Design of a Waterproof Electrode System for the Detection of Onset Decompression Sickness in Deep Water Divers

A Major Qualifying Project Report:

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By

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1. Introduction

Decompression Sickness (DCS) is a major danger to scuba divers of all levels if proper precautions are not taken prior to subaquatic decent. Although a complex resulting from a change in barometric pressure, which only affects compressible substances in the body, DCS can still affect the gases of hollow spaces and viscous organs and those dissolved in the blood. Oxygen Toxicity (OT) occurs when a human being exceeds the Oxygen partial pressure (ppO2) tolerance of 1.6 bars. Although given a standard maximum breathing tank air concentration of 21% O2, OT can cause a diver to into seizure from an attack on the central nervous system. Other types of OT can affect the lungs and vision, causing drowsiness, hallucinations, visual disturbance, and paraesthesia. Both of these scuba diving dangers can be caught through the use of R-R Interval monitoring, measurement, and signal processing. Alterations in breathing occur from both OT and DCS, which could be found in said monitoring; and after certain algorithms could determine which affliction the diver was suffering from. The use of electrocardiography (ECG) for monitoring individuals undergoing rigorous exercises is gaining interest because it can be used and a diagnostic aid in the detection of various cardiac abnormalities. The MQP was tasked with designing an electrode specific to the technical diving. Deep water diving presents a variety of risks to divers, the most prominent of which is Decompression Sickness (DCS). Decompression sickness is caused by the rapid expansion of nitrogen molecules inhaled by a diver when ascending from an environment of high pressure to an environment of lower pressure. The MQP group sought to design an electrode that would be used by technical divers to assist with the detection of the onset of DCS. This would mean the electrode would have to with stand a minimum dive time of two hours in a salt water environment as well as a minimum effective depth of 60 meters, which would in turn require the electrode to with stand an atmospheric pressure of roughly 6.017 atm.

2. Background

The History of Scuba

Diving has been an important part of military operations for over 5,000 years. Originally diving was used to salvage wrecks and for military operations. The earliest divers used tubes that were sent to the surface to provide fresh air. There is no proof that this method worked. Once a diver is below three feet he or she would not be able to move air through a tube due to the pressures of water. Between the years of 1500 and 1800 diving bells were used to provide air for divers. A diving bell was an inverted bucket that was lowered into the water. The diver could work under the bucket or even leave the bucket to work then return back to it for air. This allowed divers to stay underwater for hours.

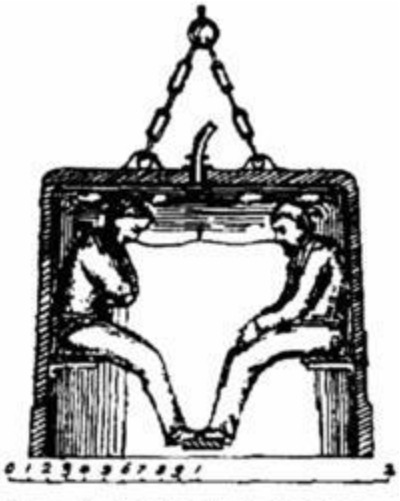


Fig. 1. Taucherglocke.

Figure 1 - Diving Bell

The diving bell soon improved into what became to be known as a caisson. Pumps were added to provide enough pressure to keep water out completely. Caissons became big enough for several men to work underwater for several hours in a completely dry environment. As caissons became more popular workers began to develop sickness as they returned to the surface. These were the first instances of Decompression Sickness.

The idea to store air in a personal portable container was discussed long before it was possible. Technological limitations of air pumps and compressions techniques did not allow for SCUBA diving to be possible. SCUBA eventually developed into 3 different methods. Open, Closed and Semi closed circuit SCUBA diving. During open-circuit diving air is vented directly into the water. In closed circuit, oxygen is filtered and recirculated. Semi closed is a combination of both. Making SCUBA diving effective allowed for an increase scientific development, the growth of a sport, and effective military operations. Technological improvements have greatly increased the ability for deep dives. The closed system is very useful to military operations because it does not produce surface bubbles giving away the location of a diver. The initial use of closed systems began to produce oxygen toxicity among divers. This led to the development of mixed gas semi closed systems. The semi closed system allowed for longer and deeper dives.

In 1964, the US Navy adopted a semi-closed mixed rebreather for its combat dives. This system allowed for 200 feet seawater (fsw) and 3 hours of diving. Eventually in the 1980s the Navy moved to a mixed gas closed system.

The purpose of diving has not changed from its original purpose. Military operations and science has always been the primary role of diving, though sport diving is now popular. Diving is a very stressful activity that requires a lot of preparation. Divers must go through extensive training, but also learn much through experience. Divers go through many stressors when diving. The deepest recorded open sea dive was set in 1977 by a French team that descended to a depth of 1,643 fsw. The specific dangers of diving will be discussed in a later section.

The Dangers of Scuba Diving

Oxygen Toxicity

Oxygen, as a basic necessity by humans, is a vital tool in diving; however it is limited by its toxicity. [9] In 1942, Kenneth Donald began to develop oxygen tolerance limits for Royal Navy divers to allow for rebreathing units during combat. [10] For three years Donald conducted 2,000 experimental dives using RN volunteers, each of which was monitored by two attendants. His tests produced the most extensive record of human acute (CNS) toxicity. [9] [10]

Oxygen Toxicity (OT) has a wide range of symptoms and signs, including: lip twitching, convulsions, vertigo, nausea, respiratory change, drowsiness, visual disturbance, hallucinations, and paraesthesia. There are three principal forms of OT, which are classified as follows:

Type	Effects
Central Nervous System	Convulsions followed by unconsciousness.
Pulmonary	Difficult breathing and chest pain from breathing high pressures of O_2 for elongated periods.
Ocular	Ocular alterations when breathing high pressures of O_2 for elongated periods.

Oxygen Toxicity can cause a diver to go into seizure from an attack on the central nervous system, however it is avoidable. [13] Prevention of such seizures can be attained through several methods, including full-face diving masks and maximum operating depths. Oxygen clocks are also used, which are clocks that increase speed at increased partial pressures of Oxygen ppO_2. [14]

OT is classified as: $ppO_2 > 1.6$ bars

When plugged into the equation

$$P_O = \frac{N_o}{N_t} * (1 + \frac{D}{10})$$

With the standard dive O_2 concentration of 21%, the result states that the maximum operating depth without risk of oxygen toxicity is D = 99.19 meters.

Decompression Sickness

Decompression Sickness (DCS) is a complex resulting from a change in barometric pressure. This is a major danger to scuba divers who do not take proper precautions prior to underwater ascent. Although changes in pressure only affect compressible substances in the body, the gases of hollow spaces and viscous organs and those dissolved in the blood can still be affected.

There are two types of DCS that can affect the body. Type 1 is acute, and can be characterized by any combination of the following symptoms: temporary mild pains, itching or burning sensations on the skin, and violet-colored epidermal rash. Most patients with Type 1 DCS experience the bends (muscle pain), a throbbing pain commonly found in joints, tendons, or tissue.

Type 2 DCS is more severe than Type 1, and is characterized by pulmonary systems, hypovolemic shock, or nervous system involvement. It consists of Cardiopulmonary DCS that is nonlethal, and neurological DCS that can be lethal. Although Type 2 is more severe, pain is only reported in approximately 30\% of cases. [18]

DCS can be caught through strict monitoring of patterns in the body's systems (specifically through monitoring a diver's R-R interval of their ECG signal with the correct algorithms), and possibly prevented through oxygen pre-breathing. This is a method of highly concentrated oxygen intake prior to a dive.

Prebreathing

Oxygen Prebreathing consists of breathing pure 100\% O_{2} before a dive to flood cells of oxygen into the lungs. This prevents uptake of nitrogen, bubbles during decompression, and interstitial damage. Prebreathing oxygen also decreases air bubbles and platelet activation, which may help to reduce the onset of decompression sickness. [19]

Scuba

Scuba diving is a form of diving in which an apparatus is used to breathe for long periods of time at extreme depths. Scuba was originally coined in the 1950s standing for “self-contained underwater breathing apparatus.” [8] Scuba diving is both recreational and professional activity.

Bioelectricity & The Heart

In order to understand the need for the design of an underwater electrode, basic bioelectricity, biomagnetism, and physiology must be understood. Bioelectricity can be described as the “ability of tissue to generate electricity.” [1] An example of this is the electricity produced by the heart that is recorded in the form of an ECG signal. The electrical current flowing through tissue is the flow of ions between cell membranes. In order to record such signals the flowing ions must be converted to electrons.

The electrical current in cells is the result of the flow of ions across cellular membranes. Ions are “electrically charged particles obtained from an atom or a chemically bonded group of atoms by adding or removing electrons.” [3] Ions flow between cells to create a current through tissues. The current is caused by the difference in charges inside and outside the cell or intracellular and extracellular. Potential is used to refer to the charge of a substance.

The resting potential refers to when a cell is not allowing the flow of ions. When ions are moving across the membranes of cells the charge that is present is referred to as the action potential. The action potential is the result of ions flowing through channels within the cell membrane. [5] The flow of ions during the action potential is the current that is recorded as electrical biosignals. The electrocardiogram is an example of this action potential.

