MD-Link: A Portable ECG monitoring with dry electrode and its validation

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***Abstract*— Recent advances in technologies have been profoundly enhancing the quality and efficacy of medical care. In attempt to reduce the risk of the cardiovascular diseases (CVDs), the use of wearable and portable electrocardiogram (ECG) system provides efficient possibilities to promptly preclude patients from severe situations, reducing the fatality rate of CVDs. In this paper, we present a portable battery-less ECG monitoring, namely MD-Link based on active dry electrodes. A comprehensive software system was developed with two mobile applications for patients and doctors, and a web server for data logging and computing. We also conducted several empirical experiments for device's usability assessment and validation. The results showed a high consistency of usability and reliability assessment with low standard error of means, 4.96% and 4.14%, for the difference between trail 1&2 and trial 2&3, respectively. Moreover, high correlation was achieved in the comparison of standard outputs produced by MD-Link and benchmark (Nioh-1250K).**

***Index Terms*— Cardiovascular diseases (CVDs), MD-Link device, Empirical experiments, ECG feature extraction.**

I. INTRODUCTION

Each year, about 40 million people in the world die from non-communicable diseases (NCDs), which is equivalent to 70% of all mortalities globally [1]. Among NCDs, cardiovascular diseases (CVDs) are the leading cause of death, with 17.5 million people dying from them annually [1, 2]. Heart attacks and strokes account for 80% of all the CVD deaths. Moreover, over 75% of deaths caused by CVDs occur in low-and-middle-income countries [2]. In Vietnam, the number of people annually suffering from diseases related to cardiovascular problems increases rapidly. CVDs account for about 33% of total deaths among the Vietnamese population each year. In 2012, stroke was the leading cause of death, killing 112,600 people [3]. Thus, detecting cardiovascular problems early has been becoming increasingly important, especially since there are interventions that can reduce the mortality rate once these problems are discovered.

One of conventional methods to detect cardiovascular problem is to use a 12-lead ECG system which is only available at hospitals or primary clinics. Unfortunately, not all people can access clinics and they themselves are not able to predict when an adverse cardiovascular event happens. As a result, portable home-base ECG devices have been developing. Commercially available ECG devices (*e.g.,* KardiaMobile and KardiaBand) are from AliveCore as typical examples. While the KardiaMobile was designed as a piece of metal with two electrodes to get the ECG signal within 30 seconds, the KardiaBand was integrated to Apple watch, making it more feasible to collect the data. L. Desteghe, *et al.* [4] reported a performance of handheld ECG devices including MyDiagnostick and AlivCor to detect atrial fibrillation (AF) in at cardiological or geriatric wards . The study result showed that while the sensitivity and specificity of AF detection conducted by MyDiagnostick were 81.8% and 94.2%, respectively, that for AliveCore was 54.5% and 97.5%, respectively.

For the ease and convenience of ECG recording for users, many studies have been exploiting various type of electrodes which paves the way for completely replacing conventional electrode (*e.g.*, Ag/AgCl). C. Tseng, *et al.* [5] developed a wearable mobile ECG monitoring system using novel dry foam electrodes. The effectiveness of the new sensor is validated with stimulated ECG signals. Our group recently developed non-contact ECG electrode for firefighters, which showed comparable result with the conventional one [6]. The MD-Link device in this paper was utilized by active dry electrodes (silver-coated plate) with the unity gain buffer assistance which significantly reduces the impedance, enhancing the signal quality [7].

In this paper, we introduce a new version of MD-Link device by upgrading the physic of device and software program including mobile application for patient and doctor along with web server for data saving and computing as well. Furthermore, empirical experiments were conducted for the device's usability and accuracy assessment.

II. MD-LINK DEVICE

Fig. 1 describes the overview system, MD-Link prototype and ECG display software of the device. As mentioned in our previous work [7], the system as shown in **Fig. 1a** comprises of two dry electrodes which were deposited by a thin layer of silver over copper plate, analog circuitry including differential amplifier and anti-aliasing filter with 150-Hz cutoff frequency and microcontroller MSP430G2553 (*Texas Instrument*, *Dallas, TX*) for converting analog signal to digital signal and transmitting the data to smartphone Universal Serial Bus (USB)

