ABSTRACT

YIN, LANJUN. Design of Screen-Printed Electrodes on Infant Garment for Electrocardiogram Measurement. (Under the direction of Dr. Jesse S. Jur).

The growing attention on personal health suggests that the impact of wearables technologies for healthcare will be significant. Wearable biosensors combined with clothing to provide long-term monitoring of vital signs is very useful for the prevention and timely diagnosis of diseases. In this thesis, an infant garment with screen-printed biosensors for electrocardiogram (ECG) measurement was designed and evaluated. The biosensors for ECG measurement, were produced by screen printing of Ag/AgCl conductive ink. Physical tests for electrodes showed that the electrodes have good abrasion resistance and washing resistance. Skin-electrode impedance measurement suggested that the screen-printed electrodes had similar performance to commercial wet electrodes. Air permeability of electrodes was altered by the incorporation of open access holes that provide air movement through the textile to the skin-side of the electrode. Although higher impedance was measured when the hole area was increased, the breathable electrodes are shown to be a valid approach to improved comfort for long term use. Finally, infant onesies were knitted with for testing of the electrode designs. The knit structure was altered by the use of spacers and elastic yarns to help maintain the skin-electrode contact without sacrificing comfort. The infant onesies were evaluated by two 3-6 month old infants for ECG measurement and the test indicated that the QRS complex could be well recognized for the evaluation of heart rate variability. This analysis provided the framework for a future clinical test with customized ECG data collection and analysis system that aims to be conducted.

Design of Screen-Printed Electrodes on Infant Garment for Electrocardiogram Measurement

by
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A thesis submitted to the Graduate Faculty of
North Carolina State University
in partial fulfillment of the
requirements for the degree of
Master of Science

Textile Engineering

Raleigh, North Carolina

2017

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BIOGRAPHY

Lanjun Yin was born in the lovely town of Jinan, Shandong, China. She obtained her Bachelor of Engineering in Textile Engineering from Jiangnan University, China, in 2016. She has been studying at North Carolina State University from August 2015 to pursue a Master of Science degree in Textile Engineering. During the study at NC State University, she got involved in E-textiles research and started learning related technologies under the direction of Dr. Jesse Jur. She loves the way to brainstorm cool ideas and seek a solution to bring the idea to reality. It is joyful to imagine the future and it is also interesting to learn about history. Lanjun Yin likes spending time in museums, learning the profound history and experiencing diverse culture. She hopes she can keep the curious heart, as always, to explore the world and enjoy life.

ACKNOWLEDGMENTS

I would first like to thank Dr. Jesse Jur, my thesis advisor, for his support, mentorship, and guidance throughout my research. I appreciate all his contributions of time, ideas, and funding to make my master experience productive and stimulating. He is enthusiastic, energetic, and supportive, which encouraged and inspired me all the time. I am thankful for the exciting research he has provided and I am grateful for the opportunity to learn and work.

I also thank my committee members Dr. Emiel DenHartog and Dr. Katherine Annett-Hitchcock for their scientific advice and knowledge, as well as insightful discussions and suggestions. I would like to acknowledge our project manager, Allison Bowles, who worked together with me on the project. She has been very helpful throughout my research. I am thankful for the onesie prototypes she has designed and provided. Raj Bhakta, Hasan Shahariar, and Jack Twiddy all provided valuable perspectives and help when I had questions about my experiment and research. My sincere gratitude also goes to all the other members of the NEXT (nano-extended textiles) group: Amanda Myers, Alexa Kearns, Wade Ingram, Nathan Weiner, Cemile Aksu, Brian Lezzi, Furkan Kose, and the numerous rotation students who have come through the lab. All these nice and helpful people with different backgrounds make this great group a source of good advice and collaboration, as well as joy. I thank Tahmid Latif for helping me to do the skin-electrode impedance measurement in the College of Electrical and Computer Engineering. I also appreciate Jeffrey Krauss, Judy Elson, Jan Ballard, and Teresa White, the lab managers and research specialists in the College of Textiles for their help during my research. I would also like to thank Dr. Eric Hodges and the group at the School of Nursing at the University of North Carolina at Chapel Hill who provided the infant mannequin for my design and offered the opportunity for preliminary infant testing.

I would like to thank all my friends and family for their support and help over the past school years. I also thank Dr. Hongbo Wang, the Dean of College of Textiles, and Dr. Changhai Xu in the College of Textiles at Jiangnan University, who provided me with this overseas study opportunity and encouraged me to pursue it. Last but certainly not least, I must express my profound gratitude to my parents for their love and support. My parents have sacrificed their lives for me to provide unconditional love and care. I would not have made it this far without them.

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Chapter 1. Introduction

1.1 Motivation

Smart garment and e-textile technologies are rapidly evolving in a broad range of application areas. Health, wellness, fitness, military and first responders are some dominant applications that drive the growth and development of innovation in wearable technology [1]. Traditionally, clothing is used to cover and protect the body from elements or is used for aesthetic purposes. Smart textiles technology has added opportunity to provide higher value to clothing that protects, monitors, and determines body status to avoid potential dangers. Smart textiles are projected to have a great impact on healthcare, which will help the healthcare system be more effective and efficient [2]. During recent years, more and more experienced nurses have retired from pediatric care, while the family is paying more and more attention to an infant's health and wellness. There is a large demand for people with special skills and rich experience who can take care of infants who need careful, multi-focused and long-term health monitor and care [3][4]. This care is labor intensive and time-consuming as monitoring never stops for infants who do not have the ability to explain their health status. Smart textiles technology provided new opportunities in vigilant infant monitoring.

Cardiovascular disease is a leading cause of death worldwide. Electrocardiography (ECG) is the most commonly used non-invasive method that provide numerous and useful information for cardiac diagnosis [5]. Under normal conditions, ECG signal is a regular pattern that indicates the ordered electrical activities during every heartbeat. If any cardiac disorder occurs, they can be reflected by abnormal patterns in the ECG signal. An experienced clinician can diagnose various conditions of the heart by visual analysis of abnormal ECG patterns [6]. ECG data collection is universally applied for the health examination of infants and many life-threatening disorders can manifest during this period of life [7]. An ECG test is a primary method for early diagnosis for heart diseases such as congenital heart disease and arrhythmias [8]. To achieve effective diagnosis of cardiac abnormalities, vigilant monitoring is necessary. ECG monitoring helps identify whether the infant is born with a heart defect or not. Sudden Infant Death Syndrome (SIDS), which is the unexplained death of a baby less than one-year-old, has become one of the biggest concerns for parents[9][10]. ECG monitoring is the most efficient method of early detection, aiding in diagnosis, treatment, and prevention of SIDS. For example, a study has indicated that some infants with prolonged QT interval in the first week of life had a higher risk to be a victim of SIDS [7]. Preventive diagnosis can only be effective under vigilant long-term monitoring because it is hard to predict when the disordered signal may occur and it is necessary to compare present and previous signals. However, today's monitoring methods in hospitals or neonatal intensive care units (NICU) are not always user-friendly. Most monitoring methods prevent infants from moving freely because of connected wires. Furthermore, the medical instruments are expensive and spacious, which is not suitable for use at home. Thus, the combination of ECG measurement and garments is perceived as a solution for continuous baby health monitoring that bridges the use case scenarios in the NICU and home.

1.2 The Electrocardiogram

An electrocardiogram is a recording of the regular electric waves generated during heart activity. The abnormal or changed regularity can be identified by interpretation of the ECG [5]. A normal heart beat is initiated by a small pulse of electric current and this electrical impulse is generated in the sinoatrial node (SA node) cells [11][12]. The autonomic nervous system controls the rate of the SA node sending out electrical signals [11]. Generally, the SA node, the heart's pacemaker, generates 60 to 100 impulses per minute [13][14][7][15], but for neonates, the normal heart rates can be 150 to 230 beats per minute [7]. ECG needs to be obtained by placing electrodes on the skin and the electrical signal would be transferred to a visual trace by an ECG machine [11]. In the early 1900s, Wilhelm Einthoven invented the electrocardiogram and provided the theoretical Einthoven triangle, which is a three-limb leads placement used in electrocardiography (Figure 1- 1) [12][13][14]. Three potential differences between each two electrodes can be obtained as lead I, II and III [16].

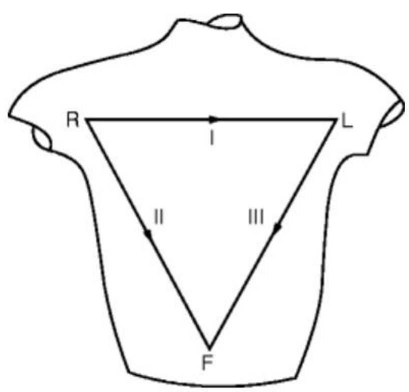


Figure 1- 1 Einthoven triangle is formed by three leads (I, II, III) using three limb electrodes: right arm, left arm and left leg (R, L, F)[16]

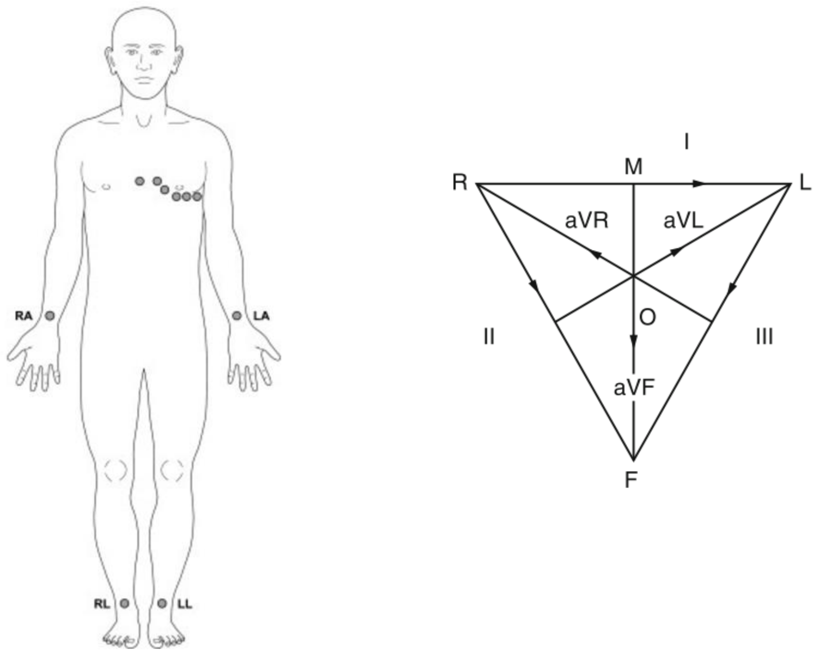


Figure 1- 2 Standard 12-Lead ECG electrodes placement using 10 electrodes[17] and a diagram of 6 leads (I, II, III, aVR, aVL, aVF) obtained by three limb electrodes (R, L, F) [16]

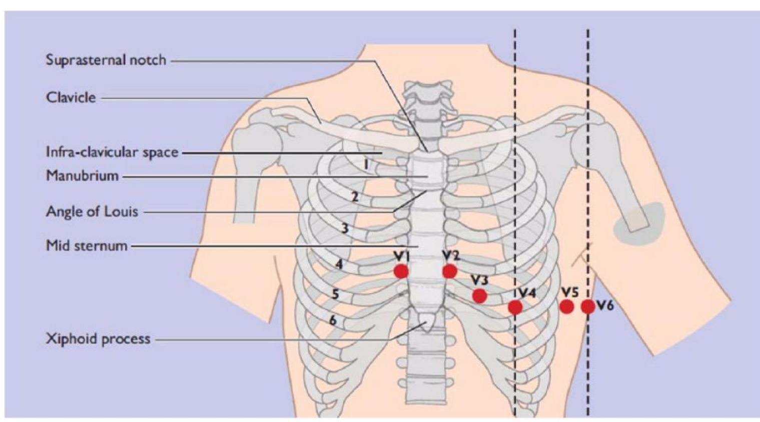
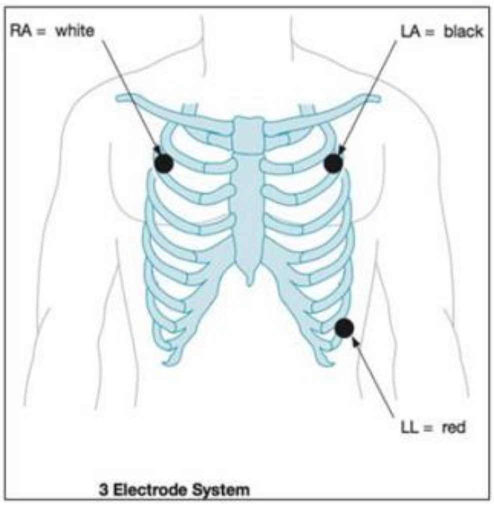


Figure 1- 3 In 12 leads ECG placement, six electrodes place on the chest. The anatomy of the thorax and the six electrodes placement [18].

In clinical practice, 12-lead ECG placement (Figure 1- 2 and Figure 1- 3) is a standard measurement method. The 12 leads stand for 12 different perspectives of heart. This is the most comprehensive way to monitor the status of heart. 12-lead ECG placement uses 10 electrodes [19]. Six leads (I, II, III, aVR, aVL, aVF) can be calculated by three electrodes on the limbs (right arm, left arm, and left leg). Another six leads are provided by six electrodes placed on the chest. The 10th electrode is known as the right leg electrode. It works as a ground lead to provide reference [5][13][16][19].



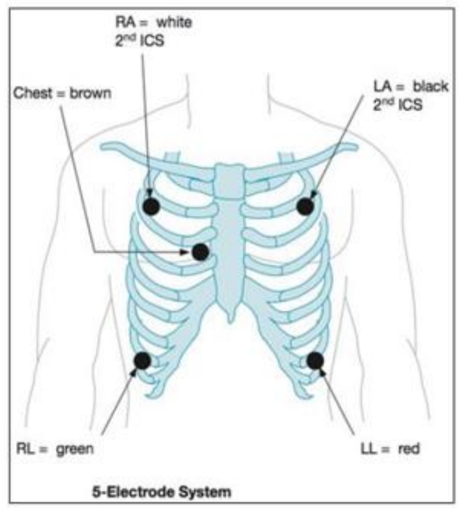


Figure 1- 4 ECG electrode placement. Left: Standard 3-lead placement. Right: Standard 5-lead placement[20]

There are standard 5-lead and 3-lead placement as well (Figure 1- 4) [20]. These methods are more applied for long-term monitoring for arrhythmias that does not require a complete 12 perspectives of the heart[21]. 3-lead placement of the Einthoven triangle is the most common method for ECG acquisition. The three electrodes include the right arm (RA), left arm (LA) and left leg (LL). These three electrodes are all located on the torso. Lead II is the most important one among these three leads. It is the potential difference between RA and LL and this lead is more correspond to the direction of current flow in the heart. 5-lead placement adds two more electrodes to increase the quality of the ECG signal. One is a right leg (RL) placed on the right lower abdomen and another one placed on the V1 position on the chest[20][21]

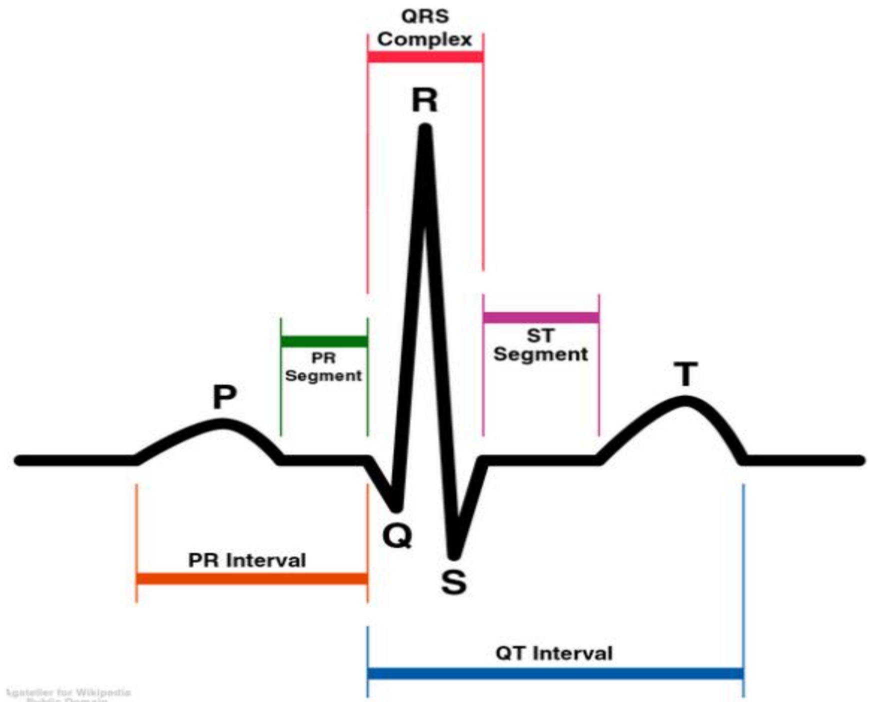


Figure 1- 5 The ECG Waveform[22]

Compared to adults, infants under one-year old have more variable and unpredictable ECG because of their fast growth rate. Any change of the size or position of heart can bring new features to the ECG pattern [7]. This necessitates the need for continuous monitoring. It has been previously shown that ECG is the most sensitive method to detect heart rate that allows the most effective evaluation of the heart condition. It plays an important role of neonatal resuscitation[23]. There is a significant amount of medical information that can be obtained from an ECG signal including arrhythmia, defects in the heart, inflammation around the heart, improper blood flow rate, etc. [7][24]. An ECG displays a single heart beat in a regular P-QRS-T waves sequence (Figure 1-5). Different waves represent different activities in the certain region of heart chamber [25]. The QRS complex can be easily recognized because of the large amplitude of the R peak. A typical way to determine the heart rate is to calculate the time between two sequential R peaks [5]. The variation of this heart rate over time, or heart rate variability (HRV), can provide further information about a person's stress, mood, and fatigue. Under different conditions, our bodies react with physical, mental, and emotional responses which elicit a heart rate change, controlled by physical signals of the autonomous nervous system (ANS)[26][27][28]. For infants who are not able to express their feelings, ECG analysis is a way to show their mood and lead to better communication between parents and their children.

In summary, ECG analysis is able to provide vital information about a person's physical health. With the development of wearable technology and more attention on individual health and wellness, the popularization of a miniature and portable ECG wearable system is a future trend that can help people to monitor their mental, physical and emotional conditions whenever and wherever needed.

Chapter 2. Wearables for Infant Health Monitoring

A wearable system used for physiological parameters monitoring consists of sensors, microcontrollers, conductive interconnects, input/output, power, wireless communication and garments or accessories [29][30][31]. Garments or accessories are the substrates of a wearable system, and all the other components are required to be compatible with textiles or accessories that have similar properties to textiles. Thus, electronic or mechanical components in a wearable system should be miniaturized, unobtrusive, flexible and comfortable. In addition, the system is required to be washable, or at least removable prior to washing[31].

With the development of biosensors, wireless communication, and power supply technologies, wearable sensor systems provide significant potential in the field of health monitoring, especially in vigilant health monitoring of infants. Since infants are unable to articulate pain and discomfort, continuous monitoring is crucial for clinicians and parents to know their health conditions. Vital physiological measurements can be achieved either in the hospital or at home by integrating sensors into clothing. Wearable systems for infants are aimed at providing every day monitoring for infant health status without disturbing their daily activities. A reliable wearable system can ease parents' concerns, reduce manpower of infant supervision and reduce the cost of hospital-based clinical care.

