed by our research, its size and weight was declined from 22.5% and 30% than commercial reference systems, respectively. Furthermore, the proposed analyzer was designed such that the potential and measurement time can be set through a convenient interface, which is used to save and display the results graphically, as well as numerically. Because the PSoC MCU,

CY8C5888, supports programmable analog functions, the functions can be actively changed or developed based on their usage, without changing the circuits. The MCU and Bluetooth modules both consume low power, and exhibit high performance. The system has no difficulty operating with a low-capacity battery (120 mAh) that can be replaced with a battery of a higher capacity.

Figure 2.4 shows the printed circuit board (PCB) configuration of the proposed analyzer. It comprises a data processor that includes a microcontroller unit (MCU), along with analog processing, power, and communication parts. To accurately measure the microcurrent generated by an electrochemical reaction, a universal subscriber identity module (USIM) connector, a connector that is connected to a piece of ITO glass ,is placed near the components used for analog processing. The use of the shortest possible distance for the circuit line minimizes the inflow of external noise. Because noise from the digital processing significantly affects analog processing, we alleviated the interference between the analog and digital components by dividing the power and ground layer in the PCB, as shown in Figure 2.4(b). This structure provides a stable output signal in the tests. The electrochemical experiment uses a low potential and current; thus, very low noise has a negative impact on the result.

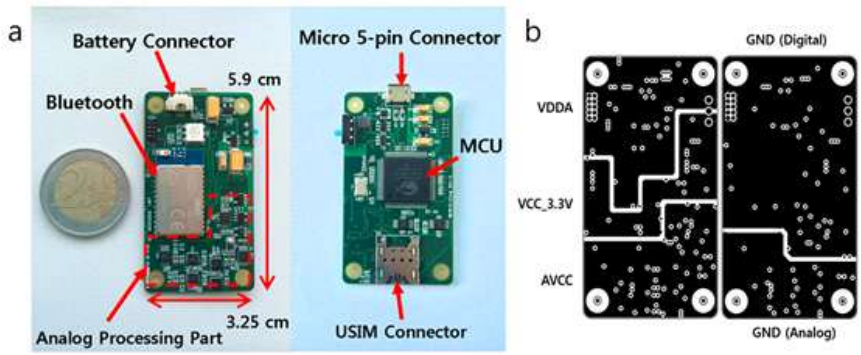


Figure 2.4. (a) PCB of miniaturized amperometric analyzer; (b) Scheme of the ground and power layer.

This division enables the accurate detection of a signal without effects from each part. In this study, we used a 3.7 V, 120 mAh lithium polymer battery for performing operations for 2 h 40 min, including data processing and Bluetooth communication. This enabled the analyzer to be operated 60 times when the measurement time was set at 50 s. The battery can be recharged through a micro 5-pin USB cable. To transmit the data processed by the MCU, a Bluetooth 4.0 module (WT-12, Bluegiga, Espoo, Finland) was used. The CY8C5888-LP based on the Cortex-M3 (Cypress, San Jose CA, USA) was used as the MCU, exhibiting a high performance and low power consumption. The CY8C5888-LP is a programmable system-on-chip (PSoC) series, the use of which made it possible to generate an analog block in the MCU via programming. This enables 12-bit digital-to-analog conversion (DAC) in the MCU and easy editing of the device functions. The PCB occupies an area of 3.25 × 5.9 cm^2. Table 2.1 shows the performance of the proposed system.

Table 2.1. System specification

	Specification
Electrode	ITO glass (CE: Ag, RE: Ag/AgCl)
Technique	Chronoamperometry, Chronocoulometry
Channel	1 - 4 ch
Potential range	0 - 2.1V
Potential step	10 mV
Sampling interval	10 - 1000 msec
Sampling count	100 - 3000
Current resolution	0.4 nA
Power supply	Li-polyer 120mAh
Display	PC, Tablet PC

The power source of the analyzer supplies power to various functions including Bluetooth, the digital part, and the analog part, as shown in Figure 2.5(a). The analog part consists of a potentiostat, including the counter, reference, and working circuits, an active filter, and a 16-bit analog-to-digital converter (ADC). An OPA2376 (Texas Instruments, Dallas, TX, USA) op-amp is used for the reference, counter, and active filter circuits. An OPA381 (Texas Instruments), a high-resolution current-to-voltage (I/V) converter is used for the working circuit. When a potential is applied to a solution, the reference circuit stabilizes the output voltage of the counter circuit using a feedback loop.

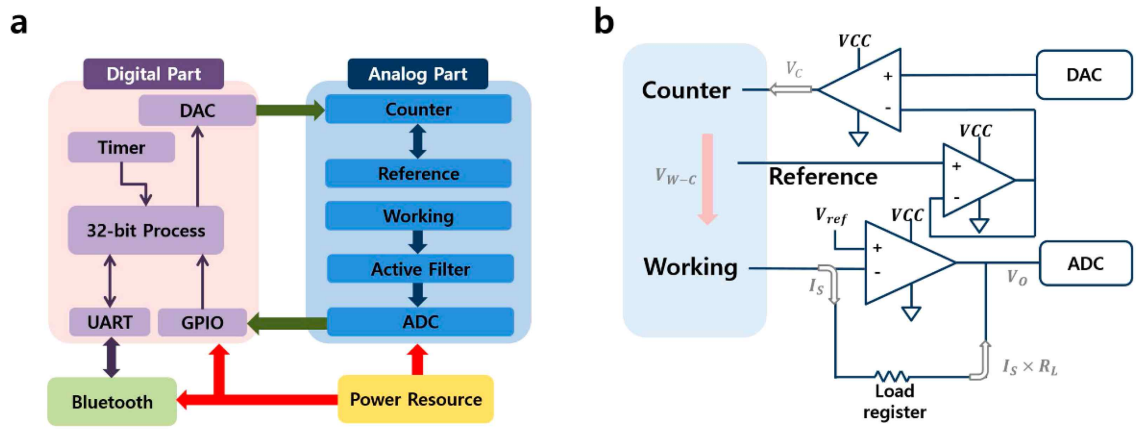


Figure 2.5. (a) Device block diagram (b) Configuration of sensing part

The electrochemical signal from the analog part is converted into a digital value via the ADC and is then transmitted to the MCU. The data is processed into packets for wireless communication. Figure 2.5(b) shows the current flow generated by the redox reaction. Vref, which is the basis for the working voltage V_W, has a value of 1.2 V, and V_C is controlled by the DAC. Potential VP is the differential voltage between the working and the counter electrodes ($V_P = V_W - V_C$), and R_S is the solution or sample resistance. The electrochemical reaction of the solution represented by the potential produces IS, which is equal to $V_P \div R_S$, based on Ohm's law. This current flows in the load register R_L, which has a value of 1 MΩ, and is then converted to the load voltage $V_L = I_S \times R_L$.

Finally, a readable voltage V_O is produced by the sum of VW and VL before being input to the ADC. We performed an experiment with a sample resistance of 10 MΩ and a potential of 500 mV to assess the performance of the analyzer. The values of V_W and V_L were 1200 and 50 mV, respectively, indicating that a current of 1 nA is equivalent to a potential of 1 mV.

The proposed analyzer device adopts Bluetooth communication. A manager device such as a PC, smartphone, or tablet PC connected using Bluetooth provides the analyzer with settings for the potential, maximum number of

samples, and sampling interval. Electrochemical analysis starts immediately after the setting information established by the manager is transferred and continues for the entire runtime, which is the count number multiplied by the interval. When the operation is completed, the result data are transmitted to the manager, where it can be represented graphically and stored in a text file format.

2.4.2 System operation flow

The data process between the analyzer and the manager is shown in Figure 2.6. When the Bluetooth pairing between the analyzer and the manager is successful, the analyzer is ready to activate the analysis and start the timer. When the analyzer receives information regarding the requirements for a run, it starts analyzing the solution during the allocated time. All the results are converted into packets for Bluetooth communication after the completion of the measurement. The packets are numbered and transmitted to the manager in a numerical order through the Bluetooth module. Typically, when a packet arrives at the manager, the manager sends the analyzer an acknowledgement message (ACK) as per the sequence. When the analyzer receives an ACK, the next packet is transferred. Using these steps, when the last packet is transmitted, the entire operation is completed after the manager sends a termination message to the analyzer.

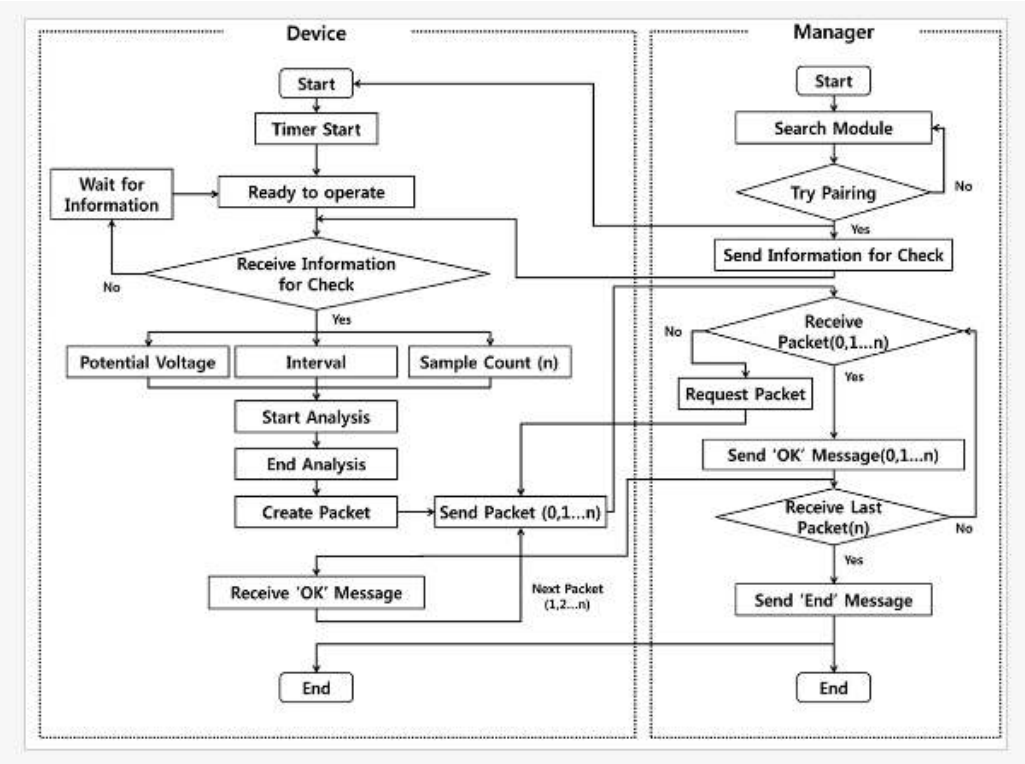


Figure 2.6. System operation flow via Bluetooth communication.

2.4.3 ITO glass sensor

In this study, an electrochemical electrodes sensor manufactured by micropatterned ITO glass was used for signal analysis. This sensor consisted of working, reference, and counter electrodes. The reference and counter electrodes treated with silver (Ag) and silver-silver chloride (Ag/AgCl) paste, respectively, in order to optimize the detection of an electrochemical signal. The use of ITO glass for electrochemical electrodes offers numerous advantages, such as a wide potential window, low capacitive currents, and highly practical fabrication of electrodes [31].

The Pattern of an ITO sensor fabricated using the same specifications as those of the USIM connector is shown in Figure 2.7. In this study, the unmarked electrodes were not used, and the wire-connected sensor was

disconnected in the test because the remainder of the ITO electrode could adversely influence results. The unnecessary area of the face was blocked except for the electrode face that is in direct contact with the solution.

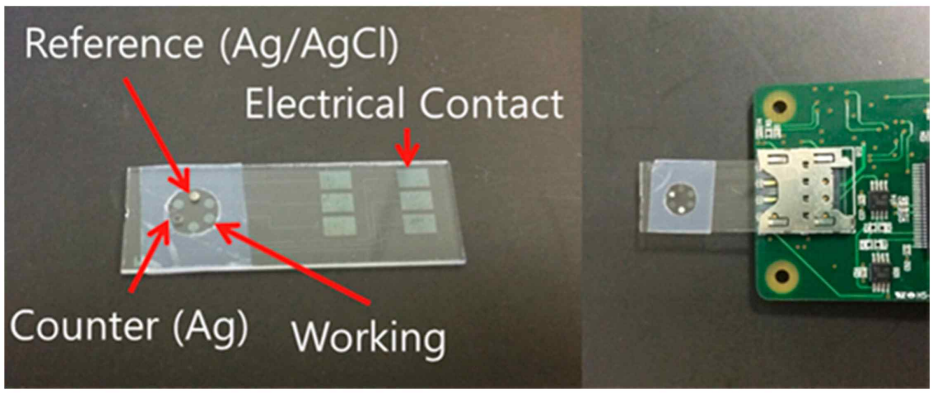


Figure 2.7. Patterned electrodes fabricated using indium tin oxide (ITO) glass.

2.4.4 Experimental results

This established settings for the experiment after connecting the Bluetooth dongle to a PC and enabling the pairing with the analyzer. Each experiment used 10 μL of the solution, at the ITO sensor. The experiment was performed at a potential of 0.2 V with a measurement time of 50 s. The measurement result was displayed in terms of the current and an integrated charge with respect to time.

For performance verification, we compared the proposed analyzer with CHI-1040C using the following solutions: 1 mM, 10 mM, and 100 mM of Ruthenium (III) chloride (Ru^{III}) in 10 mM phosphate-buffered saline (PBS) at 7.4 pH. Figure 2.8 shows the graphs of the research results. The results of experiments with the proposed analyzer and CHI-1040C are presented for various solution concentrations to confirm the redox reaction. Although the resulting data sets have slight discrepancies between them, we could still identify a linear increase of the signal by increasing the concentration tenfold.

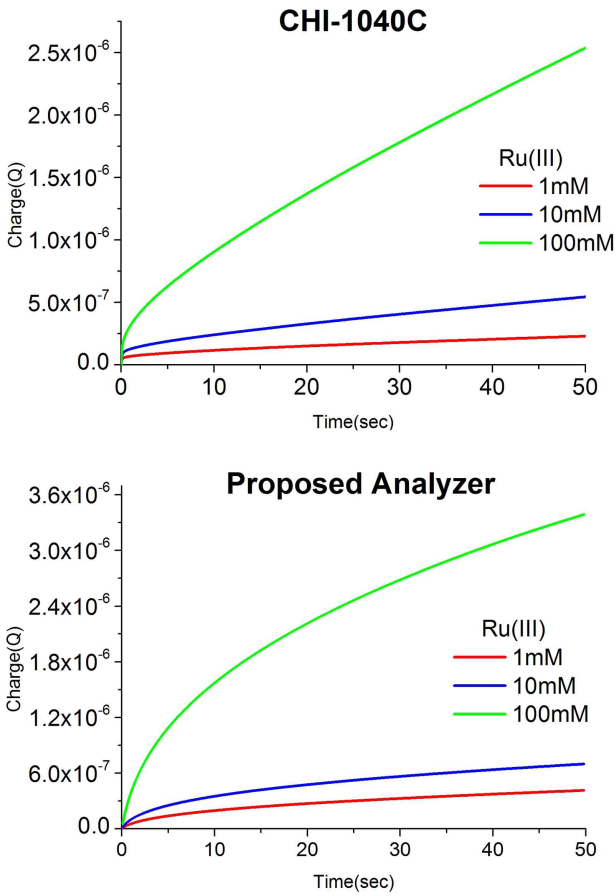


Figure 2.8. Charge variation with proposed analyzer and CHI-1040C.