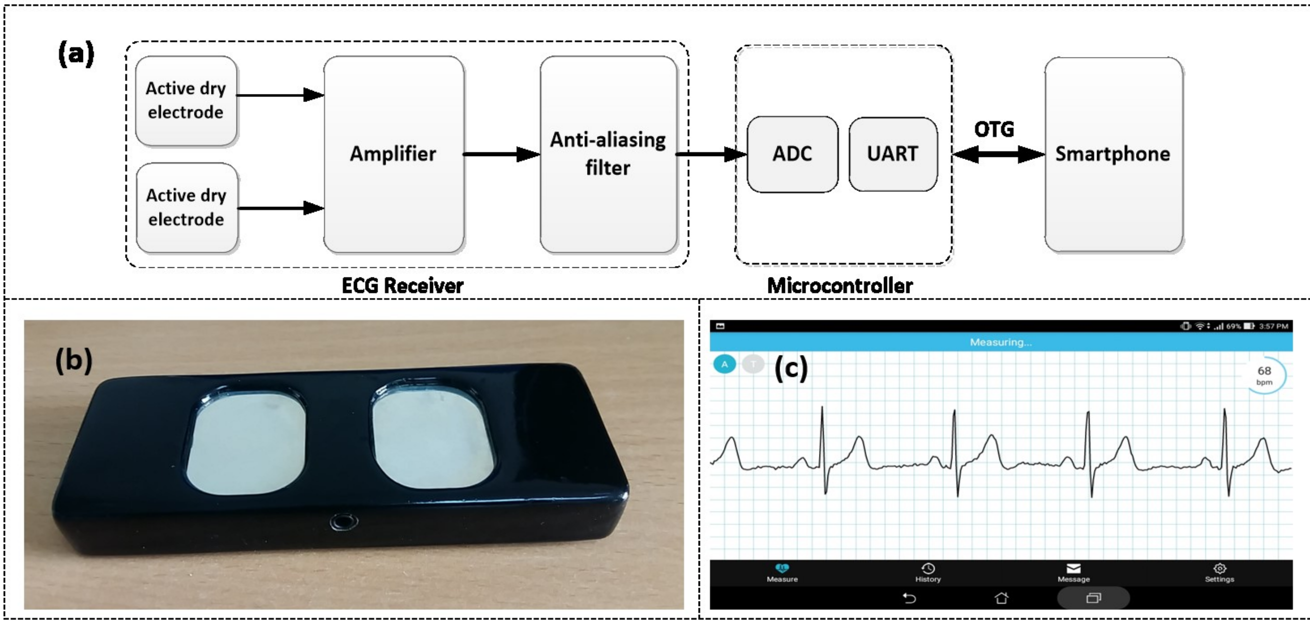

Fig. 1. The MD-Link device: The overview system of device [7](**a**), MD-Link prototype (**b**) and ECG display software (**c**)

On The Go (OTG) protocol. The prototype has been improved in comparison with original version described in by receiving the feedbacks of customers : 1) the box was designed more attractive by replacing the previous one to a polished and black appearance; 2) the electrodes (*i.e.,* two shiny silver plates as shown in **Fig.1b**) were securely squeezed underneath top side of the box and 3) the circuit was adjusted about the length, increasing the comfort of holding the device while measuring ECG signal. The ECG user interface (**Fig. 1c**) has been upgraded other features so that users would spend first few seconds to adjust position before getting the ECG signal and the application detected itself whether the collecting-ECG signal is inverse and if so the App will convert to correct sign. More details will be described in the next section.

III. Mobile Application and Cloud System

A) Mobile Application for Patients and Doctors

For patient mobile application, it needs to meet the following requirements: 1) real-time receive and process the data from MD-Link device and update heartrate value every 5 seconds during measurement; 2) save data to the database which would be synchronized with server; 3) able to enroll any doctor in available list and send message to enrolled doctor. For doctor mobile application, once a patient asks to enroll a doctor, he/she is able to accept/reject the request. Once accepted, all data of patient will be updated to only enrolled doctor, protecting the patient's privacy. SMS message function is available for doctor to contact with his/her patients if needed.

Fig. 2 describes user interface of patient application. The main display as shown in **Fig.1c** allows users to set up some parameters and display mode. A letter located in top right corner is for automatically adjusting graph size for a specific screen. T letter which is next to A is for a timer. If turned ON, the application will be started after 5 seconds, enabling users to have a stable posture before recording. Users are able to review their measurement as shown in **Fig.2b.** Once clicked to each recorded result, the information in **Fig.2c** will be displayed which can remind users the status at that recording and other notices as well.