2.1 Previous Work

2.1.1 Academic Research

There are many academic research prototypes related to infant physical monitoring through the use of many different sensors. Respiration, heart rate, and body temperature are the common focused vital signs. Researchers at Eindhoven University of Technology in the Netherlands have developed a prototype of a smart jacket (Figure 2- 1) for vital sign monitoring of neonates in a NICU. Three different sensors were combined with smart jacket for electrocardiogram (ECG), blood oxygen saturation, and body temperature monitoring. Silver textile electrodes were used in the prototype for ECG monitoring. This textile electrodes were knitted using a nylon yarn coated with 99.9% silver metal [32].

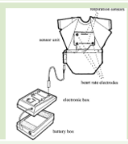
Figure 2- 1 Prototype of the Smart jacket with textile sensors for ECG monitoring[32]

Another design, K.U. Leuven, ESAT-MICAS, and Department of Textiles at Ghent University in Belgium utilized a belt/strap and a baby pajama (Figure 2-2) through the integration of woven and knitted stainless steel textile electrodes into fabrics This garment was intended to again monitor ECG and respiration rate of children in hospitals. In the belt/strap prototype, only textile sensors are integrated In the infant pajama prototype, the supporting electronics are integrated into the wearable, including an inductor coil which is used to transmit data and transfer power between the wearables electronics and the base station [33][34].

Figure 2- 2 Left: Prototype belt with textile electrodes integrated into the mickey mouse ears[33]. Right: Prototype baby pajama with sensors and circuits, worn by a 21-week-old baby[34].

The two research examples mentioned above both have shown good ECG measurement results, but are still inferior to the measurements using wet electrodes. Other research that has focused on the use of different sensor materials have shown similar performance. For example, a conventional baby pajama with elastic straps used three cardiac electrodes made of silicones with carbon-doped polymer and two capacitive respiratory sensors[35] and an infant vest was proposed to monitor ECG, temperature and respiratory using silver coated silicone rubber, NTC-thermistors and carbon-filled elastomers as sensors [36]. They all showed potential for ECG monitoring, but a low frequent base line drift, obscured waves indicated they did not perform well in comparison to the stability of wet electrodes and there was no indication for a good durability and robustness of long-term use.

Table 2- 1 Academic research prototypes of infant health monitoring.

Prototype	Sensor type	Function
Smart jacket (Chen et al., 2010) 	• Silver coated textile electrodes • Pulse oximetry • Negative temperature coefficient (NTC) sensor	• ECG monitoring • Blood oxygen saturation monitoring • Body temperature monitoring
Baby pajama (Coosemans, Hermans, & Puers, 2006) 	• Stainless steel textile electrodes	• ECG monitoring • Respiration monitoring
Baby pajama (Gramse, De Groote, & Paiva, 2003) 	• Carbon doped polymer based on silicones • Capacitive displacement transducers	• ECG monitoring • Respiratory rate monitoring
Multi-sensory baby vest (Linti, Horter, Österreicher, & Planck, 2006) 	• Resistive strain sensors (carbon-filled elastomer coated on textiles) • Silver silicone rubber printed on textiles • Moisture-dependent resistance electrodes • NTC-thermistors • Textile ribbon cable (Teflon isolated micro wires) works as interconnects	• Respiratory monitoring • ECG monitoring • Excessive sweating detection • Body temperature monitoring

2.1.2 Commercial Products

Some commercial infant monitoring products are introduced below. They are designed for constant infant monitoring at home to help parents to keep an eye on their children, which provides real-time monitoring and gives feedback of the infant's health status:

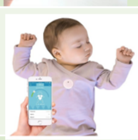
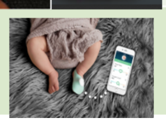
- Mimo Smart Baby Monitor: A monitoring system that includes baby bodysuits, Mimo electronics (sensors, transmitter) and the Mimo app. Capacitive sensors with Ag/AgCl ink constituent are printed on the front of the infant suit. The electronic package is connected to the baby suit by a magnetic coupling. This garment tracks an infants' respiration, heart rate, skin temperature, sleep quality and position [37].
- MonBaby Smart Button Baby Monitor: A button that can be snapped onto an outfit and snapped off. The sensor system includes a 14bit accelerometer to monitor body

position, breathing and detect fall movement. It connects to a mobile via Bluetooth 4.0 [38].

- Owlet Baby Care: A sock with a pulse oximeter that can detect heart rate and oxygen levels. The system has a rechargeable battery, Bluetooth connectivity, and removable electronics [39].

These wearable products consist of separate parts from the infant garment and the electronic part is bulky, obtrusive and rigid. This means that electronic part is not very compatible with textiles. The price of all these commercial products is about $200 US or higher which indicates the high cost of the current wearable technologies.

Table 2- 2 Commercial products of infant health monitoring.

Products	Price	Type	Function
Mimo Smart Baby breathing Monitor (http://mimobaby.com/) 	$199	Baby bodysuit with printed capacitive sensors. Electronic package connected by magnetic coupling	• Breathing monitoring • Body position and activity alerts • Skin temperature monitoring • Sleep quality indicators
MonBaby Smart Button Baby Monitor (https://monbaby.com/) 	$169	A button that can be snapped onto a outfit and snapped off	• Body Position • Breathing monitoring • Proximity Removal • Fall Detection
Snuza (http://www.snuza.com/) 	$89.99- $129.99	A device can attach to baby's diaper	• Abdominal movement monitoring • Breathing monitoring • Skin temperature monitoring • Body position monitoring and fall detection • Vibration to rouse the infant
Baby Vida (http://www.babyvida.us/) 	$159.99	A sock with pulse oximetry	• Oxygen level monitoring • Heart rate monitoring
Owlet Baby Care (http://www.owletcare.com/) 	$ 249.99	A sock with pulse oximetry	• Oxygen level monitoring • Heart rate monitoring

2.2 Wearable Sensors and Electrodes for Health Monitoring

In wearable health monitoring, sensors detect and collect body signals or properties of local environment, which play an important role in wearable systems. Wearable sensors can be classified as physiological sensors and biochemical sensors [4][31]. Physiological sensors are used to monitor physiological sign such as respiration, heart rate, blood pressure and muscle activity. These wearable sensors provide the possibility of continuous and real-time monitoring for health status outside the hospitals. In turn, these wearables are a potential asset to a person's primary health care [31]. Biochemical sensors are used to monitor chemical compounds both in human bodies and in an in-vitro environment. For example, the level of blood glucose, CO_2 concentration can be detected by biochemical sensors. In order to get accurate measurement, implanting sensors into the body is generally required for biochemical sensors to detect body status [4]. In this thesis, ECG is the signal that is detected by this infant onesie so different physiological sensors technologies used for ECG are addressed below.

For ECG measurement, electrode sensors are used to transport electrons and produce electrical charge. These sensors are required to be close to the skin to detect bioelectric signals [40]. Wet or gel electrodes are the conventional electrode types that used in hospitals to do ECG patient analysis, but these electrodes are not suitable for long-term continuous monitoring [41][42]. For long term monitoring, it is necessary to use dry electrodes. The dominant types of existing dry electrodes can be classified as textile electrodes, conductive polymer electrodes, capacitive electrodes, and printed electrodes [29][43][44][45].

2.2.1 Commercial Wet Electrodes

Figure 2- 3 Wet electrodes placed on a child [46]

Commercial wet electrodes (Figure 2- 3) are the most used type of electrode in a medical setting. Manufacturers like 3M, Vermed, Conmed, and Philips produce countless electrodes every year used for health care monitoring. Most electrodes consist of sensor part, adhesive part, and backing part. Generally, sensor part is Ag/AgCl ink fixed on plastic film. The conductive Ag/AgCl ink is the most important functional element in an electrode. The hydrogel is the most common material used as adhesives to reinforce the contact between the sensor and the skin. The backing material includes tape, paper, and fabric to support the sensor and preserve the shape. Most wet electrodes are disposable because the hydrogel cannot be reused and it will dehydrate fast after the seal opened. Some commercial electrodes are suggested to be reused if the gel can be reactivated with sterilized water, but there is no guarantee that the gel will be reactivated successfully and dehydration will happen during long exposed time [47][48][49] [41].

Wet electrodes have competitive benefits in bio-signal acquisition compared to dry electrodes because of the gel/adhesives. The purpose for using gel is to improve the conductivity between the skin and the electrodes. The adhesive nature of the electrode reduces motion artifacts as the adhesive keeps the electrode from sliding and losing contact with the skin. The gel layer also works as an electrolyte that facilitates the movement of the ions that produces electrical potentials. In other words, the electrolyte layer helps to get better signal transduction[41] [50][47][48][49].

Figure 2- 4 Pediatric electrodes placed on an infant [51]

However, the drawbacks of wet electrodes are also evident. For example, they take a long time to set-up and can be uncomfortable to remove. Skin irritation is a big concern, especially for infants and children who have sensitive skin [52]. The biggest difference between an infant or pediatric electrodes (Figure 2- 4) and adult electrodes is the reduction of risks for irritation. Since infants have sensitive skin, these electrodes are designed with gentle, hypoallergenic adhesives and soft conforming materials. For example, a portion of the acrylic adhesive border is removed to make repositioning easier, and permeable tape or cloth is used to ensure the breathability of the skin [49]. Furthermore, all pediatric electrodes are latex free. The backing and adhesives are gentler and more comfortable compared to adult electrodes. More use directions are considered, such as using drops of water to make electrode removal easier and strictly controlling the service time of electrodes [49][53]. However, there is no guarantee for 100% protection to all pediatric patients. The humidity of wet electrodes increases ion conductivity, but it can cause bacterial growth and subsequent irritation, especially to infants that suffer from a weak immune system [41][54]. Because the hydrogel does not stay hydrated for a long time, most electrodes are designed to be disposable after a few minutes to hours of use and the recommended maximum use time is one to three days [50]. Although there are electrodes that can be worn for three to five days technically, it is not comfortable and hygienic when the electrodes adhere to the skin all the time. Re-wetting the gel surface to regain adequate adhesion may be needed as well. The gel will dehydrate and the dehydration time depends on various factors like room temperature and humidity. Dehydration of the electrodes negatively impacts signal detection due to an unstable impedance, and mostly it decreases the conductivity[55]. Thus, dry electrodes are desirable for patients with sensitive skin and long-time constant monitoring demand.

2.2.2 Textile Electrodes

Textile electrodes are commonly used in wearable health monitoring devices since they are compatible to the garment. They are typically constructed by weaving, knitting, or embroidery of conductive yarns [55]. Several types of conductive yarns are available. Complete metal yarns are made of stainless steel, copper or other alloys filaments. Polymer-metal mixed yarns can be metal filament co-spun with a polymer, metal-filled polymer fiber filament, or metal coated polymer fiber. Fibers can be coated by a conductive metal such as silver. They can also be coated by or blended with a conductive polymer such as polyaniline (PANI) or poly(3,4-ethylenedioxythiophene) (PEDOT) [56]. The dominate construction of conductive yarns is non-conductive fibers (nylon, polyester, etc.) coated with a thin layer of silver or some other conductive material on the surface. Different coating materials lead to differences in performance of textile electrodes. For instance, gold and silver coated textile electrodes can obtain a good signal since these two materials have the low resistance. However, the gold coated textile electrodes are not hypoallergenic and lose conductivity after washing compared to silver coated electrodes because gold is more chemically active than silver [32]. Although textiles electrodes can be very compatible to textiles, they might have adhesion and corrosion resistance problems [31][56].

2.2.3 Conductive Polymer Electrodes

Various conductive additives are mixed in polymers or coated on the surface of polymers to make this type of dry electrodes. Generally, conductive additives like carbon, stainless steel fibers, and carbon nanotubes are combined with some flexible polymers. Chen et al. mixed carbon into ethylene propylene diene monomer (EPDM) rubber[57], Baek et al. etched gold pattern on titanium and then deposited on the flexible elastomer poly(dimethylsiloxane) (PDMS) [58]. A foam coated with silver by thermal evaporation can make an compressible electrically conductive structure[54]. The texture of this kind of electrodes is flexible, gentle and elastic which is good for long-term use, but can be observed as uncomfortable in textiles.

2.2.4 Capacitive Electrodes

Most capacitive electrodes are used as non-contact electrodes (Figure 2- 5). This kind of electrodes utilizes capacitive coupling. Lee et al., at Walter Reed Army Institute of Research (WRAIR), tested the non-contact electrodes and reported the ability to measure the

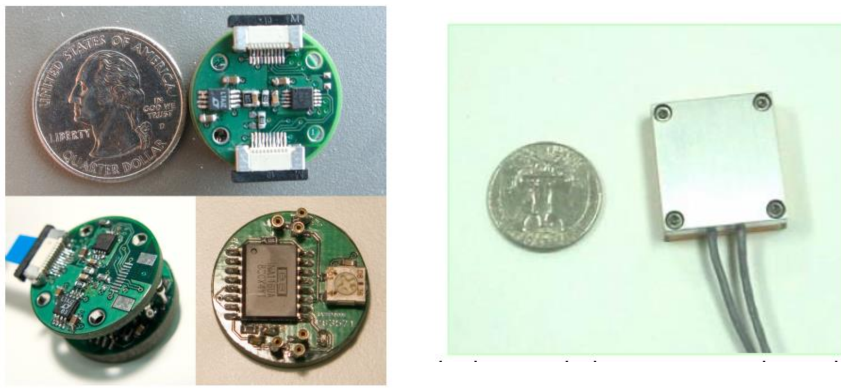


Figure 2- 5 Two types of non-contact electrodes[96][59]

ECG through cotton shirts without physical contact [59]. Although no direct contact to the skin is required, the capacitance is very sensitive to the distance between the electrode and the skin, which makes it difficult to get stable and accurate signals. Another drawback of capacitive electrodes is the change of dielectric properties because of sweat as it may cause erosion of the dielectric interface [45]. In one example of a capacitive electrode that was fabricated on silicon, a silicon dioxide dielectric layer supported a foam cushioning layer. The foam layer was described to provide protection for the dielectric layer without the risk of wearing out and corrosion [54]. However, most non-contact electrodes are made of rigid material that is not flexible and comfortable. Therefore, capacitive electrodes are considered to be a challenge for integration into textiles for long-term use.

2.2.5 Printed Electrodes of Conductive Inks

Printed electrodes using conductive inks are compatible with textile properties such as flexibility, stretchability, softness, and comfort, which is suitable for wearable use. The main composition of the ink includes conductive elements, a mixture of elastomeric polymer binder and regular binder, and solvent. The elastomeric polymer binder is used to give stretchability for the ink while the regular binder is used for attaching the ink to the substrate. The conductive particles are contained in a solvent, which provides the ink rheological properties necessary for printing [13][9]. The most well-known conductive elements are metal particles, graphene, and carbon nanotubes (CNTs). Metal particles such as Ag, Au, and Cu, are popular because of their high conductivity. There is less interest in Au-based inks because of high price and the small supply. Copper is considered as the most likely alternative to silver as it is low cost, easy to prepare, and has a good conductivity. However, copper can be easily oxidized at ambient conditions, increasing the resistivity [4][14][11]. A sintering process is a necessary step in metallic ink application as it is needed to remove the excess solvent to increase the conductivity and increase the adhesion of inks to a substrate [14]. Heating is the most conventional method for sintering. For Cu inks, a higher sintering temperature is needed to reduce the formation of copper oxides, but the high temperature may result in deformation of substrate [12]. Graphene and carbon nanotubes are an alternative ink materials. These carbon-based inks have the potential for low-cost production and easy for processing because of the inert chemical properties, but they have lower conductivity as well as poor dispersions leading to aggregation because of particulate's large aspect ratio and van der Waals forces [11] [15]. Silver is the most widespread material used in conductive ink printing because of good conductivity and biocompatibility [60]. It has the highest conductivity compared to other materials [61]. Silver ink also has better stretch-resistance when the ink is a mixture of small and large silver flakes rather than only small flakes. The mixture of large flakes and small flakes can improve the performance during stretching. Large flakes can be more connected when they are stretched. Small flakes increase the conductivity and also are able to lower the sintering temperature [13]. Figure 2-6 shows examples of screen-printed electrodes integrated into different substrates. The combination of printed conductive components and textiles shows high potential for developing novel products. Daily-use textiles are required to be comfortable and printed electrodes are unobtrusive, light and flexible that will not influence the comfort of textiles when adding more functions. They are also flexible for multilayer construction, and easy to realize different designs. Figure 2-7 shows the screen printed conductive components heat pressed onto the textile substrate [62]. The current challenge of screen printed electrodes includes the improvement of durability to weathering, abrasion, and washing [54].

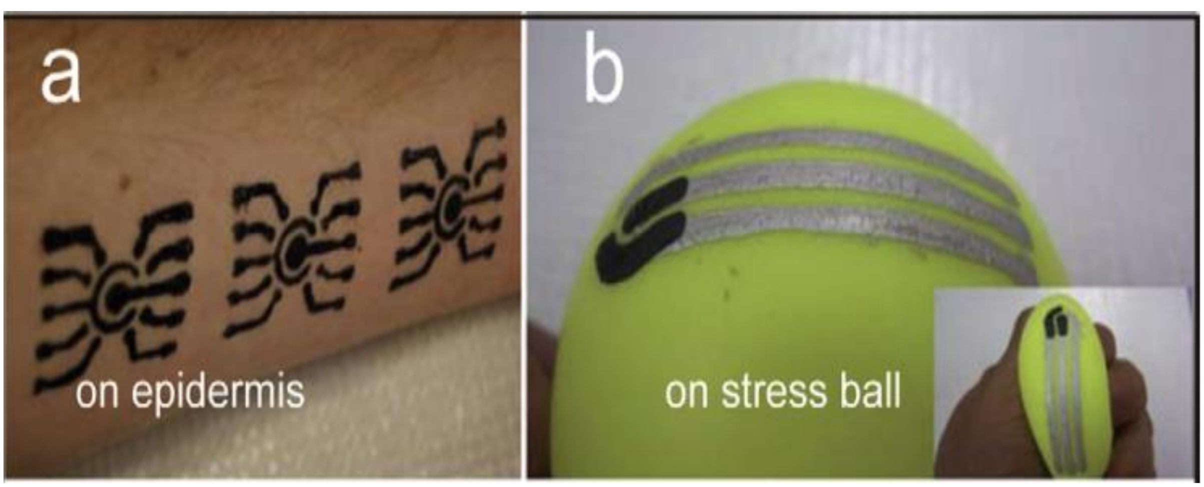


Figure 2- 6 (a) carbon ink-based arrays electrodes stamped on the epidermis (b) three-electrode contingent on a stress ball [60]

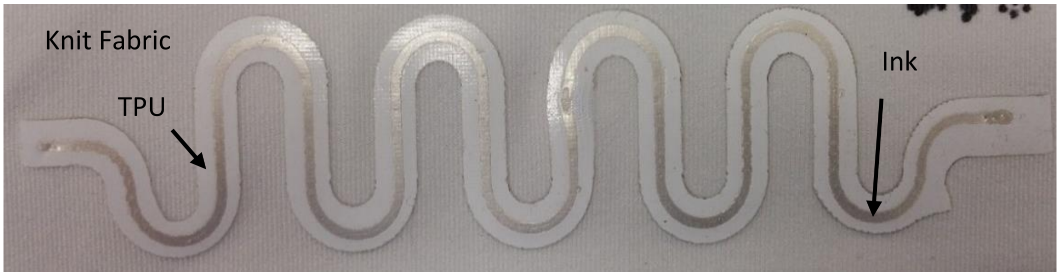


Figure 2- 7 Ag/AgCl screen printed interconnect on TPU substrate, heat pressed on knit fabric [62]. Picture credit: NEXT (nano-extended textiles) research group.

