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Escuela de Ciencias Biológicas e Ingeniería

TÍTULO:

RecaHolt: Design of a system for the detection of cardiac ischemia employing ECG waves recording.

Trabajo de integración curricular presentado como requisito para la obtención del título de Ingeniero Biomédico

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Dedication

I dedicate this work to my parents, to my brother, and to my grandmother who instilled in me values and principles, for always being with me since they have been the engine that drives me to achieve my goals in life.

To my closest friends and my girlfriend who have been with me all the time, because they have become my second family and they have guided me with their advice.

To all the people who believed in me and always gave me their unconditional support, I dedicate all this to you.

Jonathan Patricio Recalde Moreno

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Thank you very much to everyone.

Jonathan Patricio Recalde Moreno

RESUMEN

La presente tesis consiste en el análisis de la isquemia miocárdica, a la cual también se la llama isquemia cardíaca. La isquemia en un electrocardiograma es la alteración del segmento ST y biológicamente es el bloqueo de alguna arteria. En una persona común, un bloqueo imprevisto de alguna de las arterias del corazón puede provocar un ataque cardíaco.

Debido a su baja sensibilidad y especificidad, el análisis de las alteraciones del segmento ST durante la monitorización del ECG es inexacto para establecer o excluir la presencia de enfermedad coronaria. Por ello el foco del presente es realizar un sistema de detección de isquemia cardíaca, que se encargaría de monitorizar y detectar cambios en el segmento ST (segmento en la que la presencia de irregularidades equivale a isquemia), para poder realizar una detección no invasiva y sin riesgos.

Teniendo en cuenta que actualmente la mejor forma de detectar la isquemia cardíaca es provocando un esfuerzo controlado al corazón, y que esta técnica puede estar contraindicada en muchos casos; Surge la idea de la creación de un sistema para la detección de isquemia cardíaca, que tendrá la parte física en este caso el hardware no invasivo que toma las señales cardíacas y las transforma a ondas de ECG tomando como base principal el módulo AD8232 y el software que recolecta e interpreta la información que se lo desarrollo en el software Python para identificar dichas ondas y a la postre para ser estudiado por un médico para su diagnóstico.

En conclusión, se logró la creación de un dispositivo que se encarga de la toma e interpretación de las señales cardíacas, este prototipo se lo denominó RECAHOLT y tiene un costo accesible para todas las personas. Siempre se debe tomar en cuenta que el uso del dispositivo biomédico creado no sustituye al diagnóstico médico humano. Por tanto, el sistema sería encargado de dar un pre-diagnóstico.

Palabras clave: Isquemia, Electrocardiograma, Segmento ST, RECAHOLT, Costo accesible, Corazón.

ABSTRACT

This thesis consists of the analysis of myocardial ischemia, which is also called cardiac ischemia. Ischemia in an electrocardiogram is the alteration of the ST segment and biologically it is the blockage of an artery. In an ordinary person, an unexpected blockage of one of the arteries of the heart can cause a heart attack.

Due to its low sensitivity and specificity, the analysis of ST-segment alterations during ECG monitoring is inaccurate to establish or exclude the presence of coronary artery disease. For this reason, the focus of the present is to carry out a cardiac ischemia detection system, which would have the responsibility of monitoring and detecting changes in the ST segment (segment in which the presence of irregularities is equivalent to ischemia), to carry out a detection without invasive and risk-free.

Taking into account that currently the best way to detect cardiac ischemia is by causing a controlled effort to the heart, and that this technique may be contraindicated in many cases; The idea arises of the creation of a system for the detection of cardiac ischemia, which will have the physical part in this case the non-invasive hardware that takes the cardiac signals and transforms them into ECG waves, taking the AD8232 module as its main base, and the software that collects and interprets the information that was developed in the Python software to identify these waves and finally be studied by a doctor for a diagnosis.

In conclusion, the creation of a device that is responsible for the taking and interpretation of cardiac signals was achieved, this prototype was called RECAHOLT and it has an affordable cost for all people. It should always be taken into account using the created biomedical device is not a substitute for human medical diagnosis. Therefore, the system would be in charge of giving a pre-diagnosis.

Keywords: Ischemia, Electrocardiogram, ST segment, RECAHOLT, Accessible cost, Heart.

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Chapter 1: Introduction

1.1. Background and problem statement

Among the systems that the human body has, we have the circulatory system, which is considered among the most important. In particular, the main organ of this system is the heart, since without the presence of this, the other systems could not be kept functioning. It must also be taken into account that the heart is an organ very susceptible to various pathologies such as ischemia, arrhythmias, ventricular fibrillation, and myocardial infarction, among others.

There are several causes of morbidity and mortality worldwide; however, the first cause is cardiovascular disease (CVD). In the case of Ecuador, CVD causes more than 30% of the deaths of older adults after the age of 65. In general terms, in the year 2000, the deaths (mortality rate) in Ecuador was 56,420, of which 11,327 deaths are attributed to CVD, being 2,324 for ischemic heart diseases, 2,735 for cerebrovascular diseases, 2,487 for hypertensive diseases, 2,781 for heart failure and 1,000 are attributed to other CVDs (1). This corresponds to 20% of total deaths. The number of deaths due to CVD has increased, although it continues to be the leading cause of death. Based on the "Instituto Nacional de Estadistica y Censo", in its latest report in 2019 (2), there were 73,431 deaths in Ecuador, of which 19,542 were due to CVD, being responsible for 26.6% of deaths, distributed among ischemic heart diseases (8574 deaths), cerebrovascular diseases (4557 deaths), hypertensive diseases (3246 deaths), heart failure (1165 deaths) and other CVDs (2000 deaths). As we can see, the main cause of death is due to ischemic diseases with a considerably high value, followed by diabetes mellitus as we can see in figure 1.

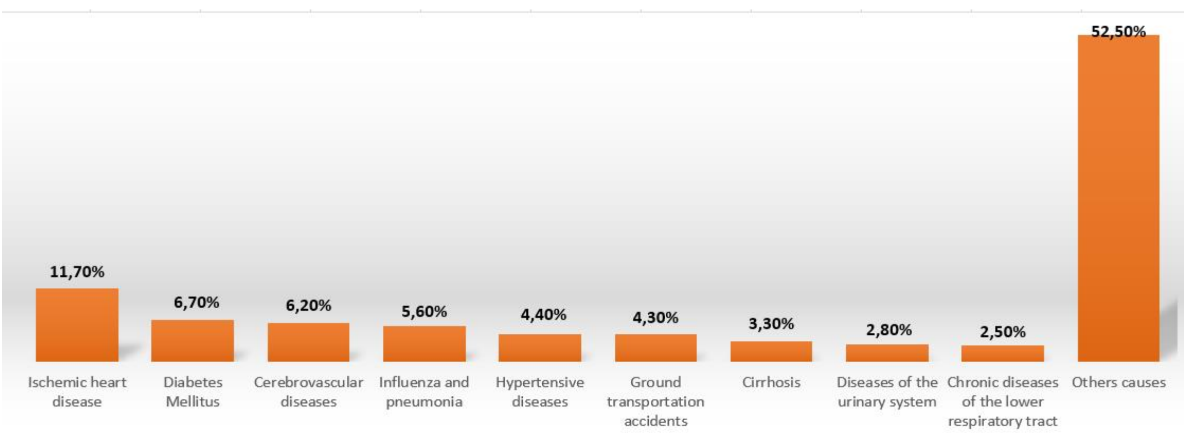


Figure 1: Statistics of deaths in Ecuador and the diseases that cause them. Source of own elaboration from: (2).

Based on official data from the World Health Organization (3), it has been possible to calculate that CVD is the leading cause of death worldwide, taking into account all age ranges. The estimated data for the year 2016 were 56.9 million total deaths worldwide and on the other hand, it is known that 9.3 million people are attributed to ischemic heart diseases, which represents 16.3% of all registered deaths in the world in a single disease (a disease that has been the leading cause of death for 15 years), followed by strokes with 5.9 million deaths. These data can be seen in Figure 2.

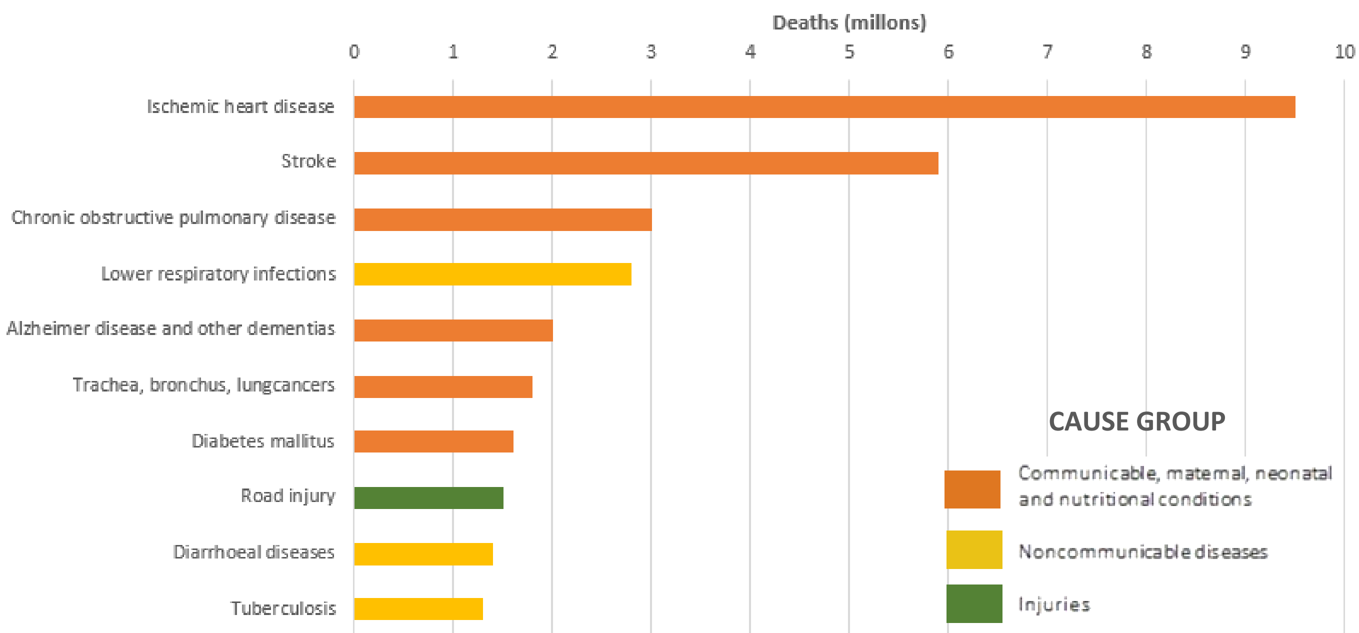


Figure 2: Statistics of the 10 leading causes of death worldwide in 2016. Source of own elaboration from: (3).

In general, CVD can be prevented by controlling the behavior of the population and profitable management of their habits, such as avoiding tobacco consumption, eating balanced diets avoiding obesity, avoiding a sedentary lifestyle by doing physical activity and avoiding alcohol consumption. This could be done using strategies that cover the entire population. On the other hand, we have people with high cardiovascular risk or who already have CVD, due to the presence of risk factors such as diabetes, hyperlipidemia, or arterial hypertension, which would be essential in early detection and treatment through drug administration (4). This is where various techniques from different environments can be brought together, including engineering, in order to develop biomedical devices capable of monitoring and detecting some risk patterns.

Over the past few years, biology, electronics, and genetics have separately developed incredible advances, however together they have developed an impressive set of biomedical devices to protect human health. Due to the above, modern medical technology has gone from being traditional hospital methods to a set of practical devices that can be used in everyday life (5).

People with CVD have more medical, social and economic repercussions since they require continuous monitoring and control in a hospital or specialized center. Also, the current system uses traditional methods of consultation, diagnosis and monitoring of patients with heart conditions (1).

Generally, patients suffering from cardiac ischemia are cared for in a hospital center. This causes them to have to wait a long time for their care due to the great demand for health in Ecuador. All this must be added to the costs of moving from their houses to the hospital since in rural areas, many times; they do not have a hospital center, which increases the cost of health care. If people with limited economic resources are taken into account, they cannot afford the high cost of medical instruments used to determine the signals generated by the heart for constant monitoring and this in the long term, causes that the disease to increase the rate of mortality.

Based on all those mentioned above, the main interest of this research is to help society with an electronic system with an application in medicine to make a constant monitoring of cardiac patients more accessible to the general population.

1.2. Motivation

According to everything presented in the previous section, it can be said that the study of the heart and its electrical activity is growing. There are many institutions worldwide that are trying to develop monitoring techniques to control and prevent cardiovascular accidents. Within prevention, our main tool is monitoring the heart to detect abnormalities in its electrical signals. With this purpose in mind, the development of an electronic system with the function of detecting cardiac parameters (normal or abnormal) is of utmost importance since it is relevant in assessing the health status of a patient.

The electrocardiograph (ECG) has had a rapid evolution since the first was developed in the nineteenth century. Alexander Muirhead created this first ECG in 1872 at St Bartholomew's Hospital in London. This ECG consisted of a cluster of loose wires without any insulation, which was placed on the wrists of patients with symptoms such as fever (6). Despite this, the person who is considered the pioneer in ECG technology is August Waller. This technology is based on a Lippmann electrometer which was modified to be able to project its image in an amplified way, as we can see in figure 3. The signal obtained could be observed in real time because it was displayed on an attached plate to a toy train for movement (7).

