Printed, Skin-Mounted Hybrid System for ECG Measurements

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Abstract

In this paper we report a design and fabrication process for a screen printed, skin-mounted hybrid system for electrocardiogram (ECG) measurements. The system consists of printed electrodes on a stretchable bandage substrate designed to be attached to the chest, an electronics module, and a data receiving device. The electronics unit is reversibly attached to the single-use electrode bandage to measure the ECG data. The ECG data is then transmitted to a mobile device via Bluetooth Low Energy and the mobile device then displays the data graphically and sends it further a cloud for storing and further analysis. The attained quality of the measured ECG signals is fully satisfactory to compute important cardiac parameters and after preprocessing the signal could be used for more profound analysis of ECG wave shapes.

Introduction

Vital sign monitoring is evolving from stationary, wire-connected monitoring to a mobile monitoring with wireless sensor systems. Monitoring systems are shrinking in physical size and weight, and the monitoring electronics are brought closer to the patient, as is already done with wearable measurement devices. Several physiological parameters can be measured without penetrating the most outer layer of the human body, the skin. Consequently, unobtrusive body monitoring, where the monitoring is done with skin-mounted devices, is a fast growing research field.

Continuous vital sign monitoring might tremendously benefit several patient groups. For example, cardiac patients may experience unpleasant sensations from the heart outside the hospital environment, and it might be crucial to be able to verify the degree of criticalness immediately when the symptoms arise. To improve the skin/sensor interface and wearability of the devices (comfort and ease of application) in these tracking situations, the development is transitioning from rigid and planar electronic systems towards more adaptable, skin-mounted electronics [1,2].

Skin-mounted electronics or epidermal electronics refers to electronic systems that have several beneficial properties, such as elasticity, thin structure and lightweight, to be mounted on the bodies' epidermis (outer layer of the skin) [3]. Skin mounted electronic systems can provide new kinds of medical applications to measure vital signs non-invasively or even offer drug delivery mechanisms through the skin [4]. To reduce costs and waste material related to manufacturing of epidermal electronics, additive screen printing can be utilized in place of multiphase subtractive lithographic techniques.

Here we report a system level description, fabrication process and electrical characterization results for a printed, skin-mounted hybrid system for electrocardiogram (ECG) measurements. Both the conductors and the electrodes on a bandage substrate were fabricated using stretchable silver/silver chloride ink and screen printing. Stretchable silver ink was deposited on top of a 50-μm-thick polyurethane film, which was then heat laminated with transparent adhesive film to provide the adhesive layer for the system. The manufacturing process together with the stretchable substrate and ink enable cost-efficient fabrication for stretchable hybrid systems.

The resulted skin-mounted system is designed for measuring the ECG using a small area electrode configuration called EAS, that is a subset of an EASI lead system introduced by Dower et al [5]. In EAS lead configuration three electrodes are located at the lower part of the sternum (electrode E), at the standard ECG V5 (electrode A) and at manubrium (electrode S). Using this small area electrode configuration makes it possible to integrate a rigid ECG measurement module with the stretchable bandage type of a substrate, and because of this, it can be used also in ambulatory situations.

ECG measurements were conducted while the test person was sitting, lying down and when the person was walking. The quality of the measured ECG signals is fully satisfactory to compute heart rate and many other important cardiac parameters. After proper preprocessing, the measured signals also offer potential for morphology analysis of ECG wave shapes.

EAS lead system

For maximal clinical impact, an electrode setup considered for ambulatory ECG monitoring requires careful balancing between patient comfort and both accuracy and completeness of the measurement setup. In vastly under-diagnosed atrial fibrillation monitoring, for example, non-invasive ambulatory electrocardiographic patch devices have been claimed superior to conventional

Holter monitors chiefly due to unobtrusive and user-friendly designs that have led to longer study periods and higher study completion rates [6]. Typically, these sorts of patch devices are measuring a single bipolar lead with a short intra-electrode distance (IED) [6], and thus are dependent on the careful placement of the device, as the prominence of atrial and/or ventricular activity in such a lead is highly dependent on the positioning of the device [7-9]. Nevertheless, the benefits of bandage type devices – including ease of use, little intrusion to daily activities, staying hygienic and resistant to water – are significant in the user's point of view to the extent of overweighting the shortcomings and having better clinical yield [6].

