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# ECG Detection Device Design and Manufacture with Interactive Interface and Portable Applicability for Massive Screening of Cardiovascular Diseases

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***Abstract*—Physical and psychological problems, and economic costs generated by Cardiovascular Diseases are affecting an important number of people around the world, and mainly in developing countries. Access to early detection and treatment is not common because of the scarcity of specialists and equipment, especially in rural areas. In order to address this problematic, an inexpensive portable Electrocardiograph device with Smartphone connectivity is proposed in this document. Firstly, an electronic circuit will be in charge of amplifying, filtering and sampling the Electrocardiogram (ECG) signal of a subject acquired by means of the use of Ag/AgCl electrodes. Then, the sampled data is transferred to an Android based system in order to be processed, displayed and analyzed on the application. Finally, the ECG time series can be printed or stored into a file which can be sent to a cardiologist. The resulting device is a less costly and easier to access gadget, which also provides a reliable signal resolution for a primary analysis of different diseases.**

***Keywords*— Electrocardiograph, ECG, DSP, Microcontroller, Smartphone, Heart Rate, 3D Printing, Biomedical Instrumentation, Portable Devices, Cardiovascular Diseases.***

## I. INTRODUCTION

Cardiac related diseases have been increasing in developing countries, as well as in the rest of the World, in the last few decades. Databases and studies have shown that cardiac related diseases are becoming the most relevant causes of death and medical treatment [12]. Even more, there is very low access to early diagnosis because of the cost of the equipment, and the lack of access to specialists. That is why in this paper we propose an economical yet effective way to manufacture Portable Electrocardiographs in order to enhance the access to early detection of cardiac conditions. This technological advancement can be achieved by exploiting the proliferation of electronic components, and emerging manufacturing techniques such as the 3D printing technology.

Risk factors of cardiac diseases include smoking, sedentary lifestyle, carbohydrate based diet, stress, hypertension, and metabolic diseases (like Diabetes and Hyperlipidemia); all of which have been increasingly affecting more and more people worldwide. In this context, the incidence of cardiac diseases has grown, and they are present now in younger people. Both male and female populations are exposed to the risk of a cardiac disease; thus, there is a detriment in the economy of young families. Plus, there is a high cost of rehabilitation for the health care system, in addition to a high cost of maintaining a cardiac elderly population for the social security system. Those Circumstances occur even though it is a well-known fact that early detection and treatment of cardiac diseases helps dramatically to improve life expectation and life conditions. That is why universalization of cardiac-condition-detection systems would generate a great impact on society.

We propose an economic yet reliable Electrocardiograph which would be well suited for screening of cardiac diseases in Primary Health Care Units; either mobile or static ones. Primary Health Care Units, which provides public health service, are in needs of different type of technologies with particular characteristics, like: reduced space for storage, small yet complete design, efficient and reliable operation, low power consumption, friendly operation, low cost, and compatibility with other technologies. Our Portable Electrocardiograph complies with the previous detailed needs and could be implemented as medical equipment for the field.

The current project is possible thanks to the technological advances in electronics, and the versatility of 3D printing based manufacturing. State of the art microcontrollers, operational amplifiers, and electronic components in general are getting smaller and smaller in size and price, while enhancing their performance dramatically. Consequently, the space and resources needed to develop a fully functional Portable Electrocardiograph can be reduced to the fraction of those of a commercial device. What is more, by using a 3D printing for making the case of the device would ease the manufacturing process. For instance, a single 3D printer can replace a number of other machines needed to produce the device's case. That case would be customizable, easy to reproduce, resistant, and light.

In addition, by exploiting the universalisation of consumer electronics, a Smartphone or tablet can be easily used for the visualization of the Electrocardiogram (ECG) output signal; taking away from the device one of the most expensive parts of a commercial ECG device which is the monitor. Thus, using and external screen would reduce both size and cost even more. That is why the proposed ECG device possesses a wireless connection to an Android based system, which can also be incorporated with an algorithm which helps with signal processing; providing a most detailed signal, carrying better information.

In the following sections, the problematic is analyzed deeply and each of the developing stages of the design of the ECG are described.

