Very Long-Term ECG Monitoring Patch with Improved Functionality and Wearability

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Abstract— **Heart activity monitoring is an important task for prevention and treatment of cardiovascular diseases. However, development of long-term, wearable electrodes remains an open issue. In fact, adhesion ability and energy consumption while preserving aesthetics is one of the major concerns to implement a minimally invasive monitoring system that measures and transmits electrocardiographic signals (ECG) during long-term periods of time. Based on the concepts of functionality, wearability, and resources, we develop a new long-term ECG monitoring system under the *wear-and-forget* principle. We also propose a system model of the electrode-skin interface that performs real-time measurements with a minimally invasive effect when compared with another competitive and implantable systems. As a result, testing of designed prototype shows that the developed very long-term ECG monitoring patch improves energy consumption and adhesion time up to 40 days.**

I. INTRODUCTION

In applications like prevention and treatment of cardiovascular diseases, there is a need for continuous monitoring of heart rhythm activity during daily life activities lasting long time periods and fairly exceeding the ability of conventional 24-hour holters. Moreover, the longer the patient is monitored - the greater the likelihood of detecting hidden cardio-pathological episodes as suggested in [1].

However, development of long-term ECG monitoring systems is not a trivial problem to overcome since improvement of some essential design elements remains an open issue. For illustration, the use of conventional gel-based electrodes and skin preparations may lead to skin irritation, and they are still not suitable for long-term periods of time [2]. Nonetheless, the primary concern is how to implement a minimally invasive monitoring system that measures and transmits ECG signals during the largest time [3]. In this regard, an ambulatory telemetry monitoring system is presented in [4] that can store and transmit information up to 30 days, but it needs to change its electrodes and charge battery on a daily basis, interrupting measurement at critical moments as pointed out in [3].

Another problem that can arise in long-term ECG monitoring systems is the presence of the ECG baseline wandering caused by irregular communication of the electrical impulses between the sensor-skin interface. This variation can be directly related to some changes of the impedance and capacitance of those elements located between the electrode and the skin. Several solutions have been explored to address this restriction, which mainly involve procedures of shortening the wires and placing all the circuitry near the sensor. Thus, authors in [5] present a second electronic skin consisting of a discrete device that perfectly adheres to the skin. The drawback of this solution is that it lasts no more than 15 days prior to detaching and collapsing. To make the second skin more resistant, the small exposed circuitry needs additional protection, leading to an increased thickness. Hence, more stable product tends to resemble a stamped temporal tattoo protected by a thin resin, like a patch. Another attempt is presented in [6] that wirelessly transmits power from a belt. Though the circuit solves the energy consumption problem partially, the recharging belt must be supplied very frequently so that so it would be impractical for the shower or to be combined with small items where the belt would affect the aesthetic appearance.

Based on the concepts of functionality, wearability, and resources, we develop a new long-term ECG monitoring system under the *wear-and-forget* principle. Besides, we propose a system model of the electrode-skin interface that performs real-time measurements with a minimally invasive effect when compared with another competitive and implantable systems, and improving the adhesion time and energy management.

II. METHODS

A. Human-centred Design of ECG Monitoring Systems

In this work, we use the human-oriented design methodology to develop the medical long-term ECG monitoring system. Specifically, our design relies on both the `ISO 13407` standard (human-centred design processes for interactive systems) [7] and `ISO 9241- 89210` (ergonomics of human-system interaction) [8]. Consequently, the most important functions required for designing personal, long-term ECG monitors are the following [9]:

– *Wearability* that is, the level of discretion of devices or the property associated with the ergonomics and product comfort, estimated in proportion to its level of imperceptibility, invisibility and lightweight. Comfort can be reflected in the product adherence to treatment.
– *Functionality* or the product's ability to perform the designed tasks providing the user security and environment safety. In case of the ECG sensors, the coupling between electrodes and skin is perhaps the most critical aspect of the electronic design.

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*This work is supported by funds: Generacion Bicentenario and Convocatoria 523 granted by COLCIENCIAS, and ARTICA-Medellin.

978-1-4244-7929-0/14/$26.00 ©2014 IEEE

– *Resources* needed to ensure the product works properly. Mainly, resources are associated with energy consumption, but also they may refer to services like Internet access, which can be quantified in economic terms.

Generally speaking, a suitable trade-off between the three sets of variables determines the overall quality of long-term monitoring systems to be designed.