We consider that many of the said beneficial aspects can be translated into multichannel realm in the proposed printed and stretchable skin-mounted system that essentially bridges the gap between traditional Holter monitors and recent patch type devices. For arrhythmia monitoring purposes, we expect that a multi-channel device could offer potential for more accurate localization of the problems, better analysis of conduction disorders, and better power especially in differential diagnosis. Due to moderately longer IED and multiple channels, the system as a whole can be less susceptible to variations in the electrode placement in the sense of diagnostic power, and offer much more potential for e.g. ischemic event detection. Ambulatory ischemic event monitoring from ECG has been shown capable of identifying high risk patient subsets, and evidence exists for improved outcomes after detection and treatment of asymptomatic ischemia [10]. What is more, monitoring of ST-segment changes can be used to monitor the response to treatment in acute MI (AMI) patients [10].

Any lead system is faced with the de-facto main diagnostic tool status that the standard 12-lead system has, as the vast body of scientific literature includes decades of work on the standard 12-lead system, its modifications and individual leads. In line with this fact, the EAS electrode setup is a subset of an extensively studied EASI lead system introduced by Dower et al [5]. Typically, the full EASI setup is used in derived lead systems which synthesize the standard 12-lead ECG channels from the measured EASI leads to conform to its aforementioned de-facto status. Moreover, the EASI-synthesized standard leads have been shown in e.g. [11-14] to offer similar diagnostic quality compared to the standard lead system, and also to have similar potential in the synthesis of leads optimized for coronary artery specific acute myocardial ischemia detection [15], for instance. Compared to the full EASI system, the reduced EAS setup is expected to retain a significant part of the diagnostic information and have potential for lead reconstruction as research exists on the individual bipolar leads (ES, AS, and AE) of the EAS system. It should be noted that only two of these are independent, and any one of them can be expressed as a linear combination of the two other leads.

The ES lead – also known as the Barker lead [16] and the vertical sternal lead – is very close to the CM2 (CM-V2) lead often used in Holter devices the difference being

in the location of the E electrode that is placed right to the standard V2 position instead of the lower part of sternum. According to [17], the ES lead exhibits larger P-wave area than the Lewis [18] lead and many non-standard bipolar leads used in Holter monitoring. A study [19] on a modification of the Lewis lead showed that in the ES lead the atrial signal amplitudes are at a similar level to the modified Lewis lead specifically developed for atrial monitoring. It should be noted that the modified Lewis lead differs from the ES lead only in the placement of the E electrode, as in the former it is placed at the fifth intercostal space to right of the xiphoid process. Additionally, the study showed that the ES lead has a similar susceptibility to baseline wander, a slightly increased susceptibility to electromyographic (EMG) noise, and higher ventricular activity amplitudes compared to the modified Lewis lead. Another recent atrial lead study [20] concluded that whilst their proposed "P-lead" provides the best P-wave signal strength, the modified Lewis lead and ES lead have an improved RMS-ratio of P-wave to the QRS-complex and T-wave. Their P-lead is measured bipolarly between electrodes at sternal clavicular junction and the midpoint of the left costal margin in-line with the seventh intercostal space. Therefore, the ES lead presents a midway compromise between the strength of the atrial activity, and the ratio of that with respect to the strength of the ventricular activity. Additional benefits include the central location of the E and S electrodes at easily identified anatomical sites on the chest separated from moving body parts and large muscle groups.

The AS lead, also known as the CM5, CM-V5 or "bipolar V5" lead, is routinely used in Holter monitoring, exercise testing and operation theaters. The AHA Exercise Standards for Testing and Training [21] recommend it as a useful lead not present in the standard lead set. It has been shown to provide high sensitivity for the detection of exercise-induced ischemia, and recommended as the most useful first lead in an ambulatory system with bipolar leads [22, 23]. It should be noted, however, that the ST level in AS lead has been found sensitive to infarcts in lateral aspects whereas septal and inferior infarcts can be partly missed, and a transthoracic lead can perform better [23, 24]. For practical purposes, however, adhesive electrodes placed on the back are not very user-friendly in ambulatory monitoring and can present signal quality challenges also in bedside monitoring while lying on the electrode. Together, the EAS combination of ES and AS leads should provide good potential for myocardial ischemia analysis since the leads CM2 (close to ES) and AS have been shown to overall have high diagnostic yield in the detection of ischemic ST segment changes [25].