Heart

The heart is a vital organ to life of a human being. It pumps blood to the entire body. The heart is located in the center of the chest, and consists of four chambers. The walls of the chambers are composed of cardiac muscle that contracts at approximately 70 to 80 times a minute. With each contraction blood is pushed through the chambers of the heart. Each side of the heart has one atria and one ventricle. The atria are above the ventricles. A wall of tissue called the septum separate the middle of the heart, left and right. The mitral and tricuspid valves separate the left and right atriums from the left and right ventricles respectively. The aorta is a large blood vessel that carries oxygenated blood from the heart to the rest of the body. The pulmonary artery carries non-oxygenated blood to the lungs. Pulmonary veins bring the oxygenated blood back to the heart. The vena cava brings blood back from the body to the heart. Below is a figure to show the flow of blood through the heart. [6]

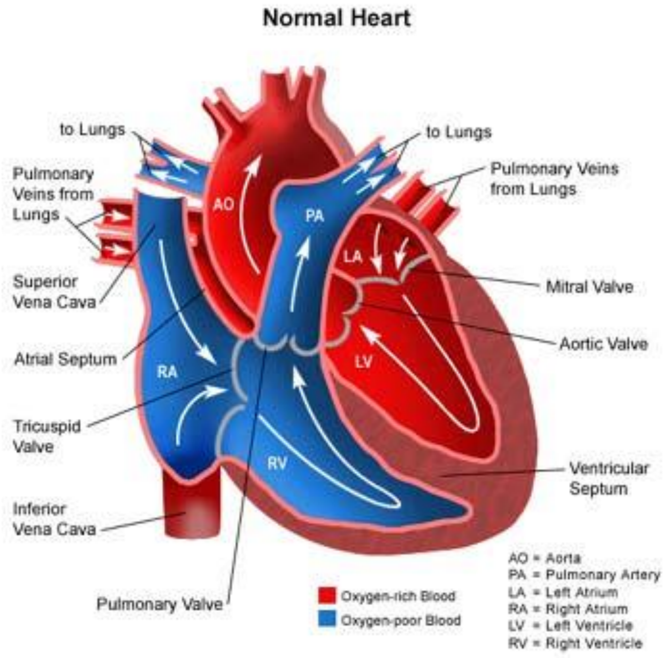


Figure 2 - Cardiovascular Flow

The heart's electrical system is the driving force behind the contractions of the heart, and is made up of three main parts: the sinoatrial (SA) node, the atrioventricular (AV) node, and the His-Purkinje System. The heartbeat also consists of three parts: diastole, atrial systole, and ventricular systole. The atria and ventricles fill with blood during diastole and the atria contract or atria systole. After contraction the atria begin to relax and the ventricles contract or ventricular systole expelling blood from the heart.

The heartbeat begins when the SA node fires an electrical signal through the cardiac muscle, which is what an electrocardiogram records. The SA node is known as the natural pacemaker. The signal produced by the SA node first flows through the atria, causing atrial systole, pushing blood from the atria into the ventricles. When the signal arrives at the AV node that is located near the ventricles, the signal is slowed to allow the ventricles to fill with blood. After the signal leaves the AV node it progresses through the bundle of His into the Purkinje fibers that connect to the cells of the heart wall. Blood is then pushed out of the heart, and the muscles relax and wait for another signal. The path of the electrical signal can be seen below.

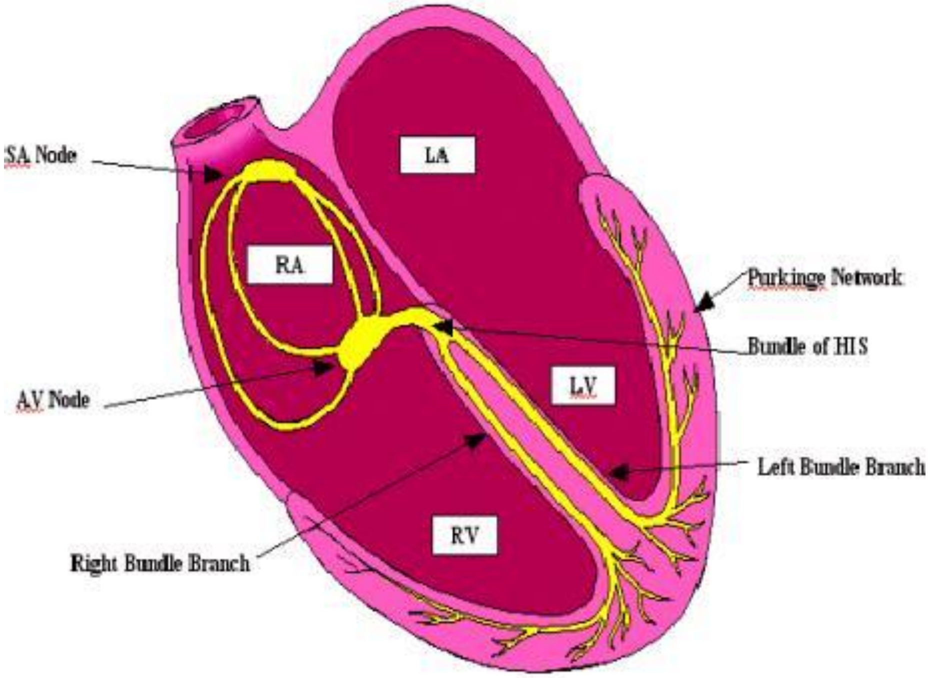


Figure 3 - Electrical Path of The Heart

Electrocardiogram

The electrocardiogram (ECG) records changes in potential from the cardiac conduction cycle through epidermal electrodes [15]. The signals are transmitted through bodily fluids, allowing the electrodes to receive signals originating from the myocardium. The ECG converts these signals into waves. When cardiac tissue is at rest, the wave is flat, but when depolarization and hyperpolarization occur, the wave will rise above or dip below the line.

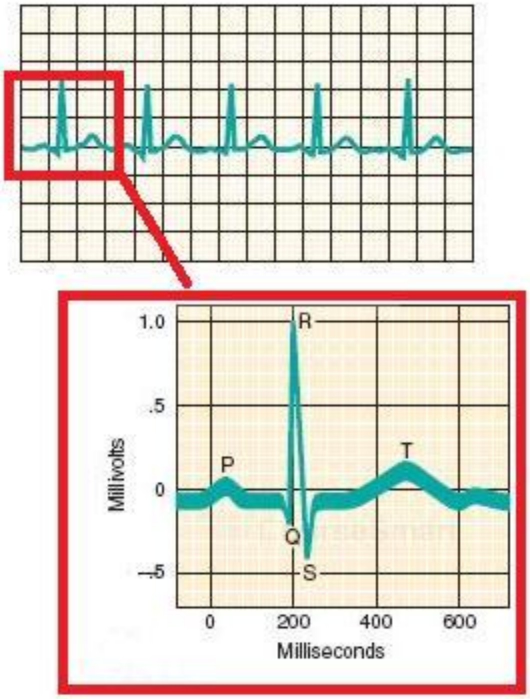


Figure 4 - Healthy Electrocardiogram

The cardiac conduction cycle is represented by the waves of the electrocardiogram. As shown above, the cycle consists of a P, Q, R, S, and T waves, each corresponding to a different step [16]. The P wave demonstrates the depolarization of the atrial fibers as the atria contract, which occurs almost instantaneously as the S-A node fires an impulse. As the atrial fibers repolarize, the ventricular fibers rapidly depolarize, demonstrated by the QRS complex. The T wave represents the repolarization of the ventricular fibers.

Electrode

The study of bioelectric signals and potentials has their origins in the 18th century. It is now established that the human body is constantly generating electrical signals, with the main source being muscles and nerve cells.

For the case of ECG electrode design, the leads are centered on acquiring a quasi- periodic rhythmic signal synchronized by the sino-atrial nodes in the heart creating a rhythm of 72 beats per minute in the average human. ECG signals are currently best acquired through the use of surface skin electrodes. Surface-recording electrodes make the transfer from ionic conduction on the surface of the skin to electric conduction necessary to record signals. In electrode design a certain set of constrains should be addressed, the most prominent of which being comfort of the electrode over prolonged periods of use, reduced or minimized motion artifact interference, and finally a convenience factor in regards to the application of the electrode.

What Can It Detect?

Electrocardiography is the interpretation of bioelectric activity of the heart as detected by specially placed electrodes attached to the outer surface of the skin. An electrocardiogram detects and amplifies the miniscule electrical charges on the surface of the skin originating from the depolarization of the heart after every heartbeat. Depending on placement and the number of leads an ECG can interpret and detect an array of signals, such as the R-R interval, P-R interval, Q-R-S complex, S-T interval, Q-T interval to name a few. Through the detected signals an array of diagnoses can be made varying from an adverse reaction to drugs observed through a shortened or elongated Q-T interval, or a possible myocardial infarction, detected through an abnormally rapid T wave. It has recently been observed that the on-set of Decompression Sickness can be detected through the observation of the recorded R-R interval in porcine samples.

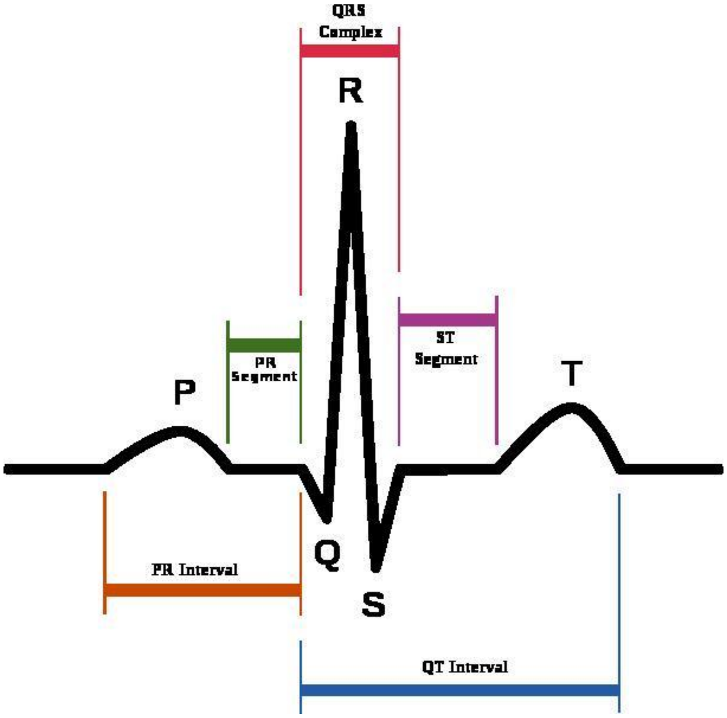


Figure 5 - Normal sinus rhythm for human heart as seen on ECG

Need for ECG While Scuba Diving

Divers, both recreational and technical face several health risks from exposure to the harsh under water climate. In the United States alone, one in 100,000 dives end with a fatality [20]. The greatest risk to divers is prolonged exposure to the ambient pressure while submerged. If a diver resurfaces incorrectly, the volume of the air inhaled at a higher atmospheric pressure will expand leading to parenchyma. [21]. Coupled with rapid resurfacing, an expansion of air and nitrogen molecules throughout the body can create bubbles that fatally damage the body. This is referred to Decompression Sickness.