Chapter 3. Criteria and Technologies for Infant ECG Onesies Fabrication

3.1 Criteria and Requirement for the Infant ECG Onesie

3.1.1 Size of Infant Onesies

Sudden infant death syndrome (SIDS) is the leading cause of death for infants under 1-year-old in the USA. It was reported that 50% of SIDS cases occurred among 7.6 to 17.6-weeks infants. 10% of cases occurred after 24.7 weeks, which means the possibility of SIDS would greatly decrease after 6 month [10]. Because the higher risk for babies younger than 6 month, three to six month babies were selected as the target group in this research. According to the common size chart of commercial baby onesies, the height and weight of 3-6 months babies are about 24-26 inches and 12-16.6 pounds respectively [63]. A baby mannequin borrowed from the School of Nursing at University of North Carolina, Chapel Hill, was used for onesie prototype fitting.

Baby (Sizes 0-24M)

US Size	Age (in months)	Height (in inches)	Weight (in pounds)
P	Preemie	Up to 17	Up to 5
NB	Newborn	Up to 20	5-8
3M	0-3 Months	20-23.5	8-12.5
6M	3-6 Months	24-25.5	13-16.5
9M	6-9 Months	26-27.5	17-20.5
12M	9-12 Months	28-30.5	21-23.5

Figure 3- 1 Baby garment size chart on Amazon [63]

3.1.2 Criteria and Standards

To design an infant wearable, various requirements need to be considered such as safety, comfort, function and aesthetics. Quality and performance of functional clothing such as dimensional properties, material properties and color fastness, should achieve the requirements and standards of normal clothing. Furthermore, health and safety requirements and standards must be considered and achieved. Harmful materials and chemicals of high concentration, mechanical hazards are some major considerations. Harmful chemicals such as lead, nickel, formaldehyde must be restricted and all the chemicals used in the clothing production process should be in acceptable levels in the finished products. Some mechanical hazards are draw strings and cords, metallic and other attachments, small parts, sharp points and edges, which have risks of choking or other physical harm [64][65]. Table 3-1 includes the standards in GB 18401-2010, which is the technical requirements of clothes and decorative textiles in China. Type A is the requirement for infant products. As can see from the table, clothing performance is assessed. These performance requirements are related to health and safety as well. For example, dry rubbing resistance indicates the performance of pilling and abrasion. If the dry rubbing resistance has a low degree, pilling will easily occur. Therefore, the garment can become worn out, and staple fibers released from the garment leads to an inhalation risk [66].

Table 3- 1 Technical requirement of clothes and decorative textiles in China (GB 18401-2010) [66]

Requirement		Type A	Type B	Type C
Formaldehyde (mg/kg)		≤20	≤75	≤300
pH		4.0-7.5	4.0-8.5	4.0-9.0
Color fastness/Degree ≥	Water resistance (C/C, C/S)	3-4	3	3
	Acid/alkaline sweat resistance (C/C, C/S)	3-4	3	3
	Dry rubbing resistance	4	3	3
	Saliva resistance (C/C, C/S)	4	-	-
Odor		Odorless		
Decomposable carcinogenic aromatic amine dyes		Banned		

An infant garment, which is sized nine months or smaller, is exempted from flammability standards made by U.S Consumer Product Safety Commission (CPSC) for children's sleepwear. This standard requires children's sleepwear for ages between 9 and 14 months to be flame resistant or tight fitting as defined by specified dimensions[67][68]. Table 3- 2 shows example rules and standards related to infant garments in U.S. Consumer Product Safety Commission (CPSC) safety standards of children's products and corresponding Code of Federal Regulations, and ASTM International standards related to fabric or clothes.

Table 3- 2 Test Standards related to infant garment

Test Standards and Criteria	
Size requirements (choking hazard)	16 CFR 1501.4
Bite test	16 CFR 1500.51 (c)

Table 3-2 Continued

Sharp point test	16 CFR 1500.48
Sharp edge test	16 CFR 1500.49
Washability test	ASTM D6321/D6321M – 14
Abrasion test	ASTM D3884 - 09(2013) e1, ASTM D4966-98, D4966 - 12(2016)
Air Permeability of Textile Fabrics	ASTM D737-04(2016)

3.2 Sources of Noise Artifacts

Close skin-electrode contact and a large contact area can decrease the influence of noises in the ECG signal. However, because of the low amplitude of ECG signals, different noise sources from both internal and external environment can cause interference. For example, power line interference is a common high frequency noise, and respiration and body movement are common sources of low frequency noise. A primary noise that can hinder the ability to interpret an ECG signal is from motion artifacts. Motion artifacts can be caused by any movement leading to inaccurate data and disturb normal signal reading. Generally, it is the disturbance occurred in the skin-electrode interface. The vertical separation, transversal slipping, friction, and stretching of the skin are all causes of motion artifacts. Other body signals or biopotentials such as electromyogram (EMG) and the change of the skin potential can also introduce noises [69][29]. In addition, these noises can be influenced by a number of other factors. For example, the skin potential can be changed because of the change of skin humidity, and the skin humidity can be different by intrinsic individual differences, different status for the same individual and the impact of external factors such as temperature and humidity of the surroundings.

3.3 Knitting technology

3.3.1 Yarns

Staple and filament fibers can be spun into yarns, which are raw materials used for weaving and knitting. Knitting is a way to make fabrics by forming yarns into loops that interconnect from one to the next. Since yarns are controlled by thousands tiny needles and large strain are applied during knitting, a relatively fine, smooth, strong yarn with good elastic recovery are required for knitting. Synthetic fibers such as polyester, nylon, are popular to use because of low-cost, good properties and high productivity. However, natural yarns or natural-synthetic blended yarns are preferred for knitting underwear, socks and other intimate garments, especially for baby clothing. Because natural fibers such as cotton and wool are generally less treated with chemicals and more friendly to the skin. The most important feature of yarns is linear density that reflects the fineness of yarns. Linear density is expressed by yarn count number. Relatively finer yarns are used in knitting compared to weaving and yarn count is an important factor that needs to be considered when applying to knitting. Because one vital parameter of knitting machine is machine gauge, which indicates the spacing of needles in the needle bed. The smaller the machine gauge, the finer the yarn count must be. Mostly used units for yarn count include tex, denier, and S. The tex system is a universal unit for all yarns that defined by the mass of yarn in grams per 1000 meters length under standard moisture regain.

Denier is used for long filament yarns. It is the mass of yarn in grams per 9000 meters length under standard moisture regain. S is a unit that for English cotton yarn count number (Ne). This is the number of 840 yards per 1 pound of mass. For example, if 1 pound yarn has 60 of 840 yards, it expressed as 60S. Thus, a greater S value is representative of a finer yarn [70][71].

3.3.2 Basic Knitting Structures

Common knitting can be divided into weft knitting and warp knitting. The four fundamental structures in weft knitting include plain, rib, interlock and purl. Various structures can then be derived from these four basic structures. For example, a fabric can be composed of one of these structures and can also be a combination of two or more structures. Plain is the most basic and simplest structure that knitted by a single set of needles. Plain fabric (also called jersey fabric) has different appearance on face and back sides and it has the tendency to curl at the edges. A rib structure is knitted by two sets of needles and has an identical appearance on face and back sides. These sides appear as the same as the face side of plain structure, but the reverse loop wales will be revealed when stretching along the weft direction. Interlock is a structure derived from rib and appears as a “double rib” that combines two rib structures and hides the back side. An interlock fabric has smoother surfaces than rib fabric and the surface cannot be stretched out to reveal the reverse loop wales because the structure is more uniform, balances and has higher density compared to rib structure. Purl is another double-sided structure that requires two needle sets. In a purl fabric, both sides have the same appearance with visible reverse loops [72]. Warp knitting structure is different from weft knitting structure because loops are interlocked in a zigzag pattern along the warp direction. The flexibility of warp knitting process enables very different and complex knitting structures such as Tricot, Raschel and Milanese. Warp knitting fabric is less elastic than weft knitting fabric and is commonly used for lace fabric and lingerie.[73][74].

3.3.3 Knitting Machines

In general, weft knitting and warp knitting are separate industries and have special machines for manufacturing. In terms of the needle bed and frame design, weft knitting machines can be broadly classified as straight bar frames, circulars and flats machines. The straight bar frames machine has a single needle bed. The flat machine has two needle beds arranged in an inverted V formation. Circular machines have the needle beds in circular cylinders or dials. Combining with different needles like latch, bearded, or compound needles, these machines can knit a wide range of different fabric structures. Flat knitting is widely used in knitting manufacturing because of high flexible process and versatile fabrication ability. For example, the needle can be selected on one or both beds, the machine gauge can be changed which provides more possibilities to use different yarns, and tubular knitting can be realized by using flat knitting machine [75][73].

In this study, the infant onesie was knit on a Shima Seiki® SWG061N2 flatbed knitting machine by Wholegarment® knitting. WholeGarment technique is a patent of Shima Seiki and it is an advanced technology based on the conventional flat knitting. This technique can integrally knit as a complete tubular garment. One can easily change the sizes and materials of body and sleeve tubes and can move or merge the tubes together during the garment knitting sequence. Another important feature is it can knit tubes of any type of plain, rib and purl construction. The tubular rib can be knitted with a high wale density to gain high extensibility. This technique helps to reduce the time of fabrication by removing or reducing subsequent making-up or cutting operations [76]. The one-piece seamless garment knitting technique is promoted as a method to save on labor costs and reduce production time [77].

3.4 Printing Techniques of Printed Electronics

Printed electronics can be flexible and stretchable which is suitable for wearable use. The primary printing techniques now include inkjet printing, screen printing, flexography printing and gravure printing [78][79]. Gravure printing is one of the cost-effective technologies that has been used for electronics since the 1980's and easy to operate. It has an impression roll and printing roll. The printing roll is immersed in an ink bath and takes ink to the interface between two rolls. The impression roll applies pressure and prints the pattern on the substrate. Gravure printing is compatible to various ink and substrate materials with high throughput, but a gravure plate is needed for each printing, increasing the production costs for small batch production [80]. The flexographic printing has a similar principle to gravure printing. However, it has more rollers or cylinders that help to get higher resolution and precision. Flexography printing can obtain relatively high resolution and the flexographic plate is low cost. The flexography equipment is complex and has short service life compared to screen and gravure printing. Inkjet printing is the only printing method that doesn't need a template. It includes continuous inkjet printing and drop on demand (DOD) inkjet printing. Continuous inkjet printer ejects ink droplets continuously and the droplets are controlled by an electrostatic field. Some droplets are deflected to an ink catcher while others print on the substrate to form pattern. DOD inkjet printer is controlled by a digital signal. Ink droplets are ejected when data pulses are applied [80]. Inkjet printing is the most accurate and ink-saving printing method as it has a rapid deposition rate. However, the ink and print head nozzle must have good compatibility. This means a strict requirement for ink and printer quality. For example, if the nozzle is not compatible to the viscosity of the ink, it can get clogged and blocked which can be costly to replace [61]. Generally, the smaller the particles included in the printing ink, the better for inkjet printing use. The preferable ink particles size is 30 to 50 nm [81]. However, the low viscosity of the inks can result in low resolution due to ink bleeding into the textile [80]. Screen printing technology is one of the most promising technology of biosensors production that is cost-effective and well-established. Historically, screen printing has been adapted from the microelectronics industry from the early 1990s [82][83]. Electrodes are printed by using a screen or mesh to apply layer-by-layer depositions of conductive ink and are commonly printed on a solid substrate such as ceramic and plastic materials[83]. Compared to other printing methods, screen printing has the lowest cost both in equipment and ink material. The ink used for screen-printing can be micro-sized and high viscous which is easier to use than nano-sized particles. Due to the high viscosity of the ink, it is easy to control the ink movements and obtain a thicker film. Screen printing is a form of stenciling that is already widely used in the textile industry, which means that the process for screen printing electrodes using conductive inks can be easily integrated into the existing textile supply chain.

3.5 Fabrication Process of Screen-printed Electrodes

The basic process of screen-printed electrodes fabrication is illustrated in Figure 3- 2. The design of electrodes can be completed on AutoCAD or Adobe Illustrator. This approach is conducive to design flexibility, process automation, and good reproducibility. In this study, the sensor area was designed as a 4.4 cm diameter round and the conductive area was 8.32 cm^2 (3.4 cm diameter and subtract about 1 cm^2 snap area). This was referred to the shape and dimension of 3M® 2248 pediatric wet electrodes. For the interconnects away from the electrodes, previous studies have shown that a sine wave pattern has better stretchability and the resistance stability during stretching than straight line pattern[84][55]. The interconnect was designed as a sine wave pattern with a width of 0.2 cm that included 0.15 cm wide conductive trace. The length of each electrodes' interconnect was dependent on the design criteris. With the pattern design, a template was printed on a vinyl stencil used in screen printing and the pattern was used for laser cut redundant thermoplastic polyurethane (TPU) film as well. A hand-held squeegee was used to print Ag/AgCl ink on the TPU film by a lab scale screen printing machine. TPU film was selected both for substrate and encapsulation layers. As the substrate layer, TPU film provides a smoother surface than textiles. Conductive ink screen printed directly on the textile would penetrate the yarns and the gap between yarns. As the encapsulation layer, the TPU film is water repellent and has relatively high strength. In addition, the TPU films are easy to integrate it into textiles by heat press because of its thermoplastic property. After screen printing, the ink was cured and the TPU film was laser cut to demanded shape. The printed electrodes would be heat pressed on the fabric substrate.

A standard snap was added as the output connector. Another TPU film encapsulated all the parts except the exposed sensor area.

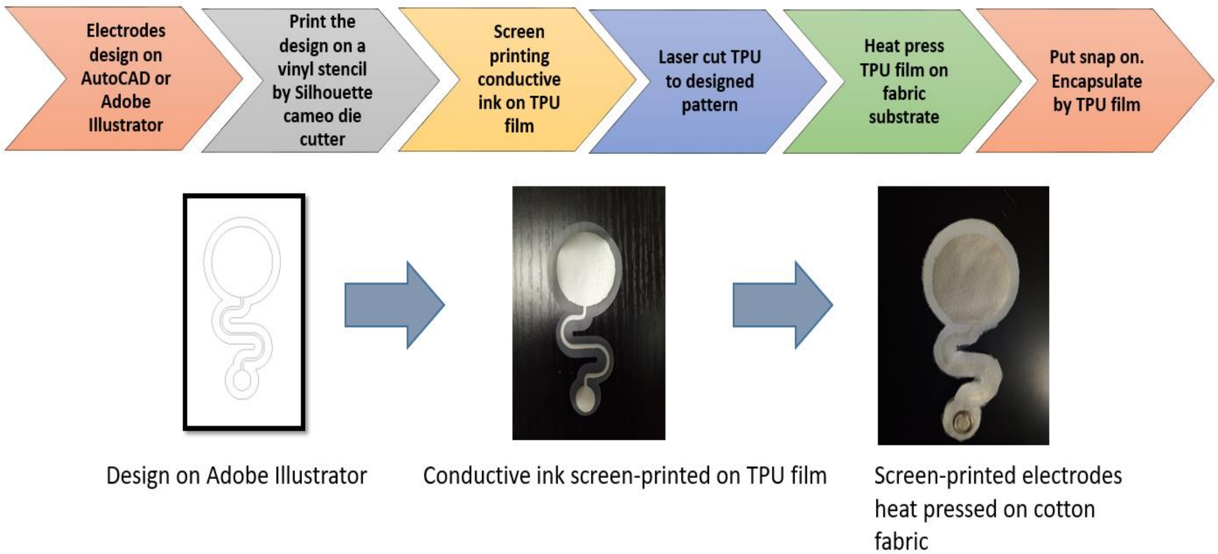


Figure 3- 2 Screen-printed electrodes fabrication process.

Chapter 4. Physical Test for Screen-printed Electrodes

4.1 Introduction of Ag/AgCl Electrodes Principle

Ag/AgCl bioelectrodes are the most commonly used type in medical application, especially in cardiology. ECG signal is detected by the transduction of ionic currents into electric currents. Ions are charge carriers for electric conductivity in the body and the electron carried current is what is required by wires and electronic instrumentation. The interaction between electrons and ions occurs at the interface solution where redox reactions happen. An electrolyte gel works as the solution layer in wet electrodes. Dry electrodes do not have the gel as an electrolyte, but the sweat on the skin under the electrode plays the role of an electrolyte layer [57]. The redox reaction can be presented as the following equations:

$$\mathrm{Ag^+ + e^- \rightleftharpoons Ag}$$
$$\mathrm{AgCl \rightleftharpoons Ag^+ + Cl^-}$$

Ag/AgCl electrodes have excellent biocompatibility. However, adhesives and gel used in wet disposable Ag/AgCl electrodes can cause skin irritation. For infants' gentle and fragile skin, even tearing the electrodes off the skin can provoke irritation. To avoid skin irritation, these disposable electrodes cannot be placed on the skin for a long time. They must be replaced after a certain time and new electrodes will be put on different sites [36]. The screen-printed Ag/AgCl dry electrodes can eliminate these weaknesses and can be used for long-term monitoring without irritation. The dry Ag/AgCl electrodes were tested for air permeability, abrasion resistance, skin-electrode impedance and washing resistance to validate the electrodes can be integrated into infant onesies. The physical tests revealed the satisfied performance of this screen-printed electrodes as well as the demand for further development.

4.2 Air Permeability Test

The air permeability of the electrodes contributes to the comfort of the electrodes. Air permeable electrodes would allow sweat to move away from the skin, which can decrease skin irritability due to moisture and abrasion.

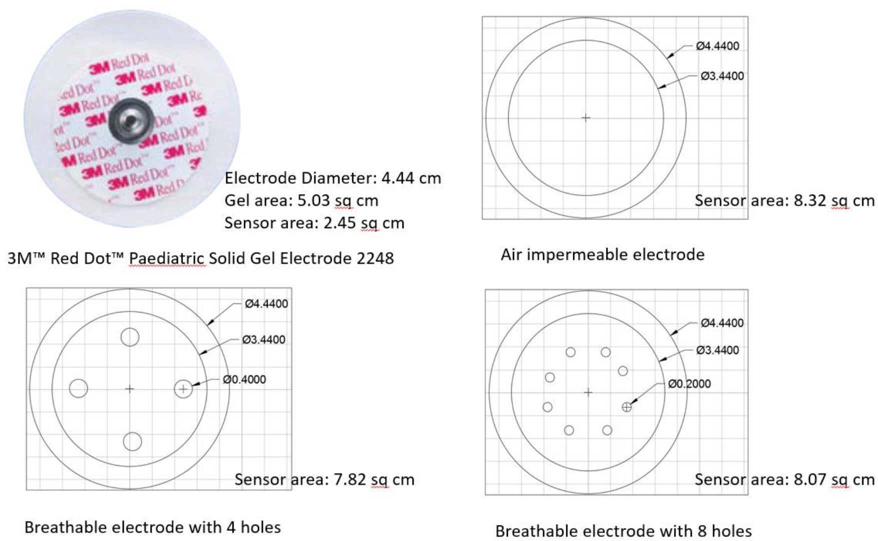


Figure 4- 1 The dimension of 3M Red Dot electrodes and AutoCAD draw pattern of screen-printed electrodes with different designs.

Since the Ag/AgCl ink covered area was not air permeable, breathable electrodes that had holes in different sizes and numbers were designed and tested. 4-holes (holes' area: 0.5 cm^2) and 8-holes (holes' area: 0.25 cm^2) electrodes were tested by using the standard test method ASTM D737. Since the specimens were not air permeable or nearly impermeable, 1 mm orifice diameter was chosen when using 1 inch test area at 125 Pa water pressure differential. The result (Table 4-1) indicated the air flow rate is basically proportional to the holes' area. The TPU film with Ag/AgCl ink was air impermeable.

Table 4- 1 Air permeability test result shows the permeability is proportional to the holes' area.