## II. Problem Description

The problematic for this project contains both the social problem generated by the incidence of Cardiovascular Diseases (CVD), and the engineering problem of acquiring data from the human body in order for an early detection of CVD. In this section both issues will be discussed.

### *A. Social Problem Review*

"Cardiovascular Diseases (CVD) generally refers to conditions that involve narrowed or blocked blood vessels that can lead to a heart attack, chest pain (angina) or stroke" [16]. In Ecuador, as a developing country, CVD are responsible for the 20% and 21% of premature deaths in males and females respectively [19]. According to the World Health Organization (WHO), 17.3 Millions of people died in 2008 because of CVD, where 37% of the deaths occurred in developing countries [17, 29]. Thus, Cardiovascular Diseases are a social problem that affects a large number of people.

Physical and psychological problems generated in people suffering from cardiac disease are important issues to take into consideration. Particularly, their life quality, which depends on the well-being and satisfaction of a person, is drastically affected [24]. When diagnosed with a heart disease, a person will have to make some changes in their lifestyle, such as: having a healthy diet, doing more exercise, and quitting smoking [27]. In many cases, those changes would affect emotionally a person more than the disease itself, and lead them to anxiety, blame, discomfort and stress. Psychological problems are even worse for people in a chronic state of the disease. They commonly experiment negative emotions like fear, rage, anxiety, and denial[24]. The last one is particularly dangerous because it would obstruct proper treatment [24].

The economic cost of treating CVD patients, along with other indirect costs, is an important problem generated by this disease. The cost of cardiovascular disease does not only come from the direct cost of treating a patient, but also from the social cost of productivity loss, absenteeism, and quality of life [1]. A study in the UK showed that the CVD's burden to that county's economy was of £29.1 billion in 2004 [20]. Health care accounted for the 60% of the £29.1 billion, informal care related expenses accounted for the 17%, and the cost of productivity losses accounted for the final 23% [20]. Therefore, direct and indirect costs of CVD represent a great loss in the economy of a country.

One of the reasons why Cardiovascular Diseases are not detected and treated in time is the scarcity of Physicians, and Specialists; especially among rural areas. According to WHO, the minimum number of health care professionals per 10 000 habitants is 23, but only 5 of the 49 low-income countries meet the threshold[28]. In countries like Ecuador, that threshold is surpassed in its three main cities; whereas, in other cities the number of physicians is far to meet the standard [3]. The situation is even worse while analyzing the number of specialists like cardiologists [3]. That is why early detection of CVD results a difficult task in developing countries.

In order to detect a heart disease, a number of preliminary tests can be done. Most of them involve physical examination and history checking. However, CVD are usually asymptomatic, so more meticulous tests have to be performed. They include: blood pressure analysis, pulse contour analysis, microalbuminuria, Ankle/brachial index, Electrocardiogram, Left ventricular ultrasound, Plasma B-type peptide (BNP) concentration, etc. It is important to detect an arterial or cardiac disease in an early stage in order to delay or prevent the disease to progress [10].

### *B. Engineering Problem Review*

The heart is one of the most important organs in the human body. It generates the blood pressure necessary to drive oxygen to every cell and to eliminate toxins from all the human systems. By studying the behavior of the heart, the performance of this biological mechanism can be tested, and heart pathologies can be detected.

In order to capture physiological characteristics of the heart for diagnosis or monitoring proposes, electrocardiography is one of the most commonly used methods. ECG is a voltage signal measured across the body that carries information of how the heart is working. In fact, it is an amalgamation of signals generated from the time the Sinoatrial (SA) node triggers atrial contraction, until the time of ventricular contraction and relaxation [22]. Analyzing the characteristics of this signal, a physician can accurately diagnose a number of heart conditions. Fig. 1a shows a typical EEG signal and its most prominent characteristics, which are the P, Q, R, S, and T pecks.

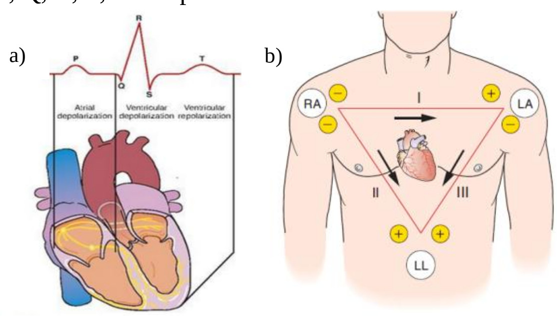


Fig. 1. a) ECG signal and its correlation with heart activity. b) Standard leads I, II, and III. Images from [12] Example of a figure caption.