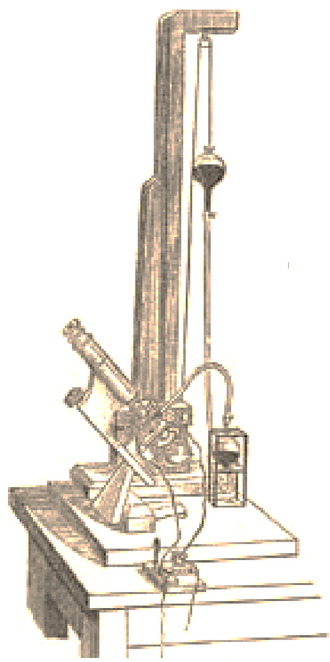


Figure 3: Gabriel Lippmann's electrometer used to create the technology for the first ECG

Source of own elaboration from: (8).

The second significant advance in ECG technology came from the hand of Willen Einthoven in 1901 when, using a string galvanometer, he developed an ECG (see Figure 4). The impact of this new technology was such that it was presented at international conferences, causing the attention of the medical world. P, Q, R, S and T were the letters that Einthoven assigned to the waves that the ECG presented (9). With the help of these waves, he was able to recognize and collect data from various cardiac pathologies, which earned him the Nobel Prize in medicine in 1924 (8).

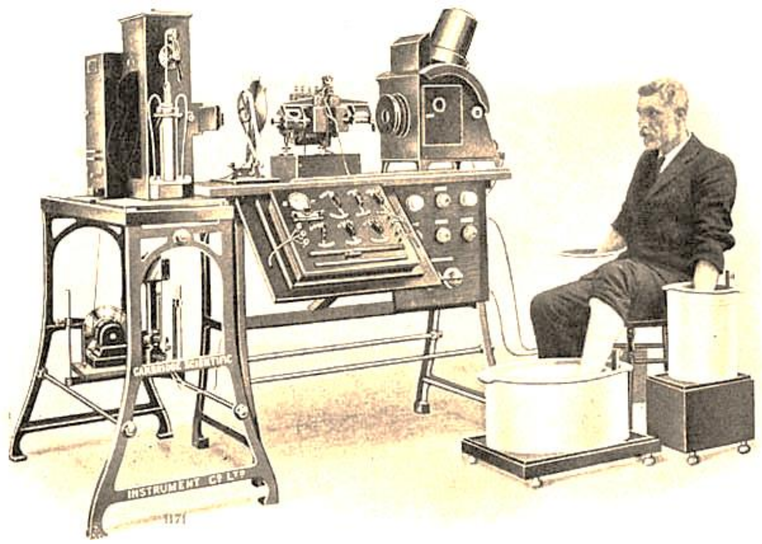


Figure 4: Einthoven string galvanometer (first ECG) (10).

In 1937, born from the hand of Taro Takemi the first portable electrocardiograph. (11). From here, portable ECGs begin their heyday due to their easy use and manipulation. Currently, and obviously, ECGs have a very advanced technology since computer processing is used to increase the signal intake and treat it.

Electrocardiographs, like all biomedical devices, are in constant change as new technologies that appear are being incorporated. For this reason, the main utility of this project is to provide patients with an adequate means to carry out constant monitoring of the electrical signals of the heart by medical personnel, serving as prevention in a critical situation. Therefore, the impact that this project will generate is economic and social, since it has the objective of being accessible to all people, improving their quality of life and helping doctors in an early diagnosis.

Chapter 2: Objectives

2.1. General objective

The general objective of this final degree project is to design and develop an autonomous and portable electrocardiograph to be able to monitor ECG for a subsequent visualization by a doctor awaiting a diagnosis.

2.2. Specifics objectives

- To implement a prototype through Arduino to take data from the patient's ECG signal, programming the software in Arduino to acquire, from the analog capture block, the heart signal.
- To evaluate the results achieved once the prototype is finished, and formulate possible future improvements.
- To carry out a processing of the data obtained with the use of the ECG, and in addition to storing them to be able to carry out their subsequent analysis.

Chapter 3: Theoretical Framework

3.1. Physiological basis

Our human body is a very complex biological structure and as such it is composed of various systems and apparatus. This is the reason because it is imperative to understand the functioning of different organs when we design a biomedical device that has direct or indirect interaction.

In the creation or development of any biomedical device, it is important to know the biological-technological interaction. Otherwise, it would not be possible to understand essential concepts such as the origin of cardiac signals and without this knowledge, the final system could be faulty. Therefore, for the development of this work, it is considered necessary to comprehend some physiological concepts of the circulatory system, one of the most complex systems of the human body.

3.1.1. Circulatory system

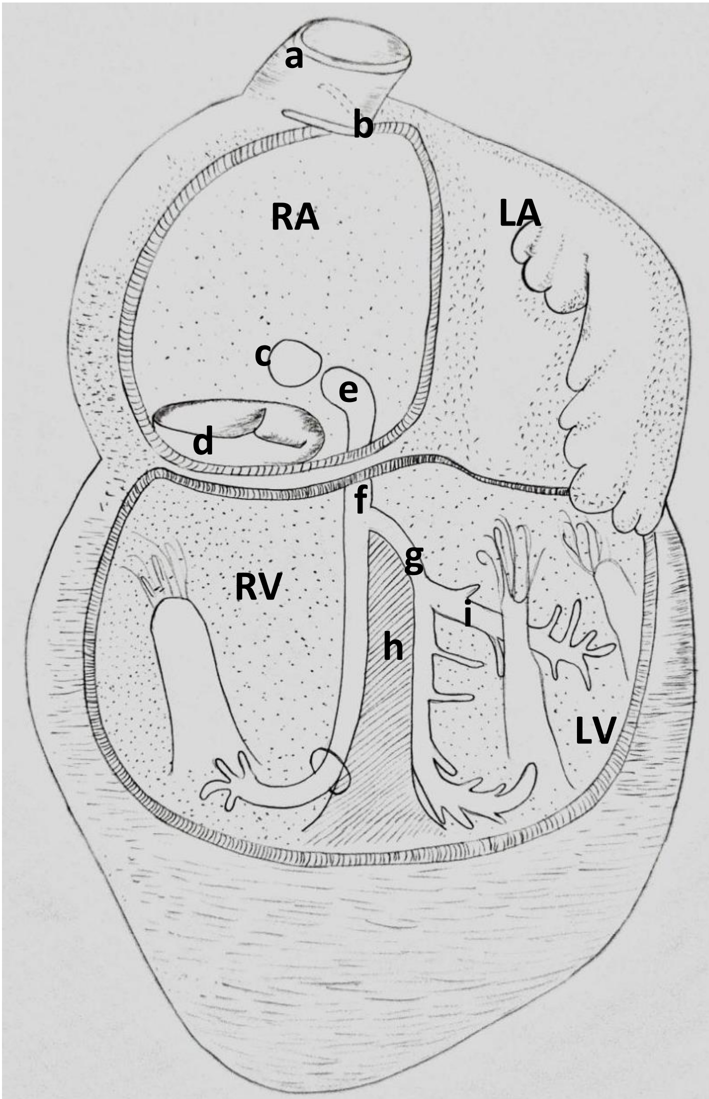
The circulatory system (CS), as it was mentioned previously, is a complex system of the human body that has the responsibility of transport substances through the blood to the entire human body. The CS has two subsystems which are: the cardiovascular system (whose main tissue is blood) and the lymphatic system (with lymph as its main component) (12).

On the other hand, the cardiovascular system is formed for veins, arteries, capillaries, and the heart the latter acts as a pump that carries deoxygenated blood to the lungs and oxygenated blood to the rest of the body (13). The science that is responsible for the study of the heart and its pathologies is called cardiology.

3.1.2. Study of the heart

A biomedical device, like any mechanical machine, bases its main operation on the use of a motor or power supply. Like a machine, the human being bases its operation on a biological motor called the heart that, when compared to the main motor of a machine, it can be said that it is among the main and essential organs of the human body and therefore, its care must be thorough.

As already mentioned, the heart is the main organ of the circulatory system and one of the most important in the body in general. Also, it is responsible that the blood reaches all our tissues. If the anatomy of the human body is analyzed, it is possible to see that in the thoracic cavity is located the heart and is divided into four chambers, two upper (right and left atrium) and two lower (right and left ventricle) (see figure 5) (14).



a) Superior vena cava
b) SA Node
c) Coronary sinus
d) Tricucspid valve
e) AV Node
f) AV Bundle
g) Bundle branch
h) Interventricular septum
i) Fascicle

RA) Right atrium

LA) Left atrium

RV) Right ventricle

LV) Left ventricle

Figure 5: Schematic representation of the human heart (Author).

The cavities that are responsible for receiving blood from different parts of the body so that it is then expelled through the ventricles are called atria. The right atrium collects oxygen-deficient blood from the inferior vena cava (blood from the abdomen, thorax and lower extremities) and the superior vena cava (blood from the head and upper extremities) (15). According to Gerald Friedland (16), these two veins are the ones that send blood to the right atrium and when the atrial systole arrives, the blood passes to the right ventricle through the tricuspid valve.

Here we find the ventricular systole that causes the blood to leave the right ventricle through the pulmonary valve into the lungs. In the lungs gas exchange occurs, oxygenating the blood, which travels through the pulmonary vein to the left atrium. Through the atrial systole, blood passes to the left ventricle through the bicuspid valve (mitral valve). Finally, through the ventricular systole, the blood would exit through the aortic sigmoid valve and with the help of the aorta artery, the oxygenated blood is transported to all cells. These cells collect oxygen, starting the cycle again.

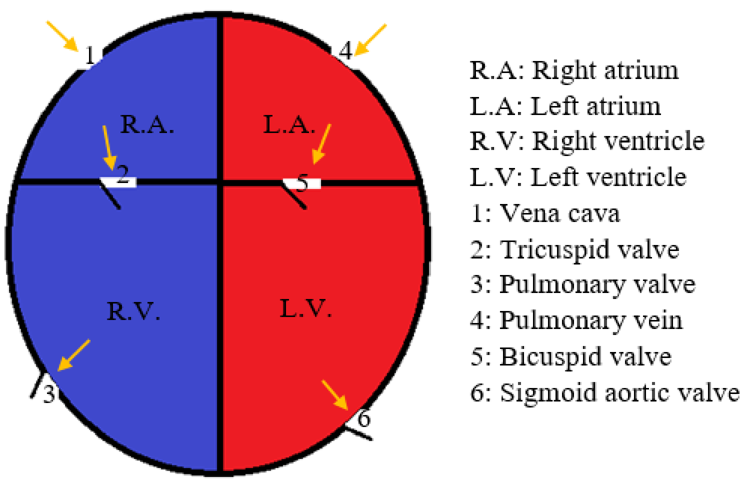


Figure 6: Diagram of the structure of the heart and blood circulation (Author).

The heart pumps blood through two movements: systole (a contraction of the heart to expel blood) and diastole (relaxation of the heart to receive the blood). At the moment of contracting, the heart generates electrical impulses that maintain the movements rhythmically (17). The device responsible for recording the electrical activity of the heart is called an electrocardiogram or ECG.

3.1.3. Electrical conduction system of the heart

The heart is an organ that can produce an electric current rhythmically and autonomously. This particularity is essential since, as it beats (pump blood) autonomously, it can keep the circulatory system working (18). A network of specialized cardiac muscle fibers is the origin of this cardiac activity. These fibers are known as automatic fibers, which are self-excitable, this being their main characteristic (19).

Among all the cells that make up the heart, only 1% of these are self-excitable with functions of great importance for the proper functioning of the heart. The primary function is to cause a rhythmic electrical excitation which causes the contraction of the heart muscles. This function is known as a pacemaker function. Another function is to act as a conduction system, this means that it provides a path for the cardiac excitation cycle to pass through the heart to be transmitted gradually (19).

If we take into account the cellular action potential, it can be said that the action potential of cardiac cells is different from that produced by the rest of the cells in the body. However, to investigate the differences, it is necessary to know the concept of action potential. According to the article of Riemer and Tung ("Stretch-induced excitation and action potential changes of single cardiac cells"), the action potential is a wave of electrical discharge (electrical impulse) that is produced when an electrical stimulus that is above the threshold of Cell excitation triggers an ion exchange between the extracellular and intracellular environment (20). The action potential obeys the law of "all or nothing", since it will occur only if the stimulus is intense enough to reach the threshold of excitement. Despite this, once the cell is excited, and the action potential is activated, the exchange of ions sodium (Na^{+}), calcium (Ca^{2+}), potassium (K^{+}) and in small proportions chlorine (Cl^{-}) (18).

Throughout history, the action potential has been studied by a variety of authors. However, the most significant study was the realized by L. Hodgkin and A. Huxley named “A quantitative description of membrane current and its application to conduction and excitation in nerve”. Their study was based on a work with large squid axons from which they obtained the action potential graph and gave a chemical explanation (21). This study helped to extrapolate the electrical model of the cell membrane, having a great repercussion since it was possible to conclude that the action potential is a physical phenomenon that can be picked up for some device.

In cardiac cells, the phases of the action potential are: depolarization, plateau (in cardiac cells) and repolarization, which will be broken down below and in the figure 7:

Depolarization	• This is when a cell is brought to the threshold potential by action potentials of neighboring cells. • It is here that the opening of sodium channels occurs, so that ions can enter. • This income generates a decrease in the potential difference, due to the flow of ions between the intracellular and extracellular medium until it is positive for a short period of time (22).
Plateau	• In this phase, we have the opening of slow voltage regulated calcium channels and on the other hand the potassium channels are also open. • Ca^{2+} enters the intracellular environment slowly and K^{+} leaves the cell (22).
Repolarization	• This final phase is characterized for the closure of the Ca^{2+} channels and by the opening of K^{+} channels, causing the K^{+} ions to leave and re-establishing the membrane potential at rest (- 90 mV) (22).