Electrodes Type	Specimen	Air Flow ($ft^3/min/ft^2$)	Average Air Flow ($ft^3/min/ft^2$)
Breathable electrodes with 4 big holes. Holes' Area: 0.5 cm^2	1	10	9.96
	2	9.94	
	3	9.94	
Breathable electrodes with 8 small holes. Holes' Area: 0.25 cm^2	1	5.33	5.25
	2	4.85	
	3	5.58	
Electrodes without holes	1	No air flow.	
	2		
	3		

4.3 Martindale Abrasion Test

Wear is a common reason that textile products, especially garments, become unserviceable. When the surface of a cloth rubs against another surface, fibers, yarns, and fabrics can be disassembled. Abrasion is another term used to describe this physical destruction[85]. The electrodes on infant ECG onesies would rub over the skin and tear by the clothing which would cause damage. Thus, they were tested for abrasion resistance to assess if the ink would rub off and evaluate their ability to withstand typical wear-and-tear of a garment.

Martindale abrasion testing was performed under the conditions of ASTM D4966. An applied pressure of 9 kPa was used for each specimen. A plain weave, crossbred, worsted wool fabric was used as the standard abradant fabric. Nine screen-printed electrodes were heat pressed on Jersey cotton fabric and three Jersey cotton fabric specimens were tested as contrast.

Table 4- 2 The observation of electrodes and cotton fabric during Martindale abrasion

After 1000 rubs: **Electrodes: No visible change.**	**After 1500 rubs:** **Electrodes: A little bit ink on the edge was peeled off.** **Cotton fabric: pilling and lint were observed**	**After 2000, 3000 and 4000 rubs:** **Electrodes: More ink peeled off from the edge and spread out.**	**After 5000 rubs:** **Electrodes: Some ink peeled off the edge. 0.07%-0.33% mass loss.** **Cotton fabric: wore away. Many staple fibers came out.**
			

Specimens were rubbed over the standard abradant fabric. The result of Martindale abrasion test (Table 4-2) showed the screen-printed Ag/AgCl electrodes had suitable abrasion resistance. Six electrodes were tested and benchmarked against three Jersey cotton fabric swatches. After 1000 rubs, there was no visible change observed both for electrodes and cotton fabric. After 1500 rubs, there was pilling and lint observed on cotton fabric and some ink on the edge was peeled off on the electrodes. From 2000 rubs to 4000 rubs, the pilling on cotton fabric increased but no significant change was observed on the electrodes. After 5000 rubs, the cotton fabric wore away and many staple fibers came out, while at the same number of rubs, only a small amount of ink appeared to have peeled off from the edge of the Ag/AgCl electrodes. A possible explanation for the ink that peeled off from the edge and spread out from these spots is that the edge that was clamped by the abrasion device observed greater tension compared to the inner planar area. The results showed that the ink on the planar area has great resistance to abrasion, which should indicate that the electrodes can withstand being worn in a garment. Weight and resistance of specimens were measured before and after the abrasion test. The average weight of air impermeable electrodes, breathable electrodes with 4 holes and breathable electrodes with 8 holes was 523.1 mg, 492.7 mg, 509.3 mg respectively. The corresponding weight loss was 0.076%, 0.325% and 0.177%. During the abrasion process, the specimens were contaminated by the abrasion instrument that led to some weight increase but the change was smaller than 1 mg. The resistance between any two points on the electrode was from 0.3 Ω to 0.4 Ω before abrasion. After 5000 rubs test, the resistance between two points on the electrodes was from 0.4 Ω to 0.5 Ω. For the points at the edges that have ink peeled off, the resistance was from 0.6 Ω to 1.2 Ω. These results reflect there was ink came off after abrasion that causes increased resistance, but the increase is small that would not have an impact on the function of electrodes.

4.4 Skin-Electrode Impedance Test

For bio-signal detection, the amplitude of the electric wave decreases when it must travel through bone and body tissue to reach the skin. Therefore, the electrodes that are applied to the skin must be sensitive enough to detect the signal. Generally, wet electrodes which are the material containing conductive media like conductive hydrogel are used to apply to the patient's skin in a hospital test. However, short shelf life, skin irritation, and dermal inflammation issues, as well as conductance variation of wet electrode gels over the time limit their usage for long term monitoring. The screen-printed dry electrodes can overcome these shortcomings mentioned above. To validate and develop the use of screen-printed dry electrodes, skin-electrode impedance testing was performed to understand the influence of the skin and skin-electrode interface. Various factors, such as temperature, humidity, measurement time, the pressure applied to the electrodes, electrode size, and location, can affect the result. By optimizing these variables, the result can be pushed as close as possible to relative constant and low impedance, which improves the ECG signal detection. The 4-hole and 8-hole electrodes, as well as electrodes with no holes, were benchmarked against 3M® pediatric wet electrodes (2248). Gamry Instruments Framework equipment and software were used to do the skin-electrode impedance measurement. The model used to do the analysis was EIS 300-Electrochemical Impedance and Potentiostatic EIS. Two-electrode configuration for skin-electrode impedance measurement was used in this test[86]. Skin-electrode impedance was measured by injecting a 10 mV rms AC current sweeping frequency from 0.1 Hz to 1000 Hz to one electrode and collect it from the other electrode. The distance between the two electrodes was 10 cm. The frequency range was selected because almost all acquired bio signals' frequency performs in this domain [87].

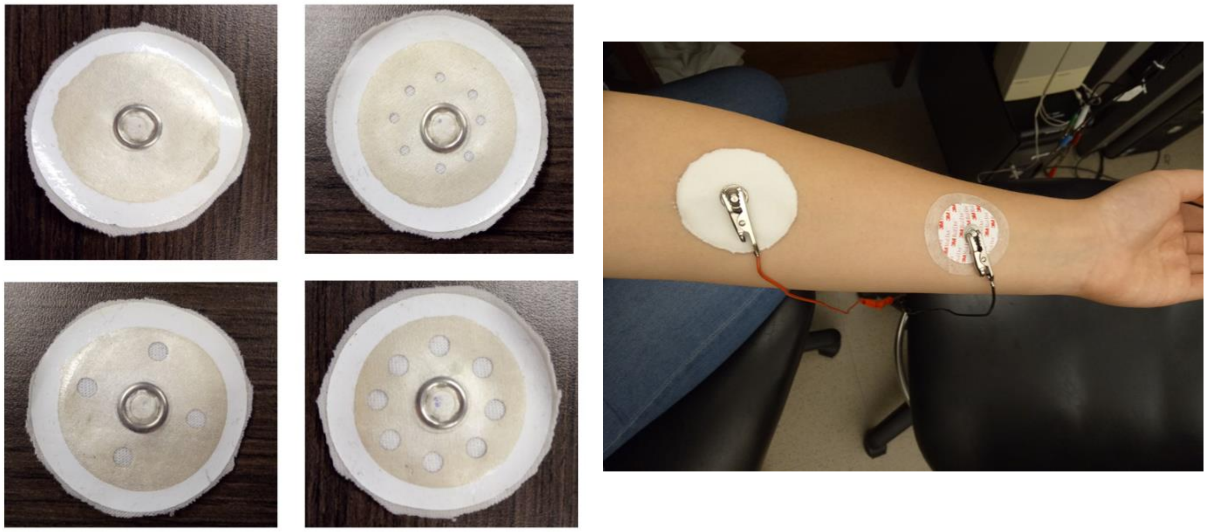
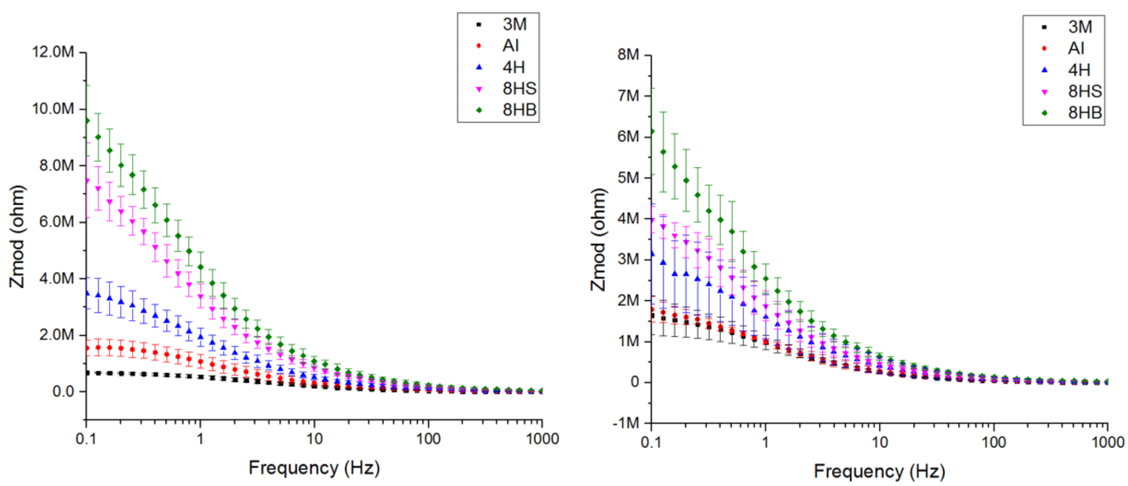


Figure 4- 2 Left: Different types of electrodes used in skin-electrode impedance measurement. Right: Electrodes placed on forearm for skin-electrode impedance measurement and one 3M electrode used as a reference electrode.



3M: 3M™ Red Dot™ Paediatric Solid Gel Electrode 2248 sensor area: 2.45 sq cm
Al: Air Impermeable Electrodes sensor area:8.32 sq cm
4H: Breathable Electrodes with 4 holes (r=0.2cm) sensor area: 7.817 sq cm
8HS: Breathable Electrodes with 8 small holes (r=0.1cm) sensor area: 8.069 sq cm
8HB: Breathable Electrodes with 8 big holes (r=0.2cm) sensor area: 7.314 sq cm

Figure 4- 3 Skin-electrode impedance for different electrodes at frequency from 0.1 Hz to 1000 Hz.

Figure 4-3 shows that both the contact area and the number of holes affect the skin-electrode impedance. The 3M™ Red Dot™ Pediatric Solid Gel Electrode 2248 and the screen-printed electrodes have the same size which is 4.44 cm diameter, while the 3M electrodes have 10.45 cm^2 adhesive area, 5.03 cm^2 gel area and 2.45 cm^2 sensor area. The gel was covered on the Ag/AgCl coated plastic sensor. In this test, a minimal application of adhesives was applied on the TPU edge of screen-printed electrodes to stick on the skin. The diameter of sensor area is 3.44 cm. The electrodes without holes that had the largest contact area (8.32 cm^2) performed similarly to the 3M wet electrodes. Higher impedance was measured when the electrodes had more holes distributed throughout the contact area. A larger sensor area, when contacted with the skin, can lower the skin-electrode impedance. However, when the sensor area is close to each other, the number of holes is shown to have an impact. Although the electrode with 8 small holes has a larger bigger sensor area (8.069 cm^2) than electrodes with 4 big holes (7.817 cm^2), the skin-electrode impedance is higher. One possible explanation for this phenomenon is the more disconnections increase the resistance and the holes work as obstacles that decrease the interaction rate between the electrodes and the skin. However, the breathable electrodes with holes have the potential to be valid. The result showed the skin-electrode impedance of breathable electrodes with 4 holes was close to air impermeable electrodes and wet electrodes. By applying standard 3-lead electrode placement on an adult and using LabQuest® measurement device, ECG was measured by using breathable electrodes and air impermeable electrodes. Figure 4- 4 illustrated that recognized R peaks, QRS complex are obtained by using the breathable electrodes. The noises in the signal can be filtered by appropriate design. It is not always essential to have low skin-electrode impedance as the impedance of skin-electrode is small compared to impedance of the skin. Constant impedance and appropriate amplifier can be more useful for good electrode performance [44].

Another observation in skin-electrode impedance measurement is that impedance decreased when frequency increased. High frequencies are better suited for impedance measurements,

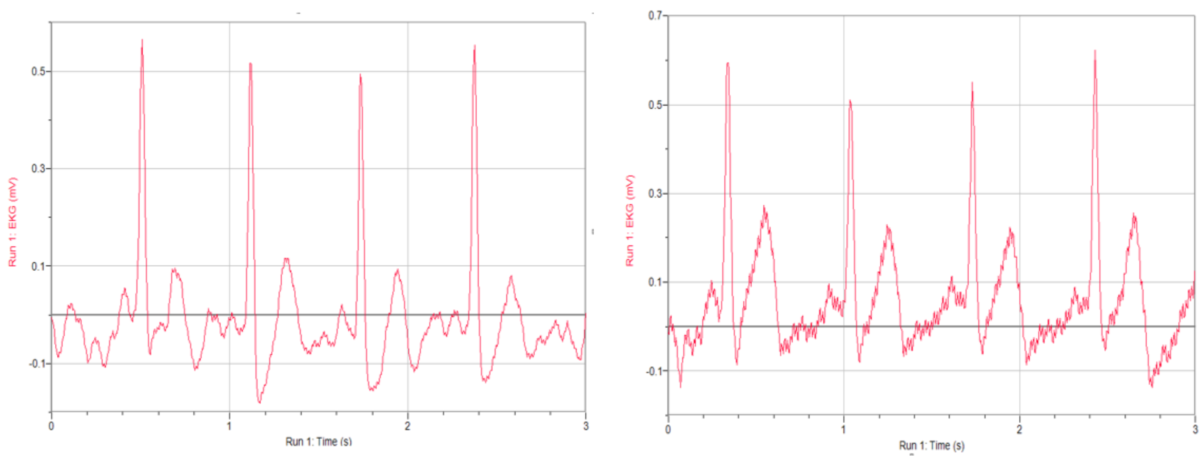


Figure 4- 4 ECG measurement by using screen-printed electrodes. Left: using air impermeable electrodes Right: using 4-holes breathable electrodes

which can be a factor to be considered for the ECG circuit design. The impedance was much lower and stable when the frequency was higher than 10Hz, which was good to the capture of ECG signal because the typical frequency ranges of R-peaks and P-peaks in ECG waveforms are 10-17 Hz [87]. However, the frequency range of T-peaks is 4-7 Hz, which means there is a higher risk for this low frequency content to be missed or distorted. This influence can be reduced by applying pressure to the electrodes and ensure a better contact between the electrode and the skin. The best effect was observed by applying 15 mmHg to 20 mmHg pressure in Cömert’s study [88]. Appropriate pressure is helpful to get constant and lower impedance [87]. Furthermore, the inner forearm has on average a higher skin-electrode impedance compared to chest [89]. Since the electrodes on the infant onesie are located on the chest, the lower skin-impedance is good for ECG signal detection.

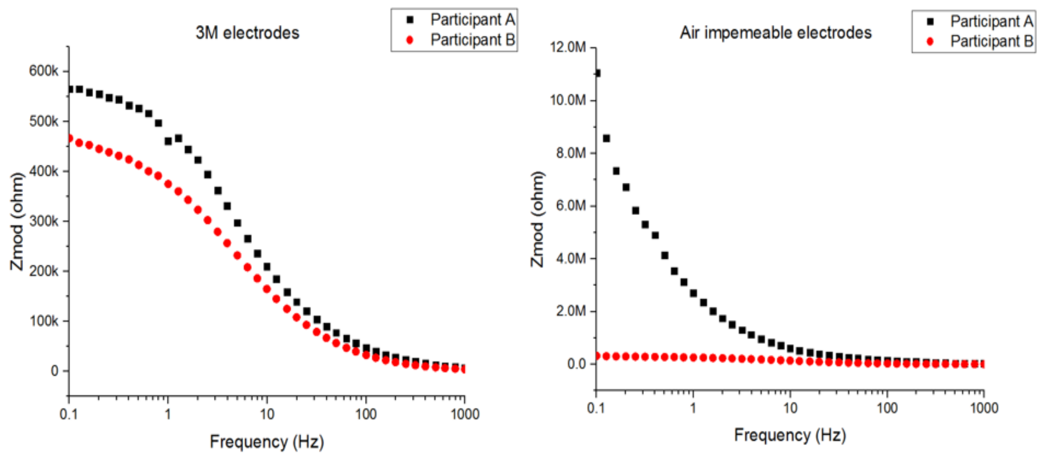


Figure 4- 5 Left: skin-electrode impedance when using 3M electrodes on 2 participants. Right: skin-electrode impedance when using impermeable dry electrodes on 2 participants.

It should be noted that various factors may influence the skin-electrode impedance and significant differences can exist from individual to individual. For example, higher skin temperature can decrease the skin impedance [90]. The amount of sweat on the skin and different body dehydration situation can cause skin impedance variation as well [87]. Figure 4- 5 shows the skin-electrode impedance measurement result for two adult participants both using 3M wet electrodes and screen-printed dry electrodes. It indicates the individual difference for skin-electrode impedance, especially for the use of dry electrodes.

4.5 Accelerated Washability Test

The washability test was carried out in accordance with the AATCC Test Method 61-Test No.2A: Colorfastness to Laundering: Accelerated. This test is for evaluating the colorfastness to laundering of textiles that are expected to withstand frequent laundering. By doing this test, surface changes can be observed resulting from detergent solution and the abrasive action of five typical hand or home launderings within one 45-minute wash cycle. As a standard AATCC instrument, ATLAS Textile Test Instruments LEF Launder-Ometer was used in the wash testing. The powder detergent used in the test was AATCC standard reference detergent WOB (without brightener) that was distributed by Procter & Gamble. According to Test No.2A, the test conditions are 45 minutes at 49 ℃, 150 mL total liquor volume, 0.15 percent powder detergent of total volume, none chlorine, and 50 steel balls in each breaker.

The process of making specimens is described below:

- Print the sensor pattern and interconnect trace on vinly paper by using Silhouette Studio.
- Stick the vinly paper on mesh and do screen printing on white thermoplastic polyurethane (TPU).
- Leave the specimens in the oven for 10 minutes at 50℃ after screen printing to dry the ink.
- Heat press white TPU on cotton fabric for 2 minutes at 125℃.
- Put snap on the output end of interconnect.

- Heat press translucent TPU on the top for 1 minute at 125℃ to cover interconnect part. For waterproof specimens, spray waterproof coating (Granger's Xtreme Repel Waterproofing Spray) on the sensor part after heat press and dry naturally.

After each accelerated washing cycle, the resistance measurement and ECG test were carried out to evaluate the influence of washing. The resistance measurement was performed in two different ways. One method was to measure the resistance from the center of the sensor to snap (Figure 4- 6 Left) and the other one was the measurement from the center of the sensor to the interconnect (Figure 4- 6 Right). An ECG test was done on me by placing three electrodes on the RA, LA and RL locations. Tape was used to adhere electrodes to the skin and the Vernier LabQuest® 2 device was used for data collection and analysis.

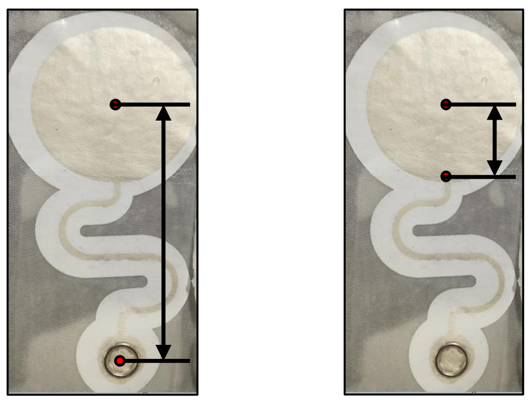


Figure 4- 6 Diagram of two resistance measurement methods. Left: resistance measurement from sensor center to snap. Right: resistance measurement from sensor center to interconnect.