ECG signal is acquired using electrodes that help in the transduction of the body's biopotentials into an electrical current. This process is needed because biopotentials occurs in terms of ions, while electrical current is the flow of electrons. Fig. 1b shows the standard three-lead system used in this signal acquisition process. The recorded ECG signal is in the range of 0.05 to 3 millivolts, and is composed of frequencies from 0.01 to 100 Hz. However, the most important characteristics of the ECG (including P-Q-R-S-T peaks) can be observed in the band of 0.67 to 40Hz [13].

The Electrocardiogram is interpreted by a physician or technician in order to determine any Cardiovascular Disease. Many key factors are analyzed in the detection of a CVD. The first one is the shape of the ECG wave; specifically, missing or abnormal peaks. The second one is the time period or intervals between the different peaks PQRST. ECG analysis

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alone can lead to detect heart conditions such as: atrial arrhythmias, ventricular arrhythmias, tachycardia, fibrillation, myocardial infarction, pacemaker failure, etc [22].

Another analysis, called Heart Rate Variability (HRV), is performed in the frequency domain. Heart Rate, determined by the inverse of the time between R waves, carries vital information of the heart´s behavior and can lead to important conclusions about the well-being of the patient. For instance, HRV analysis can determine Sympathetic and Parasympathetic activity of the Autonomous Nervous System, sleep staging, blood pressure, myocardial infarction, cardiac arrhythmia, drug usage, diabetes, and the performance of the subjects in sport activities [21, 23].

All in all, acquisition and analysis of the ECG is primordial to study the functioning of the heart, in order to detect diverse pathologies, and even to measure body performance and healthiness.

## III. Device Design

In order to address the problematic described in section 2, a portable Electrocardiograph with mobile phone integration and low cost attainability is proposed. This device can be easily manufactured and distributed to Primary Health Care Centers in order to improve accessibility to early treatment. For instance, network connectivity capabilities can be exploited so that cardiologists in main cities can receive ECG information of patients in rural areas. Although many previous efforts have being made in order to design and develop electrocardiographs with Smartphone connectivity [7, 8, 9, 11], the present work focuses on the reduction of costs in the manufacturing process, and the use of algorithms embedded in the mobile phone's application. The application will allow the user not only to capture, explore and measure the EGC, but also to obtain useful indices of the Heart Rate Variation analysis.

### *A. Hardware Design*

Signal is acquired from the patient using Ag/AgCl electrodes. They have been chosen due to the advantage that wet type electrodes introduce less electrical noise than other type of electrodes like the capacitive coupled ones [7].Only one channel of ECG is obtained by the device, either Lead I or lead II or Lead III; data which is enough for a preliminary analysis [22]. As a measure of protection, a 39kΩ resistor was added in series with each electrode. These resistors prevent a faulty current to cause any harm in the subject.

Due to the fact that ECG signal is in the range of 0.05 to 3 millivolts, and in order to sample and analyze the signal with greater accuracy, its amplitude should be at least three orders of magnitude greater. That is why an analogue amplification circuit is needed. Such amplifier has to work with differential mode because it helps reducing the common mode noise [14]. Also, ECG is contaminated by noise coming from the EMG, 50Hz-60Hz power supply, electro-magnetic induced noise, etc. That is why a filtering process is also needed to eliminate undesired frequencies. A Butterworth filter is the best option for this task, because it avoids phase shifting in the frequency domain, and it generates a sharp enough frequency cut for this application. Filter design methodology used is described by Horwitz et al. [18].

Prototype's implemented circuit, which complies with above requirements, is shown on Fig. 2 The first stage is an Instrumentation Amplifier which is designed with a gain of 1000 times. In cascade with the former is a 2-pole high-pass Butterworth filter with a cutoff frequency of 0.5Hz. In the next stage, there is a 2-pole low-pass Butterworth filter which cutoff frequency is of 40Hz. In this way, the design is optimized for the minimum amplification and bandwidth requirements; thus, the reduction of the costs of the elements needed to implement the circuit is considerable.