Figure 2.9(a) shows the measurement results for 10 mM of Ru^{III} in an environment identical to the previous one and displayed using a tablet PC. This experiment is operated by application program. When the test is finished, the results are saved in the form of a text file, as shown in Figure 2.9(b). Here, the voltage values are digitized by ADC. This data is converted to a current value, which can be displayed using a PC, through a simple modification, as shown in Figure 2.9(c), after being saved to a web server via mobile communication (Wifi, 3G, or 4G). In this study, a Samsung tablet (SHW-M500W, Seoul, Korea) equipped with a Bluetooth 4.0 module is used

and an application was developed based on an Android 4.1 (Jelly Bean) and web server was configured by APMSETUP 7 for Win-32. The PC program was developed using Visual Studio 2010, C# based on Windows 7 32-bit.

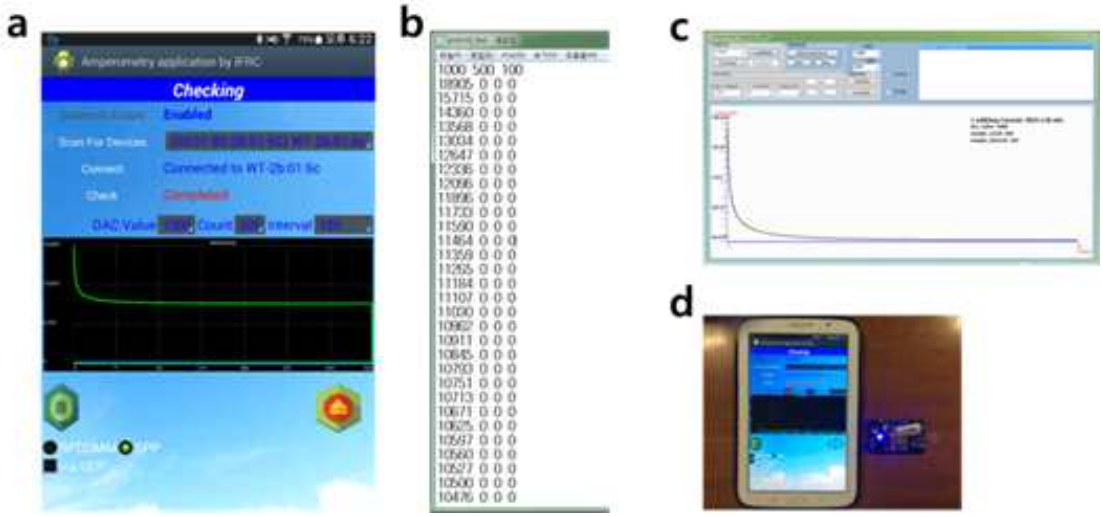


Figure 2.9. (a) Results for 1 mM Ru^{III} shown on smart tablet (b) Result data in text file format (c) Graph of the current in PC program (d) Smart table used in experiment.

This have developed an accurate and an inexpensive electrochemical analyzer based on amperometry. The proposed analyzer can communicate with various other devices through Bluetooth communication and has an intuitive interface that is user-friendly. However, the capacity of packet storage in the MCU can be exceeded by an increase in the sample amount. Real-time processing communication, wherein a packet of processing data is transmitted to terminal immediately, without waiting construction of whole packet, is appropriate to alleviate this situation. Therefore, it is necessary to synchronize the data-processing rate and the Bluetooth communication rate, when data is transmitted immediately after generating each packet. If both rates are different, the system will operate abnormally or stop. To solve this problem,

an additional study is needed about the synchronization of processing and Bluetooth transmitting rates. From the results of this research, we expect a faster data process, as well as low battery consumption by reduction of operating time from analysis to termination of communication.

In the main study, the developed analyzer is operated on the basis of Bluetooth communication. Bluetooth communication based on version 4.0 takes approximately 45 ms to transmit a data packet and receive a confirmation response at a baud rate of 115,200 bps. The amount of time spent in transmitting all of the data increases as the number of samples increases. If an abnormal packet is sent to the analyzer during communication, measurement is interrupted. To prevent the cessation of all operations in the event of lost or damaged packets during the communication process, the analyzer was designed to retransfer these packets from the device to the manager using a stop-and-wait protocol. We secured the operational stability of the proposed analyzer using this design. Subsequently, it was possible to apply the proposed analyzer to the ISO/IEEE 11073 standard protocol because the WT-12 attached to the PCB supports a personal health device (PHD) with Bluetooth 4.0. By developing a wireless healthcare based on the researched analyzer with the application of this protocol, we expect to achieve enhance data transmission efficiency and compatibility with other communication devices [32].

An ITO glass sensor with the pattern shown in Figure 2.7 was used to measure a single signal. An optimal signal was detected in a processing experiment with identical settings for the distances of the counter, reference, and working electrodes. However, additional research is required to change the magnitude of the electrode and the pattern to eliminate the oxygen-bubble phenomenon. This can be caused by a redox reaction, depending on multichannel signal detection, and the solution or experimental circumstances [33,34]. Research on the development of an electrochemical immunosensor that can detect specific biomarkers by applying an antibody fixation technology to ITO is currently underway [35]. Such a sensor is expected to be applied to a new field of POCT, as well as U-healthcare. This application will enable the

diagnosis of diseases, such as through the use of cardiac markers, by combining this type of sensor with the analyzer developed in this study.

2.5 Protocol and Software

2.5.1 Proposed AMI detection communication protocol

The communication protocol proposed in this paper between the portable medical device (agent) and its relevant management system (manager) is based on the ISO/IEEE 11073 standard. The PHD agent is on the AMI detection device and the PHD manager is on a personal smartphone. The PHD agent transmits the cardiac marker data and any operational error messages to the PHD manager using the ISO/IEEE 11073 message container. The PHD manager separates the cardiac marker data from the received message and controls the PHD agent's operation. The internal structure of the PHD agent (AMI detection device) is shown in Figure 2.10(a). In this figure, the Fluid Mechanical Processor is composed of microneedle (that extract blood), mechanical filters (that separate fluids), and microfluidic channels (that transfer fluids to the sensor). The bio-chemical sensor consists of four sub-sensors, one for each cardiac marker. A Session Handler maintains the communication session between the PHD agent and the PHD manager. A Message Handler formalizes the data to meet the protocol requirement and transmits data to the smartphone through the Bluetooth Module. A personal identification number (PIN) and link key were used for identification purposes by the smartphone connected to AMI device, which fulfills certification requirements of security services (certification, confidentiality, and permission). In the MCU module, the molarity of the cardiac markers is converted into electrical data and digitized, and then, these data are transferred to the smartphone using the Bluetooth Module. It is uncomfortable to use near field communication (NFC) for smartphones because the transmission distance is much shorter than Bluetooth,

which can transmit data within a range of approximately 10m [36]. Low-power Bluetooth (1.5-2mW) decreases the power consumption of the device compared with WiFi [37, 38]. Figure 2.10(b) shows the architecture of the smartphone application. The PHD manager receives the patient's data from the Bluetooth Module [39]. The Session Handler maintains the communication session and the Message Handler decodes the data. The application software provides the diagnosis schedule and management operation based on the physician's prescription. It sends the patient's data to the hospital server through a 3G or a Wi-Fi communication network. The DIM for the AMI detection device is shown in Table 2.2. Communication between the agent and the manager is based on the IEEE 11073-20601 protocol. The ISO/IEEE 11073 Medical Device System includes an essential set of objects that can be used by medical personnel to read a patient's medical status. Troponin is a protein secreted in the blood stream during myocardial necrosis [40]. Troponin I and T are frequently monitored cardiac markers to diagnose AMI. In our study, we selected two additional cardiac markers (CK-MB and myoglobin) to diagnose AMI. The four cardiac markers are defined as required objects in the DIM. Device status information (sensor status and patch alarm) and patient information (age, blood type, temperature, and blood pressure) are defined as enumeration objects.

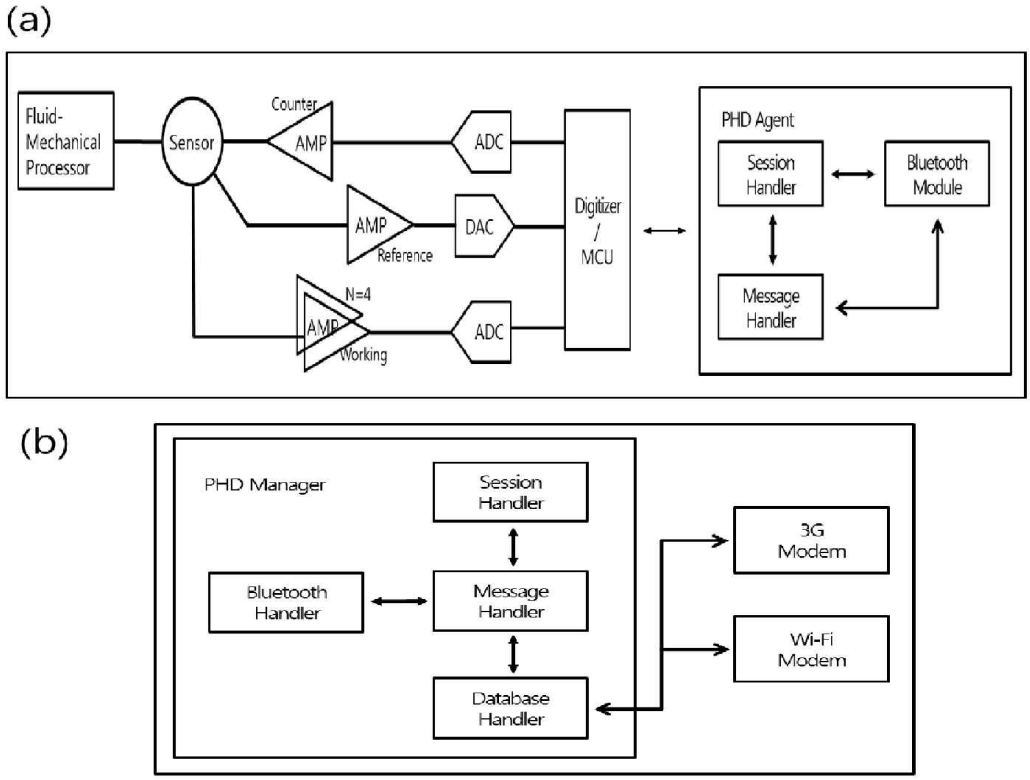


Figure 2.10. (a) Architecture of AMI detection device. (b) Architecture of smartphone.

Table 2.2. Domain information model

MDS		Acute myocardial infarction diagnostic device
Numeric	Troponin I	Molar concentration
	Troponin T	Molar concentration
	CK-MB	Molar concentration
	Myoglobin	Molar concentration
	Number of patch	Remaining number of unused patches
	Age	Patient's age
	Temperature	Patient's body temperature
	Blood groups	Patient's blood type
	Blood pressure	Patient's blood pressure
Enumeration	State of device	Current state of device
	State of sensors	Current state of sensors
	Schedule	Verification of diagnosis schedule
	Alarm	Notification of abnormal test results
PM-store	Observations	Temporary storage of all MDS objects

The data are stored in Persistent Metric (PM)-store when the data cannot be transferred to the master for some reason (for example: battery is died, internet connectivity is lost. Etc.). Hence, the data measured from the AMI device can be transferred to a smartphone safely when the battery is discharged and the devices is out of Bluetooth range between agent and manager. The data is transferred to the master when the communication channel becomes available. So, data can be saved and transferred without data loss. Table II lists the Master Data Services (MDS) attribute table of the AMI detection device. The attributes of each object are built to ISO/IEEE 1107320601 specification. From blood collection to the transmission of the analyzed data to the hospital server, an agent takes approximately 14min to detect AMI. For accurate measurement of the time taken to detect AMI, the medical staff requires a Date-Time-Info field. The objects of the AMI diagnosis protocol consist of the four cardiac markers, device conditions (state of the device and sensor, alarm, test schedule, and the number of patches), and patient information (age, blood group, temperature, and blood pressure). These objects are transferred to the manager's smartphone under the communication model for the ISO/IEEE 11073 PHD specification. Cardiac marker data transferred from the agent to the manager is stored in an array of PM-store objects following conversion to observation objects [41].

Table 2.3. AMI detection device MDS attribute

Attribute name	Qualifiers
Handle	Mandatory
System type	Conditional
System model	Mandatory
System ID	Mandatory
Dev-Configuration-id	Mandatory
Attribute-Value-Map	Conditional
Production-Specification	Optional
Mds-Time-Info	Conditional
Date-Time-Info	Conditional
Relative-Time	Conditional
Hires-Relative-Time	Conditional
Date-and-Time-Adjustment	Conditional
Power-Satus	Optional
Battery-Level	Optional
Remaining-Battery-Time	Optional
Reg-Cert-Data-List	Optional
System-Type-Spec-List	Mandatory
Confirm-Timeout	Optional

2.5.2 Smartphone application

For our field test, we used an SHV-E210 (Samsung, Android 4.0) as the PHD manager's device. A smartphone application transferred the cardiac marker data to a hospital server over 3G or Wi-Fi communication channels. Sample screenshots of the application are shown in Figure 2.11. The software is launched by clicking the AMI Monitoring System icon. Familiar login fields and four function icons (Medical Records, Medical Results, Medical Schedule, and Options) are shown on the initial screen. When a user clicks the Medical Resultsicon, their latest test results and a profile are displayed. By selecting the Options icon, the user can modify or update their personal information. On the Medical Result screen, a patient can review their test result history, which

is copied by the AMI detection device and transferred to the hospital server. A patient can also read medical prescriptions and opinions, based on their data, provided to them by medical personnel. Moreover, the patient can view their data in a graphical format. With a programmable scheduling capability, the patient can take tests regularly. An alarm bell alerts the patient of a scheduled test time. Cardiac marker data are transmitted through Bluetooth communication channels; the Bluetooth connection and device setting parameters must be configured through the parameter setting option. A manager connects to the server through the Internet Protocol (IP) address and port number of the hospital, which cannot be edited by patients [42, 43]. The hospital server or medical personnel information can also be registered or modified using the configuration option. If medical personnel presume or decide an emergency diagnosis, the patient's geographic allocation at the time can be identified using the GPS sensor in their smartphone. In such emergencies, the patient may connect to his/her primary care facility by clicking the Hospital Connection icon on the Location Information screen.