4.5.1 Accelerated Washing Test at 49 ℃

In the study, CI-4040 ink was printed on TL644 white polyurethane film and ST604 seam tape translucent polyurethane was used as an encapsulation layer. White polyurethane film was heat pressed on 100% cotton Jersey fabric. Stainless steel snaps were added to the output end of interconnects. The diameter of the sensor is 4.4 cm and the diameter of the output end of the interconnect is 1.2 cm. The interconnect length is 4.5 cm, and the width is 2 mm. Seven specimens were washed in this test. Two of them were made without a waterproof coating while five of them were treated with the Granger's Xtreme Repel Waterproofing Spray. There were three specimens with snaps on them among the five waterproof specimens. The washing process was performed using the test No.2A conditions. Three accelerated washing cycles were performed. For recording purposes, one waterproof sample was taken out after each accelerated wash cycle. Resistance measurements from the center of the sensor to the interconnect and ECG test was done after each accelerated washing cycle. The ECG was tested by using the three waterproof samples with snaps. After these three washing cycles test, three new specimens with snaps on them and without waterproof coating were added to the specimens group. Then, eight specimens continued to do the accelerated washing test: five previous specimens (two specimens without the waterproof coating and three specimens have snaps with waterproof coating) were washed three cycles already, and three new specimens without the coating and no washed. These eight specimens were washed twice. After each washing cycle, resistance was measured for all specimens and an ECG test was done by using three specimens without the waterproof coating and three specimens with waterproof coating respectively. The resistance measurement results are provided in Table 4-3 and Table 4-4.

Table 4- 3 Resistance from the center of the sensor to the snap (49℃ Test) * The resistance of the third sample started from 100 Ω and kept decreasing to 30 Ω in about 30 seconds. ** The resistance of the third sample started from 1 MΩ and kept decreasing to 0.8 MΩ in about 30 seconds.

Washing cycles	Resistance (No coating) / Ω	Resistance (With waterproof coating) / Ω
0	1.3; 1.2; 1.4	
1	1.4; 1.7; *	
2	Overflow	
3		1.2; 1.2; 1.4
4		2.7; 5.8; **
5		23, another 2 samples overflow

Table 4- 4 Resistance from the center of the sensor to the interconnect. (49℃ Test) * The resistance of these three samples was not stable. In about one minute, the resistances of three samples were 3.7 Ω-1.58 Ω, 8.9 Ω-6.7 Ω, and 42 Ω-33 Ω.

Washing Cycles	Resistance (No coating) / Ω	Resistance (With waterproof coating) / Ω
0	0.3; 0.3	0.3; 0.3; 0.3; 0.3; 0.3
1	0.3; 0.3	0.3; 0.4; 0.5; 0.3; 0.7
2	0.5; 0.5	0.4; 0.4; 0.4; 0.4
3	0.4; 0.4	0.6; 0.7; 0.7
4	0.4; 0.4	
5	0.4; 0.3	*

In this experiment, three specimens with waterproof coatings were conductive from the sensor to the output snap until four accelerated washing cycles were completed, while the three specimens without waterproof coating were not conductive after two accelerated washing cycles. For specimens that lost all conductivity after washing, a more obvious delamination of the top encapsulation layer was observed and water underneath the ink layer. Some cracks on the sensor surface were observed after four accelerated washing cycles. However, the assumption was that the waterproof coating may not influence the washability since the waterproof spray was only used for the sensor part and the sensor part was conductive even after five accelerated washing cycles. Furthermore, for uncoated specimens, the resistance of the sensor part was more stable compared to the specimens with waterproof coating. In the ECG test, because the LabQuest device was used to do the ECG test that had the filter that already processed the signal, the SNR (signal to noise ratio) was not for original signal but could indicate the tendency by comparison. SWT Denoising 1-D function in MATLAB was used to do the SNR analysis (filter selection sym 20, level 3). The SNR analysis results in Table 4-5 corresponds to the resistance measurement result. The waterproof coating specimens can detect ECG signal until four washing cycles. There was not a significant difference for the SNR after signal filter treatment by the LabQuest device. Recognized ECG signal can be obtained when it is conductive from sensor to snap (Figure 4-7) and it is possible that failure happened in the interconnect and snap parts before the sensor part lost its efficacy.

Table 4- 5 Signal to Noise Ratio analysis for ECG test.

Washing cycles	Signal to Noise Ratio	
	ECG test with no-coating specimens	ECG test with waterproof coating specimens
Before wash	25.859	
After 1 washing cycle	24.354	25.537
After 2 washing cycles	No ECG signal	26.198
After 3 washing cycles		21.348
After 4 washing cycles		25.332
After 5 washing cycles		No ECG signal

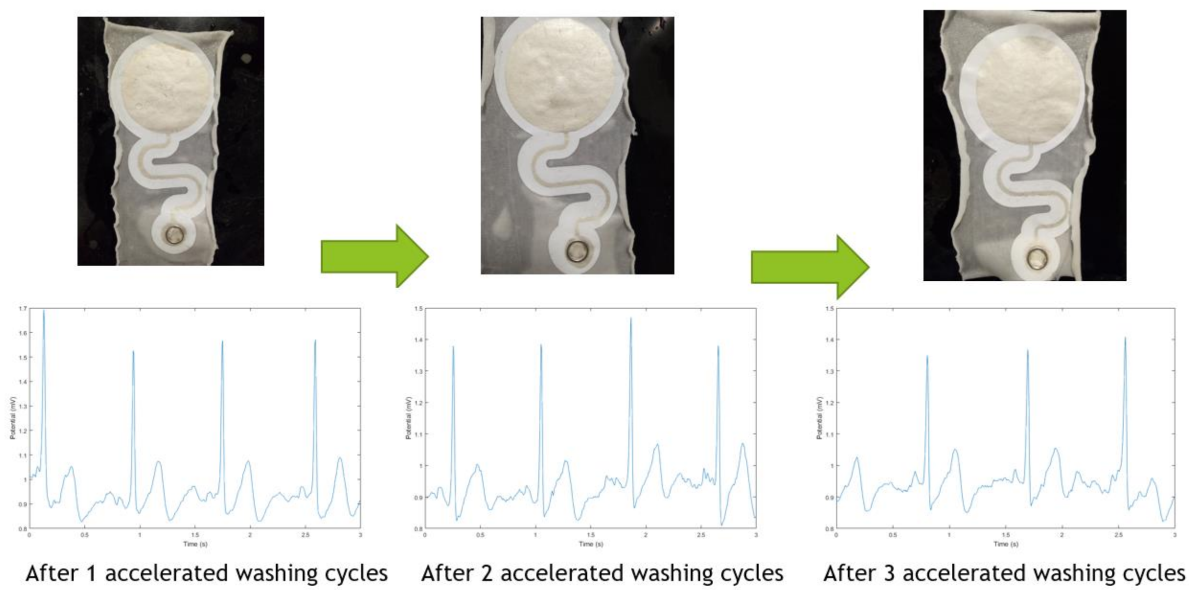


Figure 4- 7 Electrodes after washing and corresponding ECG images.

To observe the waterproof coating layer on the Ag/AgCl electrode surface, scanning electron microscope (SEM) imaging was performed. It was found that the Ag/AgCl flakes were more evenly dispersed both for coated surface and uncoated surface before washing (Figure 4-9, a, b). After two accelerated washing cycles, there were clusters of flakes on the uncoated surface which means the Ag/AgCl flakes were moved and became unevenly distributed, while the coated surface was protected by the coating layer (Figure 4-9, c, d). However, cracks appeared on the coating layer after two accelerated washing cycles (Figure 4-8). After five accelerated washing cycles, the distribution of Ag/AgCl flakes became nonuniform both for coated and uncoated surface (Figure 4-9, e, f). Although smaller particles underneath the flakes on the surface might connect to each other, it was more likely to be disconnected with more gaps observed on the surface. A possible explanation for the optical variance before and after washing process is the change of composition. The original flakes were composed of Ag (lighter shading) and AgCl (darker shading) which was dispersed evenly [91]. More bright particles were seen after washing, and it might indicate the decrease of Cl-containing areas which might be contaminated or peeled off during washing.

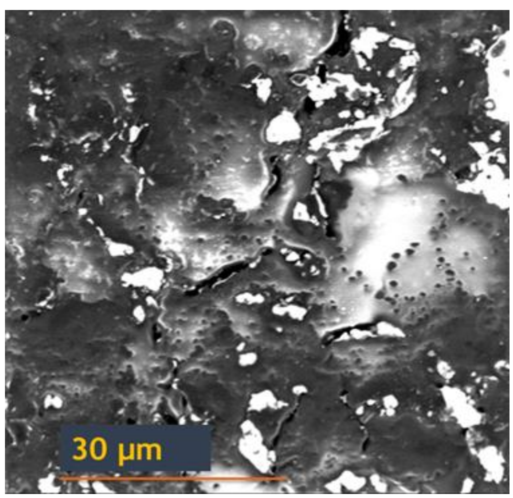


Figure 4- 8 SEM image of cracks on the coated surface after 2 accelerated washing cycles

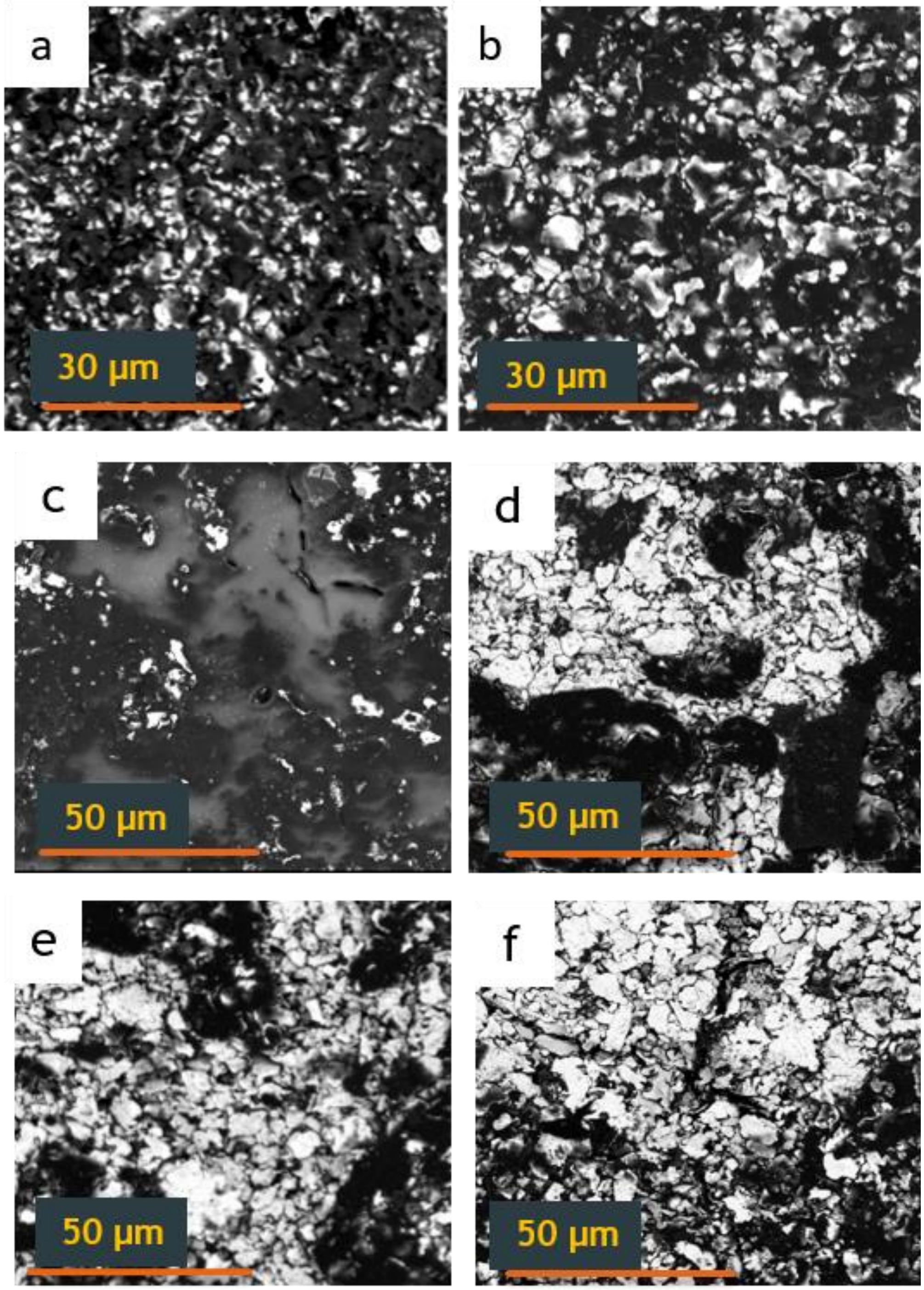


Figure 4- 9 SEM images of screen-printed electrodes. a,b- before washing. c,d- after 2 accelerated washing cycles. e,f-after 5 accelerated washing cycles. a,c,e: coated surface. b,d,f: no coating surfaces.

4.5.2 Accelerated Washing Test After Procedure Change

In order to reduce delamination of the encapsulation layer and reduce the washing impact on snaps, two steps in the production process were changed. In the previous process, a hot iron was used to laminate the top polyurethane layer to the substrate polyurethane. Since the pressure may not be enough to laminate these two layers well, a heat press machine that applied greater pressure was used. In addition, a DYMAX Multi-Cure® Adhesive & Coating (9001-E-V3.5) was used to seal the snaps to avoid water getting into through the gaps.

Table 4- 6 Resistance of 3 screen-printed electrodes before and after waterproof spray treatment.

Specimens	Resistance from center of sensor to interconnect		Resistance from center of sensor to snap	
	Before waterproof spray treatment /Ω	After waterproof spray treatment /Ω	Before waterproof spray treatment /Ω	After waterproof spray treatment /Ω
1	0.3	0.3	1.1	1.2
2	0.3	0.3	1.3	1.4
3	0.3	0.3	1.0	1.0

Before accelerated washing test, resistance was measured for six specimens in two different ways. For the six specimens, three of them were tested before waterproof spray treatment and after waterproof spray treatment, respectively. This comparison before and after treatment is provided in Table 4-6. Another comparison is between the three uncoated specimens and the three specimens after waterproof spray treatment (Table 4-7). The resistance before the accelerated washing test indicates that the waterproof spray has little impact on the conductivity of sensors and interconnects. The resistance increased a small amount but it is small enough to be ignored when compared to 10 MΩ - 1MΩ skin-electrode impedance in the final application of the ECG test.

Table 4- 7 Resistance of three screen-printed electrodes with and without waterproof spray treatment.

Specimens	Resistance from center of sensor to interconnect		Resistance from center of sensor to snap	
	With waterproof spray treatment /Ω	Without waterproof spray treatment /Ω	With waterproof spray treatment /Ω	Without waterproof spray treatment /Ω
1	0.3	0.3	1.2	1.2
2	0.3	0.3	1.4	1.3
3	0.3	0.3	1.0	1.0

Six specimens, three with waterproof coating and three without waterproof coating, were tested in accelerated washing. The test conditions followed standards AATCC Test Method 61-Test No.2A. In this test, the ink was obviously removed from the sensor by varied degrees after one accelerated washing cycle. All six specimens failed to pass the test. There was no visible flaking to the naked eye for the previous specimens in the previous washing tests. The only visible damage was that the smooth surface changed to a rough surface after several times washing because aggressive metal balls in the testing breaker. Three possibilities to explain this result are provided:

- Longer heat press treatment and greater pressure. In this experiment, the heat press machine was used to replace iron to do the heat press lamination. When putting the encapsulation polyurethane film on the substrate, three samples were heat pressed for five minutes and another three samples were heat pressed for two minutes at 125 °C. In the previous process, an iron was used to heat press the encapsulation polyurethane film for about one minute at a lower pressure.
- Ultraviolet (UV) light. UV curing was used for three minutes on each sample to cure the adhesives for snap seal. The UV curing process utilizes high-intensity ultraviolet light to cure adhesives. However, UV light can decompose silver chloride content that may change the performance of the ink[92]. There was no UV curing treatment in the previous experiment.
- Worse performance of conductive ink with time. The ink was newer during the first-time and the second-time tests. It has been almost one month when this test was done. Although the ink has not expired, the performance could get worse since the storage condition was not very good. During a month, the ink was used almost every day by different people, which might cause long-time exposure under ambient temperature and cause solvent loss. The ideal storage condition is < 10 °C with good sealing.

4.5.3 Accelerated Washing Test at 40 °C

In this experiment, nine specimens using the same material and dimension as the specimens in the previous testing (49 °C Test), but changes were made both for the production process and washing process based on previous studies and material properties to improve the performance. The softening point for TL 644 white TPU adhesive layer is 83℃ and 160℃ for the barrier layer. The softening point for ST 604 translucent TPU adhesive layer is 105℃ and 184℃ for the barrier layer. Since the material needed to be treated with heat multiple times during the fabrication, it would accelerate damage by excessive heat treatment at one time. Therefore, the temperature for the heat press on white TPU decreased from 125℃ to 120℃, and the temperature for translucent TPU decreased from 125℃ to 115℃. The heat press process also avoided pressing on the sensor region. Because the TL 644 TPU could withstand up to 60℃ wash and the ST 644 TPU is excellent up to 40℃, the temperature setting for the washability test changed from 49℃ to 40℃ to reduce the washing influence on TPU material. Other conditions and settings were not changed.

In these nine specimens, three of them were made without waterproof spray, three of them were coated with waterproof spray twice (the spray for the first time was before encapsulation and covered both sensor and interconnect parts; the spray for the second time was after encapsulation and covered the sensor part), and three of them were coated with waterproof spray on the sensor part only after encapsulation. The three specimens with waterproof coating twice were only washed three times because they were not able to be used for the ECG test after three washing cycles, but the other six specimens were washed five cycles. Resistance measurement results are showed in Table 4-8 and Table 4- 9.

Table 4- 8 Resistance from center of sensor to interconnect (* No value. The resistance is too high).

Washing cycle	Ink alone(Ω)	Waterproof coating once(Ω)	Waterproof coating twice(Ω)
0	0.3, 0.3,0.3	0.3, 0.3, 0.3	0.3, 0.3, 0.3
1	0.3, 0.3, 0.3	0.6, 0.4,0.5	0.4, 0.3, 0.4
2	0.3, 0.3, 0.3	0.4, 0.7, 0.4	0.4, 0.5, 0.9
3	0.3, 0.4, 0.3	1.0, 0.6,0.8	0.5, 3.4, 0.8
4	0.6, 0.3, 0.3	0.6, 3.0, 2.4	
5	0.3, 1.1, 2.6	1.0, *	

Table 4-8 shows there were two specimens with waterproof coating after too high resistance after five washing cycles. However, the resistance from other points on the sensor part to the interconnect was 0.3 Ω -30 Ω, which means the sensor was conductive but not conductive from the center point to interconnect. The data manifests that the resistance was very stable for the sensors without waterproof coating until 5 washing cycles. The overall resistance of specimens with waterproof coating was higher than the resistance for uncoated specimens. Naturally, the waterproof spray consists of other ingredients that have much higher resistance compared to silver and silver chloride. Still, 10x higher resistance can be acceptable as long as the sensor has stable conductivity since this resistance range is very small compared to skin-electrode impedance. In Table 4- 9, all specimens increased resistance gradually with wash cycles. One of the uncoated specimens became unstable after three washing cycles and lost conductivity after four washing cycles. One of the 2x waterproof coating specimens lost conductivity after one washing cycle and another specimen became unstable after three washing cycles. Using a single waterproof coat specimen, two of them lost conductivity after five washing cycles. Both considering the result in Table 4-8 and Table 4- 9, it suggests that the waterproof spray increases the resistance but an appropriate spray amount is helpful to withstand washing, while too much waterproof spray might destroy the good conductivity of Ag/AgCl ink.

Table 4- 9 Resistance from center of sensor to snap (* No value. The resistance is too high).