The energy needed to power the circuitry comes from two 9V rechargeable batteries. They are used as the positive and negative sources needed for all the operational amplifiers. Using two batteries has the advantage of a longer operative period of the device.

The final stage of the circuit is in charge of conditioning the signal from the filter (-9 to 9 volts) so that a microcontroller can handle it (0 to 5V). This circuit also helps on the regulation of the baseline of the ECG signal by means of the use of a potentiometer.

### *B. Signal Digitalization*

After achieving a clean analogical ECG signal, it is sampled using an ATmega328P microcontroller. This microcontroller has 2kbytes of SRAM memory, 8 channels of 10 bit-Analogue to Digital Converters (ADC), and is capable of working with a clock frequency of 16MHz. The prototype samples the signal using 7 bits of resolution at the rate of100 samples per second. Some studies have shown that Heart Rate analysis is not affected by sampling frequencies as low as 100 Hz, in comparison to sampling at 200 and 500 Hz [25];and even more, a sampling rate of 62.5 Hz is considered a good frequency for Electrogram delineation [5]. Therefore, the proposed device would be appropriate for monitoring and screening purposes.

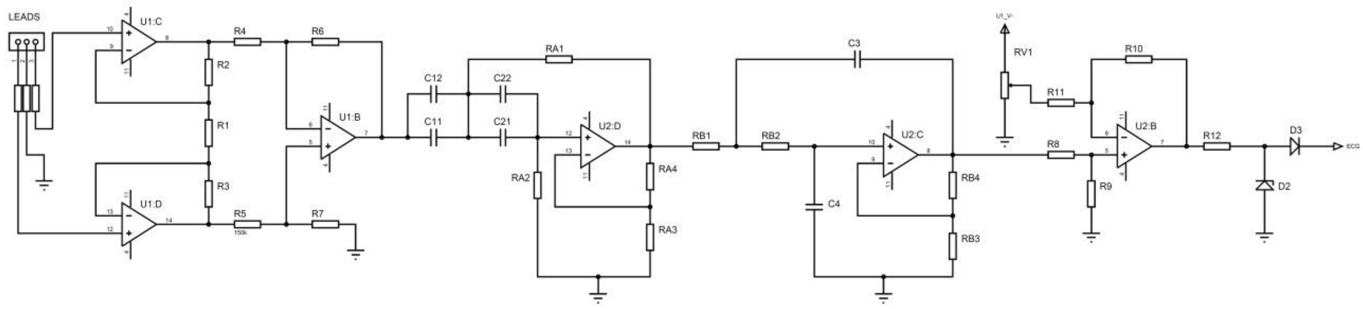


Fig. 2. Analogical Circuit of the Device

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### *C. Smartphone Application*

The sampled signal is sent over Bluetooth from the microcontroller with the standard baud-rate of 9600 bps. On the other side of the communication, the Smartphone receives the ECG signal as a stream of data to be displayed and processed. At this point, a user friendly interface helps the user connect the device, start recording, visualize and analyze the ECG signal of the patient. Touch screen capabilities are exploited to allow the user explore the entire ECG signal recorded, and measure time and amplitude intervals of interest using cursors. Fig. 3 shows the user interface, a sampled ECG, and how a time interval is measured with the "Cursors" tool.