With the associated dangers with SCUBA diving, the United States Navy developed the widely used Navy Dive Tables. These general guidelines regarding dive depth were developed with the specific task of minimizing occurrences of DCS. However helpful the dive table is, it does not account for the high variability between dive profiles

Recent studies have provided information that the onset of DCS can be detected through the analysis of acquired R-R intervals. Real-time monitoring of a diver's vital signs while submerged could in fact hold the future of DCS prevention. Currently there are no means to collect bioelectric signals from a subject while submerged.

Technical Diving

Technical diving, or diving which involves advanced technical procedures to enable divers to reach larger depths or more complex routes, such as caves, is a recreational diving market segment which would be feasible for the system. This is because the divers rely on complex air combinations such as Nitrox and Trimix and are under greater risk as they dive.

Although the exact number of active technical divers, or technical divers who participate in diving activities at least five times a year, is not available, approximations can be made using other market data. Based on approximations with current market data, it is estimated that there are approximately 264,000 people dive technically at least five times a year [22, 23].

Military Diving

The Navy has a division in its Special Operations Forces referred to as the Navy Divers [22]. There are four main areas of responsibility for Navy divers: salvage and recovery, in which divers work to find and retrieve wreckage; deep submergence, in which divers submerge to "the greatest depths in name of research and classified missions;" ship husbandry, in which divers fix and maintain the Navy's fleet; and saturation diving, in which divers live at extreme depths for long periods of time. The Navy strives for a less than 2\% prevalence of DCS during its dives (chon swine article).

Gathering market information regarding the US military was almost entirely impossible. The request through the Freedom of Information Act conducted by the authors was denied because the size of the Navy Diving group is classified information. As such, the authors chose to assume that in the United States there are 1000 Navy Divers that dive approximately 200 times a year.

Commercial Diving

Commercial divers are those who dive as an occupation. Industries which hire commercial divers include construction, demolition, oil, police and fire departments, and underwater salvage companies [22]. These divers submerge on almost a daily basis and visit depths greater than the average recreational diver, subjecting themselves to heightened chances of risk. After visiting such a deep atmosphere, the employees visit a hyperbaric chamber to decompress.

Commercial diving companies could benefit from the system by using it to tailor the length of time spent in the Hyperbaric Oxygen Therapy (HBOT) chamber to the detected risk of each employee. This would prevent on the job injuries, lower costs associated with workman's compensation, and reduce the time spent in the HBOT to what is necessary.

Although there is incentive for commercial diving companies to use the system, it is not a feasible market to pursue at this time, because of the low number of commercial divers. The US Bureau of Labor Statistics reports that there are 3,720 commercial divers in the United States [22]. This is not a large enough population to warrant pursuit in the short run, but eventually, the company could offer the devices in bulk to commercial diving organizations if pursuing the military market proved successful.

R-R Interval

The R-Wave typically has the greatest magnitude out of the parts of an ECG signal. As such it can be used as an approximate measurement of a patient's heart rate, going from peak to peak and measuring the interval in between, known as the R-R interval. The spike of the R-wave, part of the QRS complex, is caused by rapid depolarization of the ventricular fibers, as the atrial fibers repolarize. As well as measuring heart rate, variability in the R-R Interval can diagnose different heart defects or warn of possible impending conditions.

Pursuing Other Markets

The system could have several applications outside of the SCUBA diving industry. Because decreased heart rate variability is a prognostic marker for cardiovascular diseases such as diabetic autonomic neuropathy, hypertension, myocardial infarction, and heart failure, the device could prove useful for individuals who are indicated to be at high risk for cardiovascular disease [26].High risk individuals participating in aquatic exercises could use the device to monitor their heart rate variability, thereby catching a cardiac episode before it happens. Competitive swimmers could use the system to detect cardiovascular complications during rigorous aquatic exercise.

3. Product Strategy

The development of the project strategy started with the preliminary presentation to the team of the initial client statement. The project advisor, Professor Ki Chon of the Biomedical Engineering Department at WPI, played the client role. The initial client statement was as follows:

> "Design, build, and test an inexpensive ECG electrode that will make good contact with the skin and provide good ECG signals when submersed in water (up to two hours) or simulated sweat that your team must formulate."

This client statement was presented to the team during the first meeting with Prof. Chon. After the client statement was received the process of clarifying and simplifying the objectives of the project were undertaken. This started with a literature review in order to understand the greater need for a working underwater electrode. The research associated with the writing of the literature review guided the team in the formation of the objectives, requirements, functions, and constraints that would be present during the project.

Objectives and Functions

The next part of the project consisted of determining the objectives and functions of the electrode. This would provide a clear path to the development of an electrode that would work underwater. The simplified objective would provide an initial starting point to the different paths the team could take in development of the electrode. The functions of the electrode would all relate to the ability of the electrode properly functioning.

Objectives

The main objective of the project was established to be: "Design an electrode to be used by technical divers to assist with the detection of decompression sickness. " This objective would guide the team into the development of several sub-objectives. The sub-objectives would be more descriptive of the methods to be used. The first sub-objectives determined were that the electrode must be safe and reliable. Though this was a very broad statement, it allowed the team to delve deeper into the specific objectives of the project. A summary of all of the objectives can be seen in Figure 6.

The objective to develop a safe electrode specifically meant that the electrode must be biocompatible. The electrode could not cause any mark or damage to the skin while it was in use. It also had to be safely applied and removed from the user.

The sub-objective regarding reliability was broken down into three separate sections. These sections were adhesion ability, successful detection of bio signals, and durability. The ability of the electrode to maintain contact to the skin was extremely important. Not only did the electrode need to be able to make contact in a normal environment, this electrode had to stay attached for 2 hours and stay attached for two hours. Next, the electrode was required to successfully detect bio signals. The key to this objective was the ability to record the signal without a lot of noise interference. This is the basic function on any electrode. The final sub-objective under reliability was the durability of the electrode. The electrode had to be able to handle the environments it was going to enter. The electrode must be waterproof. It must also handle both freshwater and saltwater environment. The electrode was also to be pressure. Though it was not established at this point in the project the specific depths the electrode would handle, technical divers can dive far below sea level. This environment would subject the electrode to extreme pressures.

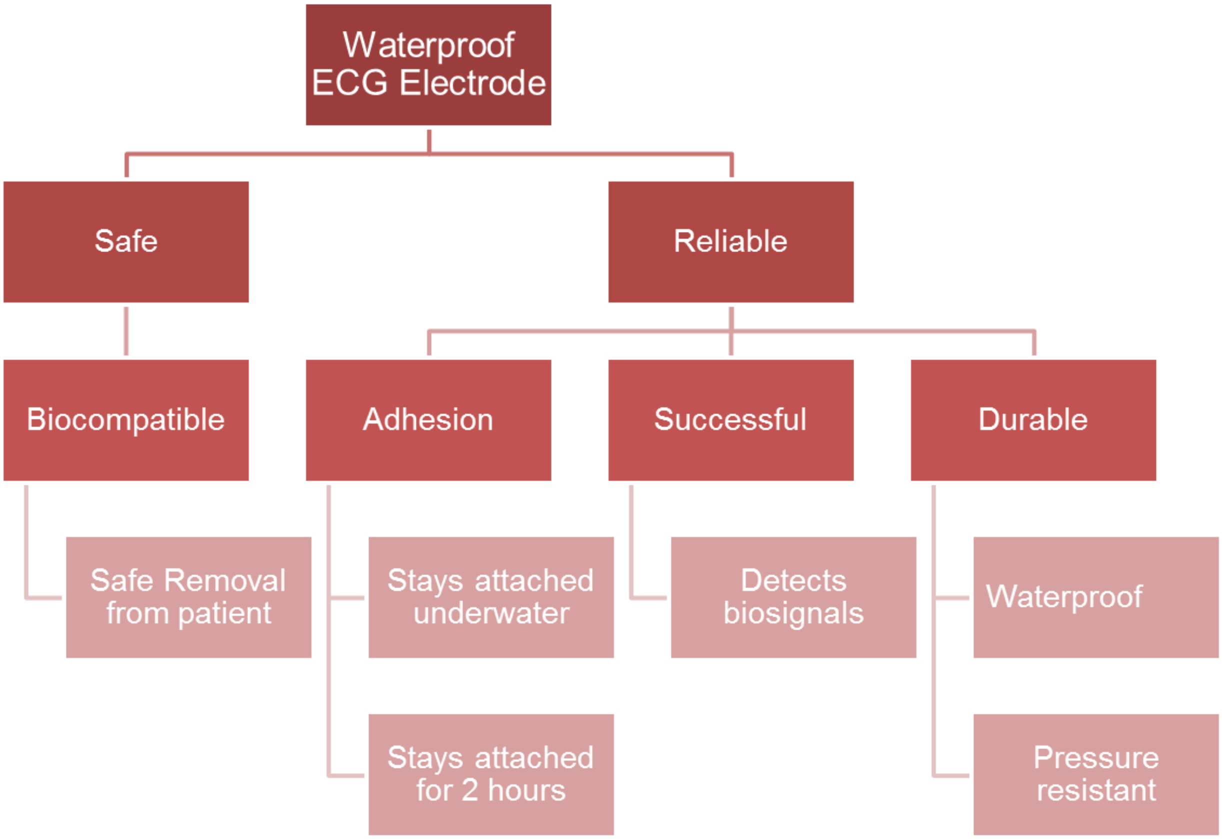


Figure 6: Objectives Tree

Functions and Means

After the determination of the project objectives, the functions of the project were brainstormed. Different means of accomplishing these functions were also brainstormed. The four main functions of the electrode were decided to be connection to an existing ECG device, conduction of biological signals, connection to the user, and waterproofing. These four functions allowed the team to proceed in developing the specific characteristics of the electrode. The team created a morphological chart and a function and means tree to determine the characteristics. They can be seen in Table 1 and Figure 7.