B. Wearable Patch for Very Long-Term ECG Monitoring

In terms of functionality and wearability, the developed Very Long-Term ECG Monitoring Patch, called Electrodoctor® patch, is similar to the one presented in [6] that is powered only from an external source. Instead, our circuit also includes a battery that allows the device operating, but without receiving power from an external source during several hours, thus providing more freedom to the user. Another difference is the resource criterion. Our circuit board is built to be separated from an incorporated disposable adhesive, and hence the electronic portion is reusable and the only disposable part is the adhesive portion of the sensor. Besides, the patch adheres to the skin by using a hypoallergenic tape of high quality, being cost-effective as compared to other Holter or stress test devices.

We also introduce a unique model of electrode-skin interface for different sensor types. Particularly, based on the design presented in [10], we propose a generalized model of the electrode-skin coupling that can deal with placing electrodes over a garment. The electrode-skin interface that can also model contacts through an ionic interface or direct contact without electrolyte is shown in Fig. 1, where c_1 is the capacitance due to an explicit gap between the sensor and body hair, clothing or air), c_2 is the capacitance of the of the ionic interface (electrolyte), c_3 is the capacitance of the stratum corneum, and c_4 is the electrode-skin capacitance; r_1 is the impedance of the electrode, r_2 is the electrolyte impedance, r_3 is the resistance of the stratum corneum, r_4 is the gap impedance, r_5 is the sum of the impedances of the garment and the body, i.e., $r_5 = r_4 + r_6$, and r_6 is the impedance of the body.

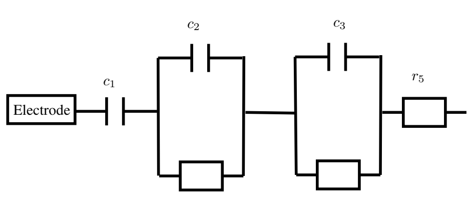


Fig. 1. Electrical model of the used electrode-skin interface.

The electric signal at the electrode is passed through an amplifier so that v_4 sums up the following voltages:

$$v_4 = v_1 + v_2 + v_3(z\alpha + \beta/c_4)$$

where v_1 is the skin voltage, v_2 is the half-cell potential, v_3 is the measured noise. The input amplifier voltage noise collects contribution of both the electrode-skin capacitance c_4 as well as the impedance between the electrode and the skin, z, that is given as follows:

$$z = \sum_{i=1}^{5} r_i$$

α, β are respectively the adjustment parameters of the impedance z and capacitance c_4 so that fixing their values the sensor switches between resistive to capacitive scheme.

In summary, the proposed model of electrode-skin interface implies that to accomplish an adequate ECG measurement, we firstly use electrodes with low half-cell potential. Then, we make the impedance get an extreme value: either zero-impedance (that is, firm contact) or inducing a high impedance when the system gets into the capacitive mode. In any case, we must keep impedance and capacitance having the smallest variations.

Concrete illustration of the above introduced skin-electrode coupling is given in the following types of sensor:

a) Rigid metal electrode: These reusable electrodes are frequently used in short-term ECG prototypes and are fixed by suction, compression or medical grade adhesive, causing traces on the skin that may remain for several days. Furthermore, they can act as vehicles of cross infection. This kind of electrodes does not work properly in motion since they detach due to their own weight. Rigid metal electrodes are in contact with the skin via a conductor gel, thus, we assume $c_1 = 0F$, r_2 and c_2 will have low values while a contact remains firm.

b) Disposable Silver/Silver Chloride (Ag/AgCl) electrodes: These electrodes are the most used in ECG, Holter, and stress prototypes since they provide adequate quality because their half-cell potential and strong adherence. However, electrodes require gels that degrade over time and cause discomfort after removal since many particles of the adhesive remain adhered to the skin, requiring additional cleaning. Thus, disposable Ag/AgCl electrodes usually detach before 48 hours and the hydro-gel causes skin irritation issues [6]. In this case, $c_1 = 0,F$, $c_2 \approx 25\,nF$, and the value r_3 ranges from $2k\Omega$ to $300k\Omega$, depending on the proportion of the manufactured conductive material.

c) Capacitive electrodes: These rigid electrodes have as advantage to perform signal measurements without direct contact. Yet, they are voluminous and induce wanders in the ECG waveform, diminishing accuracy of the signal processing. Capacitive electrodes are usually attached to the garment, thus, resistor r_4 can reach values exceeding $300M\Omega$ since for lower resistance values, the electrode can lose the capacitive influence and increase the noise gain. Also, $c_1 \approx 30pF$, r_2 and c_2 are assumed as zero-valued.

d) Textile electrodes: These electrodes ensure a smooth, natural skin contact, but they exhibit poor adhesion, causing artifacts as the patient gets in motion. Induced artifacts are partially corrected by generating an ionic interface with water or conductive gel and also combining materials that facilitate the adhesion as silicone. Textile electrodes have a resistance ranging from 1 to $100\Omega/cm^2(r_1)$, $c_1 = 0F$. Values of c_2 and r_2 depend on the chosen electrolyte that can be drinking water due to less amounts of salts and chlorine that improve the redox process.