Table 1: Explanation of phases of the action potential

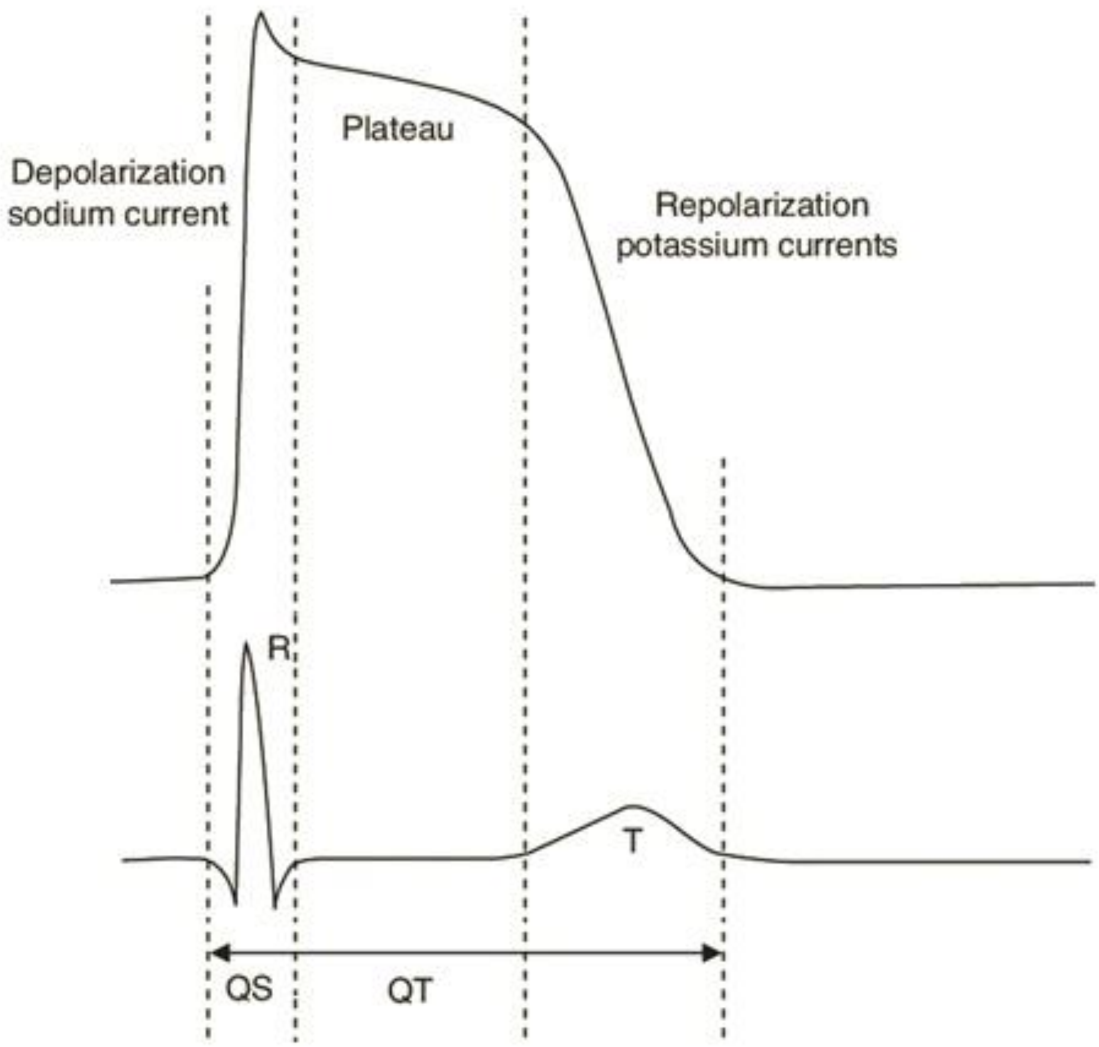


Figure 7: Graphic representation of the phases of the action potential of the heart. Source of own elaboration from: (23)

Taking into account normal conditions, the propagation of the action potentials through the conduction system occurs in several steps:

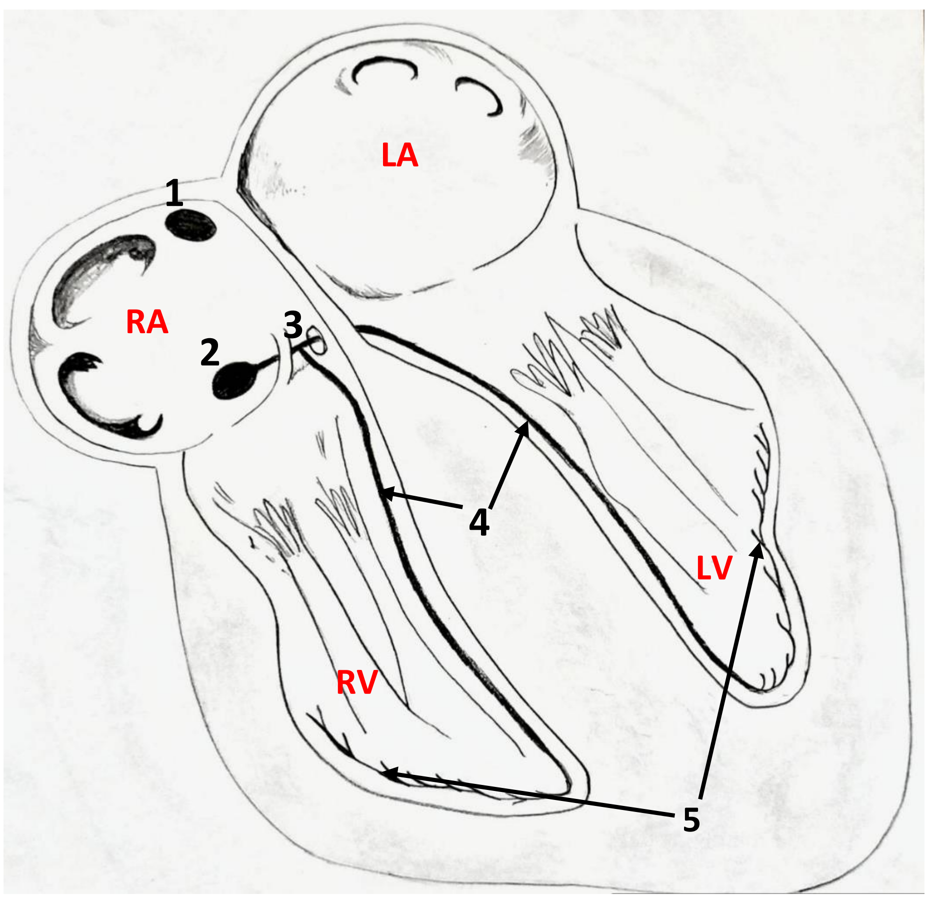
a) The process normally begins with cardiac excitation at the sinoatrial node. Here, cells rhythmically depolarize and reach threshold potential spontaneously. This step is called a "potential pacemaker".
b) The conduction passes along the atrial muscle fibers, reaching the atrioventricular (AV) node, locating the interatrial septum, in front of the entry of the coronary sinus.
c) In the AV node we find a delay, this delay is necessary for complete the passage of blood from the atrium to the ventricle. After this, the action potential goes towards the bundle of

His (atrioventricular or atrioventricular bundle). This is where action potentials are propagated from the atria to the ventricles.

d) After propagating in the Hiz bundle, the next stop of the action potential is in the right and left branches, which pass through the interventricular septum towards the cardiac apex.

e) Finally, the Purkinje fibers carry the action potential from the cardiac apex to the rest of the ventricular myocardium. This causes immediate ventricular contraction, pushing blood toward the semilunar valves (22).

Most of the elements mentioned in the previous steps can be seen in figure 8.



1. Sino-atrial node (The Pacemaker)
2. The atrioventricular node
3. The atrioventricular bundle
4. The bundle branches
5. The Purkinje fibers

RA. Right atrium

LA. Left atrium

RV. Right ventricle

LV. Left ventricle

Figure 8: Anatomical elements of the heart and its conduction system (Author).

On the other hand, the speed of the electrical impulses of the heart is highly variable and depends on the properties of the parts of the conduction system and the cells of the myocardium.

Taking the cells of the His-Purkinje system as the fastest (2 m/s), and the cells of the atrioventricular and sinoatrial nodes as the slowest (0.01 to 0.5 m/s) (24).

3.1.4. Description of the cardiac wave

The electrocardiogram or ECG is a graphic representation of the electrical activity of the heart. It can be seen that the ECG is the sum of the waves generated by the electrical signals of the different structures of the heart.

Normally, an ECG is usually represented by waves as in figure 9, these are normally 5: P, Q, R, S and T waves. These waves are classified into three parts: atrial activation, ventricular activation and ventricular repolarization (25).

- Atrial activation: it is subdivided into a P wave, which is due to the depolarization of the atria and the little-known Ta wave, which is a deflection produced at the end of the P wave and is due to atrial repolarization (25).
- Ventricular activation: this part comprises the entire QRS complex due to ventricular depolarization that measures from 0.06 to 0.1 seconds and is subdivided into Q wave which is the first negative wave found in the ECG, R wave which is positive and the largest wave in the entire ECG and S wave which is the negative wave immediately after the R wave (25).

Ventricular repolarization: it is subdivided into the T wave that is formed by repolarization of the ventricles and the U wave, which is little known and uncertain since it is thought that it is formed by repolarization of the interventricular conduction system (25).

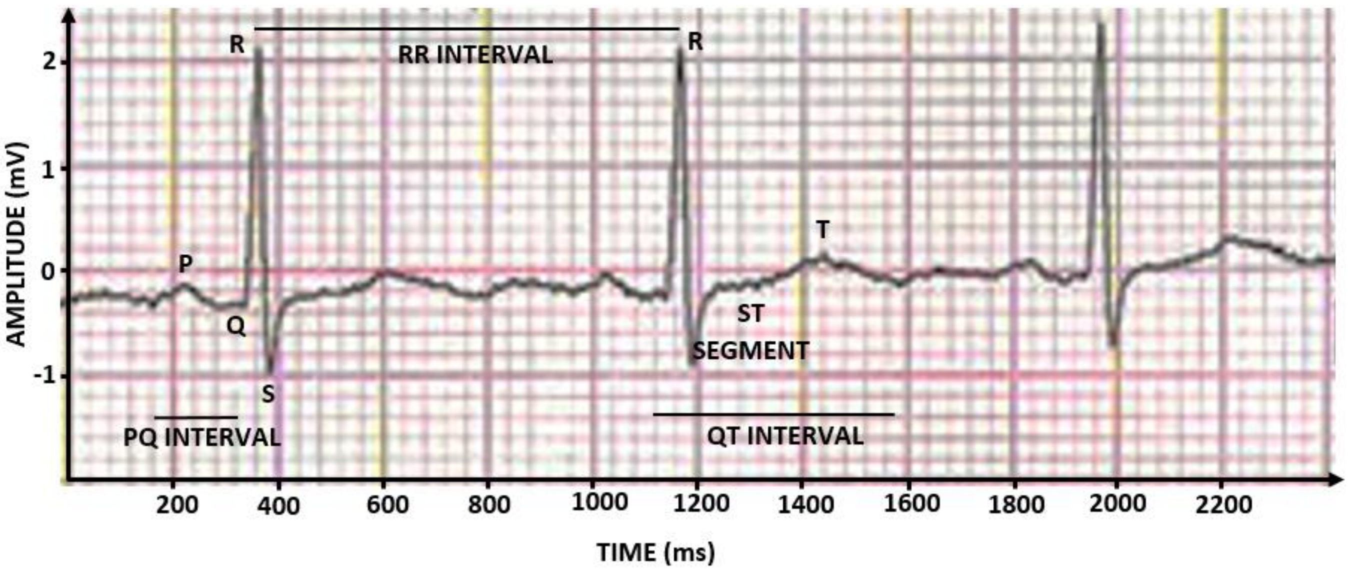


Figure 9: Recording of an ECG distinguishing its parts (Author).

When we place the electrodes to measure an ECG, we normally have 12 leads, which are responsible for simultaneously recording the activity of the heart. Figure 10 and 11 show the correct locations of a common ECG. The idea of the 12 leads can be interpreted as taking a photograph of something specific from 12 different locations.

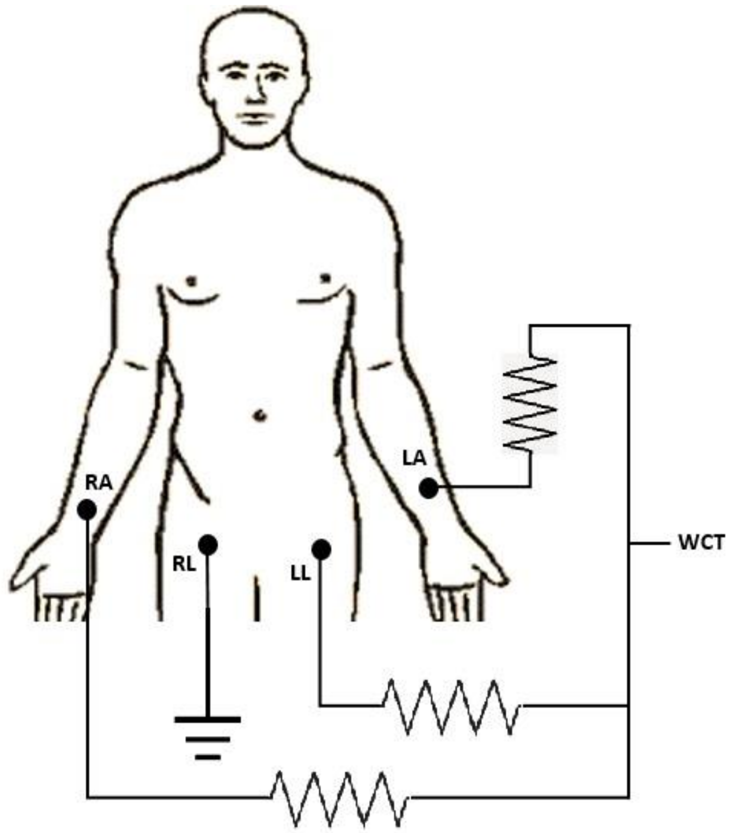


Figure 10: Connection of the central Wilson terminal (WCT) taking as reference the Einthoven triangle (Author).