The connection to an existing ECG device was important because it make the electrode usable to almost all users. Not only did was it required that the device worked with an existing device, but there was a desire to make the device have a universal attachment point. A universal attachment narrowed the electrode to either a fastener or an implanted wire. The team decided to pursue a fastener because it would allow the electrode to be more universal. The final decision came down to an alligator clip or a snap button. The snap button was pursued due to is more reliable connection.

The next function of the electrode was its ability to gather an electrical signal from the body. This meant the team was deciding between a wet or dry electrode. A wet electrode contains an electrolyte substance. The team felt this was a bad idea because the underwater environment could wash away the electrolyte, making the electrode unusable. Since it was determined that a dry electrode was needed the team attempted to find a conductive material to work underwater.

The connection to the patient was also very important. Without good contact to the skin there would be a large amount of interference in the recorded signal. The team found three ways to maintain contact with the skin. They were an adhesive substance, pressure, and integration into clothing. At first, the team pursued integrating the electrode into a diving vest. This idea never materialized because there are too many variables in diver body specifications. Also, due to the movement of clothing while worn the electrodes did not maintain consistent contact with the skin. Use of an adhesive substance was not pursued because it was believed that the substance would not be able to hold up to the underwater environment. It was decided that applying the electrode to the body with pressure from a waterproof tape would be the most successful. This allowed the electrode to stay in the same place on the body and make continuous contact.

The final function of the electrode is its underwater capabilities. The team found three approaches to this function: a suction cup, waterproof covering, or a waterproof conductive material. From the start the team pursued the waterproof material route. This would allow the electrode to more easily reproducible and reusable. Eventually a conductive material was found and the electrode created.

Table 1: Morphological Objectives Table

Attachment system	**Button**	**Alligator clamps**	**Clip on**	**Wire**
Conduction	**Dry Electrode**	**Wet electrode**	**…**	**…**
Connection to patient	**Adhesive**	**Pressure**	**Clothing integrated**	**…**
Waterproofing	**Suction Cup**	**Waterproof Cover**	**Waterproof material**	**…**

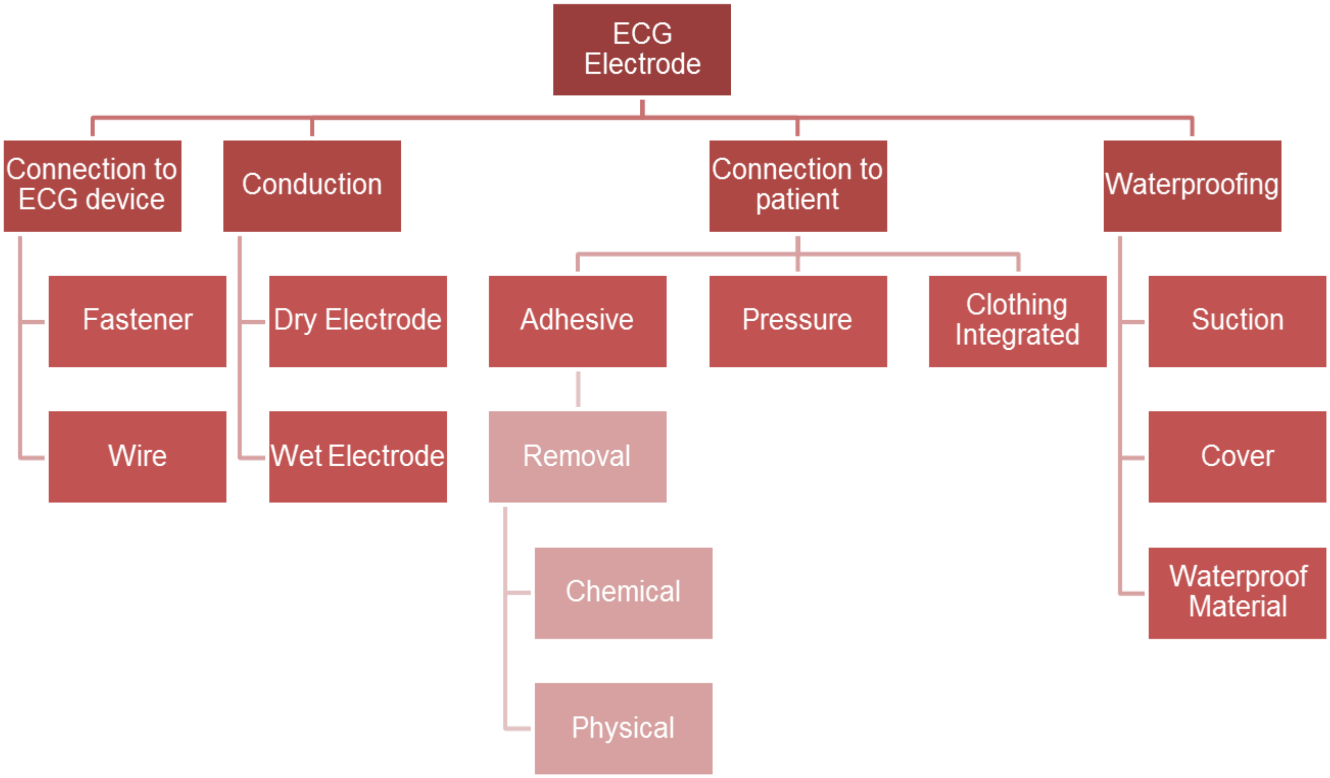


Figure 7: Function and Means Tree

Constraints

The team also established some constraints to guide the project. These constraints were determined at the very beginning of the project, so focus was not lost. The constraints established by the team were a 3-point electrode system, compatible with an existing ECG monitor, $450 budget, and project completed by the submission deadline of April 26th, 2012.

The first constraint was that the entire system must record with only 3 points of contact on the body. The purpose of this was to minimize the amount of wiring to the recording device. Too much wiring could interfere with a diver's ability to perform his duties.

The second constraint was that the device had to be compatible with an existing device. This was also discussed in the functions of the device. The more devices the electrode could work with the greater the marketability of the device.

The final constraints were time and money. The final deadline provided a timeline to complete the project. The budget put a limit on the materials that could be used to create the electrode. There was also a stipulation that the electrode not cost more than $50 market price.

After examination of the functions, means, and constraints of the project the team allowed the team to revise its client statement. The team revised a client statement and met with Prof. Chon who agreed with the new client statement, which guided the team into the design and production stages of the project.

Final Client Statement

"Design and build an ECG electrode with the ability to function underwater, for a minimum dive time of two hours, while maintaining signaling capabilities at a depth of 60 feet."

Test Protocol 1:

Compression Testing:

The purpose of this test is to evaluate the viability of the waterproof electrode design's flexibility over a set time period. Observation of normal human physiology shows repetitive expansion and compression of the chest and abdominal regions of the body while breathing normally. The average physically fit male has a respiratory rate of 12-20 breaths per minute. Because the electrode is designed to conform to the end user's body shape with the assistance of a synthetic, skin-tight vest the effect of the expansion and compression on the electrode must be taken into consideration.

Proposed Test:

1. The electrical impedance of the electrode will be measured to obtain a base line reading

2. The electrode will be loaded into an Instron test machine (Goddard Labs) with a minimal load cell (___kg) .

3. The Instron will be calibrated to compress the sample (___cm)
   After each compression, cycle the load cell will reset to the original start position.

   The load cell will compress at a rate of 1 compression every 1.5 seconds for a 1 hour period to mimic the expansive and contractile motion of human respiration of 20 breaths per minute over a 2 hour period.

- At regular 3 minute intervals the sample electrode will be removed from the Instron and the electrical impedance will be tested to see how it compares to the baseline.

Test Protocol 2:

Submersion Testing:

The Purpose of this test is to evaluate the viability of the Waterproof Electrode's waterproofing. The design calls for the electrode to be able to maintain signaling capabilities while submerged under saltwater conditions for a minimum dive time of 2 hours and depth of 60 meters below the surface at an estimated 6.95 atm or 102.17 Psi. The estimated average salt concentration of ocean water is calculated to have a 3.5% salinity, which means for every liter of water there are 35 grams of salt present.

Proposed Test:

1. Measure the electrical impedance of the electrode to establish a base line value.

2. Load the sample electrode into a pressurized salt water environment with 3.5% salinity.

3. Pressurize the saltwater chamber to 102.17 Psi

Load the sample for a minimum time of 2 hours, depressurizing the chamber and removing the sample at regular intervals (__min). At each interval test the electrical impedance of the electrode and compare with the baseline .