III. EXPERIMENTAL SET-UP

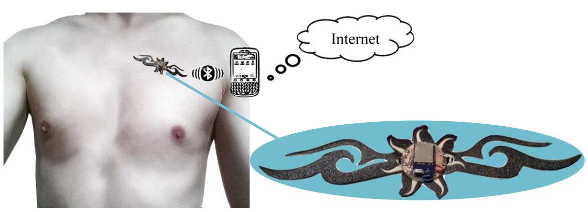
A. Human Test Protocol of Data Acquisition

In this work, the used clinical trial protocol follows guidelines of the Declaration of Helsinki, the Belmont Report [11] and the Resolution 8430-1993 of the Colombian Health Ministry. The procedure was previously approved by an ethics committee. All subjects were informed of the procedure obtaining their voluntary agreement to participate. Trials were conducted in ten men and ten women whose sizes vary between S-M-L with weights between $50 - 100\,kg$ and ages between $20 - 70$ years. The body mass index (BMI) is distributed as follows: BMI $< 24.9(55\%), 25 \geq BMI \leq 29.9(40\%), BMI \geq 30(5\%)$.

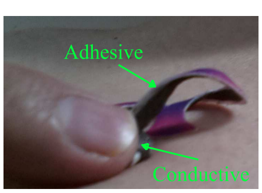
B. Acquisition and transmission hardware:

The electronic device Electrodoctor® acquires and transmits ECG signals to a mobile phone by using the Bluetooth Low Energy specification. Thus, the smartphone can retransmit information to Internet allowing for real-time data processing so that battery duration lasts between 100 and 1000 *mAh*; this aspect also influences the patch size. In the concrete case, we select a patch with two CR2032 button cell batteries providing $500\,mAh$ as one of the most comfortable options.

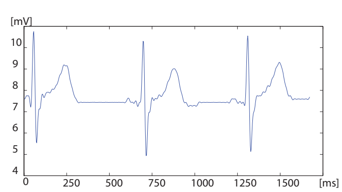
Fig. 3 shows some examples of persons wearing long-term adhesives prior to incorporating the electronic unit. Because of their reduced thickness, they are not noticeable outside of the garment and are also easy to place at different sections of the thorax. In addition, quality of acquired ECG signal remains adequate as seen from the example shown in Fig. 2(c).



(a) Electrodoctor® patch



(b) Adhesive and conductive elements of the sensor



(c) V as function of time

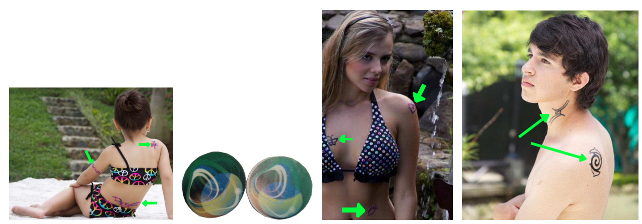
Fig. 2. Example patch combining the Electrodoctor module with a body mark (Figs. 2(a) to 2(b)), and its acquired ECG waveform (Fig. 2(c))

C. Testing Protocol

In accordance to the required functions presented in Section II-A, the test protocol includes the following steps:

1) Functionality testing: The time that each patch remains attached each patch is recorded. The following parameters are estimated: the accurate counting QRS complexes [12], the autocorrelation of the signal, the amplitude of the RS segment as a convenient way to estimate the Signal-to-Noise ratio [6]. Particularly, the two following tests are performed:

- *Adhesion tests:* several adhesive tapes including temporary tattoos approved by health agencies are tested with the purpose of granting an aesthetic appearance to the product. Adhesion quality is verified periodically. Figs. 3(a) to 3(d) display some of the products tested. The best result is obtained using a circular body mark produced by the Dazzling Summer Company [1], characterized by a peel adhesion at $180°$ angle under $2.2\,N/25\,mm$ strain. This patch is carried by a 34 year old woman in the thorax during 45 days.
- *Quality tests:* as shown in Fig. 2(c), a clean signal is acquired without software filtering, making the $60\,Hz$ filtering nearly unnecessary. The average RS-segment amplitude is $4,53\,mV$ representing a suitable amplitude with relation to products such as Polar, Zephyr and Numetrex Cardioshirt. The accuracy counting QRS complex events is 99%, and the measured autocorrelation for the same interval is 0.99.