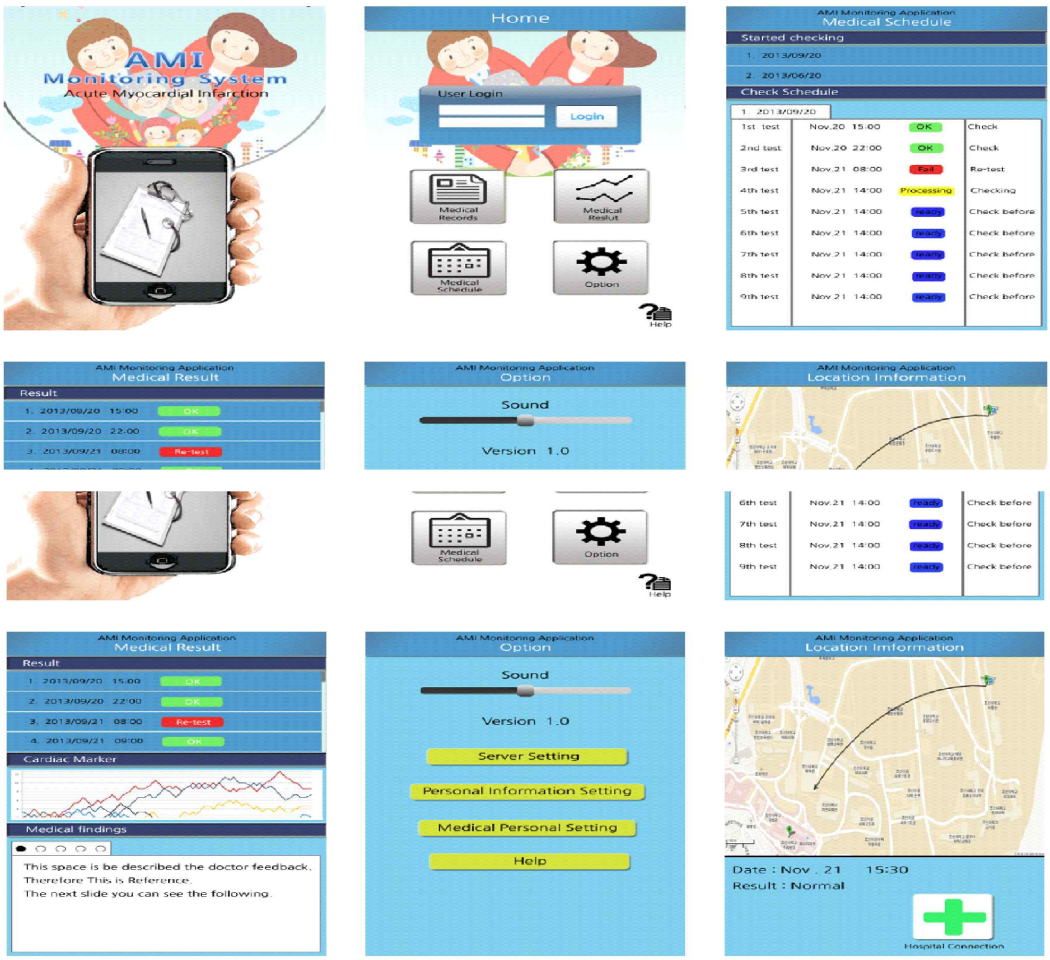


Figure 2.11. Smartphone application program UI.

2.5.3 Client software

Figure 2.12 shows the interface of our client application for physicians. After data concerning molar concentration of AMI cardiac markers (cTnT, cTnI, CK-MB, and myoglobin) in the patient's blood is transferred from their smartphone to the hospital server, then a physicianevaluates his/her biosensor data to provide the relevant medical services. The physician accesses the patient's medical data and biosensor data sent from their smartphone by connecting to the server. The client application can mainly perform four

functions. A listing function allows the physician to review patients' clinical information, medical records, and administrative status. A registering function allows a physician to add a new patient's profile to the system. Following registration, medical personnel can assign test schedules for each cardiac marker detection sensor in the AMI detection device. Patients are grouped into two lists: one is a list of serviced patients, and the other is that of patients waiting for service. The first group of patients does not have any outstanding test data, whereas the second group has at least one set of test data to be reviewed by medical personnel. The AMI detection device, equipped with three sets of sensors, can diagnose a patient three times a day, and can even perform additional diagnoses if the sensors are replaced by sensor kits. The diagnosis and treatment function enables medical personnel to review a patient's real-time AMI status based on test data received from the agent device. Medical personnel can provide a medical opinion or prescription based on the patient's medical history and past test data, as well as their latest test data. Through this function, medical personnel can convey effective medical opinions and treatment to the patient. The alarm function allows a physician to raise an alarm event when an incoming patient's cardiac marker data exceeds a threshold value. Medical personnel can then quickly provide emergency services to the patient.

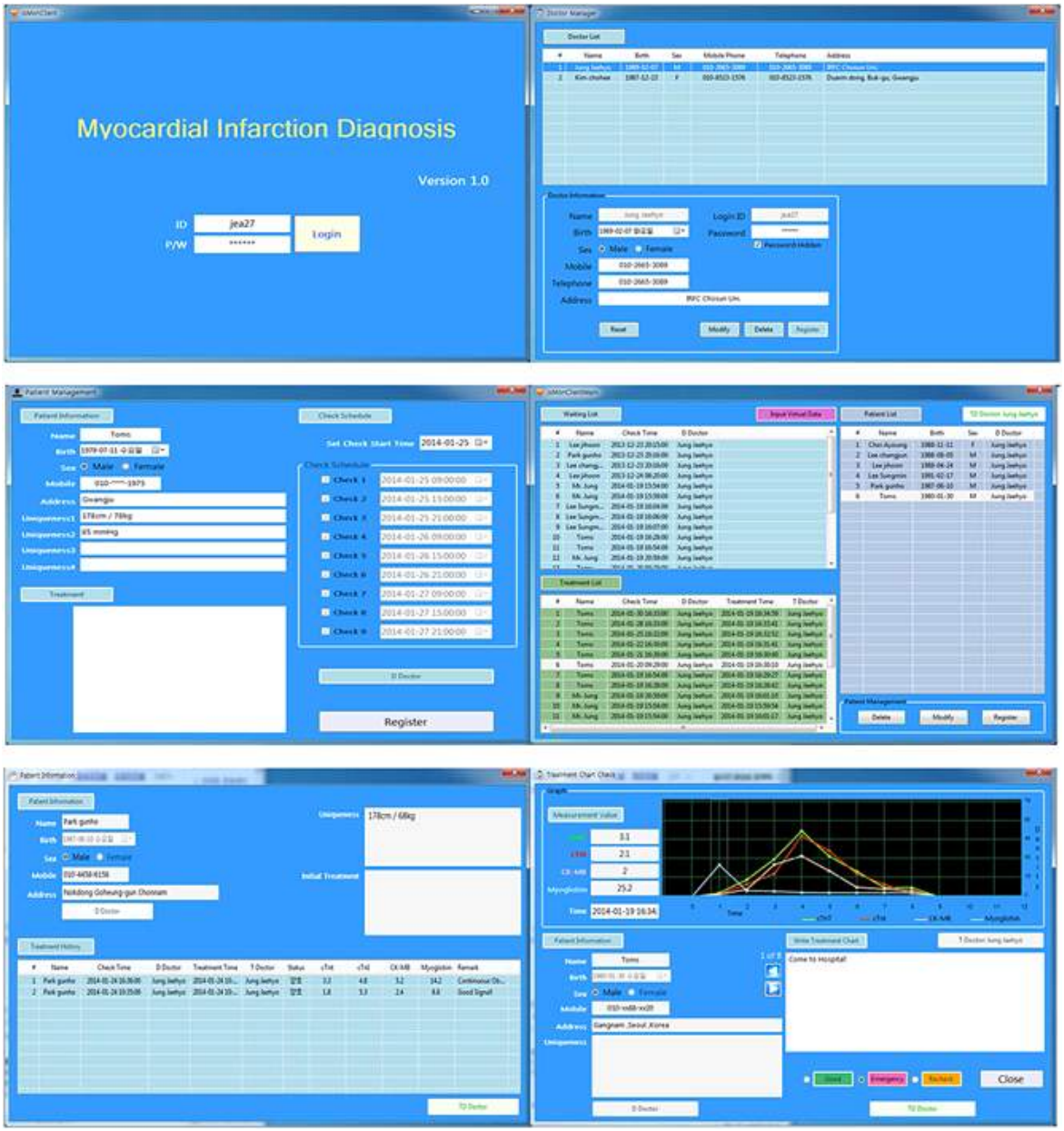


Figure 2.12. Client (practitioner) application program UI.

2.6 Results and Discussions

2.6.1 ISO/IEEE 11073 exchange message

Figure 2.13 shows a data exchange sequence between a PHD agent and a manager. In this sequence, the PHD agent sends a connection request message to the PHD manager. The manager reviews the message and sends back a connection response message to complete the connection. If they are connected, the manager stores the configuration ID of the agent. The manager then verifies the configuration ID to identify whether this is the first connection for the relevant device, or if the device is already registered. If the agent is connected with manager for the first time, the diagnostic equipment must be registered according to the ISO/IEEE 11073-20601 configuration procedure [27, 28]. Following this, the PHD agent transmits the cardiac marker data with the corresponding timestamp in an event report message to the PHD manager [41]. Finally, the PHD agent sends a disconnect request message to the PHD manager and receives a response message to terminate the session. By verifying the message exchange sequence log, we can ensure that messages are exchanged according to the ISO/IEEE 11073 PHD protocol.

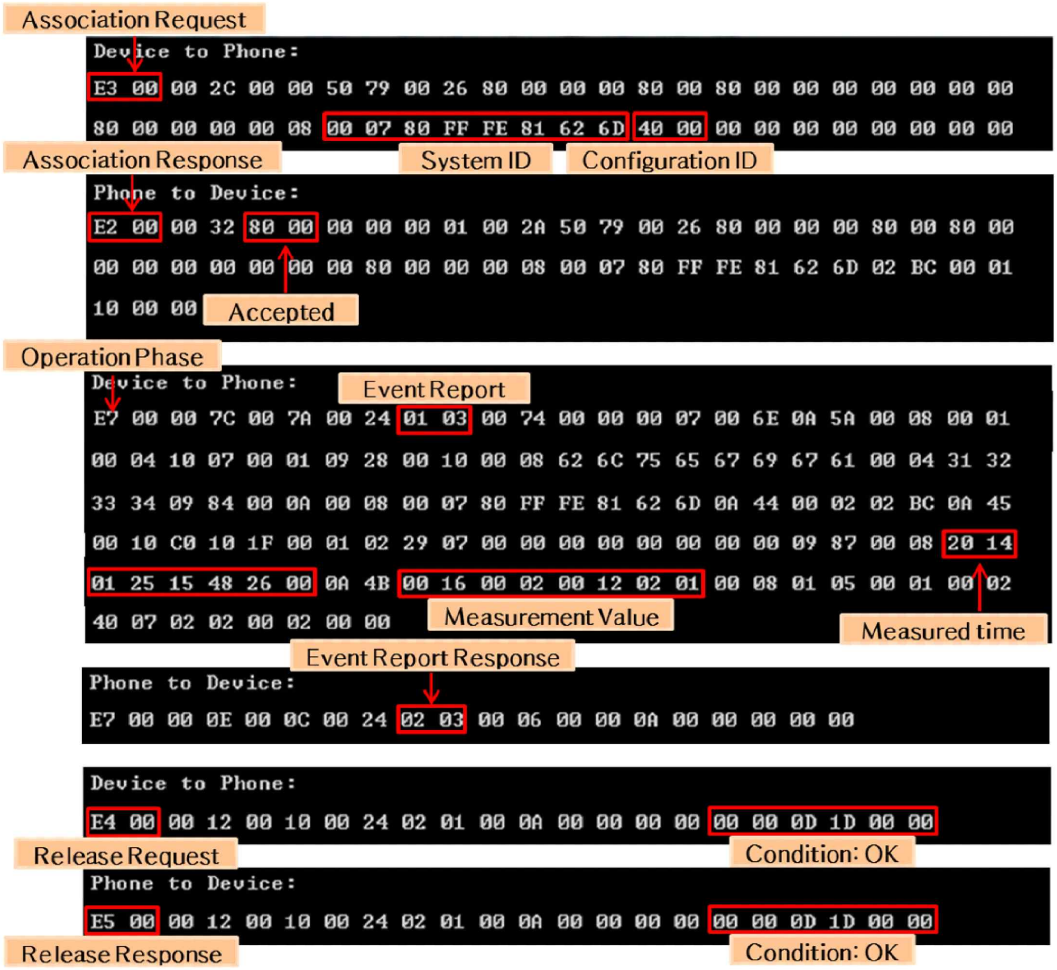


Figure 2.13. ISO/IEEE 11073 messages exchanged between PHD agent and PHD manager.

2.6.2. Experiment

Figure 2.14(a) represents the redox results of the ChronoAmperometry (CA) method, using serum containing Troponin I and the CHI 1040C 3-electrode potentiostat (made by CH Instruments, Austin, TX, USA). Before the test, the potential voltage sample for the electrochemical reaction was con firmed as 0.3V by the cyclic voltammetry (CV) method. We dropped 20μl of

sample serum 20μl on the chemical sensor, and waited 10min for incubation. A potential difference of 0.3V was applied to the electrodes between the working and reference electrode via CHI 1040C, and an experiment was conducted for200s. With this experiment, weconfirmed that the average current at the end of an oxidation-reduction reaction was 235nA. Figure 2.14(b) shows the performance experiment for the AMI detection device. We carried out the experiments using the same conditions for the sample, potential difference, incubation, and measurement time. For the AMI detection device, 220nA is the margin of error of approximately 6%, compared with the results of the CHI 1040C. To obtain a CA result for the reactions, the AMI detection device computes the number of cardiac markers contained in a solution using a firmware-based conversion formula, and transmits the result to the smartphone. The AMI device that detects damaged heart muscle is used three times a day for three days, and its results are stored in and transferred to the hospital server via WiFi or 4G mobile communications. To help physicians easily confirm the measured data, data stored in the server is displayed in the Client Program, which indicates the number of cardiac markers through graph and figures.