Test Protocol 3:

Electrical Impedance Testing

The purpose of this test is to evaluate the electrode's contact impedance without the presence of a human test subject. The electrical Impedance is the measure of the opposition that an electrical circuit presents to the passage of a current when a voltage is applied. With regards to electrode design contact impedance testing establishes a benchmark for the functionality of the electrodes being designed. In theory this tests electrical impedance between the two electrodes by applying an active current to a sample that the electrodes are placed into contact with. These measurements are interpreted with the assistance of an impedance analyzer.

Proposed Test:

1. Set the impedance analyzer (make/model) to a frequency range of .5 Hz – 100 Hz with a signal level of 25mV
2. Attach the signal probe to the sample surface.
3. Fix the electrodes to the sample surface.
4. Observe contact impedance data recorded by the electrodes

This test will be the standard procedure for measuring the impedance in the following electrode design validation protocols.

4. Designs

In order to develop a design for the project, the MQP group conducted extensive research on currently used and theoretical technologies for transthoracic interpretation of electrical activity of the heart as detected by non-invasive electrodes attached to the surface of the skin over a predetermined amount of time . Based on these methods the group compiled a record of the critical components and characteristics of existing designs as well their purpose within the design, importance, limitations and short comings. The characteristics include wet or solid, semi/weakly polar gel type electrodes, and non-polar, dry capacitive electrodes, both made up of a number of materials not limited to metals, metal composites, and filled polymers.

Needs Analysis

Given the dangers associated with SCUBA diving, the United States Navy has developed a tool to help minimize DCS by providing guidelines regarding dive depth[9, 10]. These tables are general guidelines, however, and do not account for the high variability among dive profiles [11]. In fact, Undersea and Hyperbaric Medicine found that 2.2% of those following the Navy's guidelines still succumbed to DCS, identifying an even more precarious situation [10].

Fortunately, recent studies have proven it possible to detect the onset of DCS by analyzing the R-R intervals of a subject [11]. Monitoring a diver while they are below the surface would open doors to DCS prevention, however at this time, no such measurement capabilities exist, because there are no successful methods to collect bioelectric signals while a diver is submerged.

Medical electrodes that currently exist are not capable of delivering a signal during dives for several reasons. Most electrodes are not waterproof, and simply cannot stay adhered to the subject. Those, which stay adhered, do not provide any signaling qualities. Due to the design of a pre-gelled electrode water is able to penetrate the electrolyte gel layer under the seal and critically compromise the electrolyte/skin Impedance, and/or washes away the conductive gel on most wet electrodes. The closest to a "waterproof" electrode that is presently marketed is a sweat resistant pre gelled electrode which would not provide structural integrity to withstand the pressure and forces endured while a subject is swimming and would present too large of a motion artifact. The pressure at the required depth is roughly seven times that of sea level and with the increase in atmospheric pressure it is anticipated that the motion artifact interference will increase as well producing unusable data recordings, as the subject descends into areas of higher pressure.

Gel Type Electrodes:

Biological electric stimuli are the result the flow of positive and negative ions (cations and anions) distributed across the surface of tissue. In the case of gel type electrodes the electrode tissue interface consists of the tissue contact surface, an electrolytic solution, conductive surface, and the attached lead wires. The ion current of the organic system is converted to electron current through chemical reactions in the electrolyte. As the current crosses over into the gel oxidation produces cations and electrons. The cations are discharged throughout the electrolyte, while the electrons are received by the conductive element and charge is carried through to the attached wires to a recording device. As a result of the uneven distribution of cations and anions across the two electrolyte surfaces interfaces a voltage known as the half cell potential is generated, it is critical to monitor the half cell potential as when several electrodes are used (common practice in ECG monitoring) the combined difference between half cell potentials or the offset potential can mask low amplitude bio signals and make it difficult to distinguish the desired recording from noise or other various artifacts present in a given recording. [27] Gelled electrodes are the most widely utilized type of electrode for the detection of biological signaling potentials. They have a low profile, lightweight, easily mass produced, cost effective, and most importantly reliable gelled electrodes are non-or very weakly polarized. This allows current to pass freely between the electrolyte and the electrode. A benefit of which is reduced interference to motion artifact and defibrillation current. Yet, despite all of this gel type electrodes have one critical draw back. When utilized for long term monitoring the abrasion caused by the sponge like structure, combined with the electrolyte lead to varying degrees of irritation inflicted upon the end user of the electrode. [28] Even in the absence of the porous material, solid gel electrodes have been known to cause irritation as well, and finally, they can only be utilized in one-time use applications and are impossible to reapply without reapplying an electrolyte. Despite the wide range of benefits, there lies a major down fall, not only in the previously stated but, the desired aqueous salt water end user environment, will render a gelled electrode useless.

Dry Type Electrodes:

For many years gelled electrodes have been implemented for a variety of monitoring uses. However, with regards to handling the disadvantages of wet type electrodes quickly surfaces. Yet very few dry electrodes have been developed. Presently a demand for a more user-friendly counterpart to wet electrodes has risen leading to a closer look into this type as well as an increased interest in development. Today, dry electrodes are primarily constructed of rigid materials, such as metal plates leading to obvious issues while used in monitoring a highly mobile patient, they are known to have a higher contact impedance than the tissue contact area which makes the signal susceptible to motion artifact. Yet in literature it has been reported that after an initial "settling" period the impedance can decrease along with the significant effects of the motion artifact. [29] To overcome the limitations introduced by current dry electrodes researchers have introduced several approaches [30] (abrasion, mechanical skin punching, and shaving) all of which and temporary solutions to the problem as the body begins to regenerate in as little as 24 hours rendering the approaches ineffective in the long term. A promising route that many groups are pursing is the fabrication of flexible hypoallergenic polymer based electrode. [31] [32] [33] [34] Literature has proved that flexible polymer electrodes have been successfully utilized as conductive sensor systems. [35] [36] [37] The next logical step would be to incorporate the known properties (superior flexibility, lack of electrolyte, non-polarity when constructed out of the proper materials [33]) into the development of a flexible polymer based ECG electrode. All of these characteristics led the group to believe that the development of a Dry type electrode would yield the most favorable results.

Needs Analysis

Given the dangers associated with SCUBA diving, the United States Navy has developed a tool to help minimize DCS by providing guidelines regarding dive depth[9, 10]. These tables are general guidelines, however, and do not account for the high variability among dive profiles [11]. In fact, Undersea and Hyperbaric Medicine found that 2.2% of those following the Navy's guidelines still succumbed to DCS, identifying an even more precarious situation [10]. Fortunately, recent studies have proven it possible to detect the onset of DCS by analyzing the R-R intervals of a subject [11]. Monitoring a diver while they are below the surface would open doors to DCS prevention, however at this time, no such measurement capabilities exist, because there are no successful methods to collect bioelectric signals while a diver is submerged. Medical-electrodes that currently exist are not capable of delivering a signal during dives for several reasons. Most electrodes are not waterproof, and simply cannot stay adhered to the subject. Those, which stay adhered, do not provide any signaling qualities. Due to the design of a pre- gelled electrode water is able to penetrate the electrolyte gel layer under the seal and critically compromise the electrolyte/ skin Impedance, and/or washes away the conductive gel on most wet electrodes. The closest to a waterproof electrode that is presently marketed is a sweat resistant pre gelled electrode which would not provide structural integrity to withstand the pressure and forces endured while a subject is swimming and would present too large of a motion artifact. The pressure at the required depth is roughly seven times that of sea level and with the increase in atmospheric pressure it is anticipated that the motion artifact interference will increase as well producing unusable data recordings, as the subject descends into areas of higher pressure.

Conceptual Design:

With the alternative possibilities examined the most logical development step for the project group to examine was a flexible PDMS electrode impregnated with conductive filaments. Initially the idea to implement Silver/Silver Chloride (Ag/AgCl) into the design, but the idea was short lived due to one out standing issue, polarization. Thus, Carbon black was introduced. Conductive carbon was dispersed into a PDMS producing an inert biocompatible polymer electrode . The exact methods are explained in further detail in Chapter 5.

5. Design Verification

The first step towards detecting decompression sickness (DCS) is to look at the patient's heart rate variability (HRV), which involves examining the R-R intervals of the ECG signal (shown in Figure 1 below). This requires using a peak-detection algorithm on the patient's ECG signal, which is optimized when there are clear visible R-wave peaks and minimized noise. These optimizations are met through filtering the signal, either through a combination of high-pass and low-pass filters, or a band-pass filter.