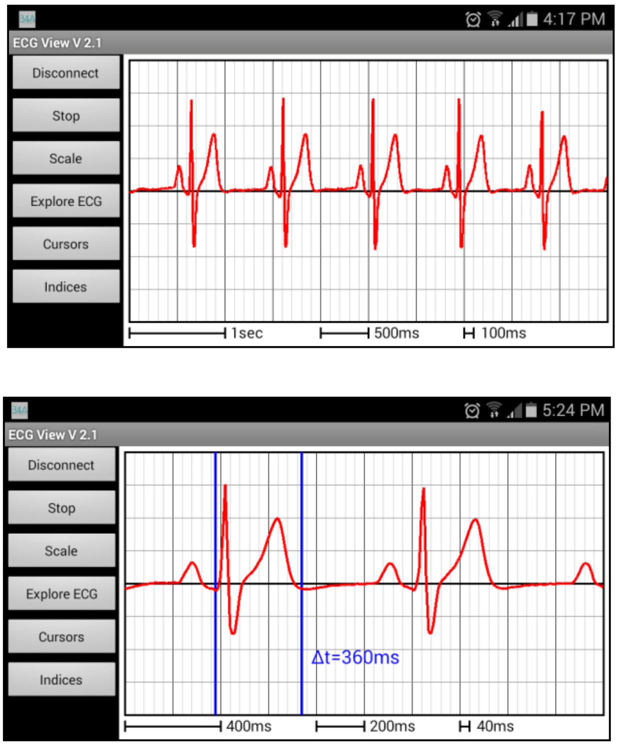


Fig. 3. Up: 5 seconds of ECG sampled with the device using lead II. Down: Use of "Cursors" tool to measure the QT interval.

Another functionality included in the application is that the recorded ECG signal is processed in order to generate Heart Rate Variability (HRV) indices. Since current Smartphone operate in the order of Gigahertz, Digital Signal Processing(DSP) can easily be done. A number of different techniques have been developed to detect the QRS complex of the ECG[2, 26], most of them attempt to detect the great slopes within that interval. One of the most efficient is the one described on equation 1 [26].

$$z(n) = 2x(n+2) + x(n+1) - x(n-1) - 2x(n-2) \quad (1)$$

After applying equation 1 over the ECG data, the Inter-Beat-Interval (IBI) time series is obtained. Each point of the IBI signal represents the time between a QRS complex and the next one. Inverting each point on the IBI, we obtain the Heart Rate time series [21]. Then, the algorithm embedded in the Android device computes several indexes of the HRV, which are: SDNN, SENN, SDSD, RMSSD, NN50%, and pNN50%;as described by Acharya et al.[21]

### *D. Case Design and 3D Printing*

The final stage in the design process is the creation of the device's case. For that matter, a 3D printer design was used, Fig. 4. Firstly, a 3D model of the case is created using Computer Assisted Design (CAD) software in a computer. This model has to account for the shape of the Printed Circuit Board (PCB), as well as the electrode leads, and the batteries. Secondly, the model is exported to a 3D printing software, where it is sliced by layers. Finally, the 3D printer forms the object by adding layer after layer of ABS plastic, giving the case the designed shape. As a result of this process, the case for the Electrocardiograph is manufactured with a precision of 0.1mm and the harshness related to the material used, ABS or PBC plastic, and to its walls' thickness [15]. The advantage of the process of using 3D printing technology is the small investment in machinery, the light weight of the product, as well as the ease to customize shape, color, and labels for every customer.

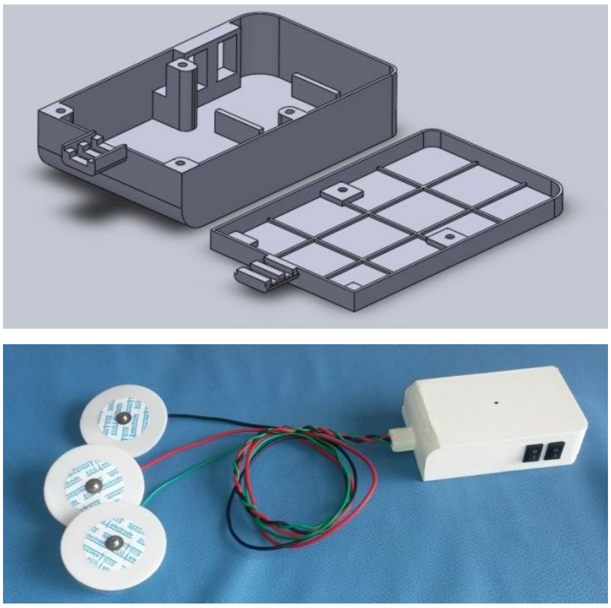

Fig. 4. Up: 3D design of the Cast. Down: 3D Printed Cast

## IV. RESULTS

### *A. Electrical Tests*

The In order to verify that all the design characteristics were met, the final product was tested under different parameters for each of its stages. The device was tested using two different experiments. In the first experiment differential amplifier Gain and Overall Gain were tested by measuring the input and output peak-to-peak voltages for a 20Hz square wave input. For the second experiment, cut-off frequencies of the filter were determined by applying a square wave input with variable frequency, and measuring the peak-to-peak voltage in the output of the filter.