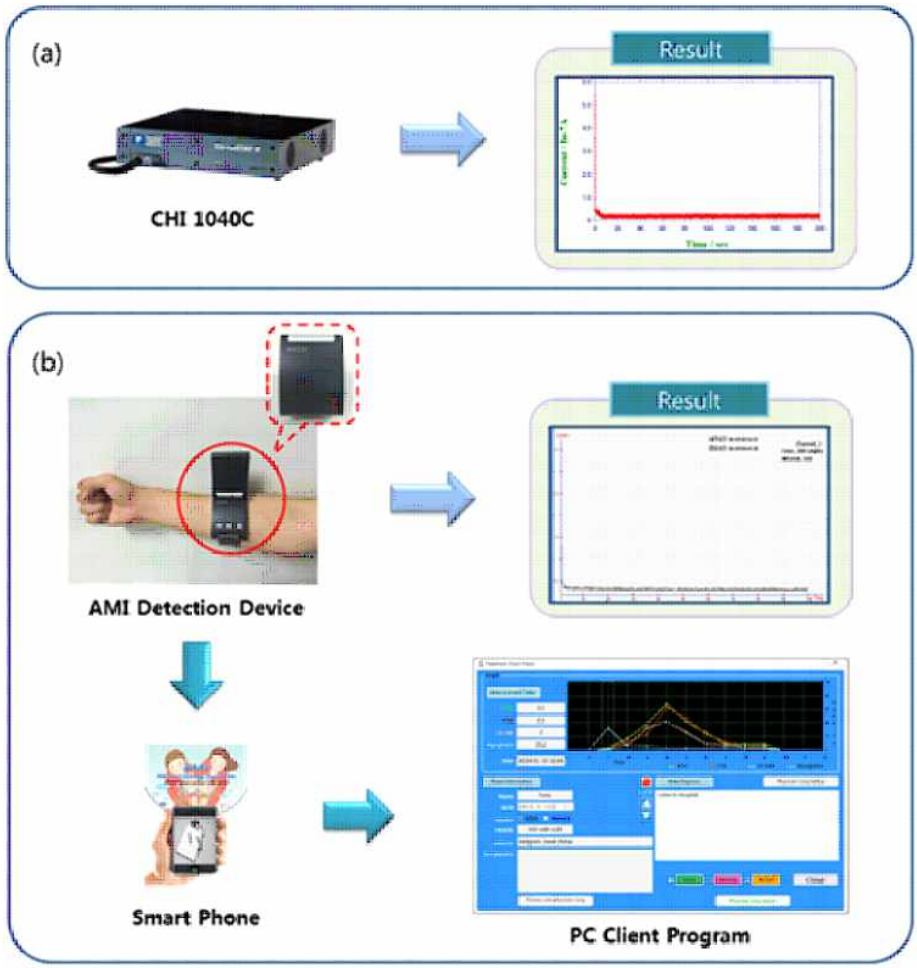


Figure 2.14. (a) Results of experiment conducted with Chrono Amperometry using CHI 1040C and serum including Troponin I. (b) CA and wireless communication results of AMI detection device.

Figure 2.15 shows each response time stage measured by Wireshark 1.10.14, which detects packets in wired and wireless networks. The communication procedure indicated in Figure 2.2(b) is divided into an Association phase, Configuration phase, Operation phase, and Release phase. We measured the result data communication speed from the start of the Confi guration phase to the end of the Operation phase. As shown in Figure 2.15, the Operation and Disassociation phase response times are 200ms and 80ms,

respectively. However, the Association phase requires an average of 5s, because it includes the Bluetooth pairing time between the agent and manager.

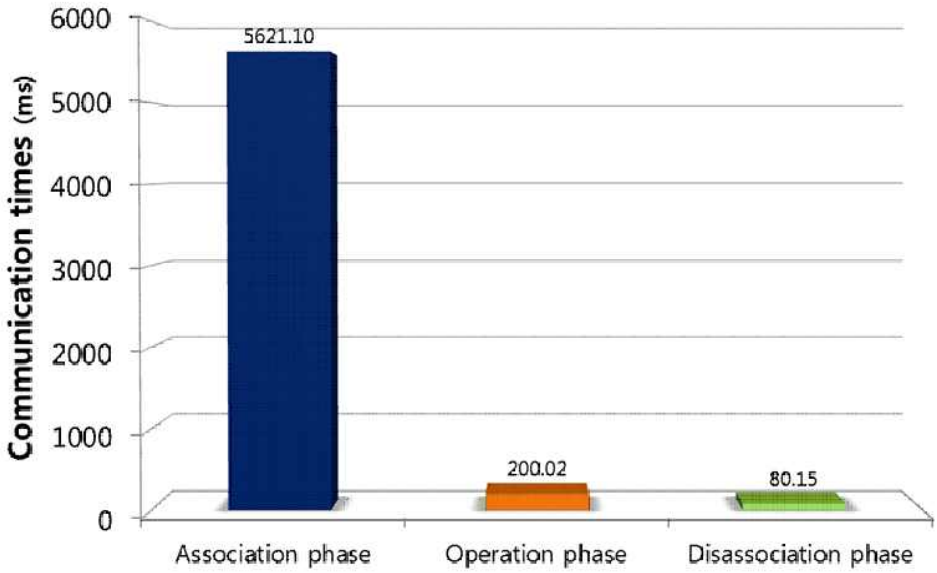


Figure 2.15. Phase response times

Figure 2.16 shows the error rate, which includes both data loss and data distortion, for 1000 tenbyte packets transferred from the AMI detector to the Bluetooth-enabled PC. In this experiment, communications using the AMI protocol produced an error rate of 0%; communication that did not apply this protocol had an average error rate of 16.1%, which increases as the amount of data is increased. We reduced the error rate by applying an end-to-end communication method to the AMI protocol. Data loss and distortion are important factors in telemedicine systems using wireless communication, because patient biometric data would be useless for medical diagnoses if communication errors occur.

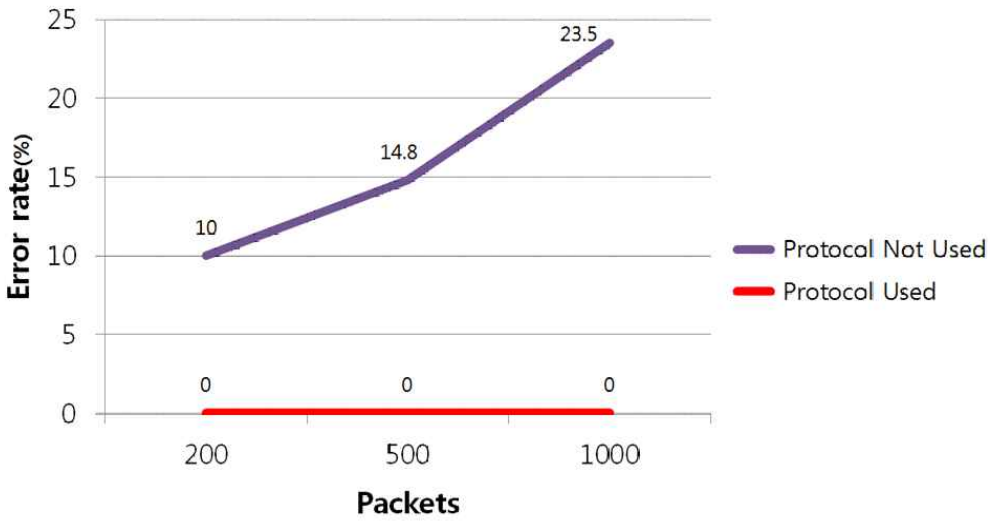


Figure 2.16. Packet loss rate for data transmissions

The i-STAT blood analyzer, manufactured by Abbott Laboratories, is a typical AMI-detecting POCT device; it can detect only limited cardiac markers such as Troponin I and CK-MB [44]. Thus, it cannot accurately determine cardiac diseases. Blood vessels may also secrete these biomarkers when patients have other diseases; these secretions will steadily decrease over time. For these reasons, at least three days are required to establish a diagnosis of AMI, and the diagnosis results are typically sent to medical staff on paper forms. Existing POCT AMI devices have disadvantages, which include lengthy checkups, a lack of reproducibility, and the complexity of the measurement process. Conversely, a U-healthcare device enables patients to easily check the diagnosis results from any connected device. However, telemedicine devices are not compatible with all independent software and hardware protocols offered by each manufacturer. In this research, we solved this problem by utilizing the ISO/IEEE 11073 standard protocol. This protocol facilitates the exchange of physiological data between an AMI detection device and a manager device. By using this AMI detection system, physicians can receive patient health data (such as cardiac states) in real time and then

provide the patient with proper feedback. Patients receive psychological stability and relieve anxiety by recognizing heart conditions with the cardiac marker level themselves. Electrochemical immunosensors include specific antibodies for the antigen-antibody reaction to detect cardiac enzymes. To generate biomarkers of electrical signals, an antibody must be combined with an antigen from blood serum. To keep the immunosensor intact, it must be refrigerated because the antibody on the sensor is destroyed at room temperature. Therefore, the immunosensors used in the AMI system must be improved to create a more stable and optimized POCT device. Moreover, IEEE 11073's security system is still weak. In this study, the proposed AMI system protocol applies an encryption authentication technique included in Bluetooth. However, this technique does not perfectly protect personal medical information from threats. Thus, ISO/IEEE 11073 must provide cryptographic algorithms to protect against any outside attacks.

The proposed protocol will contribute to the standardization and commercialization POCT devices, because it can applied to other diagnosis instruments by modifying the Domain Information Model. In addition, the protocol's security problems can be solved by using a Bluetooth beacon 4.2v; with this functionality, third parties cannot access medical information.

2.7 Conclusion

The realization of the U-Healthcare service market vitalization must be established to verify the technical standardization, reliability, and safety of U-Healthcare. In this paper, we proposed a U-Healthcare system for detecting the AMI using pre-existing mobilephone and Bluetooth networks and AMI Detection Device. Our system adopted the ISO/IEEE 11073 PHD standard for communication involving a smartphone, and our proposed U-Healthcare device. By using this standard, the proposed device can be easily integrated into the existing U-Healthcare market. Using the AMI detection device, the information obtained from the cardiac markers is transferred to a smartphone using the

ISO/IEEE 11073 message format. The device can schedule multiple tests of the patient's cardiac markers using the smartphone, and the test results can be delivered to the relevant hospital within 12min. This can reduce mortality rate of heart attacks. The development of this U-Healthcare system has the potential to reduce patients' medical expenses and save countless lives.

III. Wearable ECG Monitoring System

3.1 Introduction

Although the life expectancy of modern people has substantially increased, various adult diseases still afflict a large portion of the population [45, 46]. To prevent these problems, a wearable U-healthcare system has been developed, which is available in different forms, including as a watch, necklace, and cloth, allowing for the monitoring of standard health parameters in daily life. This system employs techniques that provide users with electrocardiogram (ECG), pulse, and temperature data and can display the user's health status in real-time [47-50]. Among the various diseases, cardiac problems cause serious damage to patients, and therefore heart-related parameters need to be examined continuously [51-53]. To diagnose these disorders, the most representative method is ECG, which detects a signal from the electrical activity of the heart, and includes wires, electrodes attached to the skin for signal transmission, and a printer or screen to display the ECG output in graphical form.

The bionic electrode, which provides the direct effect of the recorded signal, is one of the most important components of the ECG. In general, an electrode used for obtaining a bio-signal can be classified into two main types: wet- and dry-type electrodes. When used over a long period, the wet-type electrode causes skin irritation, reduces the signal-to-noise ratio, and changes electrical characteristics such as impedance owing to the dried electrolyte gel on the contact surface [54, 55]. To overcome such issues, studies have been carried out to maintain the impedance and improve the biocompatibility of electrodes. Yoo et al. developed a dry electrode by printing silver paste onto a textile, making it possible to monitor ECG parameters by simply wearing a cloth [56]. Liu et al. proposed a composite electrode consisting of carbon nanotubes (CNTs)/adhesive-polydimethylsiloxane (aPDMS) and a silver

nanowire to record signals over long durations [58]. However, these previous composites were associated with difficulty in fixing the electrode to the skin; therefore, they require an adhesive or specific instrument such as tape, a Velcro-type band [59], and customized wear. Such attachments result in inconveniences and skin irritations for the user. To overcome this limitation, in this study, we developed a self-adhesive dry electrode, which consists of a mixture of CNT and aPDMS, by eliminating the air between the contact surface of the electrode and the skin. The composite electrode is made up of arches with elasticity that can maintain vacuum states inside the electrode. To verify the use of the electrode for monitoring bio-signals, mechanical and electrical characteristic tests were conducted to record the ECG, and the results were compared with those obtained using a conventional wet electrode.

3.2 CNT/aPDMS Electrode

3.2.1 Materials

To fabricate the CNT/aPDMS electrode, CNTs were dispersed in aPDMS. Multi-walled CNTs (surface resistance: <30 Ω/sq., outside diameter: 20 nm, inside diameter: 5-10 nm, length: 25 μm) were obtained from Worldtube Corp. (Korea). A 3.0 wt% of CNTs was dispersed in IPA (IsoPropyl Alcohol) solvent and stirred at room temperature for 6 hours. After a further 24 hours, CNT dispersion was completed by removing the supernatant generated using a centrifugal separator. The aPDMS (MG7-9850, two components: Part A and B) was obtained from Dow Corning Corp. (USA). The CNT/aPDMS composite was used to fabricate the self-attached dry electrode for bio-signal measurement.

3.2.2 Human experiments

The study protocol was approved by the Institutional Review Board (IRB)

from the Ethics Committee of the Chosun University Medical Centre, Gwangju, South Korea. The experiments were carried out in accordance with the approved guidelines of IRB. The participant (male, age: 27 years old, height: 168.3 cm, and weight: 67 kg) signed an informed consent agreement before the experiment. The night before the experiment, the subjects were asked to sleep for at least 7 hours and not to consume any alcohol or caffeine-containing substances, for accurate ECG detection. When the subjects arrived for the experiment, the purpose of the study and experimental procedure were explained.

3.2.3 Fabrication of CNT/aPDMS electrode

The CNT/aPDMS electrode consists of the CNT/aPDMS substrate, a snap, and silver/PDMS. Figure 3.1(a) shows a picture of the CNT/aPDMS electrode connected to a snap. aPDMS is flexible and harmless to the skin. CNTs show excellent mechanical, thermal, and electrical properties, and have therefore been widely used in biomedical applications. These CNT/PDMS composites show great potential in the biomedical field [56]. The CNT/aPDMS composites provide biocompatibility, enhanced conformal contact, excellent contact impedance, and self-adhesion. CNTs are tangled and assembled randomly, which allows them to better contact each other when the polymer is bent or stretched. Therefore, CNTs are superior to other conductive materials (e.g., silver nanowires or silver microspheres) for application in conductive polymers as bio-signal electrodes. Moreover, CNTs are inexpensive and highly accessible. The CNTs were mixed with aPDMS to form a high conductive layer with holes to allow air to pass between the epidermis and inside the electrode, as illustrated in Figure 3.1(b). CNT and aPDMS were mixed at a 7:3 ratio. To prepare the substrate, multi-walled CNTs were poured onto petri dishes and cured at 60°C for 15 min while stirring to remove the ethanol. Next, aPDMS in a 1:0.8 ratio of component A:B was mixed with the cured

CNT for 20 min using a magnetic stirrer. The substrate frame created iron. The diameter of each hole was 0.105 cm, spacing between the holes was 0.375 cm, and there was a total of 12 holes (Figure 3.2). We conducted scanning electron microscopy to analyze the surface of the CNT/aPDMS to ensure uniformity. Figure 3.3(a) and Figure 3.3(b) shows the cross-section and top view of the CNT/aPDMS electrode, respectively. The CNT was uniformly embedded in aPDMS. The average diameter of the fibers was 20 nm. The upper layer, composed of the arch, maintained the adhesive strength by creating a vacuum inside the structure, as shown in Figure 3.1(c).