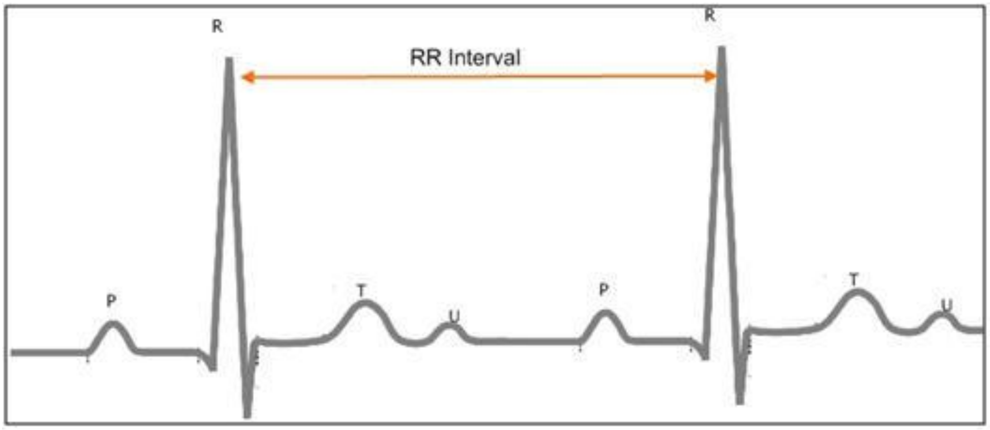


Figure 8 - R-R Interval of ECG Signal

Detection Requirements

As mentioned earlier, in Type 1 DCS the heart rate variability increases, thus the warning sign would be a decrease in the size of the R-R intervals, whereas Type 2 DCS presents itself through a decrease in heart rate variability, which is seen as an increase in the size of the R-R intervals. These changes can be detected through a peak detection method developed by Professor Ki Chon. Assuming a default heart rate of x beats per minute, we can classify DCS as the R-R intervals being outside the range of $\frac{x}{60} \pm y\ seconds$ as shown in the table below:

DCS Type	t_{RR} (R-R Interval (sec))
1	$t_{RR} < \frac{x}{60} - y$
2	$t_{RR} > \frac{x}{60} + y$

Table 2 - Range for DCS Detection

This table utilizes the variables x and y to represent respectively the normal heart rate (in bpm) of the diver and a set constant to determine the range outside of which would classify the subject as subjected to DCS. This constant y would be determined with further testing.

Signal Acquisition Verification

The first signal test is to determine if the electrodes are conductive enough to detect a sinusoidal wave, and to sweep the frequency of the wave to determine if there are any problems with the transference across the frequency spectrum. The sine wave had an amplitude of 2 volts from peak to peak and was swept from 0.1Hz to 1kHz. This was accomplished through sending a signal from the [model] function generator into the forearm with the transmit electrodes placed 15cm apart. The receiving electrodes were then placed at 5cm intervals between them, and passed into and processed by two BioPac ECG100 Modules attached to an MP100. The below figure shows the setup utilizing the carbon black electrodes.

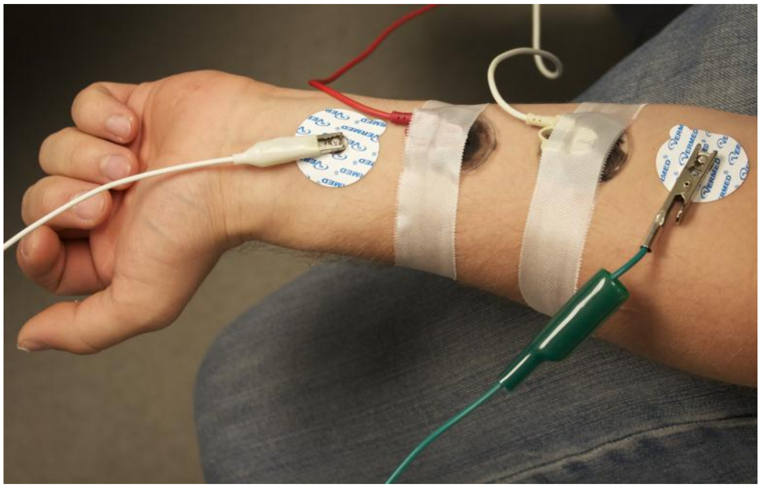


Figure 9 – Signal Acquisition Verification Setup

Preliminary Dry Electrode Test

The team started our preliminary ECG signal test by recording a 3-hour set of data using the Rozinn Holter Monitor. This test used lead placement devised from the Einthoven Triangle, as shown below, where the red lead is positive, brown is negative, and green is ground. The leads were placed with positive centered on the Manubrium, negative on the lower left rib margin over bone, and ground on the lower right rib margin over bone.

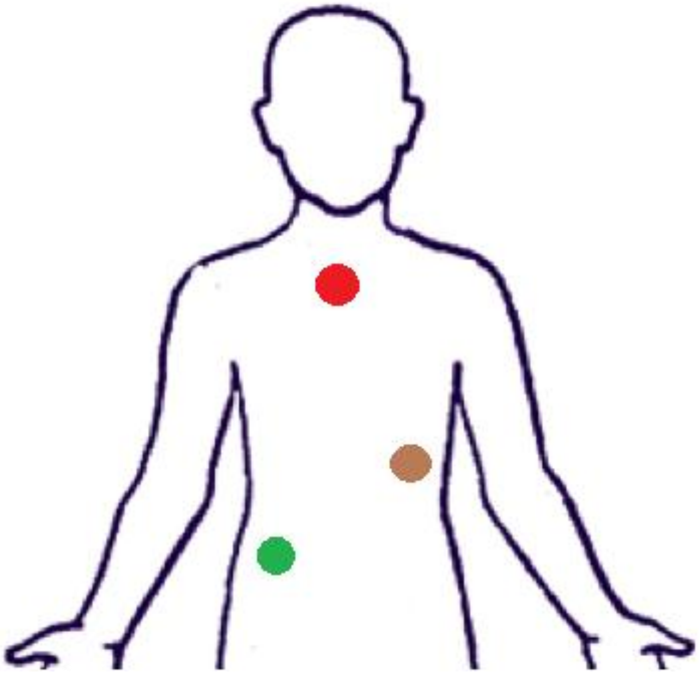


Figure 10 - Electrode Placement

Dry Electrode Comparison Test

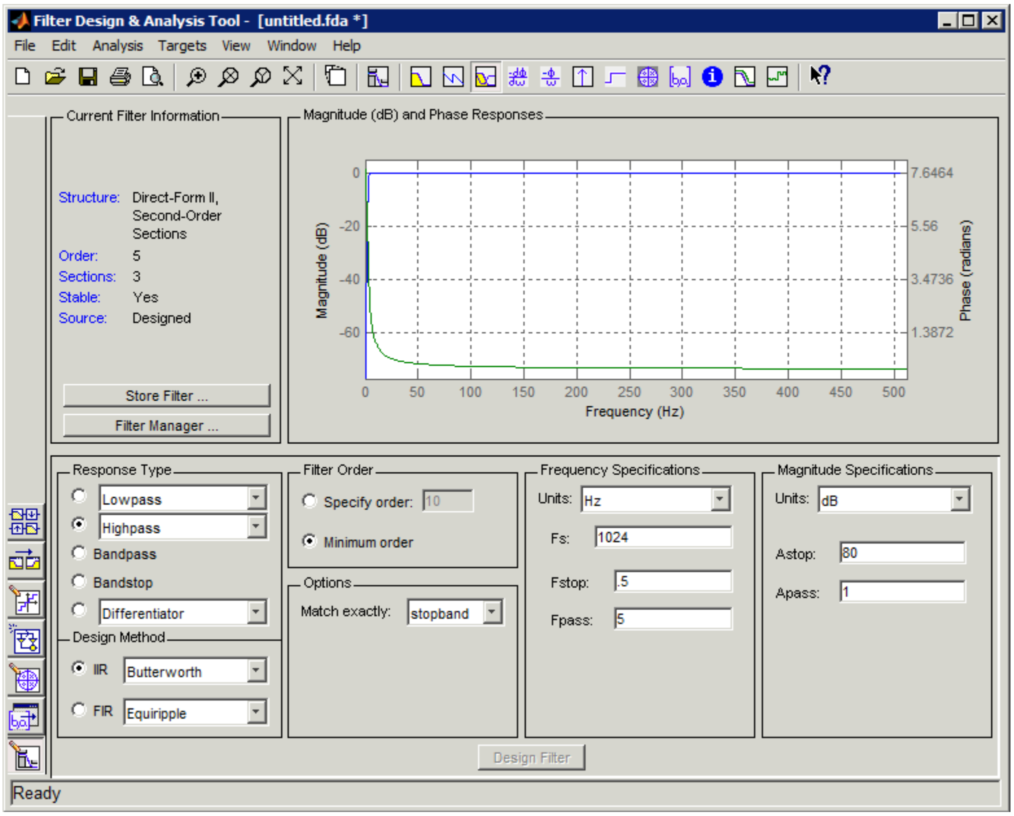
The team then ran a second test of the electrode in the dry setting; however this test recorded both our electrodes and a set of the Ag/AgCl electrodes. This was accomplished by recording our electrodes on Channel 1 of the holter monitor, and recording the Ag/AgCl electrodes on Channel 3 of the holter monitor. This test ran for a period of 3 hours, and utilized the same electrode placement as the preliminary dry electrode test.

Wet Electrode Test

For purposes of testing our electrode in a wet environment, the team recorded a one-hour period of ECG activity of a subject immersed in room temperature water in a bath tub. This test used the same lead placements as the previous two tests, and the electrodes were kept on the subject using a tape wrap of adequate pressure.

Filter Design

ECG signals tend to incur a noticeable amount of noise and motion artifacts. Sudden patient movement could cause this, or electrical noise in the environment, such as 50/60Hz found in power lines and other electronic devices. It was also found that the holter monitor was very sensitive to cell phones and computers in our testing, so this may also be a contributing factor to some of the discrepancy in parts of our signals. The team designed and applied a low-pass and high-pass filters using MATLAB that allowed frequencies between 0.5Hz and 250Hz, and stopped all other frequencies. Notch filters were also applied for 50Hz and 60Hz to account for electronics and power lines. These filters used the Rozinn Holter Monitor's maximum specified sampling rate of 1024Hz. The following figure shows the settings, magnitude response (blue), and frequency response (green) of the resultant high-pass and low-pass filters.