Washing cycle	Ink alone(Ω)	Waterproof coating once(Ω)	Waterproof coating twice(Ω)
0	1.0,1.3,1.4	1.0, 1.5, 1.1	1.5, 1.3, 1.1
1	1.0, 1.3, 1.8	1.2, 1.8, 1.3	1.3, 1.1, *
2	1.0, 1.5, 2.8	1.2, 1.5, 1.6	1.3, 2.3, *
3	1.0, 2.6, 40-60	2.5, 1.7, 2.2	1.5, 30-50, *
4	2.4, 0.9, *	1.9, 5.8, 7.6	
5	1.0, *	2.7, *	

In this test, delamination was observed after one washing cycle. Only one of nine specimens kept good lamination. The top TPU layer was re-laminated by iron for all specimens and almost of them were laminated well. Only two of them had a little delamination between the top TPU layer and the cotton fabric. The three specimens with waterproof coating twice had more wrinkles and were not as smooth as the other six specimens. Because the waterproof coating made the ink "wet" again that anti-cured the ink. The different contents can impact the performance stability. Figure 4- 10 also shows the difference between coating and no coating samples. There was more impact marks caused by metal balls on no coating samples, while more wrinkles were observed on coating samples. After one and two washing cycles, most specimens' resistance was not stable, and after iron-on treatment the resistance decreased. For

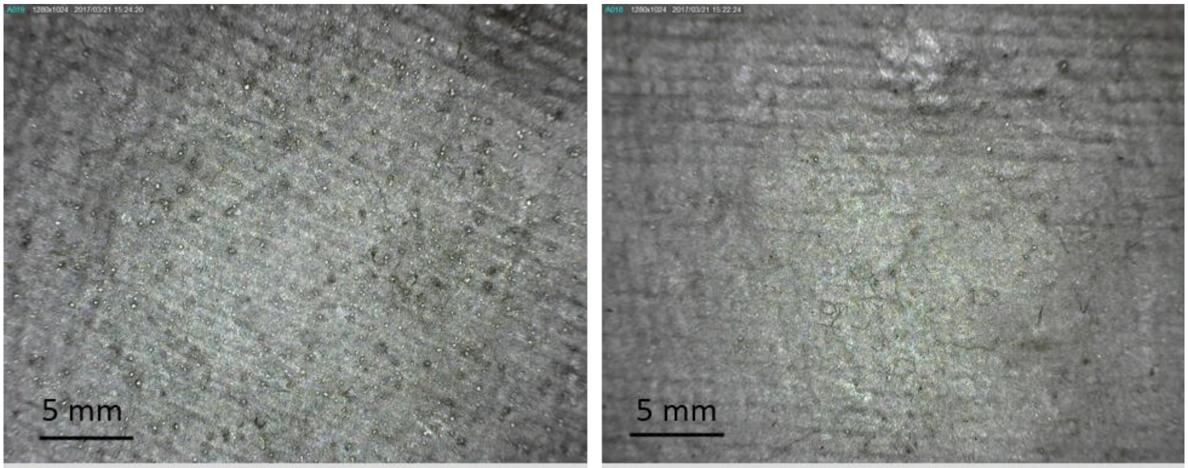


Figure 4- 10 Optical image of two electrodes surface after 3 accelerated washing cycles. Left: No coating electrode surface. Right: Waterproof coating electrode surface

example, after one washing cycle, the resistance for three specimens with waterproof coating twice was decreased from 2.5 Ω to 0.4 Ω, 0.7 Ω to 0.3 Ω, 2.8 Ω to 0.4 Ω by using iron to heat press the sensor. The heat and pressure probably helped to realign the ink particles or flakes to make them connected, and thus to recover the performance. An ECG test was done after each washing cycle. The three specimens with waterproof coating twice failed to obtain an ECG signal after three washing cycle. The other six specimens could detect ECG signal until four washing cycles but the ECG signal was not consistent after using three specimens without waterproof coating after two washing cycles.

4.5.4 Accelerated Washing Test for Separate Parts

In order to figure out the most fragile part to withstand the washing process, the interconnect and snap parts were encapsulated separately (Figure 4-11). A non-encapsulated gap between the interconnect and snap appeared. Thus, the resistance of sensor, interconnect and snap parts could be measured respectively. Specimens' preparation and washing condition were the same

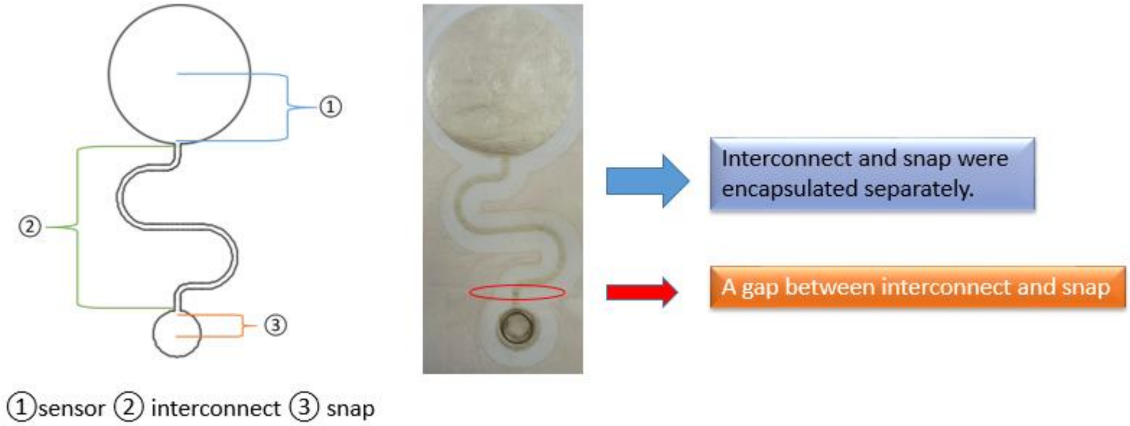


Figure 4- 11 Diagram of electrode construction and separate encapsulation for sensor, interconnect and snap.

with the accelerated washing test at 40 ℃. The results provided in Table 4- 10 and Table 4-11, indicates the resistance change with washing cycles and the resistance change before and after ironing. Figure 4-12 shows the average resistance of different parts (sensor, interconnect and snap) at different washing cycles after ironing. This is observed in the data provided in Table 4-10 and Table 4-11.

Table 4- 10 Resistance measurement for no coating screen-printed electrodes (* - Resistance was not stable. N -Resistance was too high).

No coating samples		Sensor resistance/Ω		Measurement length	Interconnect resistance/Ω		Snap resistance/Ω		Resistance from sensor center to snap/Ω	
		Before ironing	After ironing	of interconnect/ cm	Before ironing	After ironing	Before ironing	After ironing	Before ironing	After ironing
1	Before washing	0.3		4.3	1.1		0.2		1.1	
	After 1 washing cycle	0.5	0.3	4.3	1.0	1.0	0.4	0.4	1.2	1.1
	After 2 washing cycle	0.3	0.3	4.3	1.2	1.0	1.1*	1.5*	1.8-2.2	1.3
	After 3 washing cycle	0.4	0.2	4.3	1.3	1.1	5.5M	N	5.73M	N
2	Before washing	0.2		4.2	1.0		0.2		1.0	
	After 1 washing cycle	0.4	0.3	4.2	1.2	1.0	0.3	0.3	1.2	1.2
	After 2 washing cycle	0.4	0.3	4.2	1.2	1.0	0.4*	0.3*	1.6	1.4
	After 3 washing cycle	0.4	0.3	4.2	1.2	1.1	2.99M	0.3	2.93M	1.2
3	Before washing	0.3		4.2	1.4		0.3		1.5	
	After 1 washing cycle	0.7	0.4	4.2	2.1	1.8	0.4	0.4	3.0	1.8
	After 2 washing cycle	0.6	0.4	4.2	1.6	10*	1.8*	0.9*	14.3*	15*
	After 3 washing cycle	0.5	0.4	4.2	3.1	1.3	5.20M	N	5.20M	N

Table 4- 11 Resistance measurement for waterproof coating screen-printed electrodes (* - Resistance was not stable. N -Resistance was too high).

Waterproof coating samples		Sensor resistance/Ω		Measurement length of interconnect/ cm	Interconnect resistance/Ω		Snap resistance/Ω		Resistance from sensor center to snap/Ω	
		Before ironing	After ironing		Before ironing	After ironing	Before ironing	After ironing	Before ironing	After ironing
1	Before washing	0.3		4.3	1.2		0.3		1.2	
	After 1 washing cycle	0.4	0.4	4.3	1.3	1.3	0.7	0.4	1.9	1.4
	After 2 washing cycle	0.4	0.3	4.3	1.7	1.1	0.5*	0.9	2.9	1.7
	After 3 washing cycle	0.3	0.3	4.3	1.5	1.4	0.9-10	0.6	N	N
2	Before washing	0.3		4.3	1.0		0.2		1.0	
	After 1 washing cycle	0.4	0.3	4.3	0.9	1.0	0.4	0.4	1.1	1.0
	After 2 washing cycle	0.4	0.2	4.3	1.0	0.8	0.4*	0.3	2.9	1.7
	After 3 washing cycle	0.4	0.4	4.3	1.1	1.0	0.6*	0.4*	1.3	1.3
3	Before washing	0.4		4.4	1.3		0.3		1.4	
	After 1 washing cycle	0.4	0.4	4.4	1.5	1.2	0.3	0.3	1.3	1.3
	After 2 washing cycle	0.5	0.3	4.4	N	1.5	0.4*	0.5	1.4	1.1
	After 3 washing cycle	0.4	0.3	4.4	N	N	1.0*	0.6*	N	N

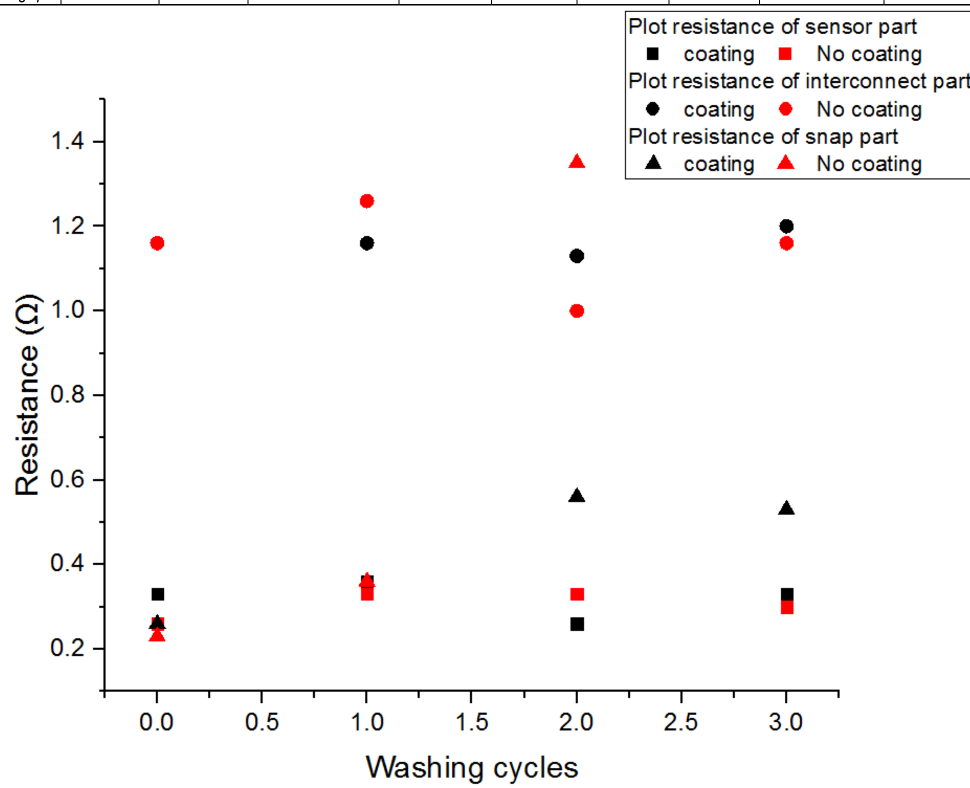


Figure 4- 12 Average resistance of different parts (sensor, interconnect, and snap) for coating and no coating electrodes. For the snap part, there was no data point at 3 washing cycles for no coating sample because the resistance was too high.

The resistance change of the snap part was greater than the other two parts. However, it was noticed that different degrees of cracks were observed on the gaps between interconnect and snap (Figure 4-13). This resulted in high resistance. To reduce the influence of the gap, cracks were crossed and interconnect and snap parts were reconnected.

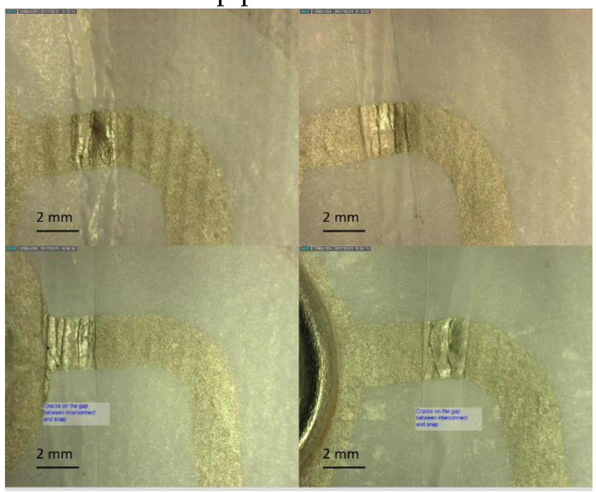


Figure 4- 13 Optical images of the cracks between interconnects and snaps after 3 washing cycles. Above: Waterproof coating electrodes. Below: No coating electrodes.

Table 4-12 and Table 4-13 show the results of original resistance with the cracks influence and the resistance that excluded the cracks influence. For the uncoated samples, because the gaps were too small, it was not possible to avoid the crack formation. Encapsulation of the snap was removed to test the resistance between two sides of the snap. The result shows that if encapsulate interconnect and snap as a whole (no gap), both no coating samples and waterproof coating samples should be able to withstand three washing cycles. To further study the performance of different parts after washing, six samples with complete encapsulation on the interconnect and snap were tested after five accelerated washing cycles. A piece of encapsulation TPU film was cut off for each sample to measure resistance for the separate

Table 4- 12 Resistance with and without cracks of waterproof coating electrodes.

Waterproof coating samples	Sensor resistance/Ω	Interconnect resistance/Ω	Snap resistance/Ω		Resistance from center of sensor to snap/Ω	
			Original	Cross the cracks	Original	Cross the cracks
1	0.41	1.10	N	0.9-1.0	N	1.5
2	0.46	1.13	0.5-0.6		1.5-1.6	
3	0.56	N	N	1.2	N	1.9-2.1

Table 4- 13 Resistance with and without cracks of no coating electrodes.

No coating samples	Sensor resistance/Ω	Interconnect resistance/Ω	Snap resistance/Ω		Resistance from center of sensor to snap/Ω	
			Original	Resistance between two sides of the snap	Original	Cross the cracks
1	0.47	1.20	N	0.3	N	2.5-2.6
2	0.40	1.17	0.4		1.31	
3	0.45	1.7-1.8	N	0.4	N	1.08

parts. For both uncoated and waterproof coated samples, one of three samples had good conductivity (resistance from sensor to snap was 1.0 Ω, 2.7 Ω respectively), the other two samples were not conductive from sensor to snap. For sample 2 and 6, there was no conductivity from interconnect to snap, but the resistance of interconnect was 1.9 Ω and 1.3 Ω respectively. Thus, there is an opening between the snap and interconnect. For sample 3, 5, and 6, most areas on the sensor lost conductivity, there were a few points on the sensor that were conductive to the snap though (Table 4-14). For the sensor part, there was very little resistance change that can be neglected. For the interconnect part, one of six samples lost conductivity after two washing cycles because of the cracks on the gap. The resistance change before washing and after three washing cycles was small within 1 Ω.

Table 4-14 Resistance measurement of sensor, interconnect, and snap. Samples 1-3 are no coating electrodes. Samples 4-6 are waterproof coating electrodes.

Samples	Resistance/Ω		
	Sensor/Ω	Interconnect to snap/Ω	Snap/Ω
1	Good conductivity		
2	1.1	N	1.1
3	N	3.3	0.4
4	Good conductivity		
5	N	2.6	0.3
6	N	KΩ to MΩ	0.3

For the snap section of the device, the resistance became unstable after two washing cycles. Because the snap part is heavier than other parts on the electrode, the gap can be subjected to a large bending force that leads to more cracks compared to other device sections. When the gap was encapsulated, cracks would be reduced since the force distribution would become more even. In conclusion, similar performance for uncoated samples and the waterproof coated samples were assessed in this study. Exposed sensor and the part between the interconnect and snap were the most easily damaged locations. The damage of these locations are the primary cause for failure during the electrode wash testing.

4.5.5 Discussion

The waterproof coating may reduce the amount of ink coming off from the substrate because it forms a protection layer covered on the top. This protection layer reduces the abrasion directly applied on the ink and the impact of the detergent solution. However, the resistance increases because of the waterproof coating. Ag/AgCl ink (80% Ag) has high conductivity and there is only negligible decrease of conductivity after washing if the ink is not removed. With a waterproof coating, the change of resistance increased after washing. This is due to the waterproof spray consisting of ingredients that have much higher resistance compared to silver and silver chloride. Based on all experiment results mentioned above, the washability test summarized as follows:

1. Under 40℃, both uncoated and coated samples can withstand 3 accelerated washing cycles and be most likely to withstand 4 accelerated washing cycles. Under 49℃, waterproof coated samples had better performance than uncoated samples.

2. The exposed sensor and the section between interconnect and snap are the most easily damaged locations. The damage of these places are the main reasons for the failure of the electrodes washability.

3. Ironing helps to recover the performance of the conductive ink. The heat may help to realign the particles or flakes. However, when there is too much disconnection, ironing is not helpful.

4. Vertical stress had less influence than horizontal forces for these electrodes. The bending and stretching during washing has a great impact on the performance of electrodes than the hitting of the metal balls during the accelerated wash testing.

5. Most delamination occurred between the encapsulation TPU layer and the cotton fabric. Shrinkage of the Jersey cotton fabric can be assumed as the main cause of the delamination. After washing, the cotton fabric shrank and became stiff. This led to delamination and introduction of water in between the layers.

4.6 Resistance Measurement for Electrodes with Different Materials and Dimension

In this study the resistance of specimens made of different TPU material and dimension was measured and compared. The specimens used EMS CI-4040 ink. For specimens one to three, both the substrate and encapsulation layers were Bemis ST 604 translucent polyurethane. The diameter of the sensor is 3.44 cm and the diameter of the output end of interconnect is 1.11 cm. The interconnect length is 4 cm, and the width is 1 mm. This dimension is smaller than the previous design used in washability test. Specimens four to six were kept using the same dimension and substrate material that was used in washability test.

Table 4- 15 Resistance measurement for electrodes with different substrate material and dimension (Specimens 1-3 and 4-6 had different dimension and substrate material)

Specimens		Resistance from center of sensor to interconnect /Ω	Resistance from center of sensor to snap /Ω
A smaller dimension. Substrate material: Bemis ST 604 TPU film	1	0.3	2.0
	2	0.3	1.3
	3	0.3	1.1
A bigger dimension. Substrate material: Bemis TL 604 TPU film	4	0.3	1.0
	5	0.3	1.3
	6	0.3	1.4

Table 4-15 shows the different substrate material (Bemis ST 604 and TL 644) and that the different dimension (small size and big size) did not influence the resistance. During the measurement process, it was found that the resistance was the same between any two points on the sensor part and the same from any points on the sensor part to the snap. Also, the resistance value was very similar for different specimens. This means the conductivity is exactly similar among different specimens. The production process suggests a good uniformity for the sensor and interconnects. Once the resistance becomes unstable, it keeps decreasing with further heat pressing. This is likely due to the realignment of ink particles with the help of the recovery of the stretchable polyurethane, the heat and the press that make the conductive ink particles reconnected.