Methods

The monitoring system

The skin-mounted ECG monitoring system consists of four printed electrodes and printed conductors which are

then connected to a measurement electronics module. The data is transmitted via Bluetooth Low Energy to a mobile gadget and a cloud service. Finally, medical personnel can go through the data and give the feedback to the patient. The overall system level description can be seen in **Figure 1**.
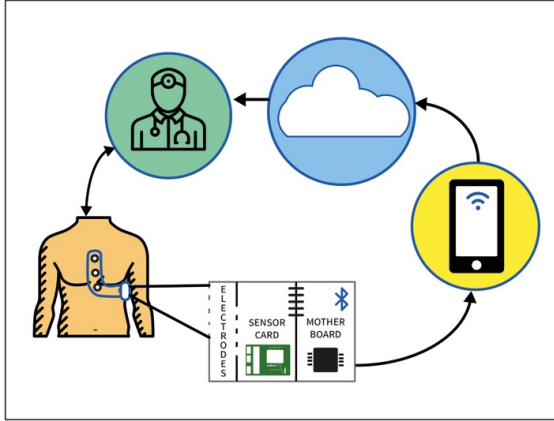

Figure 1. System level description of the ECG monitoring device, data transmission and services.

ECG measurement electronics module

The electronics module consists of two units, a digital unit and an analog unit. The digital unit houses the processing, power and wireless connectivity modules of the device. A cortex ARM M4F microcontroller TZ1001 clocked at 48 MHz from Toshiba Semiconductors is used in the design. The microcontroller also incorporates a Bluetooth Low Energy version 4.0 radio for wireless connectivity. A power management chip (PMIC), TPS65720 from Texas Instruments provides stable 3.3 V and 1.8 V regulated supplies. These supplies are made available in the half-moon edge connector for supplying power to the analog unit. In addition, the PMIC also houses a Li-Po battery charger, with the maximum charge current set to 100 mA. An external reset monitor, TCM810 from Texas Instruments, makes sure that the battery voltage does not fall below 3 V, by shutting off the battery line to the PMIC, in case battery voltage drops below the threshold. A 3 V voltage reference chip REF3330AID delivers a stable reference voltage for the ADCs. Three sets of half-moon edge connectors are provided around the motherboard to provide the necessary analog, digital and power lines to the sensor board. This includes ADC lines, JTAG programming lines, serial communication lines, GPIOs and 3.3 V & 1.8 V power lines. The micro-controller has a four channel 12-bit SAR ADC and a three channel 24-bit Sigma-Delta ADC. The 12-bit ADC can be configured in both differential and single ended modes. The 12-bit ADC configured in single-ended mode is used in the device. A basic block diagram representation of the digital unit is shown in **Figure 2**.

TZ1001 also includes a 3D accelerometer, which can be used to estimate the posture and state of motion of the person being monitored.
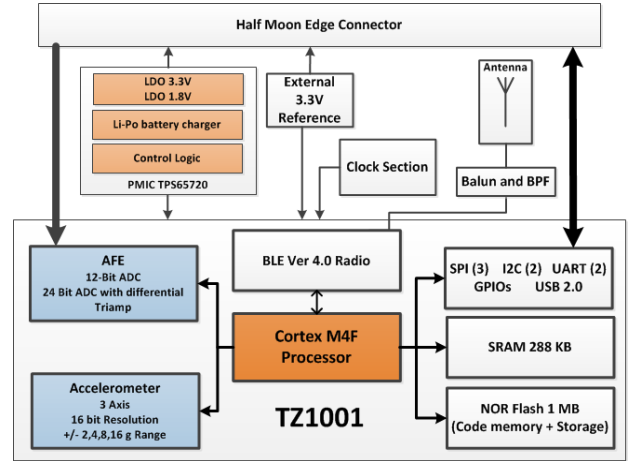

Figure 2. A basic block diagram representation of the digital unit.