Structure: Direct-Form II, Second-Order Sections
Order: 5
Sections: 3
Stable: Yes
Source: Designed

○ Lowpass
● Highpass
○ Bandpass
○ Bandstop
○ Differentiator

● IIR Butterworth
○ FIR Equiripple

○ Specify order: 10
● Minimum order

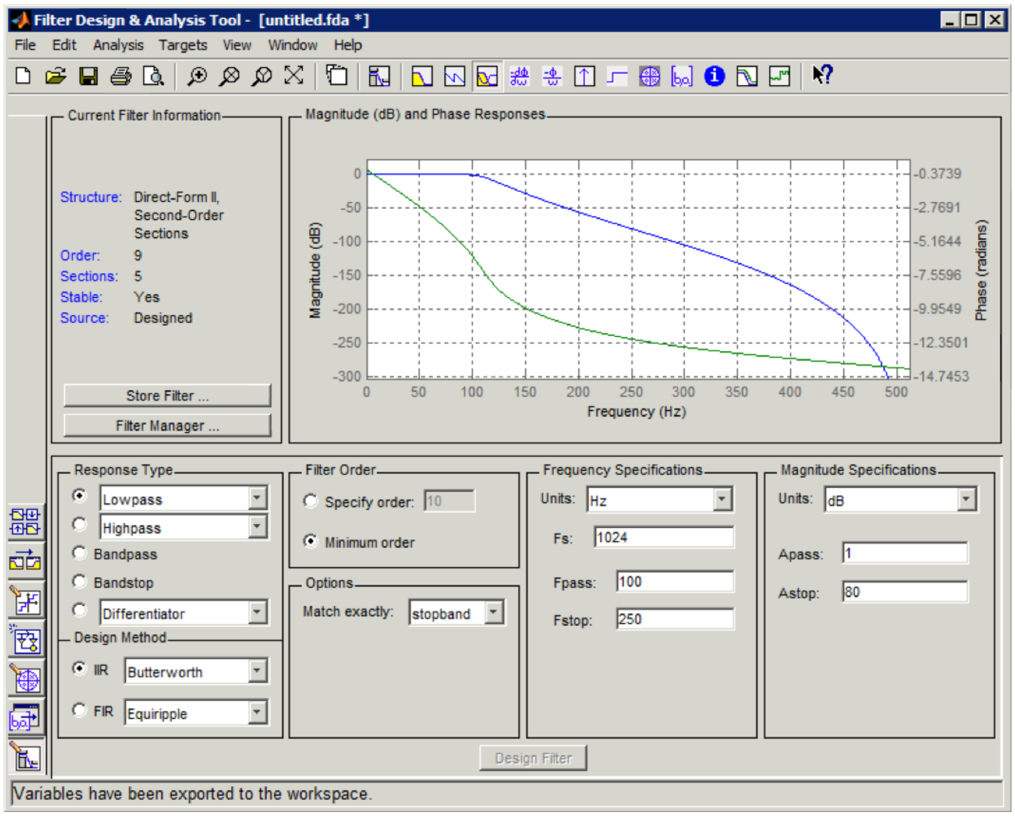
Match exactly: stopband

Units: Hz
Fs: 1024
Fstop: .5
Fpass: 5

Units: dB
Astop: 80
Apass: 1

Ready

Figure 11 - High Pass Filter Design (HPF_01)



Structure: Direct-Form II, Second-Order Sections
Order: 9
Sections: 5
Stable: Yes
Source: Designed

● Lowpass
○ Highpass
○ Bandpass
○ Bandstop
○ Differentiator

● IIR Butterworth
○ FIR Equiripple

○ Specify order: 10
● Minimum order

Match exactly: stopband

Units: Hz
Fs: 1024
Fpass: 100
Fstop: 250

Units: dB
Apass: 1
Astop: 80

Variables have been exported to the workspace.

Figure 12 - Low Pass Filter Design (LPF_01)

Signal Acquisition Verification Results

This test was run with the receiving electrodes being both a set of commercial Ag/AgCl electrodes, and our carbon black electrodes. The results showed that the commercial electrodes perfectly detected the sine wave, while ours showed the signal, albeit some noise, as shown in the figures below.

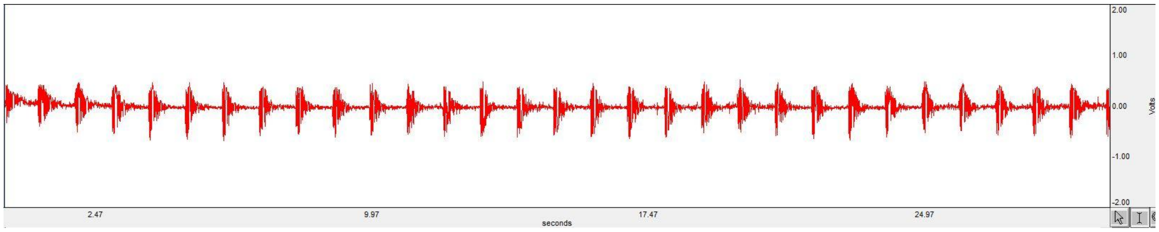


Figure 13 - Ag/AgCl Crude Test

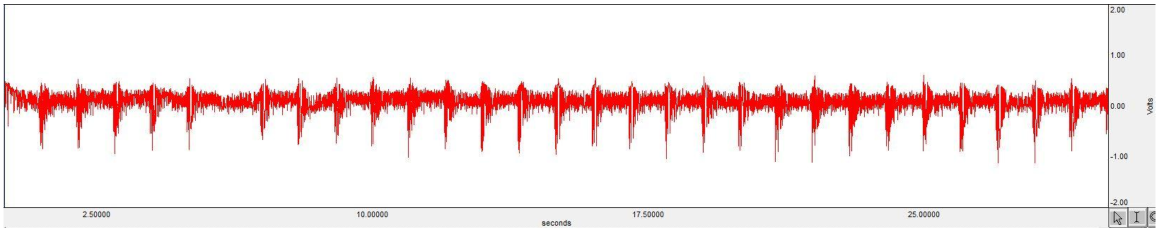


Figure 14 - Carbon Black Crude Test

Preliminary Dry Electrode Test Results

The preliminary test showed promising; and in fact we were able to visually detect full QRS-complexes from the recorded ECG signal. There were problems with motion artifacts, which can be seen in several locations along the signal. The following figure shows the visible QRS wave in our signal, as well as the results of filtering.

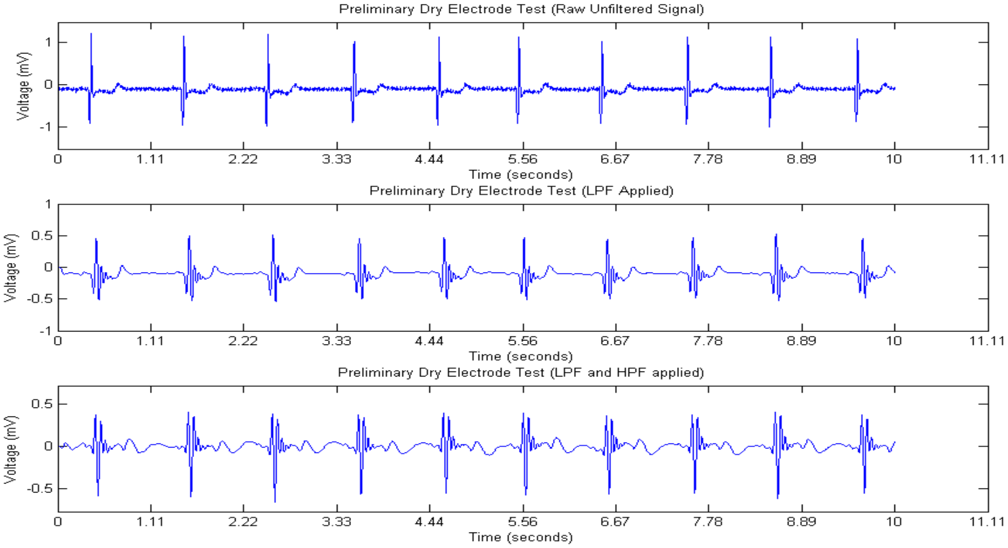


Figure 15 - Preliminary Dry Electrode Testing Results

As can be seen in Figure 15 above, the low-pass filter rids the signal of noise on the baseline, however when the high-pass filter is added to that; too much of the R-peaks are cut off, and therefore it is unusable for peak detection. For the desired use, even the raw unfiltered signal is fine; since it has sharp, well-defined peaks. Using the average sampling frequency of the Holter monitor (180Hz), one can derive the average heart rate for the 10 peaks in this segment to be equated as approximately

$$\frac{10\ beats}{10\ seconds} * 60\ \frac{sec}{min} = 60\ bpm$$

Dry Electrode Comparison Test Results

The comparison test showed interesting results, as the commercial electrodes displayed more noise in the recorded signal than our carbon black electrodes, and the motion artifacts appeared with greater magnitude. The point on noise could be due to a high-pass filtering property of the carbon black, but further testing would be required to validate this.

