Evaluation of a Capacitively-Coupled, Non-Contact (through Clothing) Electrode or ECG Monitoring and Life Signs Detection for the Objective Force Warfighter

Jaime M. Lee, Frederick Pearce, Andrew D. Hibbs, Robert Matthews, and Craig Morrissette

Walter Reed Army Institute of Research (WRAIR)
503 Robert Grant Ave
Silver Spring MD 20910-7500

Jaime.Lee@na.amedd.army.mil / Frederick.Pearce@na.amedd.army.mil / Andrew D. Hibbs [andy@quasarusa.com] / Robert Matthews [robm@quasarusa.com] / Craig. Morrissette@na.amedd.army.mil

ABSTRACT

A new device that measures ECG inter-beat intervals through clothing is described and compared to a resistive contact electrode. The capacitively coupled non-contact electrode (CCNE) underwent a 40 person human trial at the Walter Reed Army Institute of Research this past year. This sensor can detect ECG and respiratory signals thru clothing and is being considered by the US Army as a physiological monitoring detection sensor on the Objective WarFighter uniform of the future. In this study, three CCNE sensors were compared to an FDA-approved monitor (3-lead) using contact electrodes to determine if the R-R inter-beat intervals of the two methods were "the same" or not. Results of the "at rest in supine position" for determining heart rate based on inter-beat intervals of the ECG are presented. The test results indicate that, relative to the ECG contact electrode, the CCNE sensors work for determining R-R inter-beat intervals reliably. Test subject variability in the different weight categories indicates similarity between the two types of electrodes and statistics for comparison are presented. The CCNE sensor gives "unbiased" estimates (116 out of 117 difference signals gave "unbiased" estimates). The CCNE sensor gave close estimates of the inter-beat intervals in 30 out of 39 test subjects with less than 14 ms differences. The CCNE difference signals give statistically "similar" results within each test subject (37 out of 39 test subjects had statistically similar results). Females showed more variability than males for each weight class. Males and females in weight class 5 had the largest measures of variability.

Material has been reviewed by the Walter Reed Army Institute of Research. There is no objection to its presentation and/or publication. The views of the authors do not purport to reflect the position of the Department of the Army or the Department of Defense, (para 4-3), AR 360.5.

INTRODUCTION

Biopotential sensors can generally be categorized as invasive or non-invasive. Invasive sensors are implanted surgically and are used for isolation of specific potential sources in the brain or the peripheral nervous system. Non-invasive sensors are referred to as surface, skin, or scalp electrodes or sensors, and are applied to the skin surface. To ensure a good resistive contact to the test subject, such electrodes typically utilize a conducting electrolyte or gel and are hence often referred to as wet electrodes. Such electrodes are the standard method used in clinical and research applications.

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Various attempts have been made to overcome the limitations of wet electrode technology for measuring bioelectric signals such as ECG and EEG on the human body. Advances include one class of surface electrodes that does not use electrolytes. These electrodes are referred to as active electrodes and employ an impedance transformation at the sensing site via active electronics. Active electrodes are subdivided into two types—dry electrodes, which rely on a metallic surface in direct contact to the test subject that uses a combination of resistive and capacitive coupling to the local skin potential, and insulated electrodes, which utilize only capacitive coupling.

Detection of human body bioelectric signals using purely capacitive coupling was first reported in 1968 [1]. A schematic for a capacitive electrode system, comprised of two conducting plates placed close to the body and connected to the input of a differential amplifier, is shown in Figure 1. The plates have a capacitance, C_b, to the region of the body in the immediate vicinity of the plates, and a capacitance C_f, to the free space electric potential. C_f represents the capacitance to the source via all other paths except the paths close to the plate.