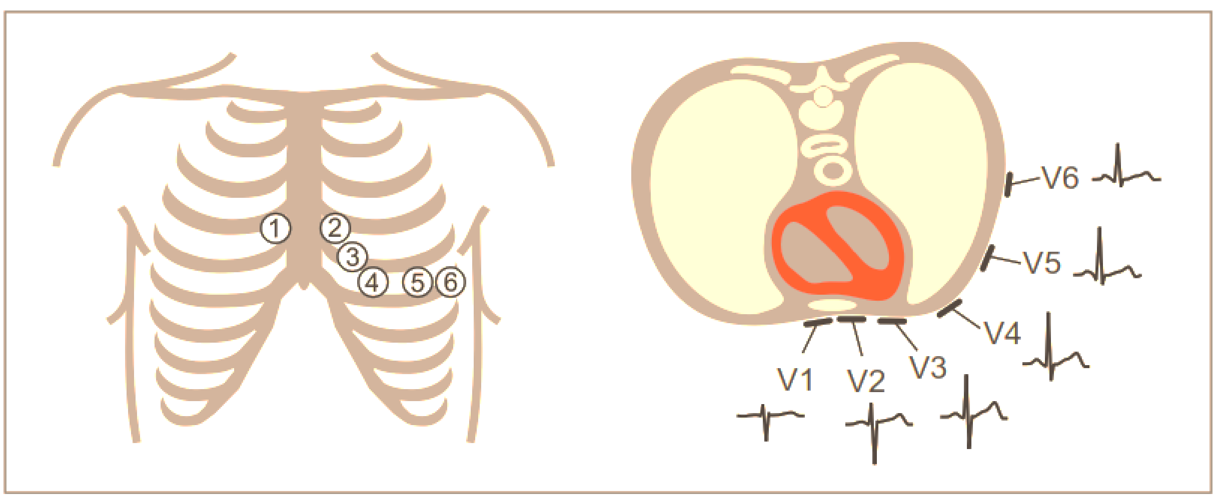


Figure 11: Position of the 6 precordial electrodes (26).

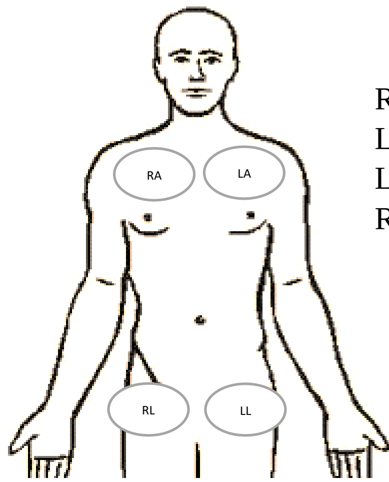
With the help of these electrodes, a recording of the heart can be obtained to get a real idea of what the heart really is like through the leads, a three-dimensional organ. Said derivations could be bipolar, if the potential difference is between two points or two electrodes, or they could be unipolar, when the potential difference is taken with a potential point 0 (27).

Bipolar leads are the ones Einthoven originally chose in 1901, recording the potentials in the frontal plane. From this conception, the idea of the Einthoven triangle was born, placing the electrodes on the left part of the body (arm and leg) and on the right part (arm), always taking into account that the heart is the central part of the triangle (28) (figure 12). This triangle has some main characteristics such as that it is equilateral, and its three sides equidistant from the heart and that it represents the frontal plane.

Figure 12: Representation of the Einthoven triangle. A. Bipolar leads B. Unipolar leads. Source of own elaboration from: (26).

At the moment of obtaining unipolar leads, a point is needed which has a voltage of 0 V, this voltage is obtained by joining the 3 electrodes located at the extremities. Therefore, the axis of unipolar derivations is obtained by joining the positive electrodes with the point with voltage 0 V as in figure 10 (29).

Despite all the aforementioned, this project will be carried out with 6 leads, taking into account that it is the minimum required to obtain cardiac ischemia. The connection would be as shown in figure 13, since from 4 electrodes we can obtain 6 leads.



RA: Right arm
LA: Left arm
LL: Left leg
RL: Right leg

Figure 13: 4-electrode electrocardiogram (Author).

3.1.5. Frequency components of the heart and Heart rate

The frequency components of the Heart are between 0.01 and 250 Hz. However, the frequency that is useful to detect any heart disease is 60 Hz, always taking into account that the 50 Hz electrical noise of all ECGs must be eliminated. (29).

The number of times the heart contracts in a minute is called the heart rate. As in most CVDs, the variation in heart rate depends on sex, physical condition, age, etc. The measurement of the heart rate in the resting state is normally 60 to 100 bpm. The typical situations that can occur in the heart according to heart rate abnormalities are tachycardia (rate greater than 100 bpm) and bradycardia (rate less than 60 bpm) (28).

To calculate and obtain the approximate heart rate, it can be done by counting 30 large squares on the ECG paper that are equivalent to 6 seconds and counting how many QRS segments are in this time interval, then we multiply it by 10 and an approximate heart rate is obtained (30).

For example, if 10 QRS complexes are found in 6 seconds of the electrocardiogram, they are multiplied by 10 to calculate the heart rate and the results is: 10 QRS complexes * 10 = 100 bpm (approximately).

3.1.6. Pathophysiology of ischemic heart disease

Ischemic heart disease, coronary myocardial irrigation deficit, myocardial ischemia, coronary atherosclerosis, reduction of coronary flow to the heart, obstruction of arterial light, atheroma plaques, myocardial necrosis and evolution of ischemic heart disease are the steps of the ischemic disease (31). Ischemic heart disease is almost always a consequence of coronary atherosclerosis, which determines a reduction in coronary flow to the heart. Coronary atherosclerosis is a slow process that begins in the first decades of life and runs asymptomatic for a long time (32).

The mechanism of atherosclerotic plaque formation (see figure 14) is complex and occurs as follows: Atherosclerosis begins with a minimal lesion in the arterial endothelium, which is a layer that is in contact with circulating blood. This lesion is favored by tobacco, hypertension, hypercholesterolemia, etc (33). Next, the so-called low density (LDL) blood lipoproteins penetrate into the vessel wall through these injured areas of the endothelium. Once inside, the LDL will undergo an oxidation process, after which they cause circulating monocytes to also pass through the injured endothelium penetrating the arterial wall. Monocytes or macrophages will engulf oxidized LDL, since they carry cholesterol inside (34).

Here, a structure with a "foamy" appearance is formed which is created by the change in the shape of monocytes. They form fatty streaks, which in principle may not hinder circulation but, if the process described continues, they increase in volume to the point of affecting circulation in the coronary artery (32). Thus the atherosclerotic plaque responsible for coronary stenosis is generated. If there is a rupture or erosion of the fibrous cover, the fat contained within the plaque and the blood would come into contact, which can cause thrombus formation; if it reaches the sufficient size, it can abruptly and completely obstruct the coronary artery, interrupting the circulation. In most cases, this is the mechanism that causes acute myocardial infarction and sudden death (33).

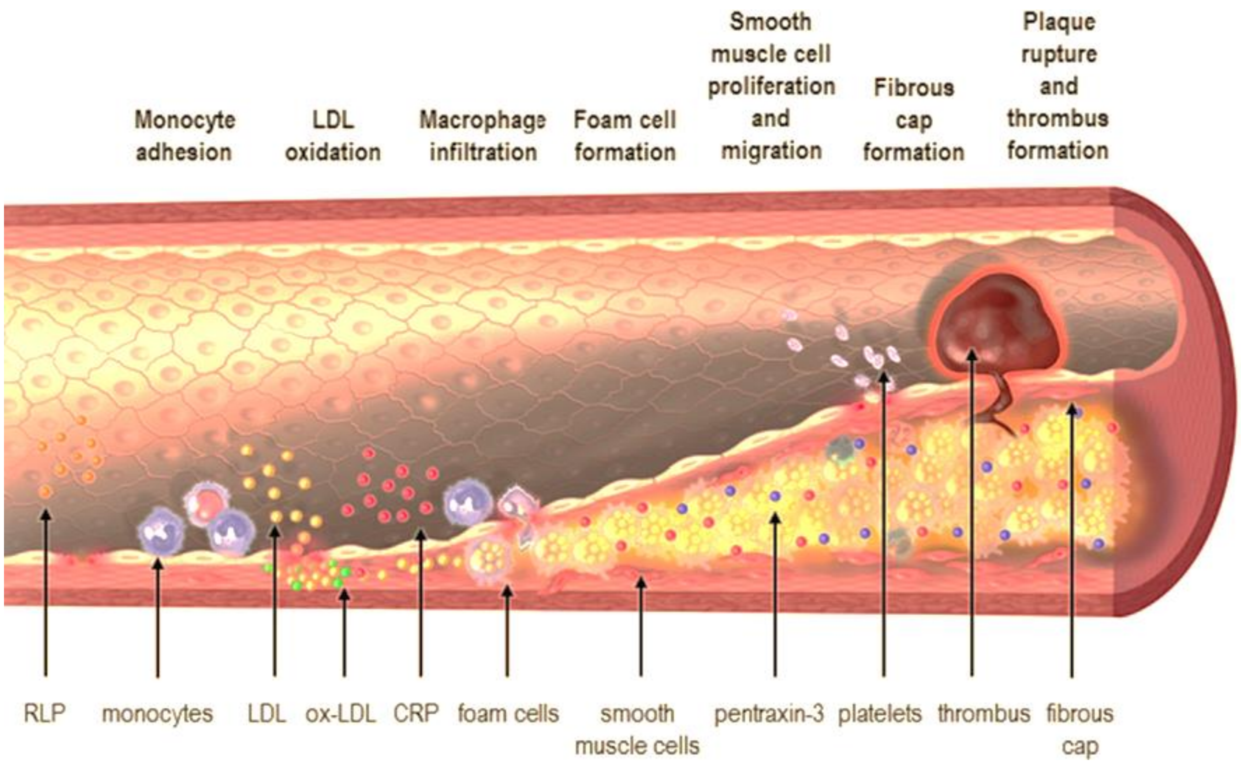


Figure 14: Graphic representation of the atheroma plaque (35).

The different types of ischemic heart disease are:

- Acute myocardial infarction (myocardial necrosis).
- Stable angina pectoris (transient ischemia during exercise).
- Unstable angina pectoris (prolonged ischemia) (34).

3.1.7. Electrocardiogram waves to cardiac ischemic (T wave and ST segment)

There are many waves and segments in an electrocardiogram examination such as the P wave, PR segment and QRS complex. However, for the development of the present thesis, the focus will be only on the T wave and ST segment.

The ST segment and the T wave reflect the electrical recovery of the cells, which we also call repolarization of the ventricles (36). The alterations of repolarization, that is, the alterations of the ST and the T wave, reflect all kinds of pathologies in which cellular functioning is altered, such as myocardial ischemia. The T wave has an asymmetric and rounded shape, so that the first part is longer than the second (37).

T wave

Negative T waves are indicative of a right ventricular hypertrophy, but it is also considered a normal variant in black individuals, especially women (38). High T waves in the form of a tent are characteristic of hyperkalemia, although they are also common in healthy people, often due to hyperventilation or a state of anxiety. When observing this type of waves, one should not always think about finding high levels of potassium in the analytical, but about the possibility of the patient presenting anxiety and considering making other records at different times or after treatment with anxiolytics (36).

It has a width of 0.10 s at 0.25 s, and measures an approximate 0.4 mV (4mm in the physical register); however, this wave depends on the R wave with a ratio of 1:3. They are regularly rounded but if there is any injury it can be elongated and pointed (38).

ST segment

In general, an ST segment elevation is considered acute myocardial infarction, and a segment depression, such as ischemia. The ST segment elevation is a normal phenomenon and is known as "high take off ST segment" (39). It should be taken into account that ST segment depression is normal in healthy people, especially obese, and especially during pregnancy.

This “non-specific” disturbance of the ST segment should not be more than 2 mm to be taken as normal. However, a depression of this segment greater than 2 mm is an indicator of ischemia and should be studied in depth (38). It has a length of up to 0.15 s, magnitude that lacks clinical importance, since the essential thing in this sector of the electrocardiogram is the presence of its deviations or displacements of the isoelectric line (39).

3.2. Electronic basis

3.2.1. Transducers

For the present work, the transducer that we will need is the electrode. An electrode is a device that allows us to measure the signals (40). In our case we need the measure of electrical signals of the heart. In short, an electrode is a conductor.

As already seen previously, inside the body we have free ions, and when the electrode is brought into contact with the skin, an ion exchange will be obtained between the electrode and the skin. As an effect of this we will have an electric potential at the electrode (40).

For the measurement of bioelectric potentials, two electrodes are needed; therefore, the voltage that is measured is the difference (subtraction) between the potentials of two electrodes (41). There are several types of electrodes; in this work, pasty disposable electrodes will be used, such as those shown in figure 15. This electrode has a sticky gel already attached to improve conduction.

Figure 15: Disposable ECG electrode for adults (Author).