Chapter 5. Infant ECG Onesies Design

5.1 Onesies Design

5.1.1 Requirements

In this thesis, the design was more focused on safety and comfort related requirements of the onesie. The goal for an infant ECG onesie includes the following statements [32][29]:

- Avoidance of potential hazards, including strangulation, lead exposure, choking, entrapment, suffocation, laceration, etc.
- Comfortable, light, avoid causes of stress or stimuli.
- Provide reliable continuous monitoring.
- Non-invasive and no disturbance for infants' daily activities.
- Easy of placement of garment on and off the infant.
- Washable (or able to remove non-washable components).
- Unobtrusive sensor system
- Aesthetically appealing to inspire comfort with the parents and clinicians.

5.1.2 Materials

A single ply of 150 denier Sapona® yarn was used to knit the infant onesies. Sapona® yarn is a very textured polyester wrapped around 20 denier Lycra®. 150 D (denier) is approximately equal to 35 S (yarn count). 40 S to 60 S are the most commonly used count for cotton yarns that applied for infant clothing. The texture of the outer polyester filaments is very soft and provide similar performance to cotton yarns. Lycra® consists of spandex fibers that have excellent elasticity and rubber-like stretchability. They are widely used in tight-fit garments such as sports wears, swimsuits etc. The Lycra® fibers in the Sapona® yarn are intended to support the construction and provide outstanding stretchability for the infant onesies, which is an important qualification for making a snug-fitting garment.

5.1.3 Construction

Two different onesies designs were created and knitted by using the Wholegarment® knitting technique. The choice of a knit architecture is key as it is generally more stretchable, flexible, and breathable as compared to woven structures. Furthermore, appropriate compression is essential for this infant ECG onesie, since keeping close skin-electrode contact is a significant requirement for bio-signal detection. Two infant onesies were designed in terms of adding compression on the area that electrodes are located (Figure 5-1). The first garment was

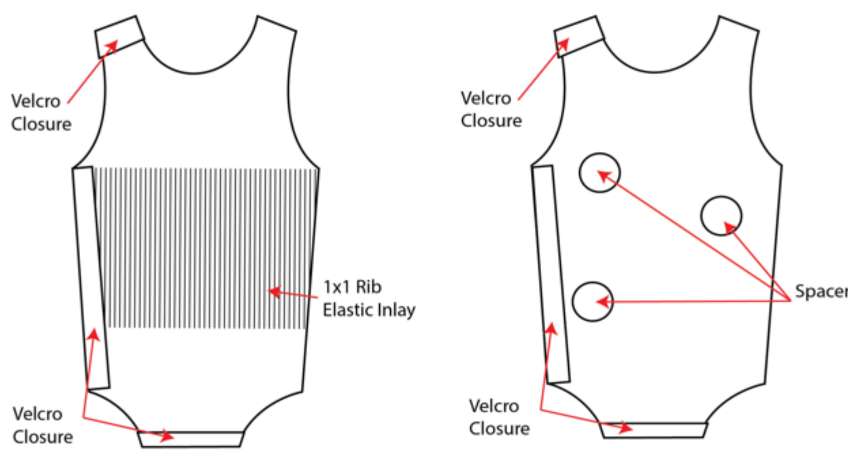


Figure 5- 1 Infant ECG onesies design. Left: Onesie with elastic inlay. Right: Onesie with spacers. Design by Allison Bowles.

constructed with an elastic inlay. A 280 denier elastic inlay around the upper torso reduced the stretchability of the electrodes area. Because the elastic inlay has less stretch than the Sapona® yarn. This upper torso area is more tight-fit than the rest of the garment. The design reduces the movement and transformation of the electrodes area on the onesies. The second garment was constructed with a novel spacers design knit into onesies at the electrodes location. The spacer is a sandwich structure consisting of two fabric layers with a yarn layer in between. The effect of spacers is to add a padding on the back of electrodes which increases the pressure on the electrode and improves the skin-electrode contact. For both designs, a Velcro closure was used to make the onesie more adjustable.

5.2 Electrodes Design

5.2.1 Requirements

The requirement of electrodes used for the infant ECG onesie is described below:

- Biocompatible and not cause skin irritation
- Be able to withstand repeated wear and abrasion (ASTM D4966-12)
- Stable and low skin-electrode impedance
- Maintain contact with the infant's skin
- Be breathable as possible (ASTM D737-04)
- Good washability (AATCC Test Method 61)

5.2.2 Materials

The electrodes on the infant onesie are made of biocompatible CI-4040 Ag/AgCl ink purchased from EMS materials. The Ag/AgCl ratio of CI-4040 is 80:20, which has an excellent ion current detection. The ink was screen printed on Bemis TL 644 TPU film and then heat pressed onto the textile of the onesie. Stainless steel snaps were added on the end to connect electrodes to the ECG electronics board. A Bemis ST 604 translucent TPU film was used to encapsulate the interconnect and snap parts. The design of the TPU and the electrode was completed using Adobe Illustrator. A tabletop Silhouette Cameo die cutter was used to print the drawn design on a vinyl stencil. The patterned vinyl stencil was adhesived to a lab scale screen printing mesh and ink was transferred to the TPU film substrate by using a hand-held squeegee. The screen-printed electrode was then cured at a temperature of 50 ℃ in a Thermo Scientific lab heating and drying oven. The electrode snap and translucent TPU encapsulation were added after curing. For better conductivity between the screen print ink and the snap, Curcuit Works CW 2400 conductive epoxy was used to seal any potential air gap.

Figure 5- 2 An electrode used for the infant onesie. It is Ag/AgCl ink screen-printed on white TPU film and a snap is the output at the end of the interconnect.

5.2.3 Placement

Several studies have focused on placement of electrodes on an infant to determine the optimal location for ECG signal detection. Baird et al. studied a system of 12 electrodes on the infant's chest and abdomen that were tested in a pairwise combination to monitor ECG and breathing

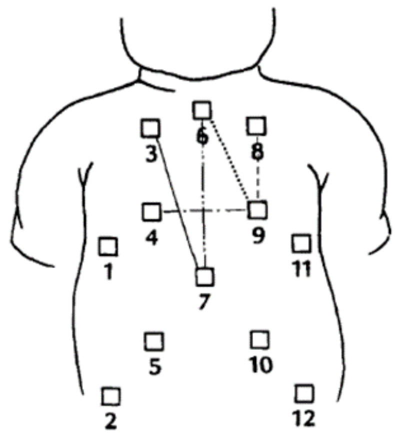


Figure 5- 3 The placement of 12 electrodes on baby's torso as demonstrated in research by Baird [55]. The electrodes pair (3-7) located at the right mid-clavicle and at the xyphoid gave the maximal amplitude ECG signal.

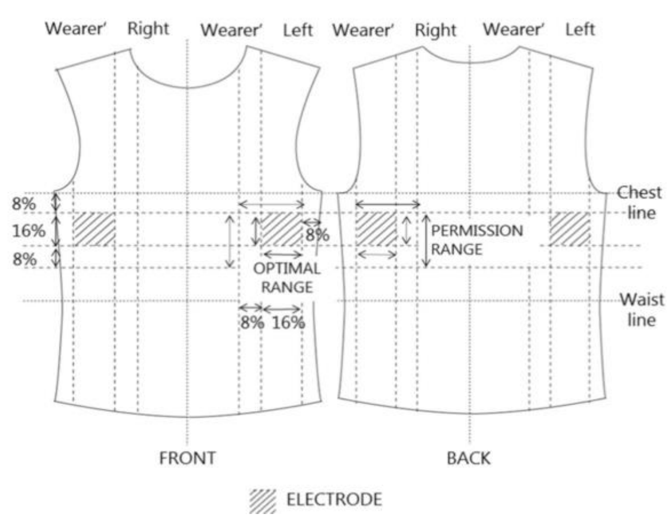


Figure 5- 4 A platform for garment-formed ECG monitoring [28]

of full term and premature infants. The optimal ECG signal was reported with one electrode at the right mid-clavicle and one at the xyphoid (Figure 5-3)[93]. Cho and Lee used a similar strategy to study the optimal ECG lead positions for an adult [94]. It was found the best locations were near the chest line where were the minimum dynamic zone in the human bodice (Figure 5-4). Positions below the musculus pectoralis major on the front torso and below the latissimus dorsi muscle on the back torso resulted in the highest amplitude of ECG complex in this study.

To validate the optimal electrode locations, four different placements a, b, c, d (Figure 5-5, Figure 5-6) were tested on an adult. The red, white and black dots represent the positive, negative and reference sensors in the Vernier EKG Sensor. 3M™ Red Dot™ commercial wet electrodes were used to assess the optimal electrode placement. The ECG data was collected

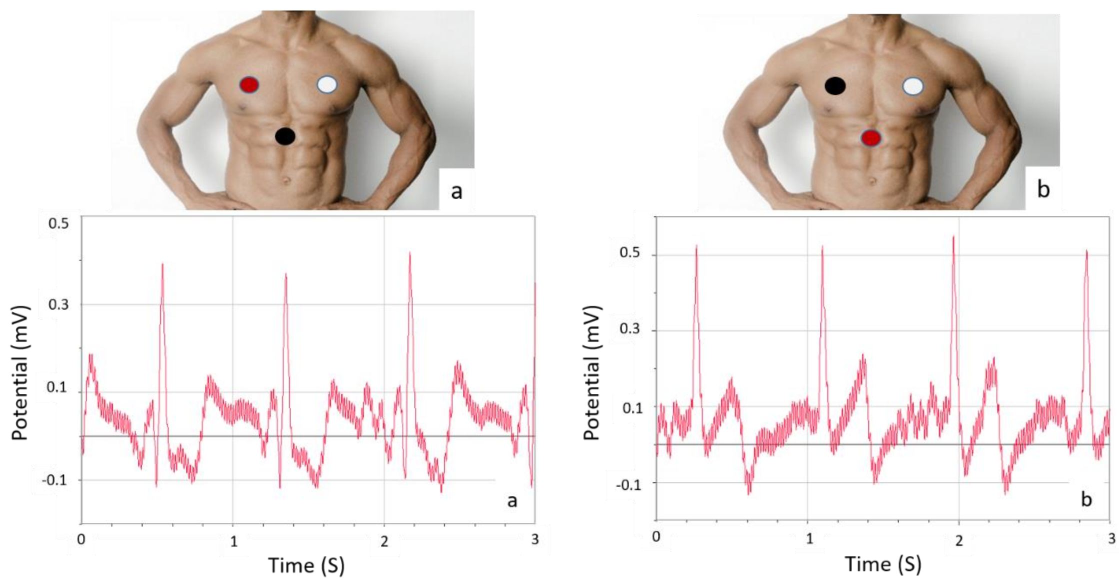


Figure 5- 5 Two electrodes placement methods of ECG measurement based on Baird et al.'s study [93]. The corresponding ECG measurement images are provided below.

and analyzed by Vernier LabQuest® device. By comparing the ECG images, the results by using the c and d placements were better than a and b placements, and the best clear signal was obtained by using d placement in Figure 5-6. However, infants have a very different body size from adults that leads to different heart and muscle locations. Although the test result cannot be applied to infants test drectly, two active electrodes placed on chest and one reference electrode placed on abdomen was considered to be a good option to test for infants. The RA (right arm) electrode under infant right clavicle within the rib cage frame, the LA (left arm) electrode under infant left clavicle within the rib cage frame, and a reference electrode on the infant's lower left or right abdomen. For comparison, the RA and LA electrodes would be placed on the back as well to evaluate the placement on the back.

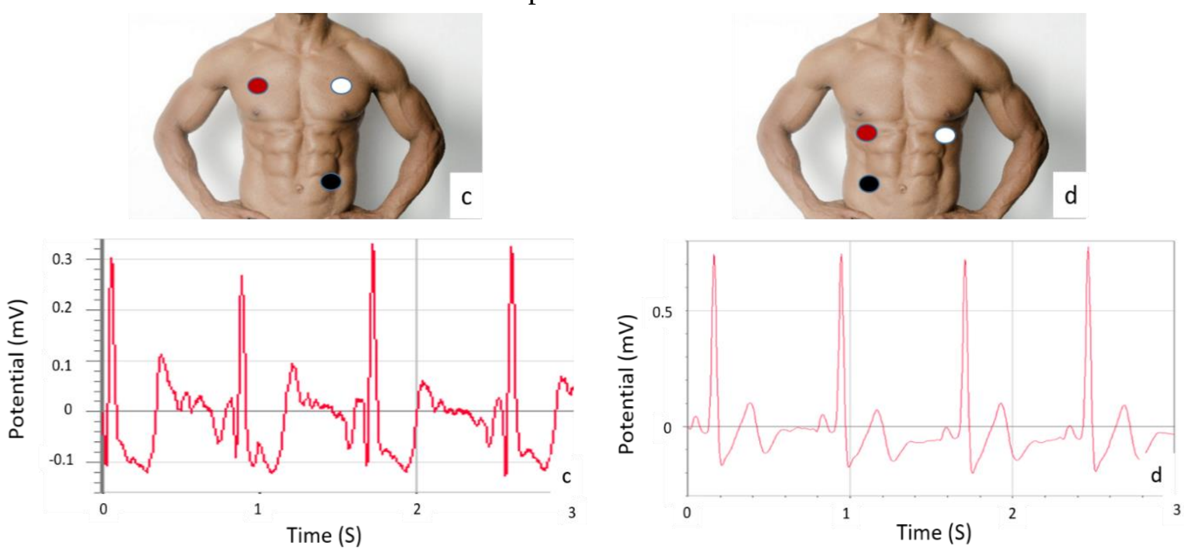


Figure 5- 6 Two electrodes placement methods of ECG measurement based on standard 3-lead placement (c) and adult optimal location study (d) as reported by Cho and Lee[94]. The corresponding ECG test images are provided below.

Chapter 6. Infant Testing Protocol

6.1 Infant Testing Protocol

6.1.1 Objectives

The objectives of this testing were described as following:

- To determine the best locations of electrodes on the ECG monitor onesie
- To evaluate ECG signal quality of different ECG onesies structure
- To evaluate the comfort level and aesthetics of the ECG monitor onesie

6.1.2 Introduction

Three onesies were tested and evaluated. The first onesie designed with spacers had three electrodes on the front based on the standard 3-lead placement. The other two onesies designed with elastic inlay. One of them had RA and LA electrodes on the back that were symmetric with the front electrodes location, and two reference electrodes on the front. The other one had six electrodes on the front to test different placement.

6.1.3 Testing process

- The participant group consisted of two 3-6 month infants, with each infant trialing out each of the three different onesies.
- In the initial stage of the experiment, the onesie was placed onto the infant by the parent and an ECG signal was collected after a 5-minute waiting period.
- After the initial waiting period, the ECG measurement was recorded as the infant was flat on their back, sitting on parent's lap. In total, about 10 minutes of data collection was acquired via the Vernier LabQuest® 2. Different onesies and different electrodes

placement were tested. In addition to the stability of signal, the skin contact condition was observed.

- During the study, the parents and medical staff were questioned regarding their perceptions of the ECG onesie.

6.2 Initial Infant Onesies Fitting and Testing

6.2.1 Pressure Test

In order to evaluate the pressure applied to the different electrodes positions, the three onesies were(Figure 6-1) placed on an infant mannequin and the pressure was measured using a Pliance X interface pressure testing system. The pressure test sensors were placed between the onesie and the skin of infant mannequin while the manniqin was lying on its back. In the test of the onesie with the active electrodes on the back, pressure was also measured when the baby mannequin sitting against the wall to reduce the impact of the mannequin's weight on pressure.

Figure 6- 1 Three different onesie prototypes used for testing

The results showed the electrode C2 on the onesie with spacers (Figure 6-2 a) had higher compression compared to C1 and C3, because it was located in the middle among the three electrodes where was the biggest circumference of the torso. C1 and C3 had loose skin-electrode contact that gaps were observed. In Figure 6-2 b, C1 and C2 were the electrodes on the back. The pressure was different when the baby lay on the back and sat down, because the external pressure applied on the garment changed when the baby's posture changed. In Figure 6-2 c, C1 to C4 placed on the chest within the region of the elastic inlay had the highest compression. Electrode positions C5 and C6 were outside the elastic inlay region and close to the side of the torso. They had a loose contact with the skin. Although the baby mannequin has a big belly, the chest is flatter than the belly, which provides better skin-garment contact. Because the curve of the body, there were more gaps between the skin and garment near the neck, the side of torso, and the base of thigh. The test indicated the pressure was 0.2-0.3 kPa for electrodes without good contact with the skin and it was the normal pressure in the interface of skin-garment. With the help of elastic inlay and spacers, electrodes on the upper torso that can keep good contact with the skin, the pressure could be 0.6 to 1.2 kPa. The design of elastic inlay provided larger area that can keep good skin-electrode contact. This also improved the flexibility of the placement of electrodes while the design of spacers required more precise position of electrodes. The position of spacers would get better effect if they were close to the flat chest area.

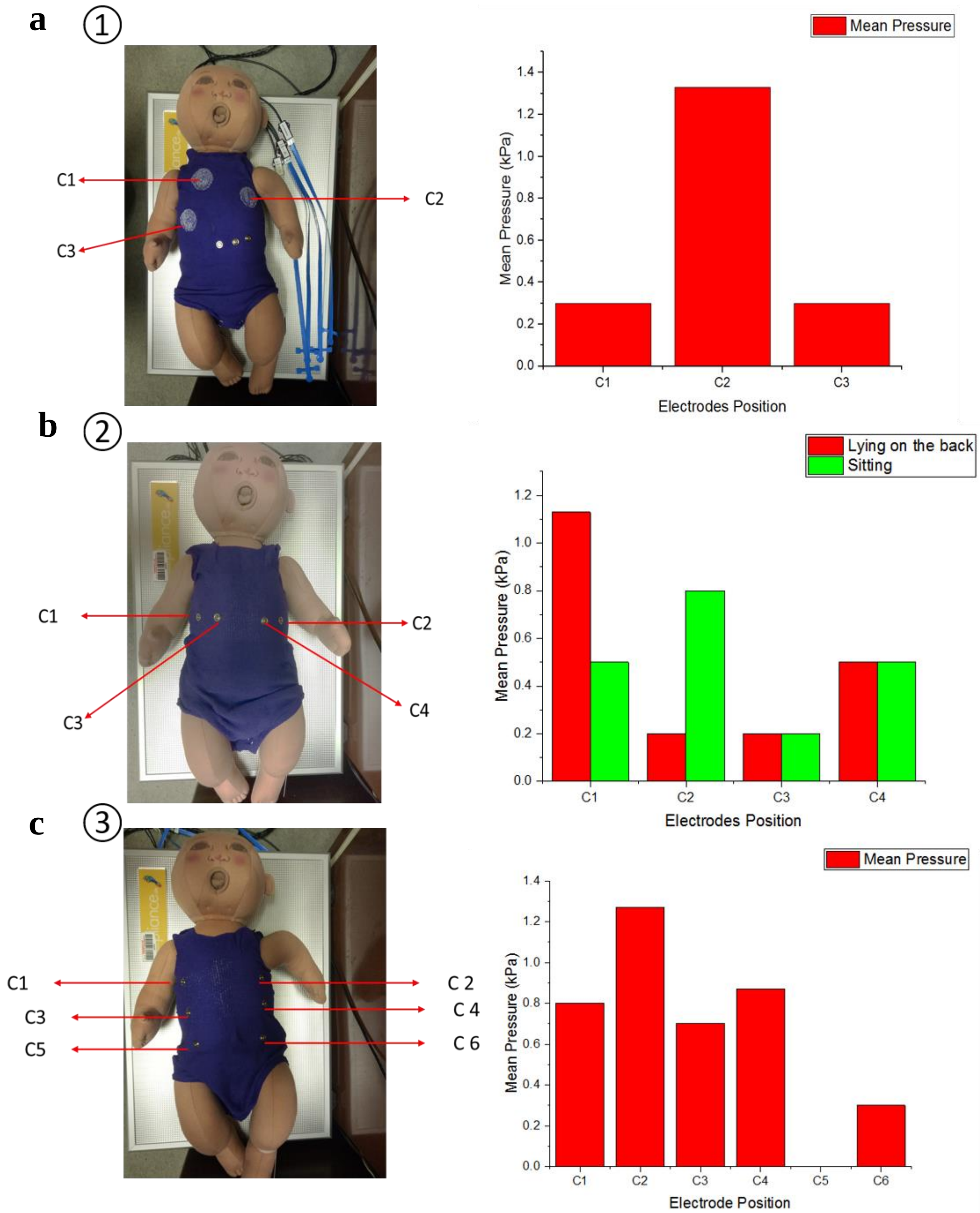


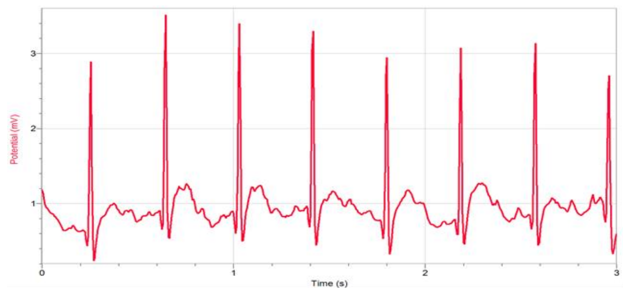
Figure 6- 2 A baby mannequin wore three different onesies and the pressure of each electrode position. a: onesie with spacers and three electrodes on the front. b: onesie with elastic inly and two active electrodes on the back and two reference electrodes on the front. c: onesie with elastic inlay and six electrodes on the front.