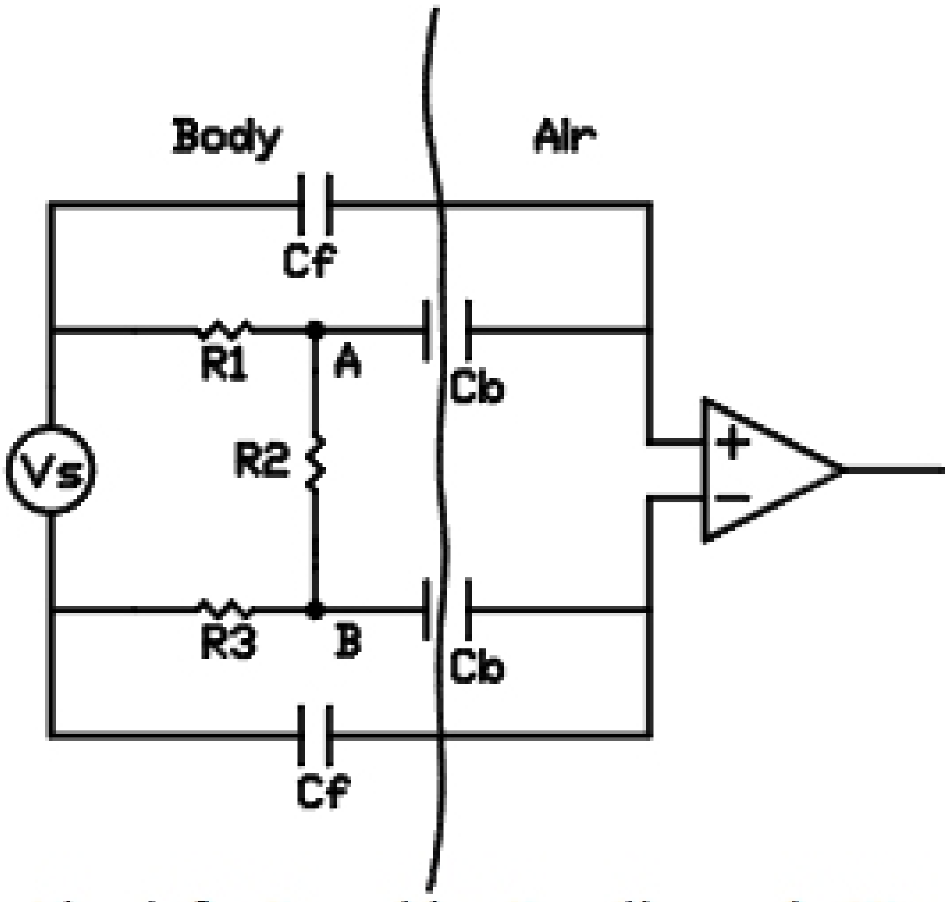

Figure 1: Approximate Equivalent Circuit for Capacitive Coupling to the Human Body

For prior capacitive electrodes, C_b had to be high—typically 1 nF to 100 nF. C_b is approximately given by the standard expression for a parallel plate capacitor, and is thus inversely proportional to the spacing between the electrode and the body [2,3]. This dependence is so sensitive that if the electrode moves from being on the surface of the skin to just 100 μm away, C_b changes by approximately a factor of 10. Thus, even though they do not require direct resistive contact to the body, traditional capacitive (insulated) bioelectrodes are very susceptible to displacement.

In 2001, researchers at Quantum Applied Science and Research (QUASAR) developed a new class of sensor that measures the electric potential in free space, i.e. without physical contact to any object. It was observed that the sensors were able to measure the ECG of a fully clothed person standing within a range of about 10 inches. (Patent Pending) In 2002 QUASAR developed a compact version of the sensor, termed the capacitively-coupled noncontact electrode (CCNE), specifically to measure ECG through clothing (See Figure 2) This first version of the ECG electrode, including all amplification electronics, is approximately 1 inch square with thickness of 0.35 inches.

This report describes the results of the first human trial of this new electrode technology. The goal was to compare the CCNE operating through regular clothing with a conventional 3-lead ECG using resistive electrodes for the purpose of measuring interbeat intervals.