One of the main reasons for choosing this electrode is that it is made of silver and chloride (Ag + Cl / AgCl). This material is one of the most used in the creation of electrodes as we can see in figure 16, in addition to having a conductive gel which facilitates the passage of current.

Metal and Reaction	$Ag + Cl^- \rightarrow AgCl + e^-$
Potential E^o (V)	$+0.223$

Figure 16: Most commonly used metals for the creation of electrodes and their respective oxidation reactions. Source of own elaboration from: (41).

In general, and especially for ambulatory applications, disposable electrodes are used. They consist of a foam disk that contains the electrode, which on one side has a male snap-type connector to connect it to the cables. On the other side, on the electrode there is a sponge impregnated with conductive gel. The conductive gel ensures good contact between the electrode and the patient's skin, as well as reducing the high impedance presented by the outermost layer of the skin (42).

Disposable ECG electrodes must follow a standard established by the AAMI (Association for the Advancement of Medical Instrumentation), called ANSI / AAMI EC12: 2000. This standard stipulates labeling requirements, tests to evaluate adhesiveness, and minimum conditions of electrical performance for disposable electrodes. It is specified, for example, that the offset voltage of the electrodes should not exceed 100 mV. Other requirements refer to the impedance value of the electrodes, which must be as low as possible, the stability of the offset and their internal noise (43).

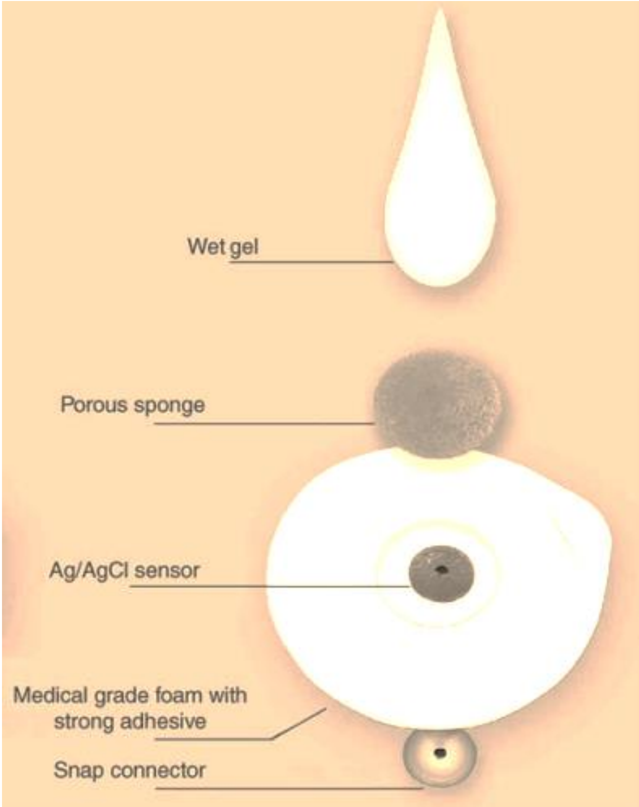


Figure 17: Design of a disposable electrode (42).

To improve the linkage between the electrodes and the skin, it is advisable to clean the skin with alcohol before placing it to remove the oil from the skin, and take off the hair in the areas where the electrodes will be located (40).

3.2.2. Power supply and data storage

The analog and digital circuits will be powered by 9 volts batteries. Two batteries will be used to get + 9V and -9V, to power the operational amplifiers and the arduino board.

Regarding storage, the best option was to obtain and store data on an SD card due to the size of its socket, for which an SD MH module is used. This module allows us to store information digitally on an SD card. Among the best features of this module we have to it works with an external card, therefore you can choose any desired storage memory, with the additional advantage that it can be easily extracted and connected to a computer, without considering its characteristics that are exposed. in table 2.

Detail	Characteristics
Operating voltage.	3.3V – 5V
Reading interface.	SPI
Size	5.1cm x 3.1cm
Card	SD standard

Table 2: Technical characteristics of the SD module (44).

Figure 18: Photograph of the SD module (Author).

3.2.3. Operational amplifiers

All measurements are made with operational amplifiers or systems using operational amplifiers (Op amp). The operational amplifier is an electronic device that has two inputs and one output. It is fed between two potential differences by two terminals. It is usually fed symmetrically, although this is not always the case.

This device can be used in various configurations that could be grouped as those with negative, positive, or no feedback. In an open loop, that is, without feedback, it is usually used as a comparator where the output will saturate towards one of the power levels depending on the inputs. In closed loop it can be used with positive or negative feedback. Negative feedback is the most used since we can stabilize the output with resistors.

3.2.4. Analog Front-end

We know as analog Front-end the part of an electronic circuit, which has the first contact with a measured signal after its acquisition, to later treat it as the case may be.

To acquire the signal, a board developed by SparkFun was used, called "AD8232 Heart Rate Monitor". This module incorporates a powerful AD8232 chip that is designed to extract, amplify and filter small biopotential signals in the presence of noisy conditions, such as those created by electrode movement. This integrated allows to carry out signal conditioning in a simple way thanks to the fact that it has a built-in instrumentation amplifier (IA), operational amplifier (A1), RLD right leg amplifier (A2), a buffer (A3) and a circuit of fast stabilizer (45), this can be seen in figure 19.

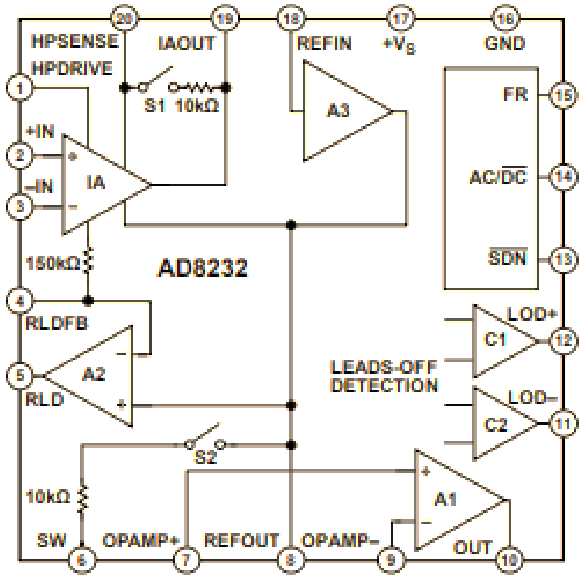


Figure 19: Functional diagram of the AD8232 integrated circuit (45).

On the other hand, we have below the main characteristics of the AD8232 module, which are described in the official data sheet.

Characteristic	**Value**
Low supply current	170 µA
Common-mode rejection ratio	80 dB (dc to 60 Hz)
High signal gain	G = 100
Filter	RFI (Integrated)
Number of electrodes	3
Operating voltage	2 V - 3.5 V

Table 3: Technical characteristics of the AD8232 module (45).

The AD8232 heart rate monitor has nine connections that can be soldered with cables or the header pins, this can be seen in figure 20 where we have a clear image of the AD8232 module of the TOP face and the BOTTOM face.

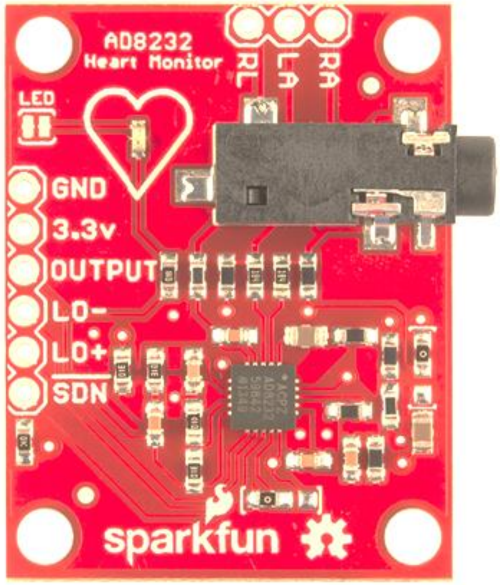


Figure 20: TOP face of an AD8232 Printed Circuit Board (PCB). (Author)

3.3.5. Arduino board

To read the collected signal, the Arduino Mega environment has been used, which has a low price and can easily be connected to the Sparkfun board through a set of pins, as can be seen in Table 4.

Board Label	Pin Function	Arduino Connection
GND	Ground	GND
3.3v	3.3v Power Supply	3.3v
OUTPUT	Output Signal	A0
LO-	Leads-off Detect -	11
LO+	Leads-off Detect +	10
SDN	Shutdown	Not used

Table 4: Recommendable connections from the module to the Arduino of the five main pins (46).

Arduino is about a device that connects the analog environment with the digital one. Arduino board is based on an 8-bit Atmel AVR microcontroller, existing of different types depending on the model of board that is purchased. For example, for the Arduino Robot version a board based on an ATmega32u4 is used, for the Arduino Uno version an ATmega 328P microcontroller is used and for the Arduino Mega version an ATmega2560 microcontroller is used (47).

Another of the main reasons why the Arduino development platform has been chosen for this project is the price. While other development platforms offer little variety of items with different characteristics, Arduino presents a great variety of boards with different functionalities. There are some with the possibility of a WIFI connection module already incorporated, although an external one can always be connected, others with higher data processing speed and others with less, and many other functions. Next, table 5 shows a comparison of development platforms present in the market and their prices.

Due to problems with the memory of Arduino Uno, the microcontroller that was selected for this thesis is Arduino Mega and because it has 16 analog input pins.

Model	**Price**
Arduino UNO	$ 9.99
Arduino Mega	$ 14.99
Raspberry Pi	$ 89.9
BeagleBone	$ 113.8

Table 5: Microcontroller price comparison.

Chapter 4: Methodology

When designing a system, certain important decisions have to be made, such as choosing the type of methodologies to be developed, as well as the type of data visualization, among many others.

First, it was previously decided to use Ag / AgCl electrodes. However, there are two types of electrodes in terms of the type of use that are wet and dry electrodes. Wet electrodes are more prone to electronic noise from electrode movement and varying electrical charge. They also have an impedance effect because to place it on the patient's skin, a conductive solution must be used that improves the passage of electrical current between the skin and the transducer layer of the electrode. Dry electrodes, on the other hand, are less influenced by variations in electric current, but they have poor long-term behavior and can distort the results. Therefore, wet electrodes are chosen for this system.

The data display of this system will be done on the computer. A visualization through a liquid crystal display (LCD) or other type of display has not been considered pertinent since the data will be collected on an SD card to be later transferred to the computer where the data analysis can be carried out. There are other data storage possibilities; however, it is considered for the first prototype of this project to use an SD card as it is a simple, cheap, efficient solution and saves consumption.

To understand the different modules that make up this project, a block diagram has to be made where it is determined what functions and parts each one has. This diagram is the one presented in Figure 21.

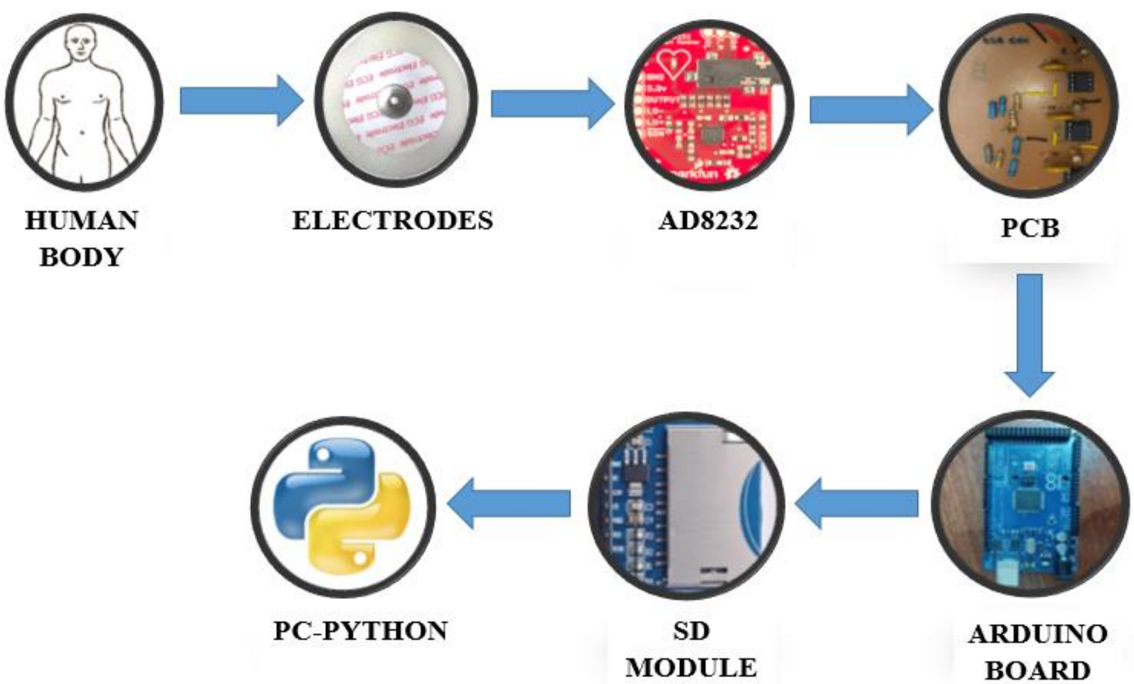


Figure 21: System block diagram (Author).

The heart, which generates electrical signals, as mentioned above, are of very low amplitude and it is necessary to amplify them. We are actually going to measure the bipolar leads. This means that we are going to measure a signal of the difference of two parts of the body.

Therefore, we need the difference of two signals with respect to a potential, the reference potential. This reference potential will be the right leg (potential 0).

For the pre-amplification stage, the front end AD8232 was used, but from this module the data acquisition of the RA, LA and LL electrodes was used since these are connected to an instrumentation amplifier; however, at the time of the acquisition of the signal it could be observed that the signal was very noisy since this module is designed for the acquisition of a single resulting signal and for the development of the work 6 different signals and a resultant are used.