The signal conditioning in three ECG channels is realized with identical single stage amplifier connections using INA333 instrumentation amplifier. The inverting inputs of each amplifier are connected to a common reference electrode. An RC high-pass filter in front of the amplifier takes care that high enough gain (i.e.123 in our case) can be set without a risk of saturating the amplifier by a possible DC-offset produced in the electrodes. The analog high-pass and low-pass cut-off frequencies have been set to 0.28 and 106 Hz, respectively. Electrical safety is ensured by limiting the patient auxiliary current in case of a single fault condition to 21 µA with the resistors in the amplifier input. The amplifier and other electronics of the device are protected against ESD with zener diodes. **Figure 3** shows the schematic of a single ECG amplifier section.
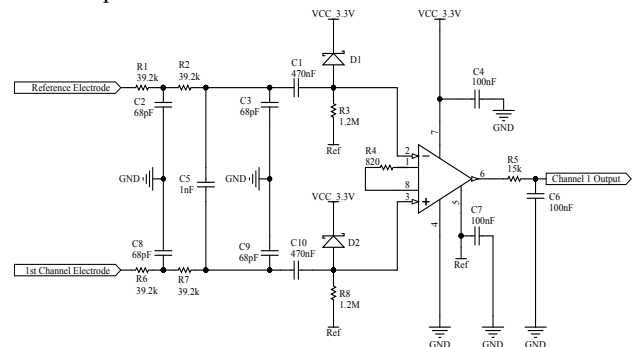

Figure 3. Schematic diagram of the amplifier connection of one ECG channel.

The input referred RMS quantization noise of the ADC alone is 1.7 µV, which is caused by the quantization step of 6.2 µV. The total RMS noise of the electronics (including quantization noise) was measured to be 3 µV when referred to the amplifier input.

The average current consumption of the entire electronics was measured to be 5.8 mA when transmitting the signals of the three ECG channels with 250 Hz sampling frequency. With the nominal battery capacity of

220 mAh, the estimated operation time of the ECG monitor approaches 38 hours.

Mobile app and cloud

In this section we briefly describe the Bluetooth communication between the ECG bandage and a mobile device, then we focus on how the data is stored and viewed on the mobile device and last we come to the cloud service and how the data is transferred and stored there.

The mobile application, developed for the Android platform, was designed to enable a mobile device to acquire ECG data from the ECG bandage via Bluetooth low energy (BLE), graphically display the ECG data, record the data, and send them to the cloud for storage and further analyses. To receive ECG data from the sensor patch, the mobile application first initiates and establishes a connection between the mobile device and the sensor patch and then registers for notification so that ECG data could be transferred from the sensor to the mobile device as notifications at some set intervals. Data transfer continues as long as both devices are connected. Here, the data transfer is done using a custom BLE service developed by Nordic Semiconductors, Nordic UART Service, which emulates UART/Serial port over BLE. This BLE service was used here because of the flexibility it offers for this research and development. Mobile application can read data from multiple sensors on each BLE connection and as well from multiple BLE connections simultaneously. This allows the application to act as a central unit for a complete body area network formed by multiple sensor devices that are each carrying out multiple measurements.

The mobile application decodes the ECG data packets received from the sensor patch to retrieve the ECG samples, and then displays them graphically using a commonly used open source Android charting library called AchartEngine. It also provides the user an option to locally record some of the data for up to ten minutes and storing them on the mobile device for later reference. The recorded data are stored in a json file, one separate file per record, together with some metadata needed for further processing and analyses like the recording time, the sequence numbers of the packets and the name or identification number of the sensor patch from which the data were received. The stored data could then be forwarded to the cloud via HTTP for storage, further processing and analyses. HTTP is used at this stage of development because security is not yet a concern. A secure protocol, HTTPS, would be used later in the development.

The cloud service is intended to store ECG data and other related data such as the time the data were acquired, patients' basic information related to the data, the identification numbers of the sensor patches, etc. It is also intended to perform some analysis on the ECG data and store the result to be viewed and interpreted by qualified medical practitioners.