Fig. 5 shows the peak-to-peak voltage of this experiment for frequencies between 0.1Hz and 200Hz.

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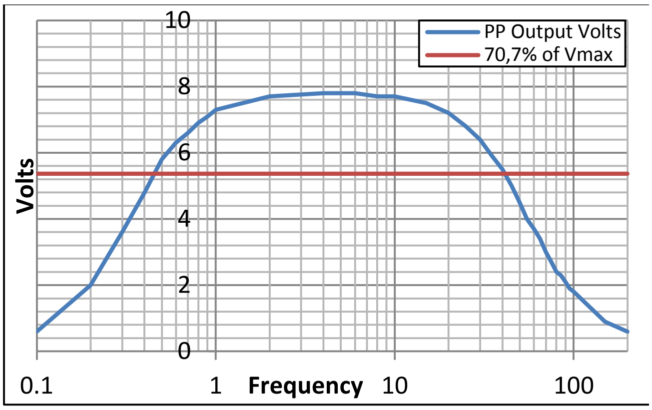


Fig. 5. Band-pass behavior of the Analogical Circuit

Bandwidth limits are measured in the 3dB Gain reduction zone, which corresponds of a 70.7% of the maximum output amplitude [4]. The results of both experiments can be seen in Error! Reference source not found..

TABLE I. EXPERIMENTAL CHARACTERISTICS OF ANALOGICAL CIRCUIT

| Amplification Stage | |
|---|---|
| Gain Value: | 1230 ± 29 |
| Filtering Stage | |
| High-Pass Cut-Off Frequency: | 0.43Hz |
| Low-Pass Cut-Off Frequency: | 40Hz |
| Conditioning Stage | |
| Overall System Gain: | 1396 ± 17 |
| Offset Value: | 1.61 V |

It can be seen that all these values are generated near the desired ECG theoretical values. This means that the final device will perform according to the specifications of an ECG monitoring device.

### *B. Experimental Comparison of ECG Devices*

Medical Electrocardiograms have been developed with different characteristics which allow Doctors and Specialists to analyze the normal behavior of the heart and in specific cases to detect different type of diseases. Under this perspective, a comparison test between our device and medical certified Electrocardiographs used in a medical facility has been performed. Table 2 show us the result of the comparison of the main operation, ECG signal acquisition, interface ergonomic design, and electrical characteristics between the medical Electrocardiograph Schiller AT-1, the medical Electrocardiograph Welch Allyn CP 150 and our Electrocardiograph device (Prototype).

Data in Table 2 were obtained from the respective manuals of both commercial devices; and from electrical and physical tests on the prototype. The results present different physical aspects to consider. Firstly, the volume of our device is 18 times smaller than that of Schiller AT-1, and 80 times smaller than that of Welch Allyn CP 150. A similar comparison is encountered in the weight parameter among the three devices. Secondly, another main characteristic of our device is its power consumption; which is lower than the other two models. Even though it is portable, it will allow a continuous work of 5.57 hours, and by replacing its interchangeable batteries, it will continue working for even more time. A final physical aspect is its output. By having connectivity to an android device, our device has the advantage of possessing all the three outputs: on-screen view, paper, and digital file. The other devices only have one or two of them.

The next aspect to consider is that for our device, the sampling frequency and the frequency response are reduced. Although it would mean that our device is performing with lower parameters, as explained before, the sampling frequency will not affect the degree of reliability and specificity of the ECG signal for a preliminary medical analysis. Also, the frequency response will allow us to directly obtain the ECG signal within its frequency range for behavioral response. Both considerations remark our device as a technology created for screening purposes of a massive part of the population.