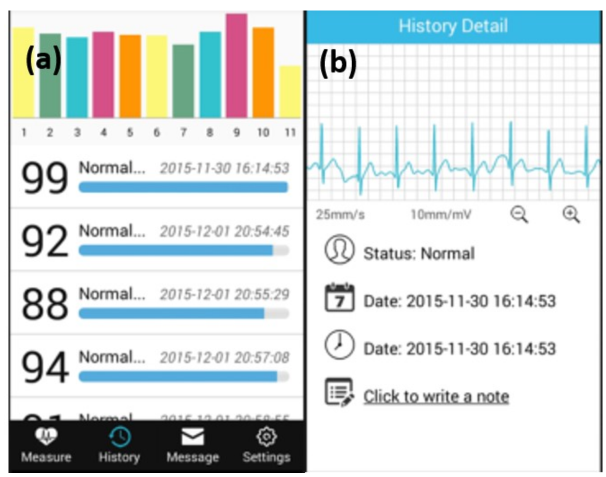

Fig. 2. The patient application: History tab (**a**) and history detail of each measurement (**b**)

Fig. 3 depicts the doctor application. As described above, a doctor can choose various features from the main display (**Fig. 3a**). To exam the ECG recording of any patients that were under his/her treatment, patient tab should be chosen, and all the ECG recordings of a specific patient will be displayed as shown in **Fig. 3b.**

B) Cloud System

Fig. 4 depicts the cloud system which create an interaction among patient and doctor application along with a web browser. The cloud server was designed to store data received from patient mobile application. The applications communicate with

Fig. 3. The doctor application: Main display (**a**), History of ECG recoding of a patient (**b**)

the server through application/JSON Hypertext Transfer Protocol (HTTP) request. After finishing ECG measurement, the data were saved to the local MySQLite database on patient's smartphone. Once an Internet connection in smartphone was established, all data including ECG data and patient's information such as name, age, address, etc were sent to the server via an HTTP request and the server stored the data into the MySQL database. Doctor of a patient can view this data through the doctor application or web browser.

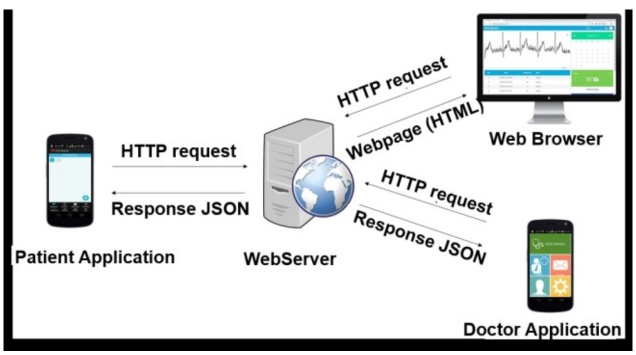

Fig. 4. The cloud system for the MD-Link device

IV. Empirical Experiments

A) Usability Evaluation of the MD-Link

The experiment was in compliance with the Institute of Population, Health and Development (PHAD) protocols (2016/PHAD/ECG-01) and the agreement of Hanoi Metropolitan University where volunteer students come from. A total of 234 health young college students were invited to participate in the study. Three identical MD-Link devices were used for this empirical experiment and each participant was measured the ECG data in 1 minutes with 3 trials. Background information questionnaires were collected prior to take the data and a survey also was conducted once the participants fished their measurement. This aims to ask the one's feedback regarding to the appearance of device for further improvement and expected price which they can afford. All data collected during the experiment were automatically synchronized to web server which were used to process later.

The below are steps to measure the ECG data:

1. Connect the tablet to the device, and then connect the device with MD links and sticker.
2. Sit in a comfortable position: leaning back in their chair, with two feet touching the ground.
3. Put the sticker on the front of the wrist, on the pulse points.
4. Put hands on thighs and put 1 cool electrode into the right hand. Note there is contact between the cool electrode and the palm of the hand.
5. Press the "+" button in the right corner of the screen to start measuring ECG within 1 minute.
6. Keep stable posture during the measurement.
7. After 1 minute, the device will provide the heart rate and ask questions such as "How do you feel to day" before sending the data to a server.

Usability of the device was assessed through the reliability of the measures and feasibility of use during intervention. Standard error of measurement (SEM) and intra-class correlation coefficient (ICC) estimations were used for reliability [8, 9], while structured questionnaire administered before and after measures was used for feasibility assessments.

B) Characterization and Validation of the MD-Link

This study was received Institutional Review Board approval from the Committee for the Protection of Human Subjects at Dartmouth College (STUDY00030415) and the Institute of Population, Health and Development in Hanoi, Vietnam (2017/PHAD/ECG-01). In this experiment, the MD-Link was designed to simultaneously measure ECG data with a standard ECG machine in clinic, namely Cardiofax S (*Nihon Kohden, Germany*) on about 30 patients. We aim to firstly evaluate and characterize the accuracy of the MD-Link through a comprehensive comparison of standard outputs such as PR interval, QRS duration, QT or corrected QT (QTc) interval, etc. Finally, the ECG data of both system will be interpreted by two cardiologists.