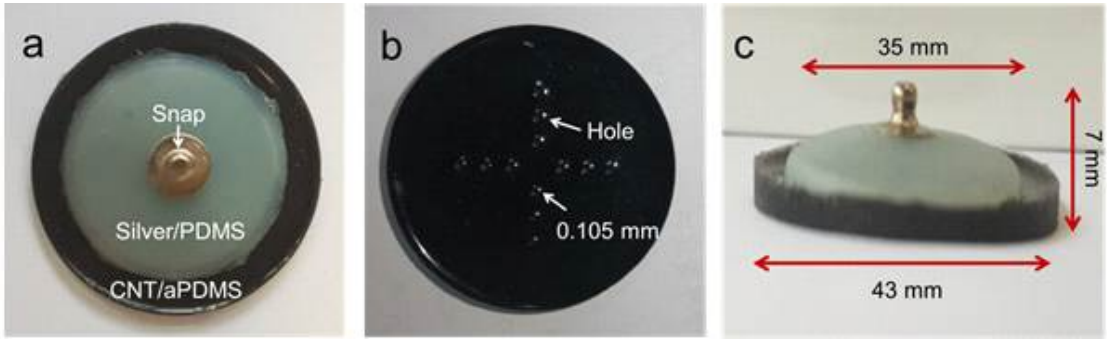


Figure 3.1. Photographs of the CNT/aPDMS electrode. (a) Upper surface, (b) bottom surface, and (c) side of the CNT/aPDMS electrode.

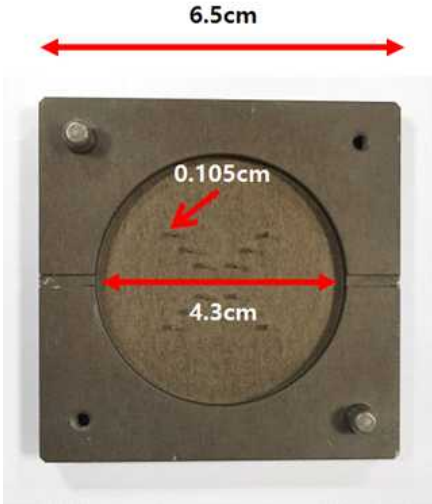


figure 3.2. Electrode frame.

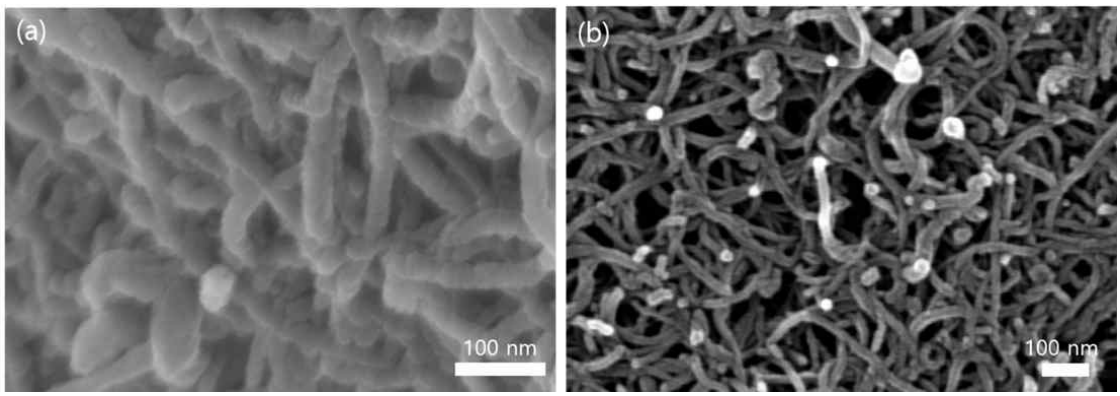


Figure 3.3. SEM analysis (a) Cross section and (b) top view of the CNT/aPDMS composite electrode.

The manufacturing process of the composite electrode is presented in Fig. 2. To make the substrate, multi-walled CNTs were poured onto petri dishes and cured at 60 °C for 15 minutes with stirring to remove ethanol. Then, aPDMS with a 1:0.8 ratio of component A:B was mixed with the cured CNT for 20 minutes using a magnetic stirrer (Figure 3.4(a)). The mixture was poured into a metal frame to make the substrate, as shown in Figure 3.4(b), and a schematic of the substrate is shown in Figure 3.4(c). Figure 3.4(d)

shows the frame of the upper layer. The upper layer was made with the usual ratio of PDMS, and then produced with the abovementioned processes (Figure 3.4(e)). After drying at room temperature for 5 hours, the upper layer and substrate were combined using silicon paste. To transfer the electrical signal to the snap, the upper layer was coated with silver, using DC magnetron sputtering. After ultrasonic cleaning of PDMS (diameter of 35 mm) for 10 minutes with acetone, methanol, and distilled water in that order, the moisture was removed using nitrogen gas. We used commercial silver with a 46-mm diameter and 3-mm thickness as the target coating material, set the vacuum degree to less than 10^{-6} rr in the chamber, and injected argon gas as the inert process gas. The signal path was constructed to snap with silver to exhibit electrical characteristics such as low impedance and high conductivity. The principle of the proposed self-adhesive electrode is schematically depicted in Figure 3.5. This structure, which maintains a vacuum state by sucking up air in between the skin and the composite, was designed to be able to attach onto the skin without requiring glue or an instrument for adhesion. When pushing the electrode, the air between the skin and the electrode wrinkles, and the air inside the electrode is released outside, as illustrated in Figure 3.5. After releasing the electrode, it is stuck on the skin because the upper layer consisting of PDMS is restored to its original form owing to its elastic property, which then creates a vacuum on the inside.

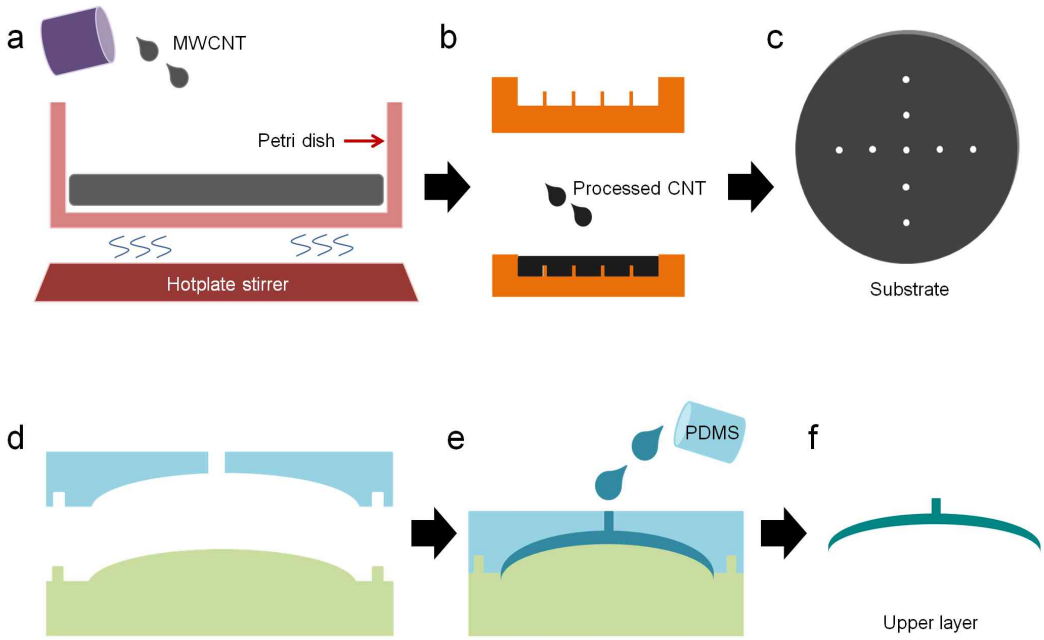


Figure 3.4. Configuration of the CNT/aPDMS electrode. (a) Cured CNT, using a hotplate stirrer. (b) Mixture of CNT and aPDMS in a metal frame. (c) Schematic of substrate. (d) Frame of upper layer. (e) Manufacturing process of upper layer. (f) Schematic of upper layer.

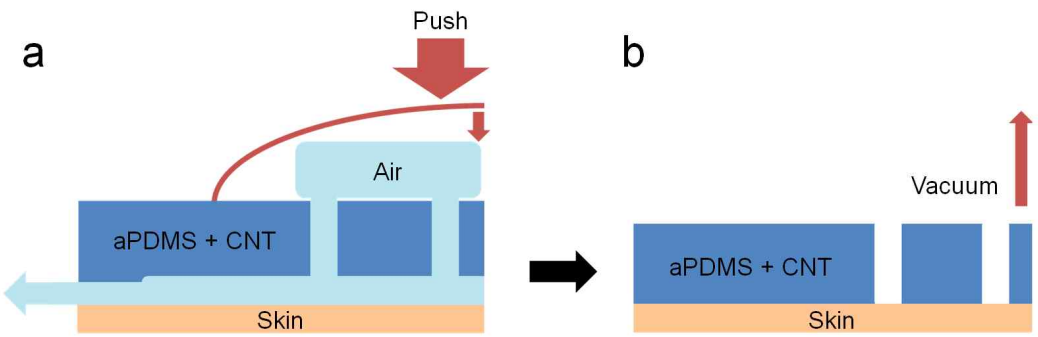


Figure 3.5. Principle of the CNT/aPDMS electrode. (a) Structure of CNT/aPDMS during pushing motion. (b) Structure of CNT/aPDMS after releasing motion.

3.2.4 Result and discussions

The good mechanical properties of CNT/aPDMS should be considered as an important factor. Electrodes for the mechanical test were prepared with tensile equipment (MCT-2150, A&D, Japan) [60]. The test samples were stretched at a 30-N extension force with a speed of 200 mm/min. We experimented with the adhesive force by attaching the electrode onto the skin with 100 replicates, as illustrated in Figure 3.6. The conventional wet electrode showed a dramatic reduction of adhesion when it was reused. In addition, the aPDMS-based self-adhesive dry electrode required a clean contact surface to enable a certain number of usages. In contrast, the CNT/aPDMS electrode had a very low tensile damping rate upon several reuses without requiring a cleaning process. The average tension of 3.86 N/cm^2 could be maintained. Therefore, these electrodes can be repeatedly used, even if debris such as dust particles is present on the skin, which would otherwise affect adhesion. The wet electrode initially showed high adhesion because of the adhesive. However, with an increased number of repetitions, adhesion became weaker. Because the dry electrode had no adhesive, the adhesive force was zero. This is because the CNT/aPDMS electrode only requires a minimum adhesive force to maintain a vacuum state. Moreover, it is possible to measure even strenuous activities such as walking and running without dropping the electrode. Hence, this electrode can be considered as a new dry electrode for signal monitoring, regardless of various human motions.

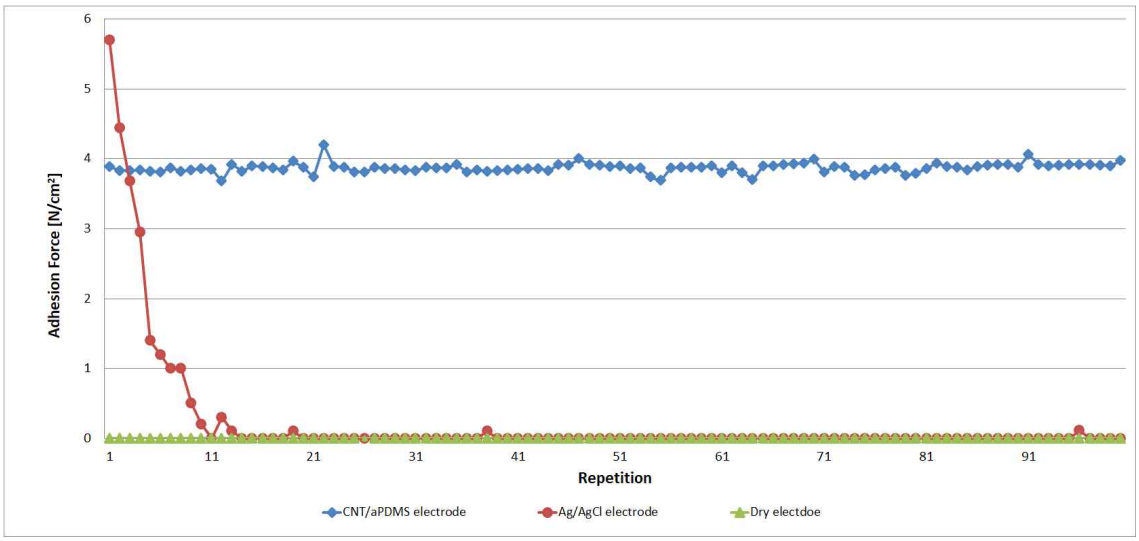


Figure 3.6. Cyclic adhesion properties of the CNT/aPDMS electrode (blue), Ag/AgCl electrode (red), and dry electrode (green).

Bio-signals show various frequencies, including those measured with ECG (0.15-150 Hz), electromyogram (EMG; 5-500 Hz), and electroencephalogram (1-50 Hz). These methods are significantly affected by contact impedance and cause abnormal signals such as distortion, reduction, and noise. Therefore, the electrical characteristic of the electrode used to record a bio-signal is a crucial properties.

Figure 3.7 shows the contact impedance of the conventional Ag/AgCl electrode and the proposed electrode. To measure the impedance, two electrodes were attached to the forearm at a distance of 8 cm from each other. The contact impedance of the CNT/aPDMS electrode and reference electrodes was compared from 1 Hz to 1 KHz. According to these measurements, the impedance of our CNT/aPDMS electrode was much higher than that of the Ag/AgCl electrode at a frequency lower than 200 Hz. However, these impedance differences were similar at a frequency higher than 200 Hz.

The surface of the dry electrode is coated with gold. As a result, it always showed a higher impedance than the other electrodes in terms of

frequency changes. The impedance changed over time because the development environment and storage conditions varied. However, the ECG signals were stably measured despite these impedance variations.