6.2.2 Onesies Fitting and Testing on Infants

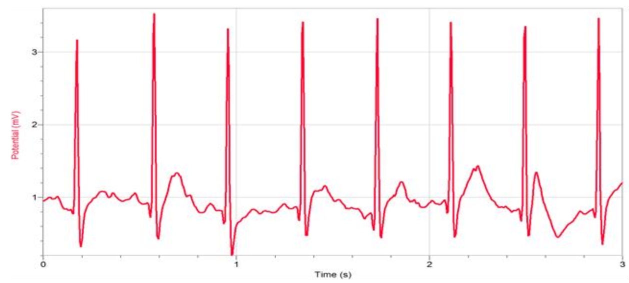
The initial fitting and testing was carried out at the School of Nursing at the University of North Carolina, Chapel Hill. Two healthy infants ages 3 to 6 months participated. The first infant (a 3.5-month girl) was tested when she was semi-lying in her mom's arms. The second infant (a 5-month boy) was tested both when he was lying flat on his back and when he was sitting on his mom's lap. The three onesies used in pressure test were tested for each infant. For all testing, baby lotion was applied on the skin of the infant before testing to reduce individual skin condition variability. During the study, the ECG monitor onesies performed like a normal onesie and no disturbance for the infant was observed. The participant's parents and doctors were satisfied with the soft hand feeling, good stretchability and elasticity of the onesies. Parents said the onesie with electrodes on the back was difficult to apply to their child as compared to the other two onesies designs. This was caused by the long interconnects that stretch across torso. Figure 6-3 showed examples of the ECG measurement when infants wore the three different onesies. Based on the ECG test, the onesie design with spacers had a more stable performance due to it having a better fit to the infant. The onesie design with elastic inlay and two active electrodes located on the back performed better when the infant lay on their back than when they sat there. More pressure was applied on the electrodes location because of the infant's weight. For the onesie with six electrodes on the front, the two electrodes (C5, C6) on the bottom outside the elastic inlay region were not able to detect good signal because of a very loose contact with the skin, which corresponded to the pressure test result. When using the upper two electrodes as active electrodes and the middle electrodes as reference electrodes, a clear signal was obtained. Because infant's body is so small and compacted, and three electrodes can cover a big area, there was no big difference reflected on the ECG signal using different electrode placements as long as they located on the torso with a good skin-electrode contact.

A

Age: five months



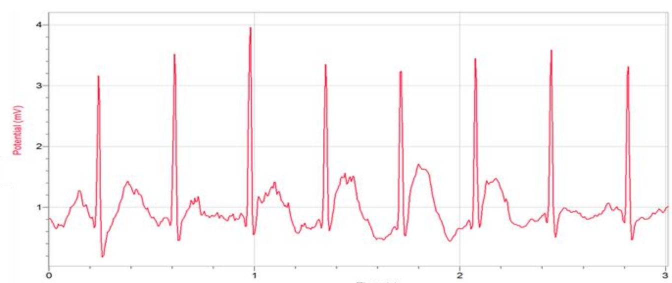
Baby was lying on his back



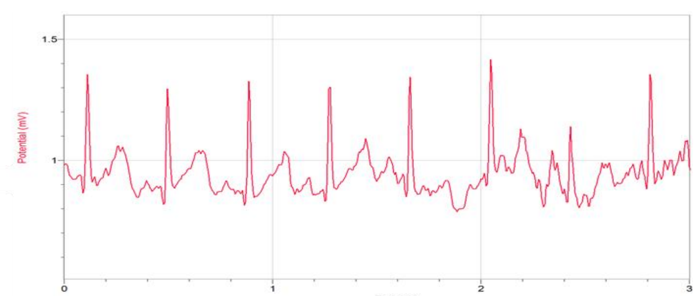
Baby was sitting down on mom's laps

B

Age: five months

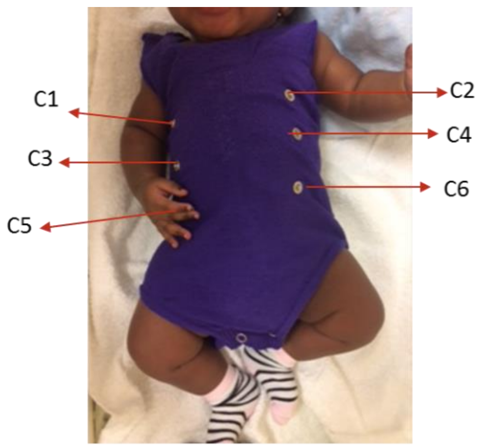


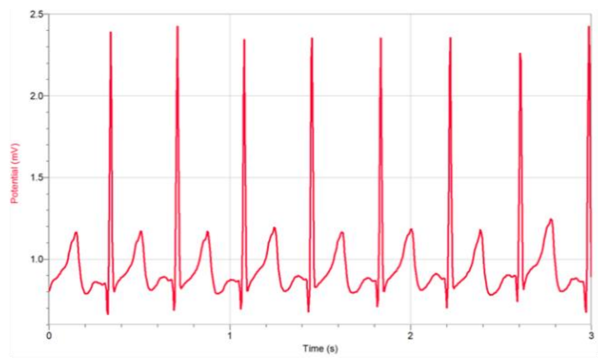
Baby was lying on his back



Baby was sitting down on mom's laps

C





Baby was semi-lying in mom's arms.

Age: three and a half months

Figure 6-3 ECG signal obtained from three different onesies on infants. A: a five-month infant wore the onesie with spacers. The two upper electrodes were active electrodes and the lowest one on the left was the reference electrode. B: a five-month infant wore the onesie with elastic inlay. The two electrodes in the back were used as the active electrodes and two electrodes on the front were reference electrodes. C: a three and half month infant wore the onesie with elastic inlay.C1 and C2 were active electrodes. C3 or C4 worked as reference electrodes.

The ECG measurement also indicated different postures were not a critical influence compared to skin-electrode contact. Figure 6-4 is four ECG images captured from Logger Lite software when the infant wore the onesie with elastic inlay and two active electrodes on the back. When the infant was sitting, recognized R waves can be obtained from run 1 and run 2, P wave and T wave were obscured for some period though. In run1, almost every PQRST waves were well-recognized. Only one R wave that occurred around the 13th second was not clear during 30-seconds measurement. As all S waves were clear identified, the position of R wave can still be found. In run 2, all R waves can be recognized except two R waves that occurred from the 2nd to the 4th second. Compared to run 1, the P waves and T waves in run 2 were distorted. When the infant was lying on the back, there was distortion in run 1 and run 2, but clear signal was obtained during most of the time. In run 1, all R waves were well-recognized and there was clear QRS complex. In run 2, the distorted signal occurred about 7 seconds total during 30 seconds measurement. Overall, a clear view of ECG image with recognized QRS complex can be obtained no matter whether the infant was sitting down or lying on the back, but distorted waves were observed when the infant was crying or had substantial movement.

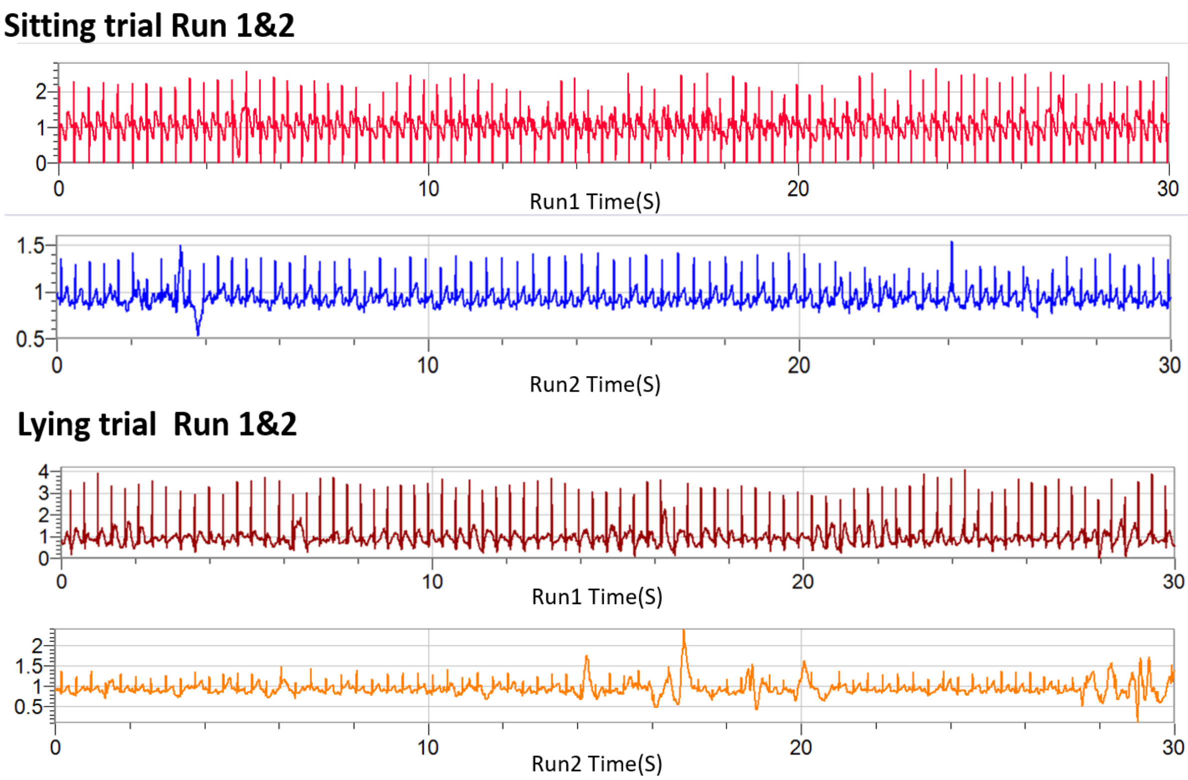


Figure 6- 4 ECG signals obtained when infants were sitting and lying on the back.

Since a clear R peak can be obtained, heart rate variability can be analyzed using the RR intervals based on the ECG data. R peaks can be easily detected because of the highest amplitudes and RR intervals can be calculated then. Heart rate can be expressed by beats per minute (bpm). Figure 6-5 is the ECG image of sitting trial run1 in the first 10 seconds processed in MATLAB (Findpeaks function). A total of 25 R peaks were detected and the time intervals between R-R peaks and corresponding heart rates were calculated. It showed the heart rate of the baby fluctuated between 150 bpm and 164 bpm.

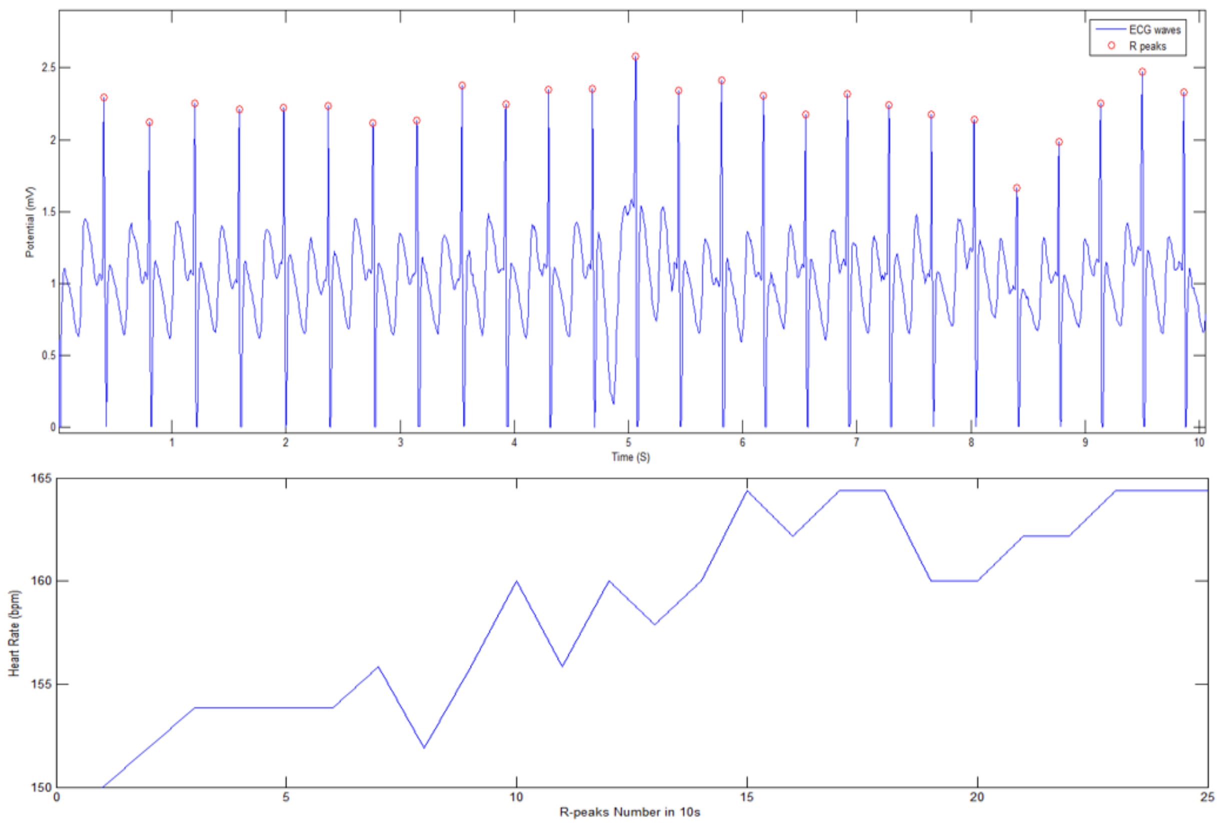


Figure 6- 5 A baby's ECG image and the corresponding heart rate variability in 10 seconds

Chapter 7. Conclusions

7.1 Summary

Fitting and testing of infant ECG (electrocardiogram) onesies with screen-printed dry electrodes on the fabric has been demonstrated as a viable monitoring for comfortable health monitoring. During the design process, it was discovered that the screen-printed dry electrodes have a unique design flexibility, where a diverse set of designs can be developed based on the needs for the ECG monitoring. For example, the shape and size of electrodes can be adjusted based on the construction and size of clothing. The screen print electrodes (Ag/AgCl) are supported on the clothing by a smooth TPU (thermoplastic polyurethane) film that can be heat laminated. Since TPU is elastic and melt-processable, it is easy to use in manufacturing and provides a reliable combination with a broad set of textile materials. The physical test results have shown that the screen-printed Ag/AgCl electrodes have good abrasion resistance (5000 rubs) and washing resistance (20 home launderings), which meet the primary requirements for a clothing-based application. A waterproof coating spray suggests a possible improvement at a washing temperature higher than 40°C. The skin-electrode impedance measurement indicates that the screen-printed electrodes can have similar performance to wet electrodes when the area of the skin-electrode contact is suitably large. Finally, air permeable electrodes were explored to improve the wearability and comfort of the ECG electrodes.

The initial infant testing indicated that the QRS complex can be assessed during an infant's daily activities. The detection of clear R peaks can be used to evaluate heart rate variability by analyzing the RR intervals. Heart rate variability is important for indicating or predicting various risk factors associated with physiological and psychological health conditions such as heart disease, emotions, and stress. However, the duration of stable signal was limited to minutes in the initial testing. Distortion of signal was observed when the infant was crying or moving. This distortion was caused by the inability to maintain a suitable contact between the skin and electrode surface.

7.2 Discussion and Future Work

The goal of this research was to demonstrate the potential of the infant onesie for electrocardiogram measurement. The screen-printed dry electrodes are easy to design, manufacture, and combine with fabric. Snug-fitting and compression design of onesies can provide good skin-electrode contact, which is important for ECG signal detection. The design of this infant garment for ECG measurement is a positive step toward promotion of home-based health monitoring development for infants. For the next design process, the infant wearable ECG system will be completed by the integration of ECG circuit, microcontroller, data analysis program, and wireless connection with a soft packaging for the electronics. The complete ECG circuit includes three major components: amplifiers, band-pass filters, and electrodes. According to the skin-electrode impedance measurement study, the design of the amplifier and ban-pass filter can improve the electrode performance. For example, high input impedance of the amplifier can reduce the distortion of signal [87][95][96]. Furthermore, it is suggested that the garment can be knitted with finer yarns to get higher fabric density. In this way, the fabric surface will be smoother for maintaining skin-electrode contact. Air permeable electrodes should also be studied in more detail for optimization of the design and evaluated when combined with a customized ECG data process system. To improve the washability of the electrodes, a better output to replace the snap is necessary. It would be better if the output had similar mechanical properties to the other parts, which leads to more even force distribution. Much further development can be achieved if the intrinsic properties of the conductive ink can be improved based on washable requirements. Further, the TPU material may be replaced by plastisol ink, which is more compatible with the conductive ink. Cracks may be reduced due to decreased stressing. The substrate fabric can also be preshrunk cotton fabric or other fabrics that will not shrink much after washing. In this way, delamination can be reduced. To investigate the whole garment washing performance, home laundering could be done. The impact of different fabric and clothing construction on the electrodes can be assessed. Adding foams or sponges on electrodes can be tested to validate the effects of pressure on skin-electrode contact. Harmless solution (basically water and salt) could be stored in the foams or sponges to improve the interaction on the interface of the skin and electrode, which acts as the lotion applied on the infant's skin during testing. This idea can combine with the breathable electrode designs that have open cells. In this way, the electrodes will be designed as detachable parts so the garment can be washed. The electrodes' reaction to sweat needs to be studied to predict and evaluate the durability of the electrodes. The addition of an accelerometer may be used to quantify the breathing cycle of the infant which in turn can also provide information about body positions and reduce the influence of breathing on ECG signals. Finally, further clinical testing is necessary to validate the infant onesie with the complete wearable ECG measuring system. The protocol established in this work can be used toward an IRB and at least three subjects ages 3-month to 6-month should be recruited. Standard wet electrodes should be used to compare the signal quality. Video recording could be carried out to study the ECG signal under subjects' different situations and movements.

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