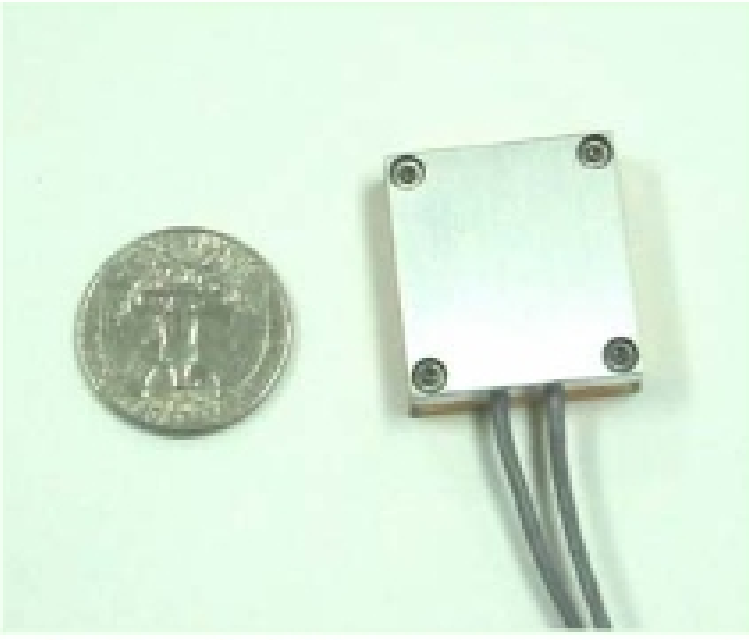

Figure 2: Capacitively Coupled Noncontact Electrode used in this Study

The principal application envisioned for the technology is continuous readout of ECG of military personnel as part of the Objective Force Warrior (OFW) soldier uniform. OFW is the Army's flagship Science and Technology initiative to develop and demonstrate revolutionary capabilities for Objective Force soldier systems. Including physiological monitoring such as ECG in the Objective Force Warrior and Land Warrior systems is of great interest to the Army. It is widely known that there are many problems associated with contact electrodes for long-term ECG monitoring, including loss of contact to the test subject due to drying of application glue or environmental factors (e.g. rain) and test subject resistance to wearing the electrodes due to discomfort caused by factors such as skin irritation. Therefore, a non-contact system would be of great benefit to the Army.

It has been observed that 90% of combat fatalities during conventional warfare occur forward of the battalion aid station (BAS), the first organized medical treatment facility, and that two-thirds of these fatal injuries involve significant hemorrhage [4]. Furthermore, about 60% of these deaths occur within the first 10 to 15 minutes after injury. These statistics underscore the importance of the Army's equipping their medics with the capability to rapidly locate, assess, and effectively treat the wounded. It is estimated that about 25% of these casualties might be salvageable with prompt hemostasis, and some degree of fluid resuscitation to sustain them until definitive surgery and resuscitation can be achieved in the later phases of their care [5]. Since the medic carries so little resuscitation fluid (only enough to replace a 15% blood loss) and he has to often deal with many potential casualties at once, he must use his resuscitation resources judiciously, deciding when and how much fluid should be given. The medic will need reliable physiological monitoring that is already on the soldier. A non-contact based system would easily be integrated into the OFW program and provide the foundation for operational and combat medic medicine. The information provided by such a system would be helpful to the combat medic to properly ascertain the level of injury and survival potential of the injured, and provide optimum care in the battlefield.

Methods and Materials:

The WRAIR Clinical Trials Division solicited test subjects for 5 weight groups of 4 test subjects each; one set of the 5 groups was to be females and another set males, for a total of 40 test subjects. The inclusion criteria were that they be healthy males and females with no known heart defects, who ranged in weight from 101->173 lbs for females, and 124->220 lbs for males. This sampling represents the majority of the men and women in the Armed Forces today. Table 1 shows the different weight groups is as follows:

Inclusion: Healthy Men/Women with no known cardiac defects, Civilian/Military, ages 18-50, Weight- female: 101-->173 lbs or greater; male: 124-->220 lbs or greater