Despite the fact that the front end AD8232 performs a pre-processing stage of the signal, using signal amplifiers, there are many harmful effects that can deteriorate the quality of the signal such as electromagnetic disturbances due to electromagnetic compatibility between devices that are in the environment and noise crashes in the arduino system.

For these reasons, it is necessary to perform signal processing, reducing certain frequencies of noise, as well as effects of the baseline (isoelectric line). To improve the previously acquired signal, a printed circuit board (PCB) was designed in the PCB wizard software.

For the purpose of amplifying and filtering the signals, so a passive RC filter and a voltage follower were implemented on the PCB with help of the TL081 operational amplifier, all this serves as electronic isolation and can be seen in figure 22.

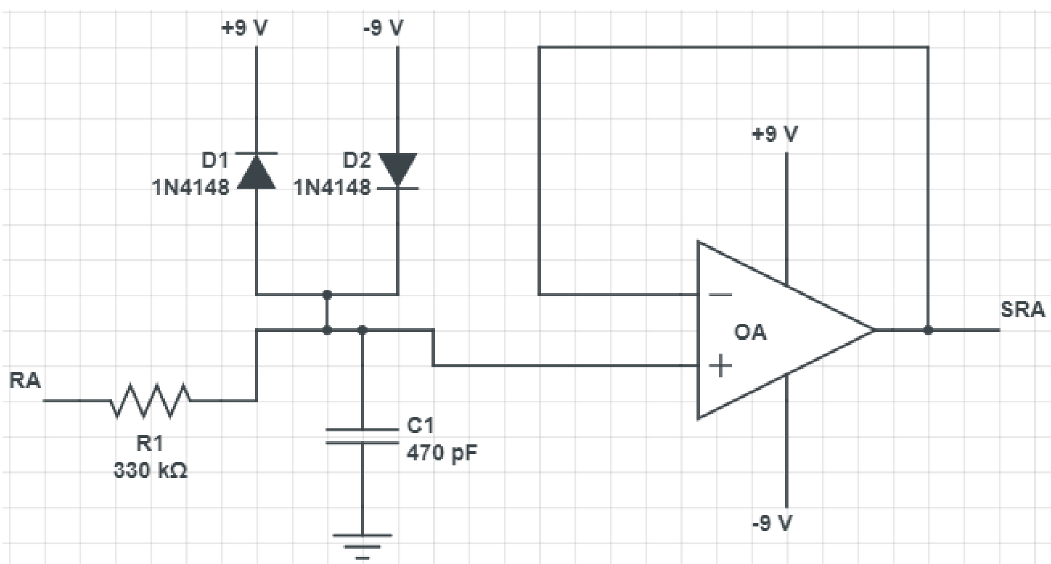


Figure 22: Electrical isolation circuit (Author).

The electrical isolation has been designed because the AD8232 module is very sensitive to electromagnetic interference. The passive RC filter avoids interference and its cutoff frequency is 1KHz, which is obtained thanks to the formula $f_c = \frac{1}{2\pi RC}$, having C = 470 pF and R = 330 kΩ. For protection against defibrillations not contemplated, this stage also consists of IN4148 diodes to protect the patient against surges (48).

The circuit developed in figure 21 is represented with the RA input from AD8232 and an output signal called SRA, however, this same circuit was used to work with LA and LL, obtaining SLA and SLL to later go to the Wilson Central Terminal.

The Wilson Central Terminal is known as CTW and is the reference point 0 (potential 0) in the human body and is used to obtain unipolar potentials of cardiac activity. This network is generally composed of 10kΩ resistors as can be seen in figure 23.

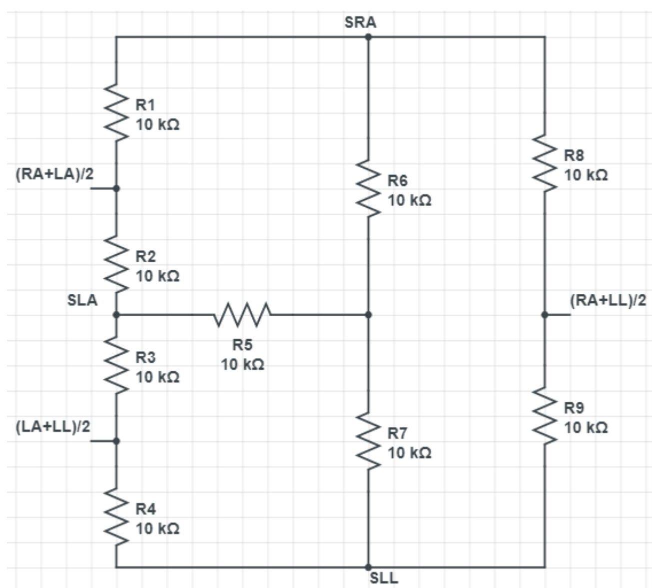


Figure 23: WCT Circuit (Author).

At this point, the electrode of the right leg (RL) is taken as ground since it is connected to GND of the AD8232 module, taking into account that this module has a virtual ground.

From here, we enter the phase of signal formation and analog-digital conversion. As it is required to store the data of the cardiac signals in a micro SD it is primordial to convert the analog signal to digital.

The arduino Mega consists of 16 analog pins that are defined as A0… A15, which has all the functionalities of the digital pins, that is, the analog and digital pins can be used. It is recommended to add a small delay before reading the data as this will prevent electrical noise from being generated and being introduced into the system.

Although Arduino board was used for the conversion of the analog signal to digital, it is also used for the generation of the final leads and for a digital filtering stage. One of the advantages of this software is the cost, easy to program, friendly compilation and loading of source code in the flash memory of any type of Arduino hardware, allowing to visualize the execution tests in real time.

Before proceeding with the development of the source code, a flow diagram was drawn up detailing the processes involved in each programming stage, as detailed in figure 24.

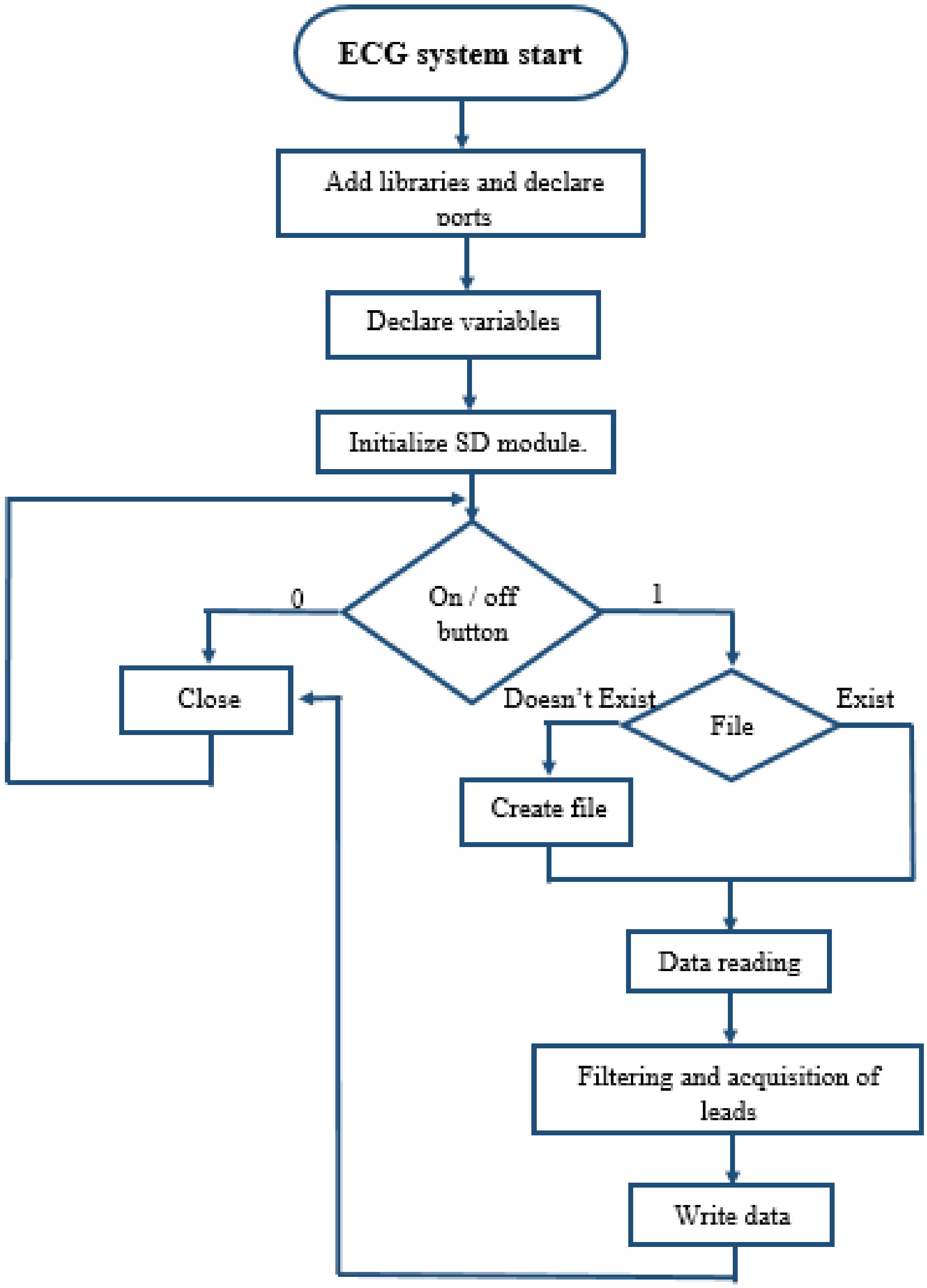


Figure 24: Arduino program flow chart (Author).

When the signal is received in Arduino, it arrives amplified separately; however, to obtain the total derivations, it is necessary to apply mathematical operations that are indicated in table 6.

Lead	Lead Type	Calculation
I	Bipolar	LA – RA
II	Bipolar	LL – RA
III	Bipolar	LL – LA
aVR	Unipolar	RA – (LA+LL)/2
aVL	Unipolar	LA – (RA+LL)/2
aVF	Unipolar	LL – (RA+LA)/2

Table 6: Way to obtain the leads through the electrodes.

One more contribution of Arduino is filtering, since, despite having previous filters, at the time of visualizing the wave it still presents a lot of noise, especially in the segments that you want to know. Because of this, the decision was made to implement a digital filter called EMA (Exponential Moving Average).

In this thesis, this filter was used for its good results and a simple but efficient implementation. Theoretically, this filter consists of obtaining a filtered signal from the equation $A_n = \alpha M + (1 - \alpha)A_{n-1}$, A_n is the filtered value, A_{n-1} the previous filtered value , M is the sampled value of the signal to be filtered, and α is a factor between 0 and 1.

The factor α is the parameter that conditions the behavior of the exponential filter and we have that if α = 1 the output is a signal without a filter, if α = 0 the filter value will always be zero. The result of an EMA exponential filter is a smoothed signal where the amount of smoothing depends on the α factor. Therefore, an exponential low-pass and high-pass filter (EMA) was implemented and a filtered signal was obtained as we can see in figure 25.

From here the signal goes to an SD memory, to read and write to the SD card from the microcontroller, the library must be declared (include <SD.h>) in the header of the program, then we define the pin variable to select the SD card, considering that on the arduino board the communication is established by the SPI bus through digital pins.

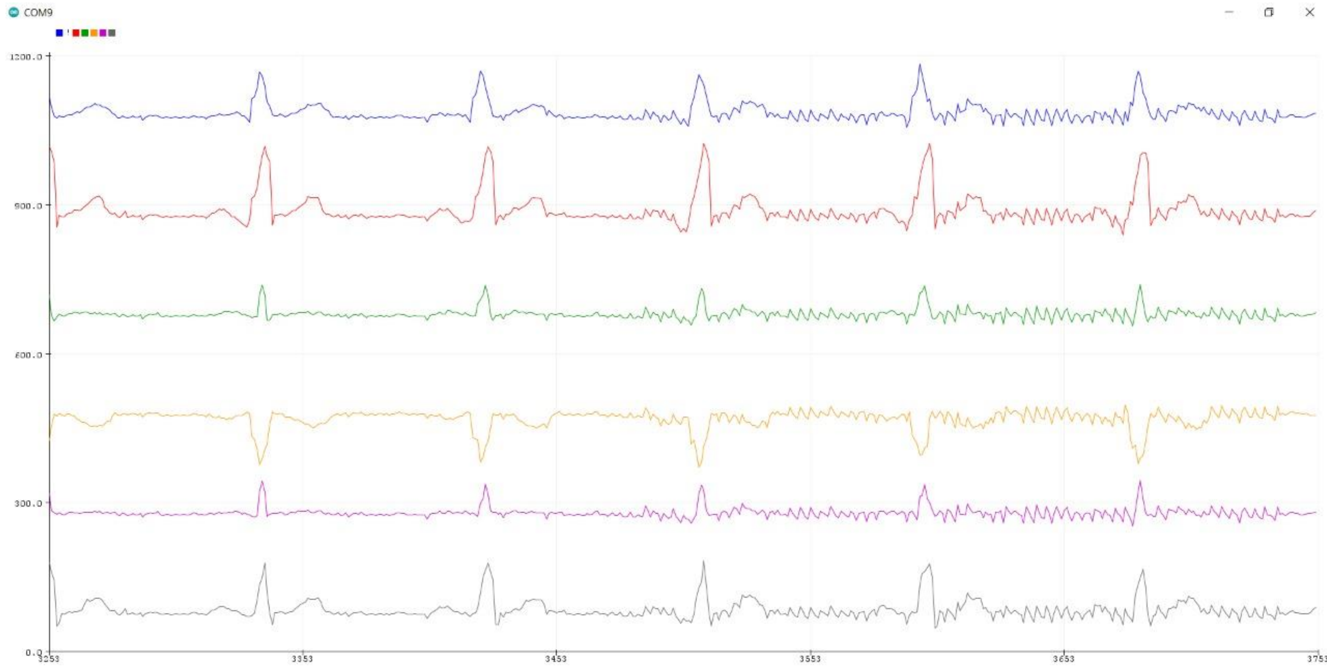


Figure 25: Graph of the 6 leads on the serial plotter. Initially it is a clean signal and then an interference was applied to the electrode (Author).