We conducted several on-site visits at Thanh Chan Clinic, a primary care clinic in Hanoi, Vietnam, where ECG measurements will take place. Subjects were recruited from among patients with cardiac arrhythmia who receive treatment at Thanh Chan Clinic. All subjects were 18 years old or above and followed study procedures and provide informed consent. The data acquisition process proceeded in the following 3 steps: (1) an interview before ECG measurement to collect patient demographics and CVD risk factors; (2) ECG measurement using the Nihon Kohden Cardiofax S, specifically a full 12-lead ECG recording, was performed by a trained technician and saved on an SD-card; and (3) successive lead I, lead II, and lead III ECG measurements using the MD-Link mobile device were conducted immediately after step 2. The data collected by the MD-Link after were synchronized to a Web-based software platform by 3G or Wi-Fi. Each participant took 30 minutes for an interview and taking ECG measurements.

V. Results and Conclusions

For the usability assessment, SEMs and ICC were estimated based on the heartrate values calculated at each trial. **Table I** describes the results of those parameters with 90% confidence interval (CI). It is obvious that no major difference was found in SEMs between trials 1 & 2 and trial 2 & 3 with 0.0496 and 0.0414, respectively. A slight improvement was observed in ICC of trials 2 & 3 with 0.95 in comparison to one of trials 1 & 2 with 0.94. The SEM and average ICC of all trials were 3.41 and 0.96 respectively. Questionnaires before and after measurement report that 45% of participants thought the device would be suitable for their parents while 69% thought the device would benefit their grandparents the most.

Table I: The Performance of The Device's Usability and Reliability

Comparison between trials	SEM (90% CI)	ICC (90% CI)
Trail 1 & 2	0.0496 (4.61- 5.37)	0.94 (0.92- 0.95)
Trail 2 & 3	0.0414 (3.85- 4.48)	0.95 (0.93- 0.96)
All three trials	0.0341 (3.17- 3.69)	0.96 (0.95- 0.96)

Fig. 5 illustrates about the comparison of standard outputs between the MD-Link device and 12-leads ECG (Nihon-1250K). It is obvious that the HR values achieved the highest correlation with a factor of 0.954, followed by the correlation of the QT interval and QTc interval with 0.882 and 0.790, respectively. The significant difference between two devices was found in PR intervals and QRS complex interval which obtained a correlation factor of 0.65 and 0.576, respectively.

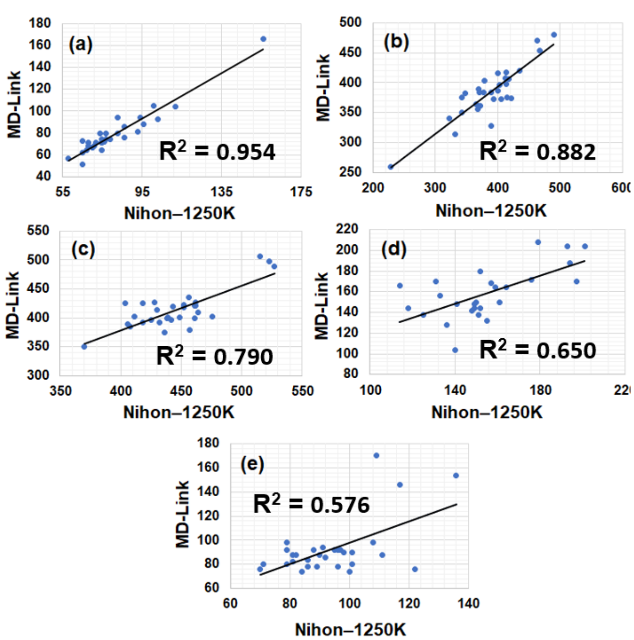

Fig. 5. Comparison of standard outputs between MD-Link and 12-leads ECG (Nihon-1250K): HR value (Unit: BPM) (**a**), QT interval (**b**), QTc interval (**c**), PR interval (**d**) and QRS complex interval (**e**) (Unit: Milliseconds).

In conclusion, a comprehensive system with the MD-Link device, cloud system and application software was presented. Two empirical experiments were conducted to assess the device's usability and reliability and validated the accuracy compared with standard ECG machine in hospital. In future, we would like to conduct other empirical tests with larger scale to fully investigate the efficacy of the device. Moreover, the amount of data were collected after two experiments would be a great resource so that we may leverage machine learning algorithms to early predict some anomalies, significantly assisting physicians in diagnostic.

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