Real-time cardiac monitoring through the development of a smart holter to detect pathologies through an expert algorithm

Daniel Carreres-Prieto, Fernando Cerdán-Cartagena, Juan Suardiaz-Muro, Andrés Cabrera-Lozoya

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Abstract

Background: Constant monitoring of the heart's state is essential for the early detection of pathologies. In the past, this analysis could only be carried out in hospitals, using sophisticated equipment handled by qualified staff. Today there is a wide range of portable monitoring devices (Holters) on the market but with a set of drawbacks (low number of leads supported and their low signal quality among others) that make it difficult to consider them as a viable replacement for the equipment used in medical practice

Objective: This article describes the process of designing and implementing a Smart Holter able to record up to six leads at the same time, providing a signal quality comparable to the equipment used in medical practice, but with the dimensions, consumption and ease of use of portable devices. We also describe the workings of the expert algorithm for detecting cardiac anomalies in real time monitoring, which is embedded in the device itself, and which is capable of detecting tachycardia, bradycardia, ischemia and atrial fibrillation episodes with a high success rate.

Methods: The hardware developed, performs the acquisition of 6 leads simultaneously, with a signal quality comparable to that of equipment used in medical practice. Each of the signals are processed by the algorithm described in this paper. This algorithm decomposes each lead into each heartbeat and extracts each of the segments that compose it (QRS complex) as well as a series of additional parameters. Based on the duration, amplitude and different thresholds, the system is able to detect with a high success rate, the existence of a certain cardiac pathology.

Results: Performance evaluation shows the capacity of the Smart Holter devised to offer a high quality signal that combined with an embedded expert algorithm is capable of detecting tachycardia, bradycardia, ischemia and atrial fibrillation episodes in real time with a high success rate.

Conclusions: Development presented in this paper offers better characteristics, because it resolves a wide range of drawbacks inherent in that type of portable medical equipment, mainly in terms of signal quality. One aspect to highlight is the improvement in noise immunity of the equipment. Although it is not possible to compensate large artefacts produced while playing sports, which still remains a challenge for current monitoring systems, an important step has been taken in the right direction to achieve even greater attenuation in the future, through the use of dynamic filtering systems controlled digitally, unlike the systems currently present on the market.

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Real-time cardiac monitoring through the development of a smart holter to detect pathologies through an expert algorithm

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Abstract

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Keywords: ECG algorithm; holter; cardiac monitoring; cardiac abnormalities algorithm.

1. Introduction

According to data from the World Health Organization (WHO), cardiovascular diseases are the main cause of death in the world. Data from 2015 conclude that there were 17.5 million deaths as a result of this cause, which represents 31% of all deaths in the world. Of these, 7.4 million were due to coronary heart disease and 6.7 million were due to cerebral vascular attacks [1].

More than three-quarters of the deaths from cardiovascular disease took place in countries with a medium or low per capita income, where there is limited or poor access to health systems.

For people with cardiovascular illnesses or those who are at high risk of cardiovascular disease due to the presence of one or more risk factors, such as high blood pressure, diabetes, hyperlipidemia, or confirmed heart disease, early detection and treatment are essential in order to increase the chances of survival and of preventing a worsening of the pathology [2].

However, the associated cost of continuously monitoring a patient means that many health systems cannot afford to do so and therefore its use is limited to patients with more serious pathologies or with greater purchasing power, making early detection within certain population groups impossible.

There is a great range of devices on the market to measure the user's cardiac activity in real time; they can be grouped into two categories: those devices used by medical staff in hospitals for the detection of cardiac anomalies; and portable devices designed to be used on the sports field or for home monitoring.

Hospitals use accurate medical equipment which is very expensive, large and difficult to use, such as the electrocardiograph SONOECG12000 [3]; it is widely used in hospitals and portable care units, and comes at a cost of around $30,000. The characteristics of this equipment mean that it can only be operated by clinical staff, who are responsible for placing the electrodes on the patient in the correct positions. In addition, that equipment requires the patient to be in a lying position without moving throughout the monitoring process in order to avoid causing interference that may affect the equipment's operation, so it cannot be used to monitor a patient while carrying out any physical activity.

In contrast, portable monitoring equipment (Holters) are focused on use outside the hospital setting, and are normally used for sports purposes or monitoring from home. However, equipment marketed for these purposes often presents problems relating to signal quality and the number of cardiac leads supported.