The cloud service was implemented using Node.js on the server side and Angular.js at the client side. A NoSQL database, MongoDB, was used for the database implementation. The server and the client codes belong to a single application hosted on the Amazon Elastic Compute Cloud (EC2) and the database is hosted on MLab. The key interest here is to learn more about the suitability of these technologies for this task. In its current state, the cloud service only stores ECG data along with other related data and some patients' basic information. It also displays the stored ECG data graphically. The analysis feature and the GUI to view the results of the analysis are yet to be implemented. The analysis software will be running on a server of its own and will have an API that allows the storage cloud service to connect to it. During this research we will study the suitability and scalability of these technologies for use cases that store continuous measurement data.

Fabrication of electrodes

Silver electrodes and the circuitry were screen printed using TIC SCF-300 screen printer and CI-4040 stretchable Ag/AgCl ink (ECM). The silver ink contains 40 – 50 wt% silver powder and 5 – 15 wt% silver chloride powder diluted in a diethylene glycol ethyl ether acetate solvent. The printed pattern was defined by a polyester screen with a mesh count of 79 threads cm^{-1}, a mesh opening of 69 µm, and a stretching angle of 22.5°. Printing was done on a 50-µm-thick Platilon thermoplastic polymer substrate (Covestro). After printing, the silver pattern was annealed in a convection oven at 130 °C for 30 minutes.

The print, with polyurethane substrate, was heat laminated with Opsite Flexifix transparent polyurethane film. Opsite film has an acrylic adhesive layer underneath a polyurethane layer and this adhesive layer is used to attach the bandage to the skin. One additional polyurethane (50 µm Platilon) layer is laminated on top of the Opsite and print layers.
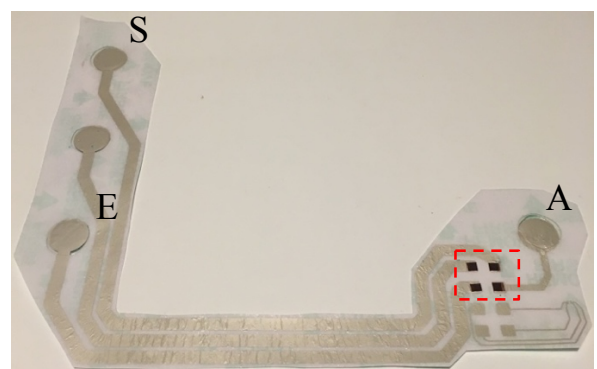

Figure 4. Printed electrodes laminated with an adhesive film. Connections for the electronics module are marked with a red dashed rectangle.

Figure 4 presents the printed electrodes without the electronics module. Anisotropic conductive tape (ACA) is used to attach the electronics to the bandage both electrically and mechanically. ACA provides electrical contacts from four electrodes via four 5 mm x 5 mm

contact areas (marked with a red dashed rectangle in **Figure 4**).

Copper tape was used to provide the electrical contact from the print on top of the bandage structure, so that the electronics module can be attached to the bandage. To improve the electrode skin interface a 0.89-mm-thick sensing gel circles were used between the skin and the electrodes.

Test measurements

Testing of the developed ECG monitoring system and the printed electrodes were done for one male volunteer who had no diagnosed heart related problems. Body hair was removed, skin was wiped with disinfectant and dead skin cells were scraped off with a rough sponge around the electrode areas prior to the measurements. **Figure 5** presents the monitoring system and the printed electrodes secured in place for the measurements.
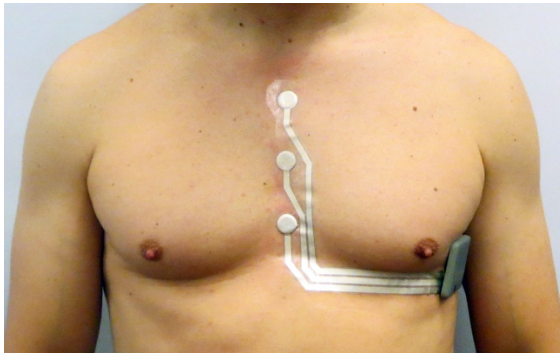

Figure 5. *Monitoring system and printed electrode placement.*

The measurements were done in three conditions: while lying, while sitting and during walking. Each of the phases were 2 minutes long and consequently the overall measurement time was 6 minutes.