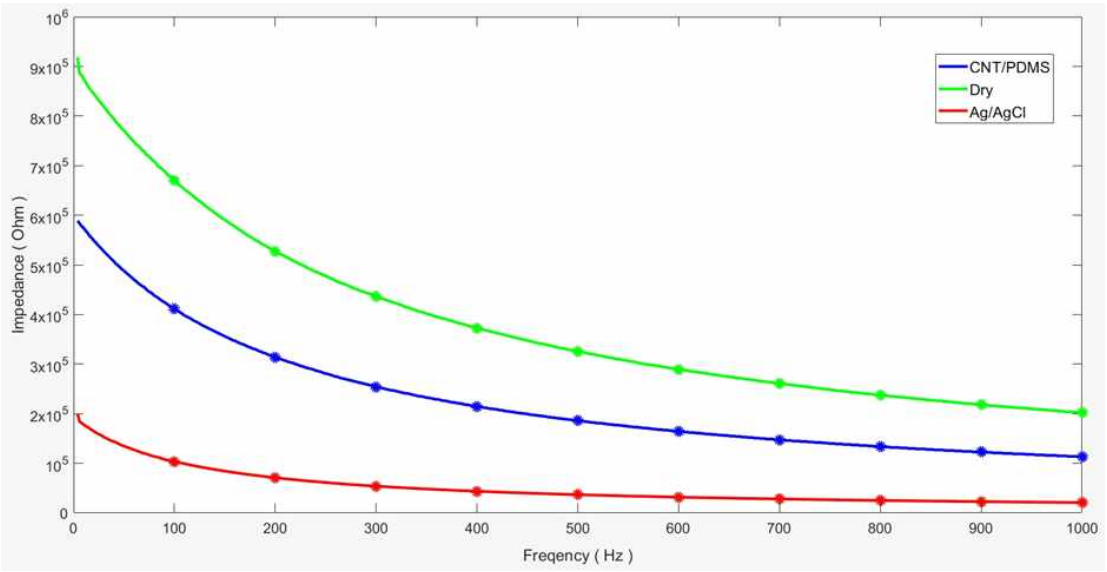


Figure 3.7. Contact impedance of the Ag/AgCl electrode (red), CNT/aPDMS electrode (blue), and dry electrode (green).

Impedance was measured using an impedance analyzer (IM3570, Hioki, Japan), and values were recorded as the frequency of the change between the CNT/aPDMS and conventional electrodes. To validate this work, we conducted experiments by using the electrodes to measure human bio-signals. To acquire ECG signals, using the CNT/aPDMS electrode, electrodes were placed on the chest. The ECG signal was amplified using an ECG detector (AD8232-evaluation kit, Analog Devices, USA) [61, 62], and signal detection was carried out using an oscilloscope (MSO9104A, Agilent, USA). To reduce artifacts, moisture was removed prior to beginning each test. The comparison of the ECG measurements between the new composite electrode and the conventional Ag/AgCl electrode is shown in Figure 3.8(a). Owing to its higher impedance compared to that of an Ag/AgCl electrode, the ECG wave obtained

with the CNT/aPDMS electrode was less than approximately 0.01 mV. The correlation coefficient was calculated as 94.33 %, using MATLAB 2016A. In this study, we chose the ratio between CNT and aPDMS as 7:3. To confirm that this proportion was appropriate, we tested three different ratios: 6:4, 6.5:3.5, and 7:3. At a ratio of 6:4, the material did not solidify, making it difficult to shape it into the electrode. However, at ratios of 6.5:3.5 and 7:3, the material hardened appropriately. Of these two ratios, the ECG signal was best detected when using the 7:3 ratio (Figure 3.9). We also confirmed the ECG signals according to the change in temperature or humidity. At temperatures ranging from 20°C to 40°C and humidity from 30% to 65%, the electrodes functioned well. However, at higher temperatures, a small amount of noise was produced because of sweating, but the correlation coefficient was examined and found to be >76% (Figure 3.10).

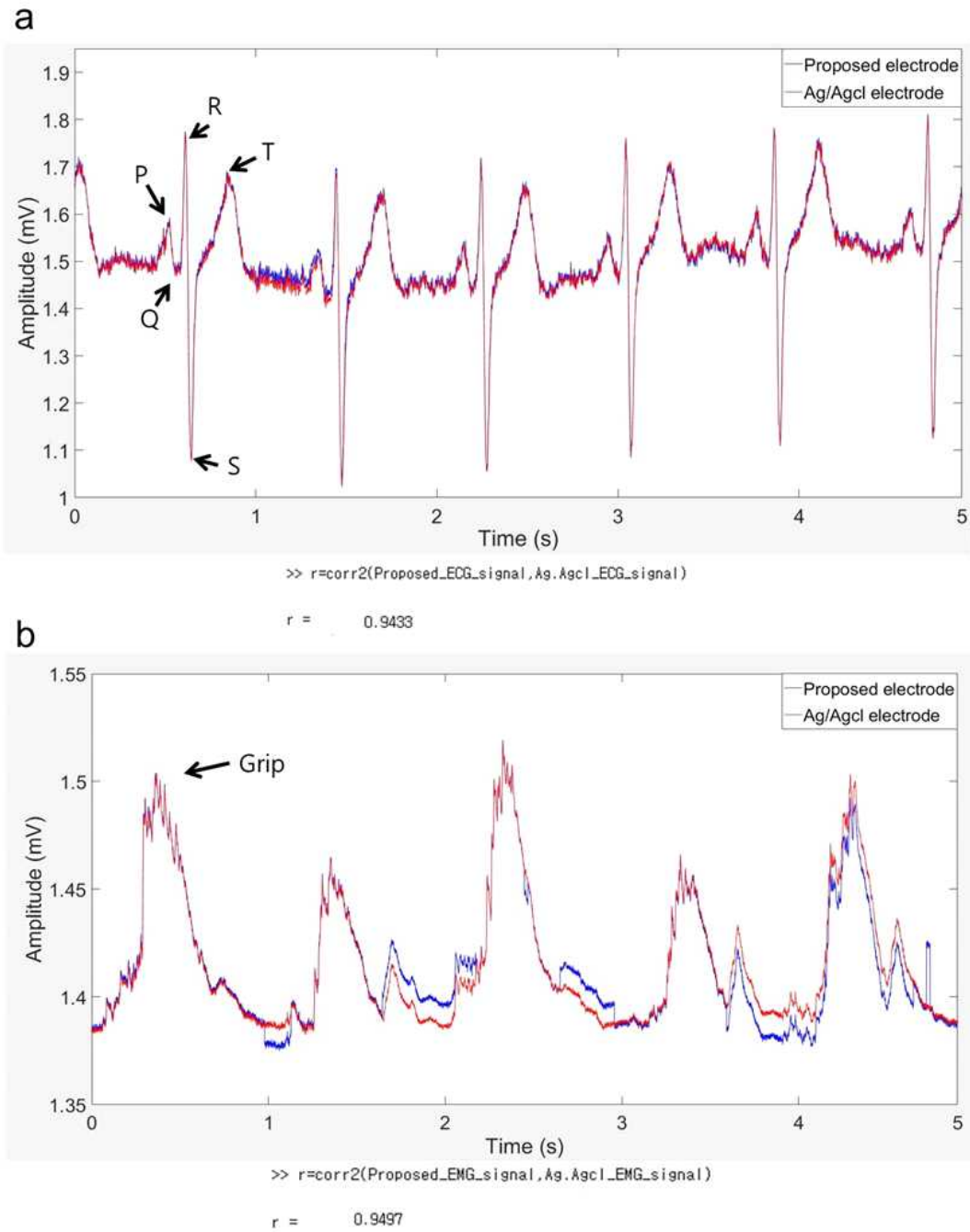


Figure 3.8. ECG and EMG signals acquired with the CNT/aPDMS electrode compared to those simultaneously acquired with the Ag/AgCl electrode. (a) ECG signals measured using the CNT/aPDMS electrode (blue) and the Ag/AgCl

electrode (red). (b) EMG signals measured using the CNT/aPDMS electrode (blue) and the Ag/AgCl electrode (red).

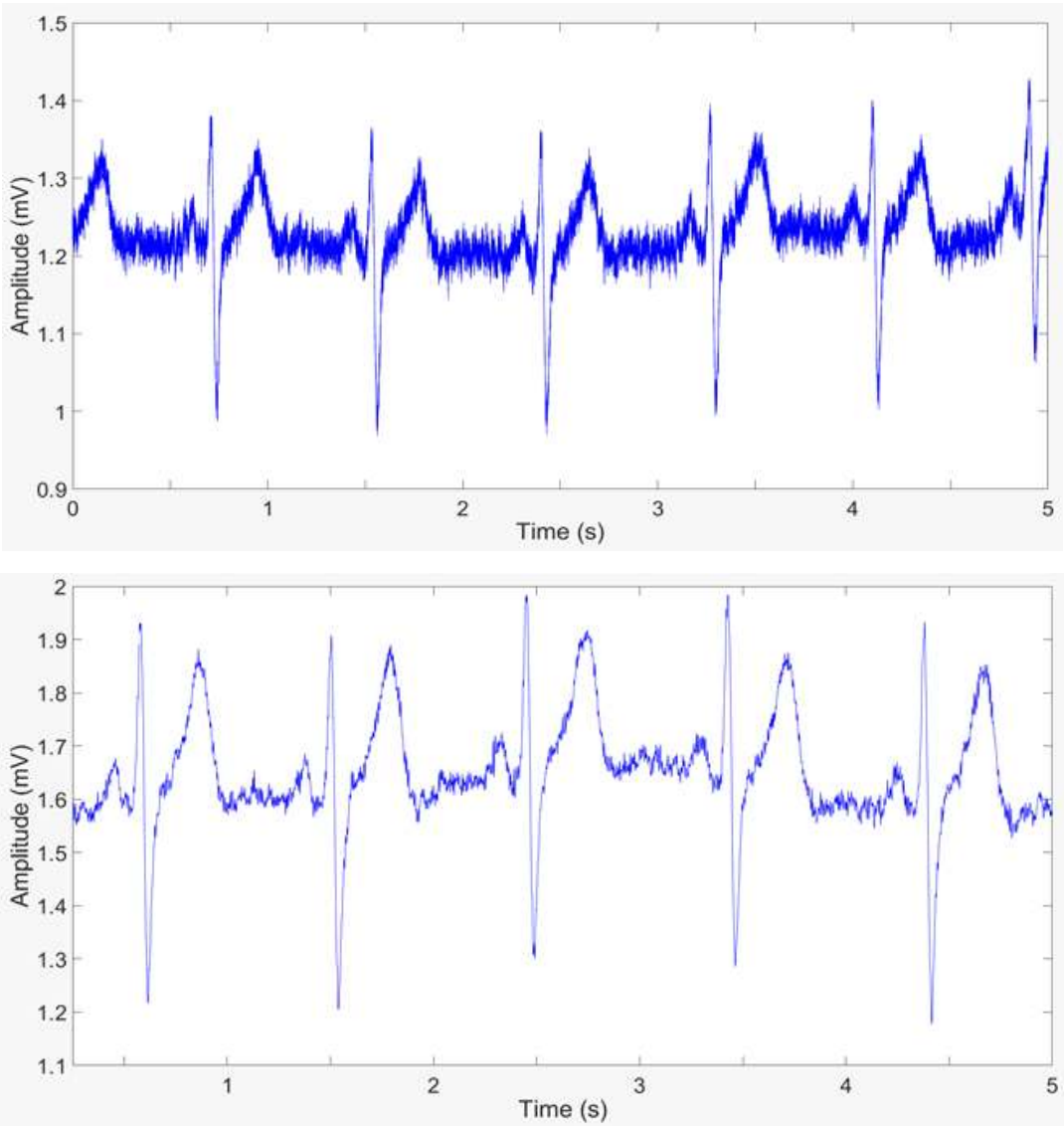


Figure 3.9. ECG signals obtained using CNT/aPDMS dry electrodes made with 6.5:3.5 (Top) and 7:3 (Bottom) ratios.

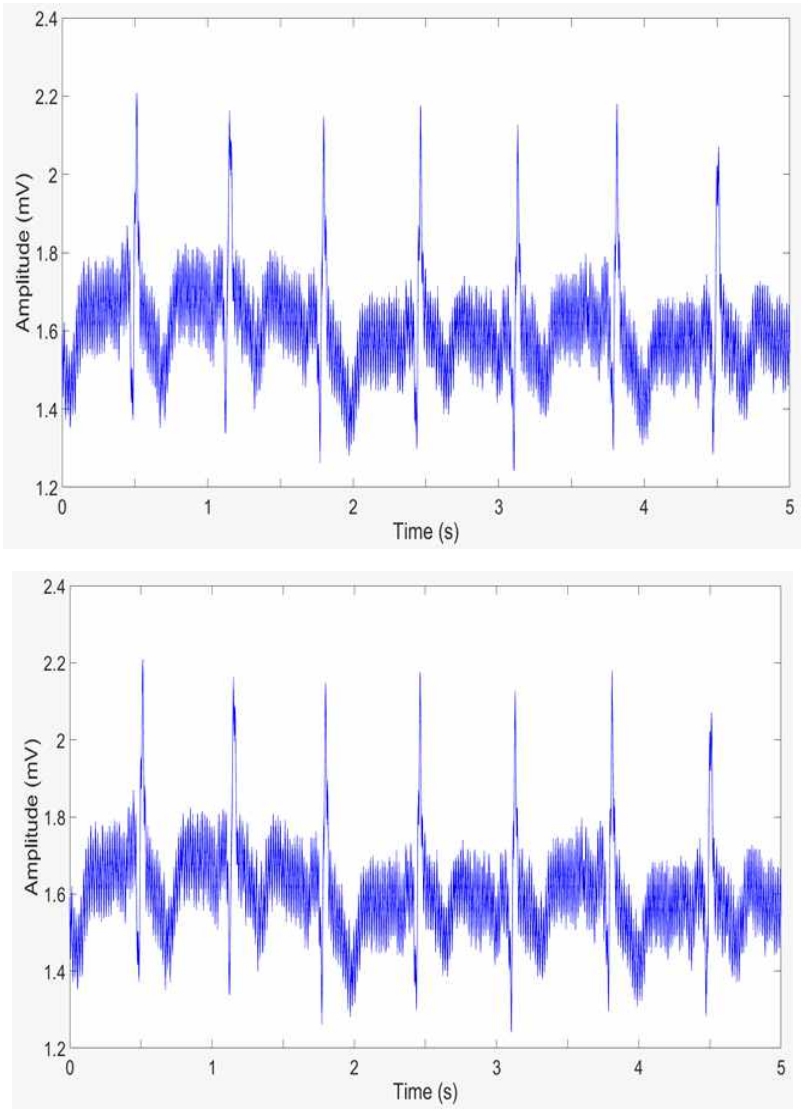


Figure 3.10. Electrode test at an ambient temperature of 40℃ and humidity of 65%. Ag/AgCl electrode (top) and CNT/aPDMS electrode (bottom).