TABLE II. CHARACTERISTICS COMPARISON OF THE PROPOSED DEVICE WITH DIFFERENT MEDICAL ELECTROCARDIOGRAPHS

| | Prototype | Schiller AT-1 | Welch Allyn CP 150 |
|---|---|---|---|
| Dimensions | 120x64x30mm | 290x210x69mm | 381x358x136mm |
| Weight | 0.2kg | 2.9kg | 5.2kg |
| Battery Characteristics | 18V, 600mAh | 12V, 4,67Ah | 10.8V, 6.75Ah |
| Power Consumption | 1.94 W | 28 VA | 9.11W |
| Continuous Operation | 5.57h | 2h | 8h |
| Number of Channels | 1 | 3 | 12 |
| Frequency Response | 0.43 - 40Hz | 0.05 - 150Hz | 0.3 - 150Hz |
| Sampling Frequency | 100Hz | 1000Hz | 1000Hz |
| Digital Resolution | 32µV | 5µV | 5µV |
| Output | Screen / Digital File / Paper | Paper | Screen / Paper |
| Commercial Cost | $52.73 | $610.25 | $995.00 |

Finally, if we review the commercial costs of the devices, the profitability of acquiring our device is high. The production costs are mainly given by the cost of electronic components: $39.59, and the cost of ABS plastic for the 3D printed case: $4,35. The last value comes from the amount of ABS plastic needed, which is of 13.6m, and the average commercial price per meter is $0.32. The commercial value was calculated by adding a 20% of profitability; therefore, the commercial value is of $52.73. This value is less than a tenth of the cost of a Schiller AT-1, and a twentieth of that of a Welch Allyn CP 150.

## V. Discussion

The device presented in this document was designed to comply with all requirements (such as gain, bandwidth, and sampling rate) necessary to acquire and sample an ECG signal that is useful for a preliminary examination. Thus, the elements needed and the manufacturing process were optimized; In other words, the costs were reduced. Under that perspective, the capability of reproducing this device and distributing it among the people who need it increase. Although Cohn et al. suggests ECG as a diagnosis test for advanced cases only [10]; this device would make it possible to be used as a regular test in Primary Health Care Units even in rural areas. In other words, access to this general diagnosis device will enhance the chance of CVD early detection, improve life conditions of the population, and reduce the economical direct and indirect costs of this disease.

This device is accessible by any user due to it has been created to fulfill two characteristics: it must not be expensive and its interface must be user friendly. Complexity of use is eliminated while ECG acquisition: efficiency and reliability, is maintained according to general parameters. Within the android interface, the environment was designed to provide the user with all the tools to present and analyze the ECG signal; furthermore, specific variables and values used in ECG and HRV data analysis are incorporated so that a diagnosis could be given by the doctor. Additionally, Smartphone connectivity, along with internet accessibility in medical facilities (enhanced by project like that of Bastidas et al. [6]) will make it possible to leave behind the need for a local diagnosis.

The major implication of the connectivity of this device is the creation of a cardiology center, were ECG signals are received and analyzed, and patients from different areas are diagnosed [7]. That center would then have a database were all the Electrocardiograms are stored for future analyses or researches [7]. Also, the economical reduced value of the device enhances research activities which could be performed under a considerable big population, with personal Electrocardiograms for each subject. Thus, costs will be reduced for different applications and specific information could be acquired.

Given the ease of production of this device, it can be also used in other sorts of applications. For instance it could be a didactical learning tool to cardiology students. It could also be used by professional athletes to monitor their hearth activity and design the best training strategy to improve their performance [21].

Future expansion of this technology includes the miniaturization of the PCB and the selection of more efficient batteries. Miniaturization must consider the behavior of electronic components and conductors at micro levels, like the generation of magnetic fields in lines. Also, the design optimization would lead to a minimization in energy consumption and to the use of different type of batteries: more compact and with reduced size.

## VI. Conclusions

The proposed device was designed according to ECG monitoring characteristics, and its operability and electrical characteristics were tested. Its interoperability issues were overcome and the final product resulted in a portable complex device of easy operation and high performance.

Filtering and amplification stages gave us a complete range of the desired signal spectrum. And even more, the obtained signal could be used to generate derivate variables used on the medical field on ECG signal analysis.

The use of a Smartphone enhanced the design by providing the device with an interactive interface and with a processor of high capabilities, leading to the possibility of data post processing and signal sketching (with graphical signal analysis).

The final product is applicable to the focused target and it could benefit in a great scope the use of medical instrumentation in the prevention, analysis and treatment of cardiovascular diseases and other related diseases.

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