Results and Discussion

Figure 6 shows five second extracts of the ECG signal from the three measurement conditions. While the measurement device uses single-ended configuration and measures the potentials of E-, A-, and S-electrodes with respect to a common reference electrode located between the E- and S-electrodes, the signals are converted to A-E, A-S, and E-S measurement leads by adding or subtracting them. The raw ECG signals of the three leads are presented with a different color. The red line (top) is the A-E lead signal, the blue line (middle) is measured between the A-S electrodes and yellow (bottom) signal is from the E-S lead. The signal plots show excellent signal-to-noise ratio even without any preprocessing thus allowing for detailed analysis of ECG morphology.

Conclusions

This paper presented a printed, skin-mounted hybrid ECG measurement system for continuous ECG monitoring. The system consists of printed electrodes, which are printed onto stretchable substrate with stretchable Ag/AgCl ink, a rigid electronics module, and a mobile user interface device. The print is laminated onto an adhesive film which is used to attach the electrodes to the skin. The electronics module is secured in place on top of the electrode bandage using conductive tape. This enables the removing of the reusable electronics part while the printed bandage is being disposed. The data from the ECG device is transmitted wirelessly via Bluetooth Low Energy to a mobile device where the data is visualized and sent further to cloud.

The performance of the device was demonstrated with measurements where a male subject wore the ECG bandage and was lying down, sitting and walking for 2 minutes per activity. The resulting signal quality is sufficient for detailed ECG analysis.
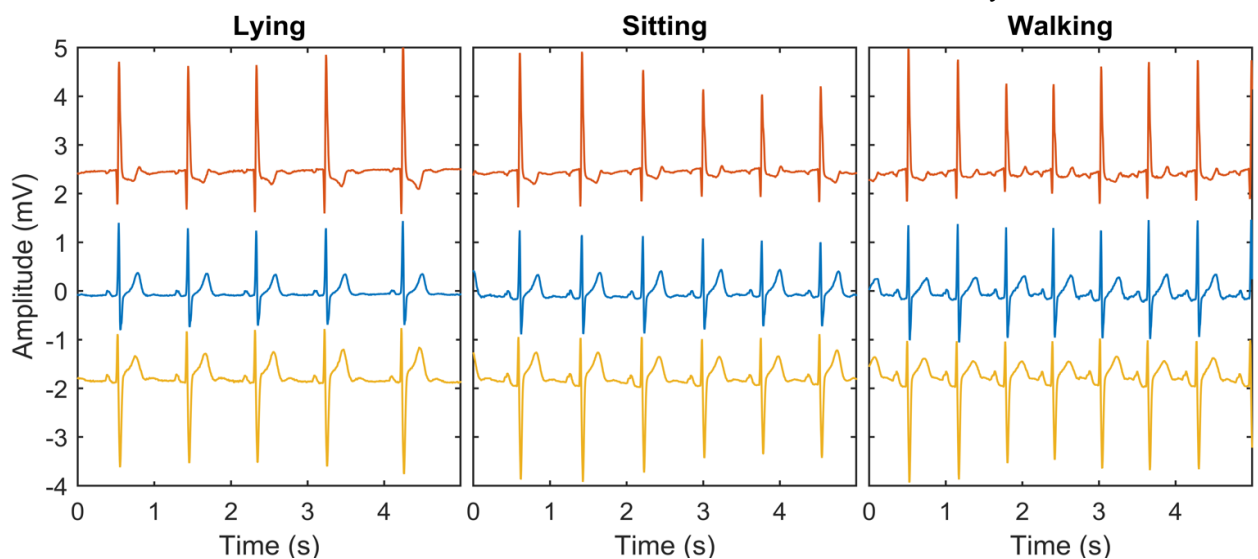

Figure 6. *Recorded ECG signal when the subject was lying down for 2 minutes, sitting for 2 minutes and walking for 2 minutes. Red: A-E lead signal, blue: A-S lead signal and yellow: E-S lead signal.*

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