Although the signal recorded by the CNT/aPDMS electrode was slightly below the electric potential obtained with the conventional electrode, the ECG waveform as a series of waves such as P, Q, R, S, and T was clearly shown without other distortions. Furthermore, we conducted the reusability test with the composite electrode by attaching/detaching the electrode onto the skin

repeatedly 30 times, and no significant change was detected in the ECG measurements or impedance. We conducted an additional test using three electrodes (of both types) attached to the forearm; the subject was then asked to repeatedly clench and unclench his fist five times, and the EMG signal was recorded using PSL-iEMG2 V1.0 (Physiolab, Korea) [61]. As shown in Figure 8(b), the EMG measurements obtained presented a similar potential level (at 94.97 %) for both the commercialized and CNT/aPDMS electrodes. Although there was a slight difference between the two electrodes, we confirmed the suitability of the CNT/aPDMS electrode for recording bio-signals. When the proposed electrode was adhered for 1 week, there was no degradation observed in the ECG signal compared to that recorded at day 1, as illustrated in Figure 3.11. This result indicates that the CNT/aPDMS electrode resolves the problems of the wet-type electrode, making it possible to record signals for long-term monitoring. Furthermore, we conducted a skin compatibility test of the composite electrode during the 7 days, and no itching or erythema was found on the skin at the site of attachment, as shown in Figure 3.12.

Several studies have reported the development of dry electrodes [63, 64]. Here, we have fabricated a flexible self-adhesive electrode composed of a CNT/aPDMS composite material. This electrode can be attached to the skin by creating a vacuum between the epidermal and electrode surfaces, allowing for long-term recording of bio-signals. The conventional Ag/AgCl electrode and CNT/aPDMS electrode were compared. The results demonstrated the capability of bio-signal detection and monitoring. Thus, the flexible and high-performing CNT/aPDMS electrode can be widely used as a wearable bio-signal monitoring system.

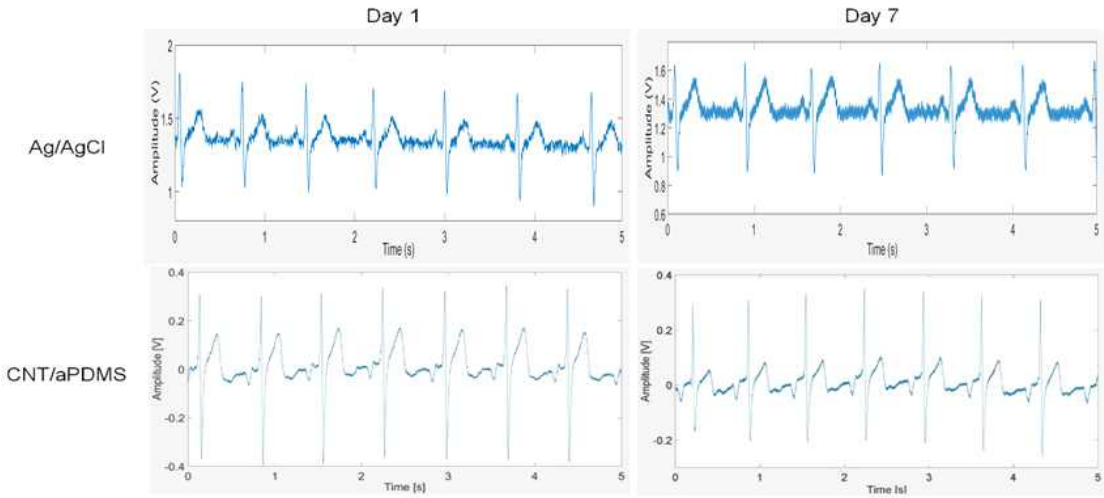


Figure 3.11. ECG signals measured at 1 and 7 days of wearing the electrode.

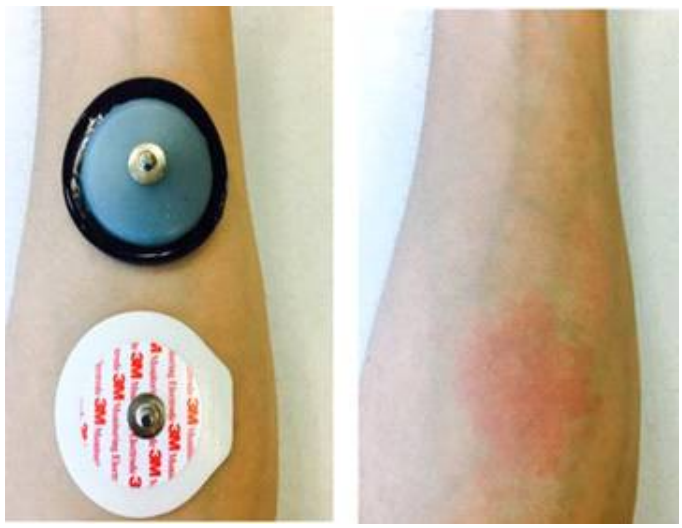


Figure 3.12. Skin of the arm of the subject after wearing the CNT/PDMS electrode for 7 days.

3.3 Wireless Communication of ECG monitoring

3.3.1 Spec. of wireless ECG system

The circuitry of the ECG monitoring device was fabricated using an MCU-based FPGA to process analog signals by programming the analog block. This system was built without separate integrated-circuit chips such as communication modules, analog-to-digital converters, or operation amplifiers to achieve a miniaturized module. The specifications of the monitoring module is shown in Table 3.1.

Table 3.1. Module specification

Item	Spec.
Size	4 x 2.5 cm
ADC resolution	12 bit
Sampling rate	1.5 KHz
Packet	6 bytes
Acceptable voltage range(ADC)	0-3.3 V
Gain	1100
Band-pass filter(analog)	0.5-45 Hz
Notch filter(digital)	60 Hz

3.3.2 Experiment environment

To examine the performance of system, we used an ECG simulator (SECG 4.0, Whaleteq Co., Taiwan) capable of generating various alternating current signals including ECG signal-based IEC60601-2-25, 2-27, and 2-47. The development kit (AD8233 development kit, Analog Devices, US) was used to analyze and compare results. In addition, the measured data for digital filtering was processed using Python 3.6 and MATLAB R2017B, and signal collection

was achieved using an oscilloscope (MSO9105A, Keysight Co., US).

3.3.3 System architecture

In this study, we fabricated a system to attach two modules to each wrist for having potential difference. The module consisted of ADC(Analog-Digital Converter), OP-AMP(Operational amplifier), and BLE in a programmable analog block running embedded software for processing the ECG data. The system also included a battery and band-pass filter for filtering the raw signal in the circuitry. A sub-module collecting negative potential data and a main module measuring positive potential data were fabricated with the same hardware architecture.

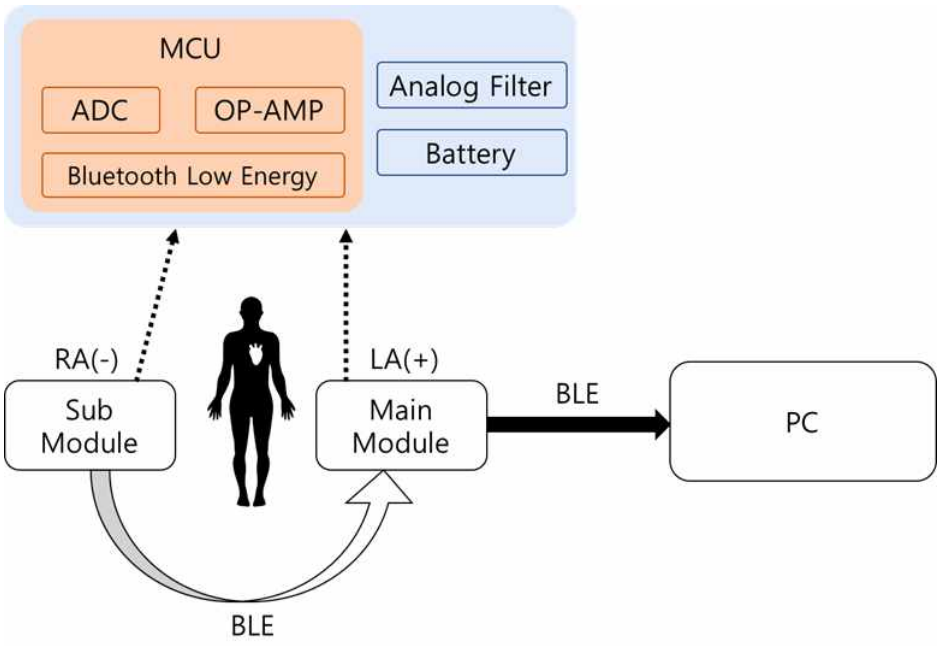


Figure 3.13. Configuration of proposed system.

The ECG was organized using a differential amplifier and OP-AMP, which limited the bandwidth and amplified the tiny electrical signal to measure the

bio-potential generated from heart. We fabricated miniaturized monitoring modules using a programmable analog block and a minimized number of elements. Fig. 3.14 shows the analog blocks and circuitry structure of the analog signal operation. Two amplifiers were used for the filter with bandwidths ranging from 0.5 to 45 Hz and the generation of mid-level voltage was used to raise the baseline of the signal. Because a single power source was used, we added a potential divider to supply a reference signal, which was the base-level of the ECG signal. Analog blocks, such as OP-AMP and ADC, have typical input voltages ranging from 0 to 3.3 V, and the filtered analog signal was converted to digital data at a sampling rate of 500 Hz.

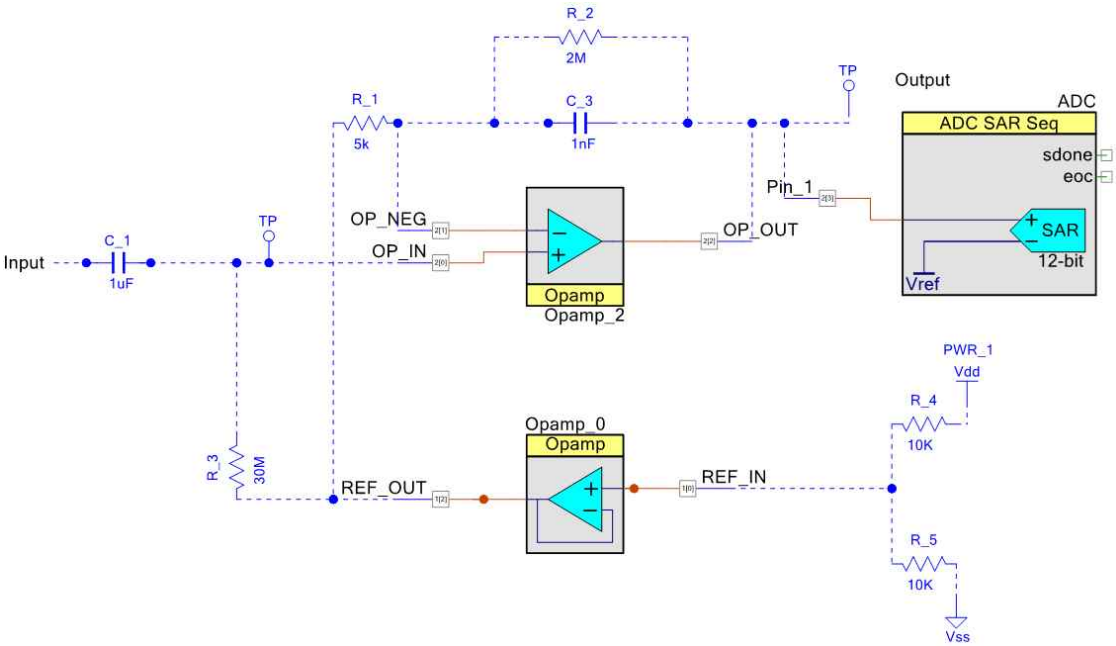


Figure 3.14. Block diagram for the monitoring module using PSoC 4.2.

The sub and main modules measure the potential difference from each wrist simultaneously, and both results are combined and calculated in the main module. Sample data collected from the sub-module was converted to a six-byte packet and subsequently transmitted to main module via BLE.

Afterwards, the received data is inverted before being added to the results from the main module to generate the ECG graph. Because noise is introduced into the internal circuitry during signal processing, we designed the digital notch filter to limit the portion of the bandwidth using Python.

3.3.4 Signal process

Two modules were used to collect an electric potential from each wrist and communicated with each other via BLE. The micro-controller installed in the module can build analog blocks such as OP-AMP for signal amplification and filtering, ADC to output digital values, timer for controlling the sampling rate, and BLE. For the communication synchronization of the modules, the timer counter was used to sample signals in a defined cycle. Because the system clock rate of the device was set to 1 MHz, the timer counter was set to 2000, indicating that the digital data created every 2 ms (500 Hz) and transmitted to the main module via BLE. If the 250 Hz processing period is altered and both modules exhibit asynchronous delay, the output of the ECG module may show seriously distort results. Therefore, we designed the monitoring modules with a sampling period of 500 Hz higher than the above-mentioned rate and synchronous issues were not considered.

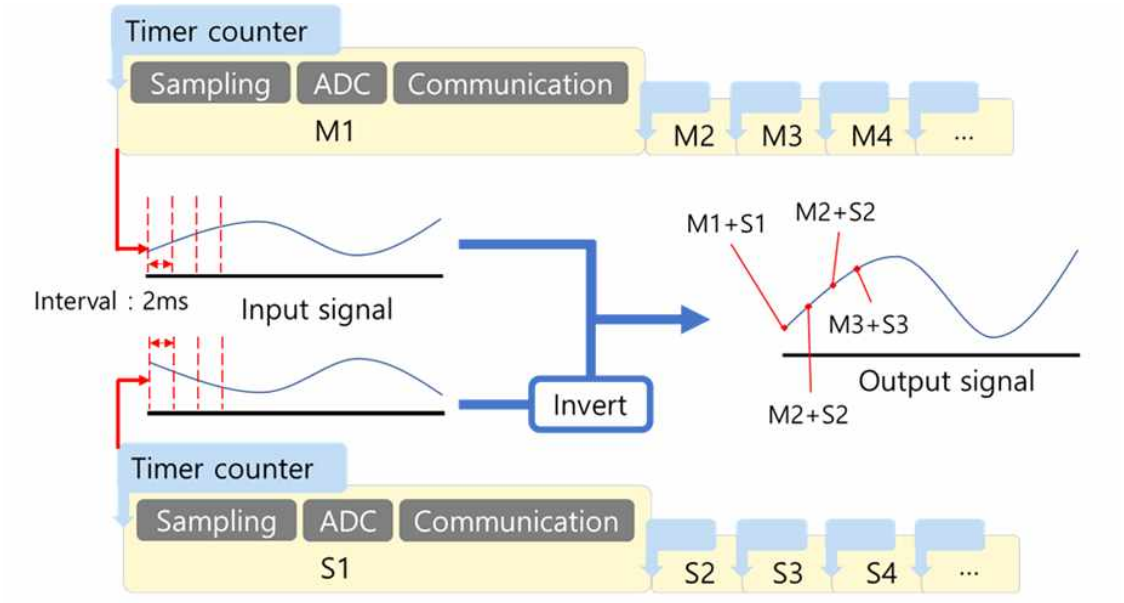


Figure 3.15. The sampling process of the two modules used to detect values according to the timer counter.