The common denominator of all these devices is the fact that they are focused on the user's comfort. For that reason, the number of supported leads is in most cases limited to between one and three, as is the case with the device shown in [4], which can only measure a single lead. This may be suitable for sports purposes, where it is only necessary to know the heart rate and waveform of the signal (typically D1), but is clinically completely insufficient.

Leaving aside the number of leads supported, the main problem of that type of devices is their inability to provide a response which is comparable to that obtained by devices used in medical

practice due to low acquisition frequencies (between 50 and 250Hz), as well as low noise immunity and inefficient signal filtering. These limitations make the detection of certain pathologies unfeasible [5] and therefore unsuitable for these purposes.

This paper focuses on the process of designing and deploying a Smart Holter that solves the current problems of the portable monitoring systems present in the market, whist describing the technological solutions adopted in order to provide a basis for the development of new equipment.

The Smart Holter is able to register up to six user-selectable cardiac leads simultaneously, as well as the acquisition of up to ten configurable physical parameters through the connection of external sensors, in order to know the physical changes that take place prior to and throughout any pathology.

The development stands out for achieving a signal quality comparable to that obtained by equipment for clinical use, but with the dimensions, consumption and ease of use of portable equipment.

In addition, the Smart Holter has been designed to achieve a noise immunity higher than equipment currently present in the market, through a dynamic compensation of small artefacts caused by blows to the cables and electrodes, an aspect that other equipment is unable to solve.

Finally, the Smart Holter implements an algorithm embedded into the device itself for the analysis and detection of cardiac anomalies, which allows it to process the signals in search of any pathology and to provide a tool for better detection and prevention of pathologies related to the heart.

The rest of the article has been organised as follows:

Section two is focused on an analysis of the main Holters present in the market, describing their shortcomings and limitations.

Section three describes the features of the Smart Holter developed, showing how the problems presented in section two are solved by the device developed and, at the same time describing the new features introduced by the equipment

Section four focuses on the description of the "Acquisition Block", which is responsible for the recovery and the signal conditioning of each of the six leads supported from an electronic point of view, describing in detail the design considerations carried out in order to solve the problems described in section two, as well as the improvements introduced with regard to the commercial equipment previously described

Section five describes the "Signal Processing Block", which is responsible for analysing both the waveforms from each of the six cardiac leads as well as the data from external sensors that provide information about physical parameters such as temperature or humidity.

Section six describes the algorithm for detecting cardiac pathologies, describing the mechanism and criteria used to detect each of the waves that make up an ECG, as well as the mechanisms used to determine the existence of pathologies such as tachycardia, bradycardia, ischemia and atrial fibrillation. This section is focused on providing the reader with a design guide for the development of a detection algorithm based on the one described in this paper.

In section seven, the results provided by the Smart Holter are shown for each of the supported leads, in order to show the high signal quality and adequacy of the results, as well as the performance of the cardiac anomaly detection algorithm.

And finally, the conclusions reached from the development of the Smart Holter are detailed in section eight.