Once the Arduino process is finished, the data obtained is saved in an Excel file in .csv format with 8 lists named x, D1, D2, D3, AVF, AVR, AVL and GENRAL, where x represents the time of the sample collection, D1, D2, D3, AVF, AVR, AVL represent the leads and GENRAL. It is the resulting wave obtained from the AD8232 module, to later be read and interpreted by the software created in the Python language.

To display the ECG cardiac signal, the PYTHON tool will be used, it is a very powerful program to perform numerical calculations with matrices, the same one that has an external interface (QyT5 Designer), which will allow you to graphically view the input of data and graphical display, all using the Anaconda GUI.

When this small program opens, the user is asked to select the file to be viewed. The file must contain the .csv extension, which is the one used by python when storing them. In order to extract the information from files with this format, an open source toolbox, Pandas, was used, which allows the files to be decoded to structures typical of the Python language.

This software created not only takes care of the interpretation of the signal to graph it, but it also takes care of the analysis, since at the moment the data is entered into the program, we can obtain the point furthest from the isoelectric line being this the R wave, we also have the implementation of the recognition of the maximum point in the P wave, and T and finally the maximum point of the ST segment. All these maximum points are printed in a report with the respective time in which this maximum peak appears.

The software performs the calculation of the heart rate taking a time of 6 seconds and counting how many QRS complexes we have in this specific time, then it is multiplied by 10 and an approximate heart rate is obtained as it was mentioned in section 3.1.5. On the other hand, the software is in charge of calculating the total time that the prototype was connected to the patient and this is interpreted in hours, converting from seconds, which is real time, to hours. The final report is created in .pdf format.

Finally, the prototype consists of 2 parts, the first is the hardware or the electronic part whose complete representation we can see in figure 26, the second stage is that of the software or creation of the program.

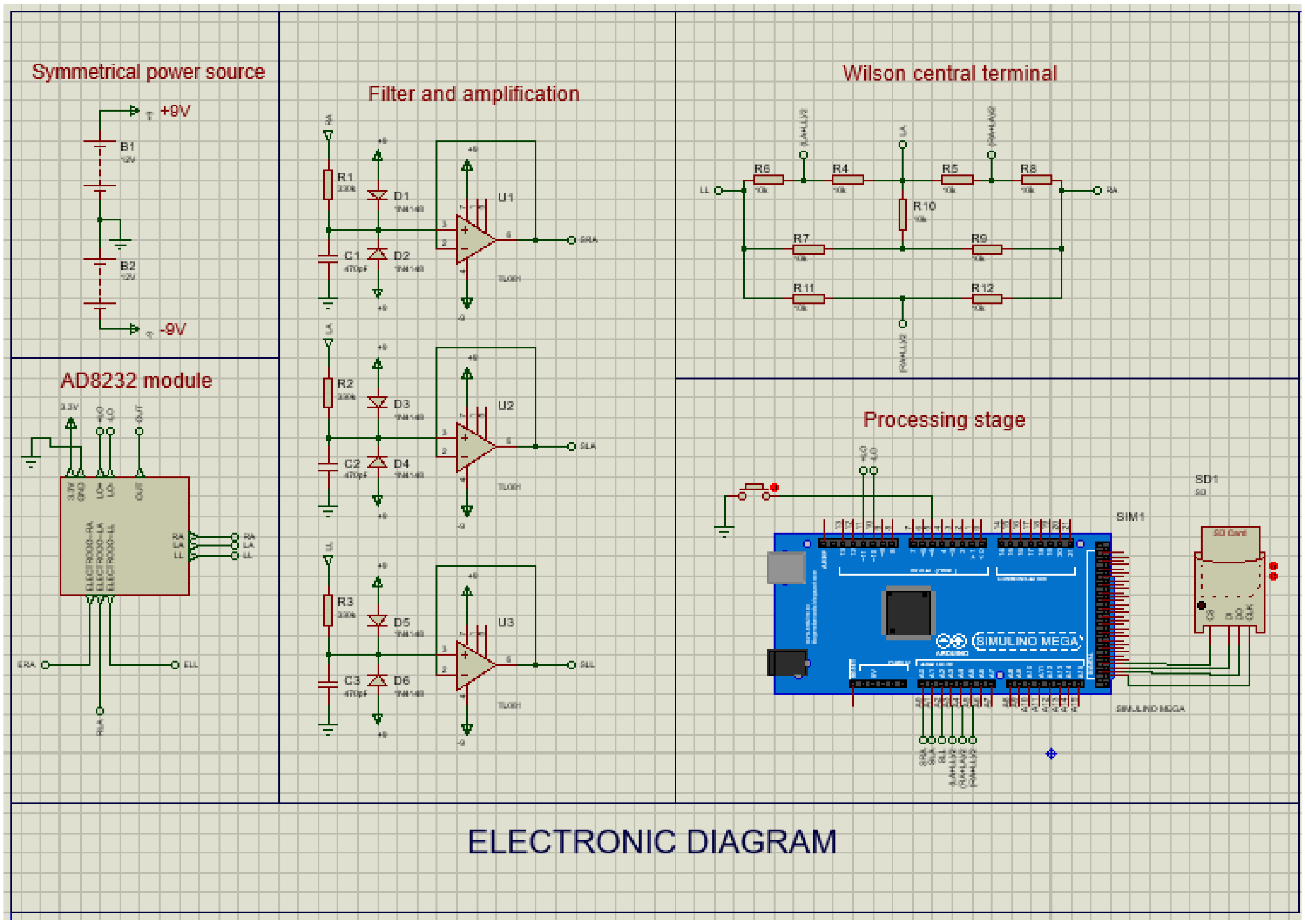


Figure 26: Complete electronic diagram of the prototype (Author).

As a complementary step, a case was made to cover all the electronic circuits. This casing was designed in the solidworks program to later be 3D printed and its shape can be seen in figure 27. The final design consists of 3 parts, the first is the one seen in figure 27, the second is the main cover and the third is the battery cover.

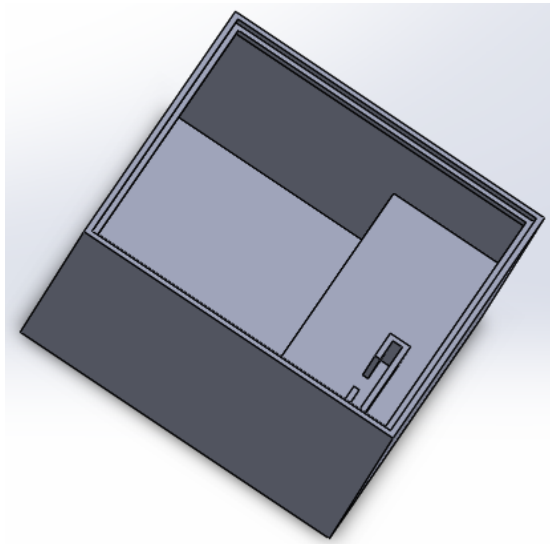


Figure 27: Design of the main part of the prototype case (Author).

Chapter 5: Results

The objective was to design a medical device capable of capturing cardiac signals, digitizing them and using a computer to process them to be graphed. The main objective was to obtain a system that obtains the signal with the least possible interference and noise so that it is a reliable replica of the heart signal.

There is a low cost portable device, easy to use, very accessible for the Ecuadorian budget, still under development; with just an Arduino board, a special purpose Sparkfun 8232 heart monitor board, an SD module, and programming code developed in Arduino platform and Python. In all electronic design, it is necessary to manufacture an enclosure in order to avoid problems due to electromagnetic compatibility, to make the system robust and easy to use. The final envelope of the current prototype can be seen in figure 28 and with a size of 11.9 cm x 11.5 cm x 5.6 cm. The final prototype has been named RECAHOLT.

Figure 28: Final assembly of prefabricated box (Author).

Taking the software into account, it was designed with the purpose of being user-friendly and so that any doctor can handle the program from a computer in an adequate and easy way. This software has a section for patient registration, where the doctor must enter the name, age and gender of the patient. The interface also has an "Open file and report generator" button which opens a pop-up window where you can choose the .csv file from the SD card, graphing the 6 leads and a resulting wave. The final interface is seen in Figure 29.

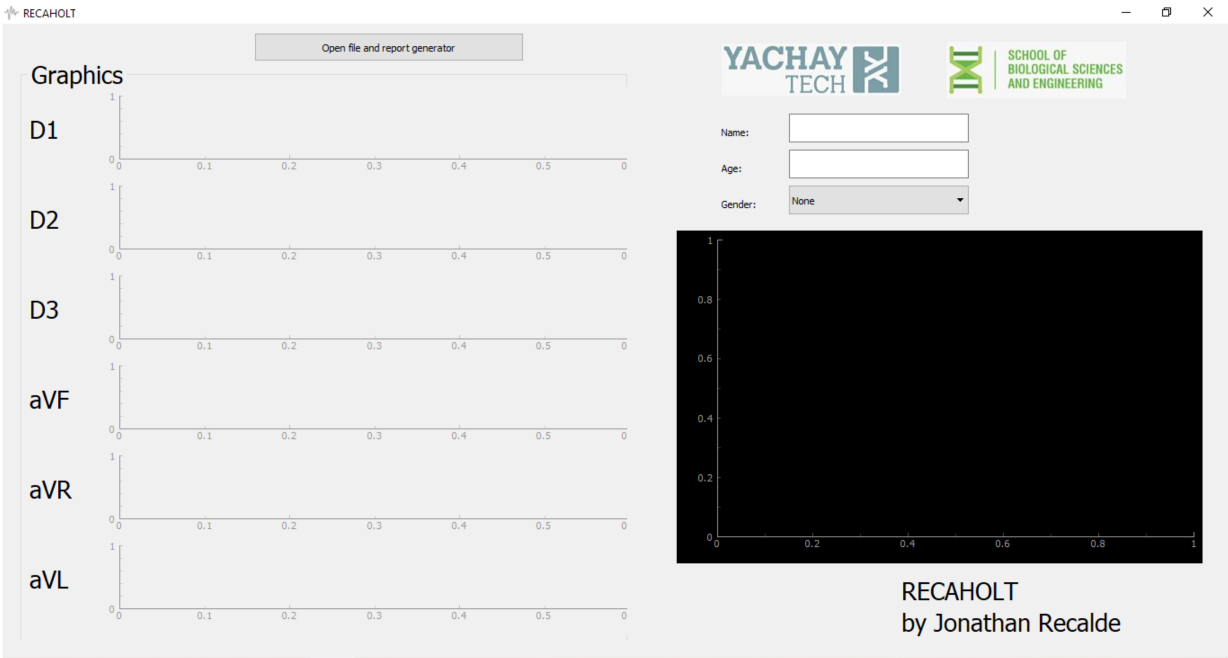


Figure 29: Final interface of the software (Author).

5.1. Obtaining the electrocardiographic signals

To verify that RECAHOLT is in perfect working order, a test was performed out with a healthy 25-year-old man, but before connecting the device to the patient, it is necessary to clean the patient's skin with alcohol, removing impurities such as sweat and fat to improve the quality of the exam.

Once the patient's skin is clean, the electrodes can be placed on the different points of the body such as the right arm, left arm, right leg and left leg. After placing the electrodes, the electrocardiographic cables are placed, finally connecting the patient with the measurement equipment. The recording of the electrocardiographic signals was taken in an interval of 4 minutes while the patient developed his activities normally and can be seen in Figures 30 and 31.

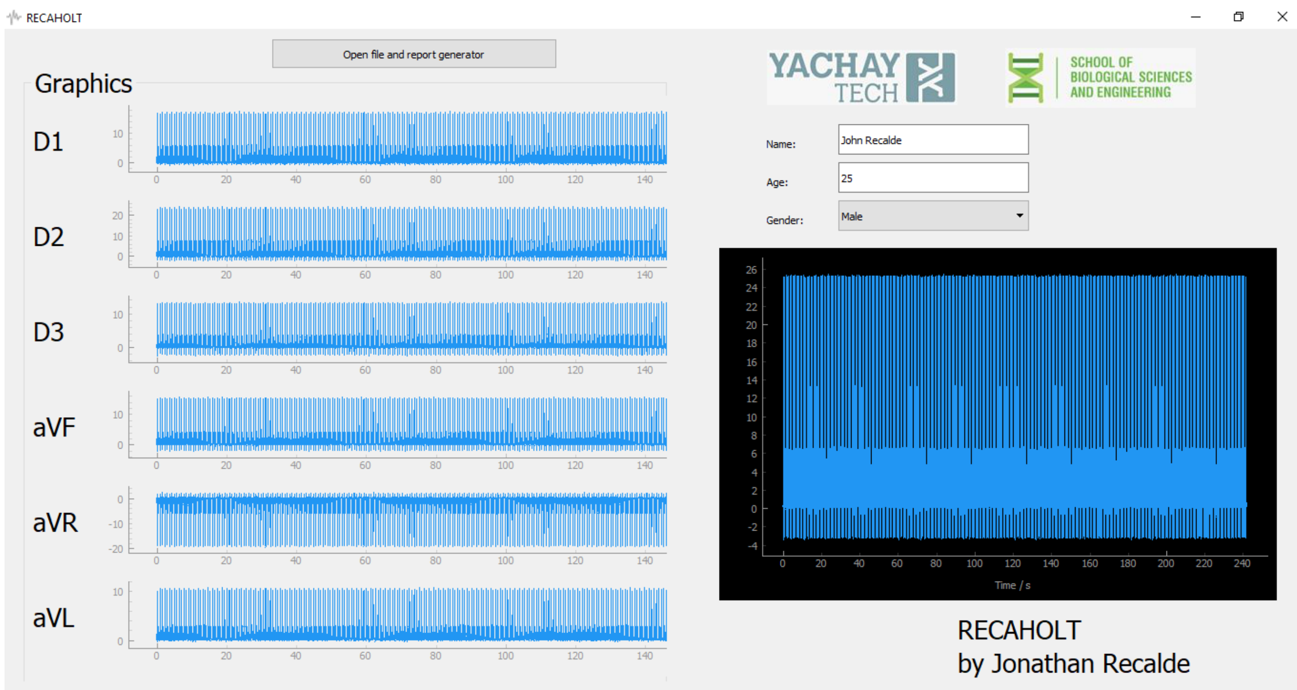


Figure 30: 100% amplified electrocardiographic signals (Author).