3.3.5 Results and discussion

i) Preliminary study

Two commercial analog circuitry devices were used, the Bino-kit as the training board and a QECG-3 to detect the signal, as used in previous studies (Fig. 3.16-a). Two Bino-amp modules were organized with differential amplifiers and OP-AMP was used to measure the electric potential via Ag/AgCl electrodes attached to each wrist. The positive port of one module was connected to right wrist and the right leg drive (RLD) wired with the negative port in the differential amplifier was brought into contact with right leg. The negative port of the other module was wired to an electrode on the left wrist and RLD and the positive pin was constructed of same environment with above mentioned. The sampling frequency of the oscilloscope was set to 10 kHz and a digital notch filter of 60 Hz was applied to both experiments for a clear

comparison. The filtered data calculated from both modules was used to generate the ECG graph shown in Fig. 3.16-b. In experiments with the aforementioned setup, the digital values from the two-analog amplifier were used to display an intact ECG graph.

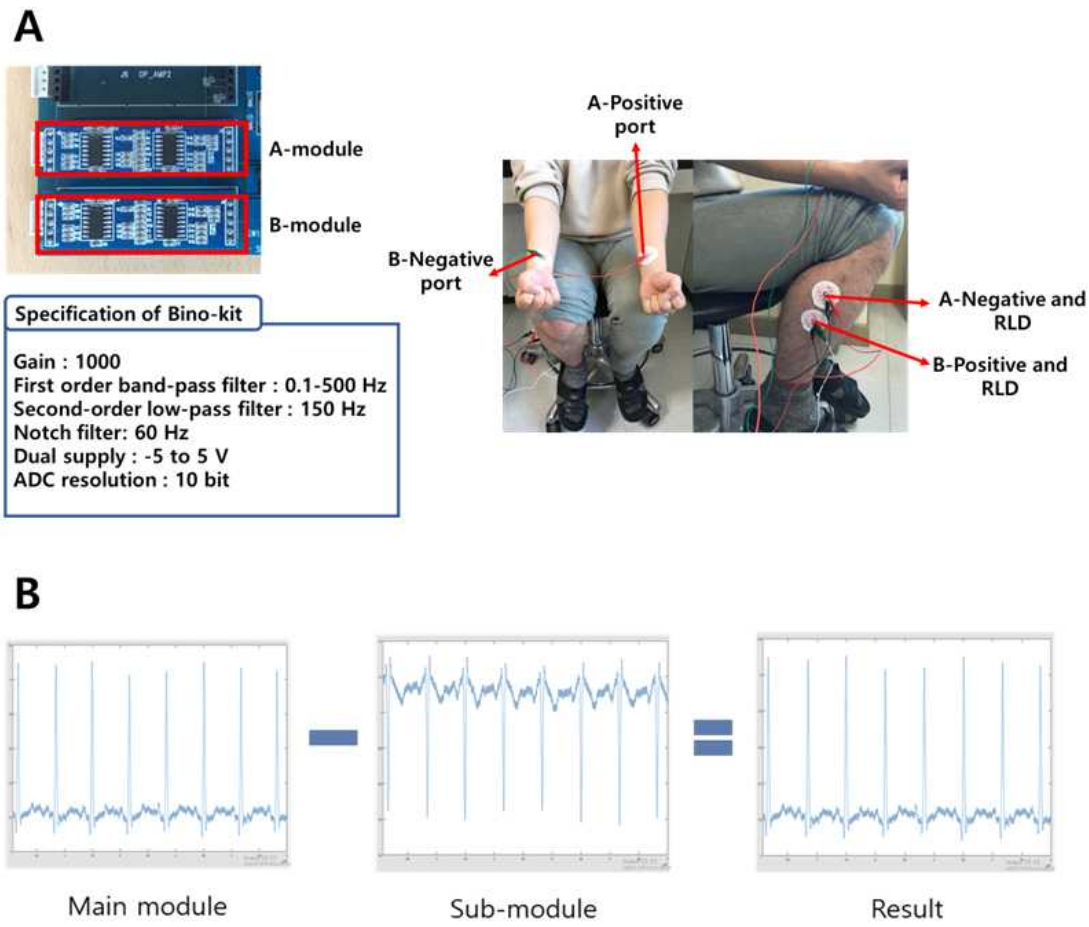


Figure 3.16. (a) The specification of QECG-3 and experimental setup to measure bio-signals from the wrists using two amplifiers. (b) Results of the filtered and calculated digital signals.

ii) Performance of the proposed modules

Fig. 3.17 shows the ECG signals using the proposed system with data generating from an ECG simulator and QECG-3 data. The Bino-kit used three electrodes, and the proposed system used two electrodes. The results were obtained by applying filters in the PC program. The ECG simulator consistently produced high quality data, but signals from the body are influenced by many variables, expect result in a noisier cardiograph.

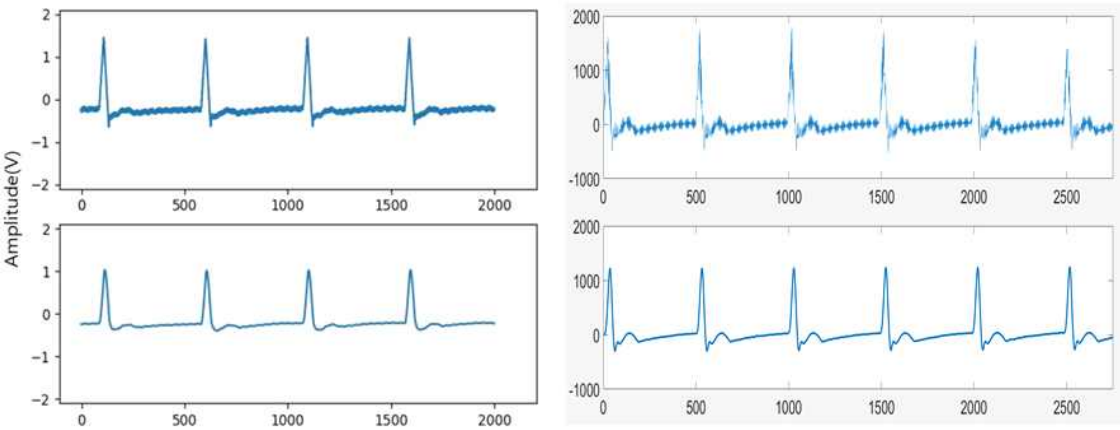


Figure 3.17. ECG measurement results. (a) ECG simulator with the proposed system, (b) ECG simulator with the QECG-3(Laxtha, Korea).

iii) Synchronization of the wireless modules

Abnormal signals due to asynchronous communication between modules may occur due to improper sampling period. This can lead to severe issues for the generated ECG, so the minimum rate of samples collection was set to >250 Hz (4 ms) during configuration of the monitoring device [65]. If the time required to operate from sampling to communication exceeds 4 ms, the main device will likely output an abnormal signal while calculating digital values from both modules. Wireless communication such as Bluetooth and Zigbee limit the number of transmission packets, so the number of cycles per sample, timer counter, and packet size must be adjusted accordingly.

iv) The challenge of system structure

To display the ECG, a voltage of approximately 1-5 mV generated from the wrists is amplified and filtered by the circuitry of the device. In general, analog circuitry is isolated from digital circuitry to reduce digital noise during the measurement of bio-signals because the results are typically vulnerable to even a small amount of noise. However, it is difficult to specifically isolate the analog and digital circuitry because analog filtering and digital processing are operated in the same controller in the adopted MCU-based FPGA [66]. To solve this problem, recently developed circuit architecture using programmable controllers can be applied to alleviate interference, and additional filtering by software is essential to calibrate the signal [67-69].

v) Application to a bio-signal sensor

Although the proposed system has several challenges to overcome, we expect it to be beneficial for easy-to-use ECG monitoring in the form of a wearable and portable machine. To detect abnormal physiological states, bio-signal sensors must work without conscious manipulation in real time. However, existing portable devices operate by touching the module, so if they are unaware of the symptoms, the sensing module is useless. In addition, a miniaturized module attached to the chest or a commercial Holter device with multiple channels wired to electrodes may cause inconvenience during the use. The developed device will provide benefits for the patients in terms of convenience, allowing for monitoring of heart conditions without the need for proactive steps. In addition, using multiplex (one-to-many or many-to-many) wireless communication it is possible to overcome the poor reliability of signal-lead ECG [70, 71], especially if technology is improved to accept result packets from multiple devices.

3.4 Conclusion

CNT/aPDMS composite electrodes have excellent properties such as low contact impedance, high biocompatibility, and flexibility. In this study, we developed a new flexible and self-adhesive composite electrode based on CNTs and aPDMS, which was demonstrated to be suitable for long-term monitoring of bio-signals without any trouble. The proposed CNT/aPDMS electrode was fabricated with a specific structure that allowed it to maintain an internal vacuum for self-adherence to the skin. The electric properties were verified through experiments showing that the contact impedance of the proposed electrode was 10 kΩ higher than that of the Ag/AgCl electrode but was lower compared to that of the dry electrode. Moreover, the CNT/aPDMS electrode showed clear ECG signals without remarkable distortion or reduction when worn for 1 week. Compared to a conventional electrode such as Ag/AgCl and metal-based electrodes, this new electrode will be very useful for maintaining contact impedance and a stable condition of the skin for long-term monitoring. Therefore, the proposed electrode can be applied as a continuous monitoring instrument, such as for pulse monitoring, as a Holter monitor, and to record EMG, and can be developed into various types of wearable devices.

This developed a wearable ECG monitoring module that can be worn on each wrist without connecting both ends by wires. Previous studies showed that digitized electric potentials from both hands using separated modules could generate an ECG signal, and remote sensors with BLE were subsequently developed. The performance of the module was verified using an ECG simulator. No significant differences were observed between the commercial ECG measurement module and the device fabricated herein.

Existing monitoring devices used to detect potential often cause discomfort during operation and must be constantly checked by the patients. The device developed here is predicted to significantly improve the wearability of health tracking systems which can be applied to clinical, sports, and military fields.

IV. Conclusion

Wearable heart monitoring system has been proposed and presented here. This u-healthcare system employs a AMI and ECG signals measurement technologies. The medical service has been evolving from systems designed around centralized hospitals to U-healthcare. U-healthcare system can facilitate real-time monitoring of patient states, and can provide medical checkups and management whenever and wherever the medical staff deems necessary. U-Healthcare services can provide chronic condition monitoring in the early stages of diseases and help execute decisive medical action in emergencies. Especially AMI is among the most critical chronic diseases and requires early detection and treatment.

In chapter 2, this presented an AMI diagnostic software technique and protocol that can support real-time communication between the patient and medical personnel. This system has been developed using a protocol based on ISO/IEEE 11073. When data is transferred from the patient's smartphone to a server in hospital, the medical personnel consult the patient's biosensor data to determine the status of the relevant disease and provide appropriate medical service. The relevant information is sent back to the patient's smartphone through a wireless network, and patients can view their data in graphical format through their smartphone.

In the next chapter, based on ECG monitoring system, this proposed a dry-type self-adhesive electrode composed of a mixture of CNTs and adhesive-aPDMS. This electrode can be attached to the skin by creating a vacuum between the epidermal and electrode surfaces, allowing for long-term recording of bio-signals without side effects. This electrode analyzed the electrical and mechanical characteristics and verified the performance of the proposed electrode compared to that of an Ag/AgCl electrode by conducting ECG and EMG measurements. Moreover, the composite electrode was attached to the skin for one week, and no skin irritation, itchiness, or remarkable

degradation of the bio-signals such as ECG was observed. This electrode enables long-term health monitoring of patients with chronic conditions. Additionally, this comfortable electrode can be applied to a wearable device, including for bio-signal detection. Also, this proposed a wireless 1-channel electrocardiogram (ECG) monitoring system that includes watch-type-2 modules and monitoring software. Each module uses not a wired connection but wireless communication such as Bluetooth, RF module to create a potential difference.

The device developed here is predicted to significantly improve the wearability of health tracking systems which can be applied to clinical, sports, and military fields.

Reference

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ABSTRACT

A Study of Wearable Heart Monitoring and Analysis System

Jaehyo Jung
Advisor: Prof. Youn Tae Kim, Ph.D.
Department of IT Fusion Technology,
Graduate School of Chosun University

In this study, a portable electrochemical analyzer and a wireless electrocardiograph were developed to monitor cardiac muscle condition in real time, and data were continuously collected to enable early diagnosis of diseases. We have developed a portable, three-electrode electrochemical amperometric analyzer that can transmit data to a PC or a tablet via Bluetooth communication, and we performed experiments using an indium tin oxide (ITO) glass electrode to confirm the performance and reliability of analyzer. The measured data can be transmitted to a PC or a smart device such as a smartphone or a tablet PC using the included Bluetooth module.

In addition, ECG system and dry electrode using wireless communication were developed to measure electrical signals of heart in real time. The existing system is required to be a physical wire and has a problem that it is inconvenient to move in the measurement. The developed wireless ECG system enables wireless measurement by synchronizing the potential difference between the main and sub-module using BLE communication. The signal was similar to that of the commercial wired ECG system by 73.95%

Finally, this developed a dry-type self-adhesive electrode, which comprises a mixture of carbon nanotubes (CNTs) and adhesive-polydimethylsiloxane (aPDMS). The wet-type silver/silver chloride (Ag/AgCl) electrode is used to record bio-signals such as electrocardiogram (ECG) and electromyogram (EMG). However, when used for long durations, an Ag/AgCl electrode with an electrolyte gel causes signal distortion and degradation and can irritate the skin. In this study, this electrode can be attached to the skin by creating a vacuum between the epidermal and electrode surfaces, allowing for long-term recording of bio-signals without side effects. We analyzed the electrical and mechanical characteristics and verified the performance of the proposed electrode compared to that of an Ag/AgCl electrode, based on ECG and EMG measurements. Moreover, the composite electrode was attached to the skin for a week, and no skin irritation, itchiness, or remarkable degradation of bio-signals such as ECG was noted. This system will provide an opportunity for the long-term health monitoring of patients with chronic conditions.

The developed electrochemical analyzer and ECG measurement system are expected to contribute to the survival rate by providing the health status of patients with chronic heart disease in real time.