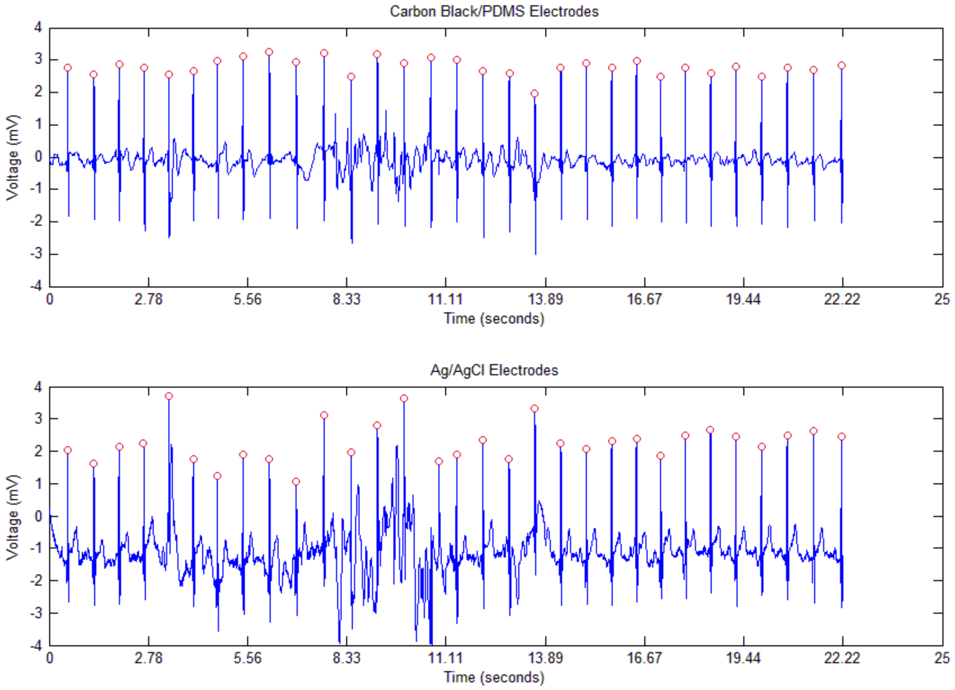


Figure 16 – Raw Signal for Dry Electrode Comparison Test

Through using these plots, we can see that there are 31 peaks in the 22.22 second interval, yielding the following heart rate:

$$\frac{31\ beats}{22.22\ seconds} * 60\ \frac{sec}{min} = \ 83.7\ bpm$$

Wet Electrode Test Results

The results of our wet environment electrode test, although noisy, were still readable. Since we are mainly looking for peak detection in the R-wave, as long as there are adequate R-peaks, the signal is still acceptable. One can easily see in these results that the subject's breathing has greater effect on the rise and fall of the peaks while submersed than when dry, as shown in figure 17 below. Through filtering, this signal can be returned to a linear fashion, and the noise can be reduced.

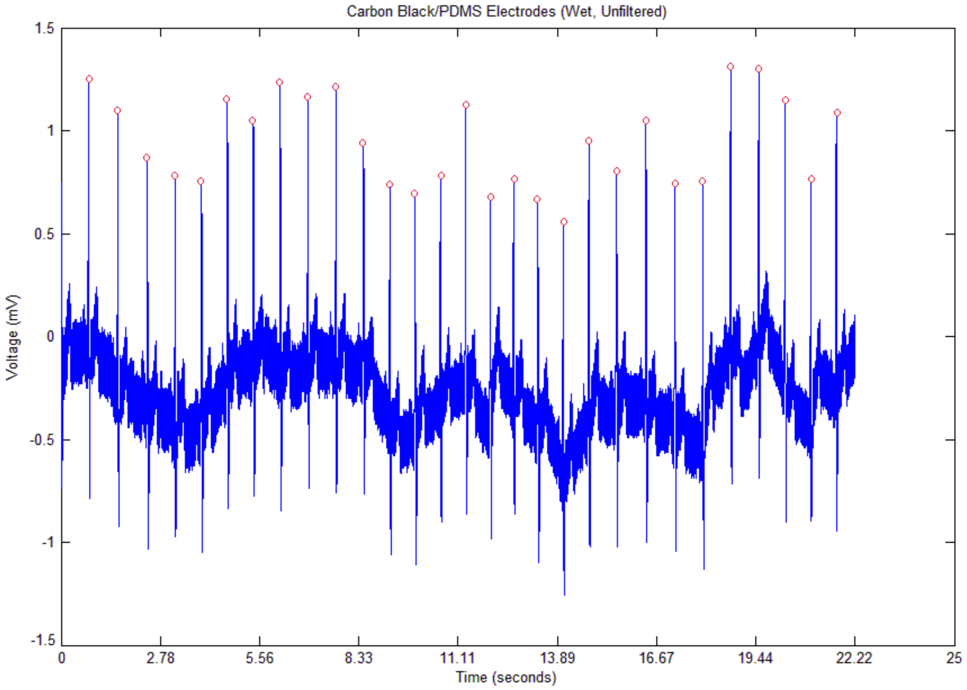


Figure 17 - Raw Signal for Wet Electrode Test

Several attempts with high-pass and low-pass filtering led to correction with the linearization of the signal, however the magnitude of the R-peaks would be severely decreased. Finally the correct settings for the filters were discovered and set, resulting in the following clean and usable signal. These filters (HPF_01 and LPF_01) were successfully applied, and the result is shown below in figure 9.

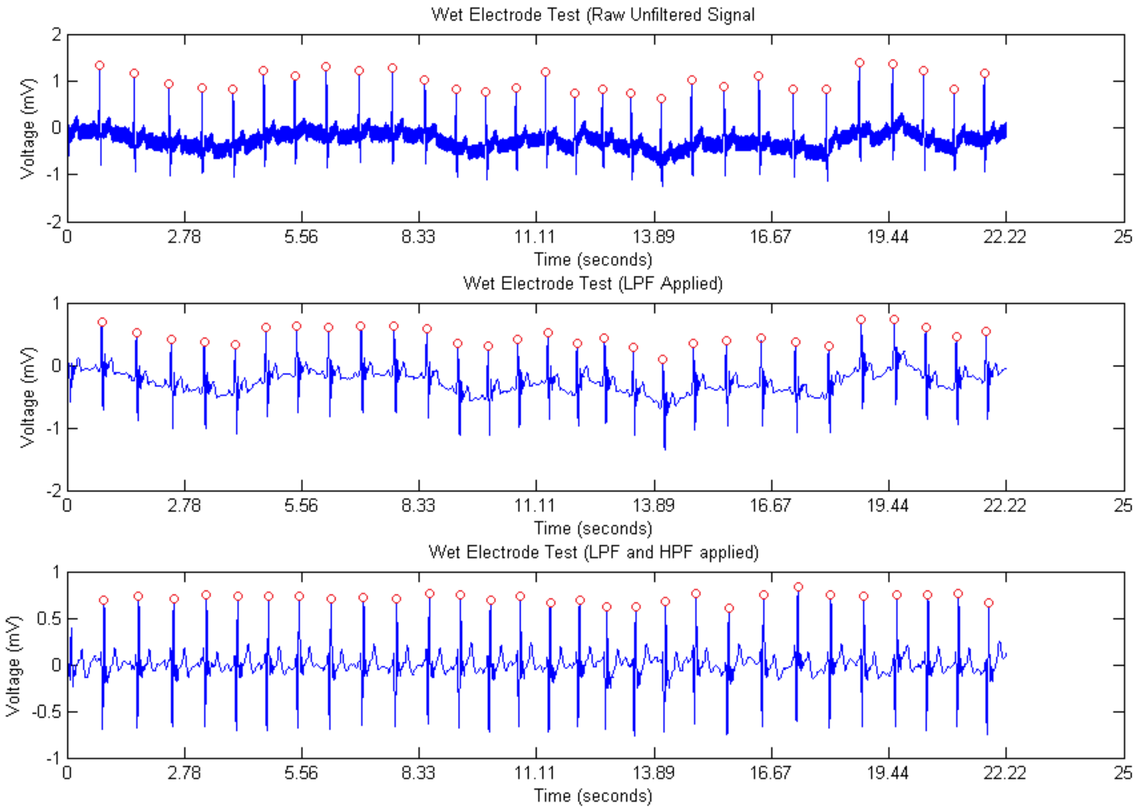


Figure 18 - Wet Electrode Test Filtering Results

From looking at the final filtered signal, we can easily see that there are 29 peaks within, the 22.22 second-segment; which (with a certain margin of error from the segment before the first peak) yields a heart rate of:

$$\frac{29\ beats}{22.22\ seconds} * 60\ \frac{sec}{min} = \ 78.3\ bpm$$

6. Discussion

Heart rate variability is a definitive way to check for decompression sickness, and as stated earlier, this requires clean signal with detectable R-wave peaks. The filters that we have developed to accomplish could be optimized with further testing and signals analysis.

As mentioned earlier, there are currently no electrodes available that are designed specifically for the testing of DCS, which requires the ability to successfully and reliably detect a heart rate while submerged under water, and be devoid of motion artifacts.

Unlike current electrodes used for this application, these can be manufactured for pennies on the dollar on a large scale, and last for multiple uses. This electrode has the potential to have an impact on the number of divers that suffer from DCS, ideally detecting and warning the user long before a major problem arises.

The resultant electrodes are for use with current monitoring technologies (such as Holter monitors), and universally attach via snap-button connection.

7. Conclusion & Future Works

The Electrode designed was able to detect the desired R-R wave intervals with an accuracy greater that that of currently existing wet electrodes. This is due to a variety of results including the general difference in composition (Wet v. Dry) and the associated qualities (lack of off-set potentials, polarization, etc). The final design was also able to meet the established constraints and objectives designated by both the design team as well as the project's advisor. The data recorded shows the patient's entire QRS complex as well as the accompanying T wave when the patient is at rest. When the subject is in motion however the effects of noise and motion artifacts do affect the signaling. Yet, the main objective, to produce an electrode capable of detecting signals while submerged was successful, and stable and constant ECG was detected underwater, with clear R-R peak detection.

Future Works

The design team was unable to conduct all of the desired tests and a full scale submersion test is still critical to completely validate the design. The group was unable to perform this due to the obvious limitations of the resources available and the specific training and equipment required carry out a 60ft dive in a saltwater environment. In addition to this further examination of a novel passive filtering quality that emerged in the electrodes must be studied. While this is a desirable quality, the cause needs to be understood. Finally in order to be a truly well designed electrode system, the significant issue of motion artifact will need to further examined, while the signal detection is superior for a stationary subject, at times just minor movement causes the data to be unusable.

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