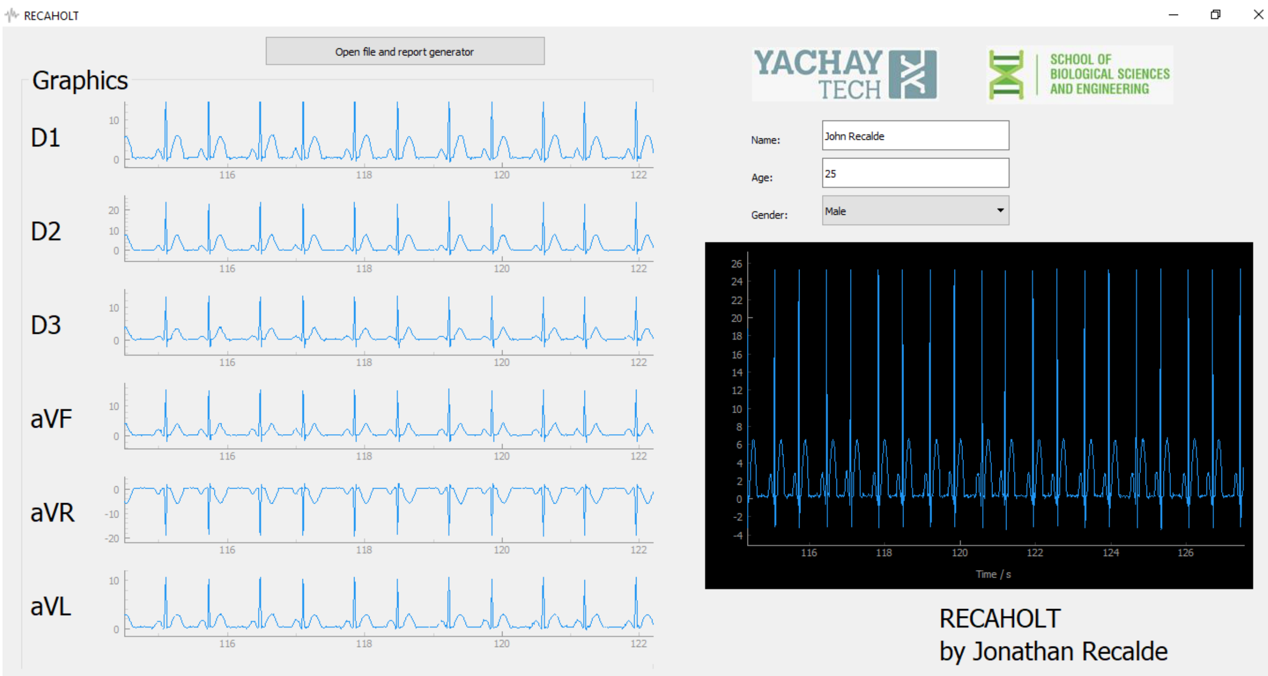
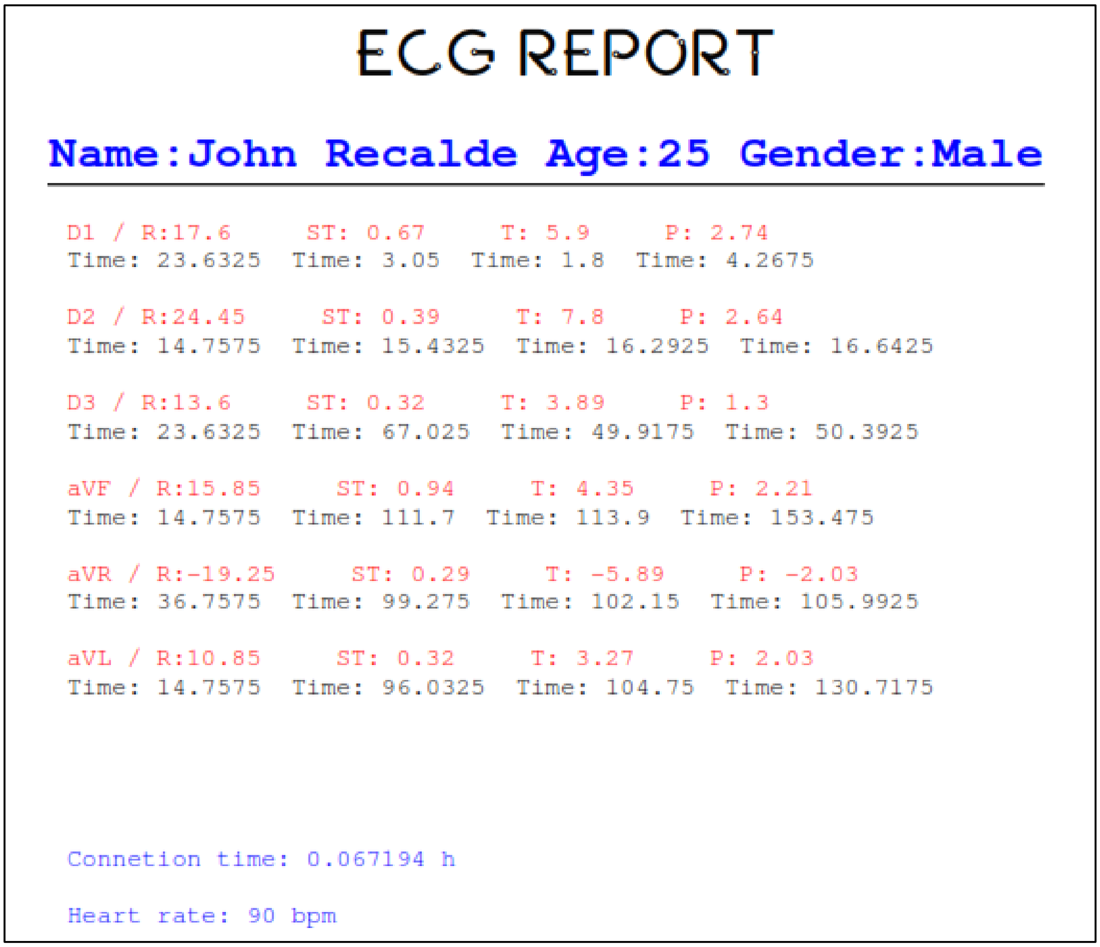


Figure 31: Electrocardiographic signals amplified at 5% on the x-axis (Author).

Obtained and stored the patient's signals, to show the results of the signals, a .pdf document is generated where we obtain the maximum peaks of the P, R, T waves and the ST segment and the times of each peak, as seen then.



ECG REPORT

Name:John Recalde Age:25 Gender:Male

D1 / R:17.6 ST: 0.67 T: 5.9 P: 2.74
Time: 23.6325 Time: 3.05 Time: 1.8 Time: 4.2675

D2 / R:24.45 ST: 0.39 T: 7.8 P: 2.64
Time: 14.7575 Time: 15.4325 Time: 16.2925 Time: 16.6425

D3 / R:13.6 ST: 0.32 T: 3.89 P: 1.3
Time: 23.6325 Time: 67.025 Time: 49.9175 Time: 50.3925

aVF / R:15.85 ST: 0.94 T: 4.35 P: 2.21
Time: 14.7575 Time: 111.7 Time: 113.9 Time: 153.475

aVR / R:-19.25 ST: 0.29 T: -5.89 P: -2.03
Time: 36.7575 Time: 99.275 Time: 102.15 Time: 105.9925

aVL / R:10.85 ST: 0.32 T: 3.27 P: 2.03
Time: 14.7575 Time: 96.0325 Time: 104.75 Time: 130.7175

Connetion time: 0.067194 h

Heart rate: 90 bpm

Figure 32: Report generated by the ECG signal (Author).

5.2. Cost of Implementation of the ECG system prototype

This project does not aim to carry out the market study, so a budget will be made as specific as possible within what can be covered. The cost of the Arduino board and modules is detailed in table 7, with their unit values.

This project does not aim to carry out the market study, so a budget will be made as specific as possible within what can be covered. The cost of the Arduino board and modules is detailed in table 7 with their final values.

Detail	Cost
ECG Kit AD8232	$ 25.00
Arduino Mega	$ 15.00
SD module	$ 4.00
16 Gb SD card	$ 5.00
9V batteries	$8.00
PLA filament	$ 22.00
TL081CP operational amplifier	$ 1.60
Various	$ 12.00
Workforce	$ 57.40
Total	$ 150.00

Table 7: Cost of the materials used to create RECAHOLT.

One of the main phases of a device development project is the development of the overall budget. When making a budget, you have to take many variables into account. Among all these, we must include the creation fees. The cost of RECAHOLT is relatively low in comparison with holters in the market when the cheapest is around 500 dollars and from time to time more expensive.

Taking into account the advantages to use RECAHOLT in comparison with other test to ischemia it is possible say that RECAHOLT is one of the most complete as is exposed below.

The most commonly used ischemia test is the stress or ergometry test: it involves walking the patient along an exercise belt similar to that of the gyms while the ECG is continuously recorded (49). The speed and the slope of the tape increase progressively and it is assessed if the patient has angina, how much effort is able to perform and if ECG alterations suggestive of ischemia appear (50).

In some patients in which a more accurate assessment is needed, an echocardiogram can also be done with the effort to find out if there are segmental contraction alterations. This test is called an exercise echocardiogram. When looking for an alteration that appears earlier in the ischemic cascade, the test is more sensitive and the echo allows a better locate the area that ischemic, since it stops thickening with the heartbeat (51).

In patients who cannot walk, pharmacological stress tests are used, in which drugs are used to increase the contractility and heart rate of the heart, which is controlled with the ECG and echocardiogram (52).

All these tests have proved to be ineffective for the detection of cardiac ischemia; however, they are the only tests we have at the moment. Most of these tests are not invasive however they have other contraindications for patients for example in the ergometry test which is the most common and effective there is a very large contraindication since there are cases in the United States and Spain where people have suffered sudden death in this test (53). Another example could be obtained from the pharmacological stress test since this is focused on people who cannot exercise, it was observed in tests carried out in Germany and Belgium that due to medications people could suffer from toxicity (53).

That is why the creation of a device that allows the efficient obtaining of the anomalies or alterations of the T wave and ST segment is of paramount importance since this would save 24-hour data in contrast to the approximately 3 minutes that the other tests last already mentioned, with the extra that the device is non-invasive.

Chapter 6: Conclusions and Future lines

The evolution of this project has followed a clear configuration, beginning with a bibliographic review, studying the attributes of the biological system to be measured and the electronic components of the system. Subsequently, the different phases of the project and how the design and manufacture of the device proceeded were discussed. Finally, the relevant validation test was carried out together with the final RECAHOLT budget.

This work ends with the following conclusions. When preparing a design and manufacturing project for a biomedical device, it is vital to be clear about the biological basis with which you are working. Without having a study base of how the physical variables that are collected are produced, it would not be possible to understand many of the decisions that are made throughout the design. This is why so much enhancement has been placed at the beginning of the project with a review of the biological part.

Regarding the electronic part, it can be said that the use of batteries and protection diodes help to provide patient safety, allowing the equipment to have the safety standards that the AAMI recommends for electrocardiographic equipment. As a personal experience, it has been gratifying to have treated a signal of such a small amplitude and with so much noise and to have come up with a promising result with which to work later.

Finally, it is important to highlight the cost of this project. Regardless of the fact that RECAHOLT's status does not allow it to be put into production and sale due to all the steps that remain to be carried out such as certifications, much more exhaustive validation tests, and other functionalities that remain to be added, the price of the system that has been made up to this point is approximately $ 150. This is a bit high price having bought the materials individually. Thus, if it were in production, all the materials could be obtained for a much more affordable price when purchased in greater quantity.

If we talk about possible future applications or future lines of work, it can be said that a complete electrocardiograph could be implemented that is carried out with 10 electrodes obtaining 12 leads. A next step to take from this project would be the transformation of the developed prototype into a marketable product.

Another possible improvement to the prototype would be the implementation of an LCD to display the waves in real time and a clock module to have a more accurate record of the moment in which the abnormalities of a wave occur.

Improve the amplification stage with the use of instrumentation amplifiers instead of the operational amplifiers used in the development of this project.

The final step in developing the proposal would be to test the product on patients. For this, it would be necessary to reach an agreement with a hospital or clinic, so that there they would ask the patients for their consent to carry out a study with this prototype.

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