(a) Infant (b) Circular (c) Shower (d) Boy

Fig. 3. The behavior of the body marks between people of different age and gender Fig. 3(a), Fig. 3(c), Fig. 3(d). Adhesives stay in place even during showering but those with lines thinner than $5\,mm$ remained adhered less than 12 hours, while the patch of $4.5\,cm$ diameter (Fig. 3(b)) is attached for 45 days.

2) Wearability Testing: These tests are associated with the ergonomics and comfort of the patient [9]. We test wearability by measuring the physical volume and weight of the device, and qualitatively asking the subjects under testing for their perception of the system. Mostly, test subjects do not feel the patch. Yet, the subjects make clear that when the patch starts peeling out, it generates itching. Therefore, the patch should be changed while remaining well adhered in order to ensure comfort, without degrading the measurement quality and the electronic circuitry.

3) Resources Testing: This test aims at determining how long the device can continuously operate based on battery capacity, system power consumption, and the recharge technique while operating. For security reasons, we chose to minimize the number of batteries in the patch, introducing a

[1]Pictures in Fig. 3 are printed under permission of *Dazzling Summer Company S.A.S.*

pair of button type batteries that are thin enough and together offer a capacity of $500\,mAh$.

Since energy consumption of the patch is $9\,mAh$, it can have a continuous operation for two days. Time operation can be extended without interrupting the measurement, by recharging the devices two or three times weekly using a battery located in the garment, for example on a shirt. Therefore, management of the energy consumption is addressed, reducing the problem of long-term measurement to the sensor-skin adhesion. Table I shows performance of different products in terms of energy consumption, adhesion time, and size.

System	**Time** ***[days]***		**Size** ***[cc]***
	Adhered	*Monitoring*	
Electrodoctor Patch	**40**	**40**	7
Electronic Tatoo	15	N/A	**0.5**
IMEC with acceleration	N/A	8	12
IMEC only HR	N/A	30	12
Zephyr	2	1	6
Health Patch	3	3	9
Yan et al.	N/A	1	N/A

TABLE I

PATCHES COMPARISON INCLUDING ADHESION TIME, CONTINUOUS MEASUREMENT TIME, AND SIZE IN VOLUME UNITS

IV. DISCUSSION AND CONCLUDING REMARKS

A system is presented allowing wireless, long-term monitoring of ECG signals. The system is based on the *wear-and-forget* principle that facilitates the outpatient screening, at the same time, simplifying the work for healthcare professionals at hospitals, homecare monitoring or emergency care. It also offers a comfortable location in surgeries with minimal distortion during showering, sleeping, and extreme activities like jumping, running, or even squatting.

Our design is supported by concepts fusing fashion and technology: functionality, wearability, and resources. These concepts are used in conjunction with the proposed model to represent the electrode-skin interface during the acquisition of ECG signals by direct contact, through ionic interface, and by capacitive coupling. The model allows inferring that an adequate ECG signal quality can be obtained by fixing the electrode-skin interface having either zero impedance (firm contact) or inducing a high impedance (capacitive domain). In the latter case, the model predicts that the dry contact sensors are able to get an adequate trade-off between functionality and wearability, provided that the sensor keeps an uniform and firm contact with the skin.

In order to achieve a stable and dry contact for long-term ambulatory ECG, we have presented a new patch-type monitor that improves contact thanks to its high-quality adhesive ability. From the patch tests, it is concluded that there is a relationship between time of adhesion and contact surface, i.e. a larger area and a longer adhesion. As a result, despite the natural exfoliation of the skin, the developed patch can remain attached for over a month. Since it is unlikely that dry contact electrodes ever replace the adhesive [10], applications of continuous ambulatory monitoring find a suitable option in non-irritable and of long-term dry sensors, as the patch presented in this paper.

The patch is competitive in comparison to other state-of-the-art products, particularly, against the second electronic skin and the electronic Tattoo of Rogers et al. [5] (both get out after two weeks due to natural exfoliation). Th proposed path also overperforms the IMEC that continuously monitor and transmit data, at the most, for a month, but transmitting only heart rate, and with a thickness greater than $1\,cm$ which affects the system wearability [13].

The presented patch also provides advantages compared with the system developed in [6] since our patch looks more flexible and discrete because of its $3mm$ thicknesses. It works during the shower and is energetically autonomous for several days. It does not need other garments to perform activities lasting less than 24 hours, like taking a shower or using small clothes. Also, it is rechargeable during the use and provides continuous ECG transmission for time periods exceeding 40 days.

As future work, the authors plan to carry out testing for adhesion regarding transpiration and analysing in detail reusable adhesives without chemicals, such as self-cleaning adhesives based on the Van der Waals forces with Gecko effect [5].

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