2. Problematic of current Holters

An in-depth analysis of the portable monitoring systems currently available on the market is vital to know their deficiencies and limitations.
A wide range of commercial equipment is on the market aimed at monitoring the user for sports and/ or clinical purposes, providing both information relating to the heart, as well as additional parameters such as the user's posture, temperature or respiratory rate.
As there are so many devices on the market, the analysis has focused on those with the greatest commercial development or which have introduced some outstanding novelty with respect to traditional systems.
One of these devices is the Holter Minder™ [6], developed by the company NUUBO™, and which is capable of acquiring up to a maximum of three predefined leads: V1, V5 and D1, although the electrodes are placed outside the clinical standard. This device requires the use of a Smartphone to enable the cardiac activity data to be gathered, thus making it necessary for the user to have certain digital skills to manage it.
The need for a Smartphone in order to be able to use the equipment, implies an obstacle for certain more elderly population groups, who are less versed in new technologies, yet these are in fact, the main target public for this type of systems.
The Holter Minder™ is marketed with a textile that contains the electrodes for greater user comfort; however, the electrodes are not located in the same positions as in medical practice, causing the waveforms obtained to differ from those obtained by equipment for clinical use [4].
Another device worth mentioning is the Holter called "Smartheart Pro" [7], which has been designed to be placed on the chest in a similar way to equipment for sports purposes, with the difference that it can acquire twelve cardiac leads. The main problem with this device is the fact that the signals obtained are calculated using statistical correlations from the biopotential of an area close to the heart. This method of working reduces the number of electrodes, thus improving the user experience, albeit at the cost of a worse signal quality, since the data recovered are the result of mathematical approximations and therefore, the results provided cannot be compared to those obtained by precision medical equipment.
Monitoring of all leads used in medical practice involves the use of ten electrodes connected to the user's chest and limbs, which can make it difficult to use because of the complexity of placing the electrodes. Systems such as ECGraph [8] solve this problem. This Holter is based on a band with electrodes that simplifies their positioning. However, despite being able to monitor all the leads used in medical practice, there is no information available regarding the design and working of the signal acquisition and conditioning electronics, so it is not possible to evaluate the performance of the system, although it probably makes use of some commercial ECG signal processing integrated circuit.
Companies such as Texas Instruments have developed integrated circuits specifically designed for the acquisition and conditioning of cardiac signals, such as the ADS1198 chip, widely used in twelve-lead Holters, as is the case of the one shown in [9], which is also able to register the respiratory activity of the user.
There is only one data channel internally that is shared by all leads. By means of a multiplexing stage, the information from each of the electrodes is collected at a certain frequency, switching the channel between all the information sources. This method of proceeding has two main problems: Firstly, there is no real time acquisition from all the leads, but because the same signal input channel is shared, the integrated circuit must collect data from each of the electrodes at different times. This translates into a lower immunity to electromagnetic noise, since the oscillator used for the commutation could stop working correctly in the presence of external interference, with the

possibility of mixing input signals, thus producing an inadequate response. Secondly, it is not possible to achieve specific signal conditioning for each of the signals independently. This reduces the flexibility of the system, since, for instance, precordial leads usually have a higher ripple as they are calculated based on the average bioelectric potential of the limbs in order to determine the value of the Wilson central terminal. Therefore, the same conditioning system may not be suitable for all users, from a morphological point of view.

3. Smart Holter

In order to solve all the problems related to cardiac monitoring devices present on the market, we have developed a device called Smart Holter, which has been designed to provide better performance than the equipment currently available.

A critical aspect of this kind of systems concerns the size, which is closely related to the number of leads supported. A total of twelve leads are used in medical practice to know the state of the heart from different points of view, however, not all are strictly necessary to evaluate the state of the heart. It makes no sense to develop a Holter that registers certain signals that will not be used later, especially due to their redundancy. For example, the aVR lead is the inverse of the D2 lead, so one can be obtained by the other. In addition, within the precordial leads, V2 and V3 provide a very similar waveform, as do V5 and V6.

Thanks to the cooperation carried out with cardiologists from the Region of Murcia, it has been considered that the use of six leads is enough to detect the existence of a cardiac anomaly with a high success rate.

A recurrent problem when limiting the use of the equipment to specific leads is the loss of flexibility in the system, for instance when, for reasons of a specific application, it is necessary to register other signals than those supported.

In the beginning, the Smart Holter was designed to retrieve and analyse D1, aVF, V1, V2, V4 and V6 signals, but as described in the results section, it is possible to measure other leads by repositioning the electrodes.

The Holter carries out the acquisition of each of the electrodes at the same time, and thereby, of each of the leads. For this reason, when the acquisition and signal conditioning modules are independent, it is possible to minimise the interferences produced by the different signals. Integrated systems such as the ADS1198 described above do not allow different configurations to be applied for each signal to be acquired. This reduces flexibility in the design, proof of this is the case of precordial signals. When the signal is calculated based on the average potential of the Wilson central terminal, which is also calculated from the bioelectric potential measured in the right arm (RA), left arm (LA) and left leg (LL), they usually have a higher signal ripple; so in these cases, it is recommended to design a specific filtering for this type of signals. This is specifically one of the novelties introduced with respect to the other cardiac monitoring systems on the market: the fact of being able to control each of the leads individually, which results in better signal quality.

All the information collected by the Smart Holter is processed by an expert algorithm that determines the existence of a pathology based on the analysis of the cardiac signal, whose functioning will be described in section six.

It is important to note that relying solely on the evolution of the myocardial signal to detect pathologies may not always be the best option. For this reason, measuring these types of parameters is interesting, in order to provide a more accurate early diagnostic.

The Smart Holter has been designed to be able to acquire up to ten external analogic sensors that can be selected based on the patient’s particular needs, in order to provide a higher number of parameters to be able to determine the existence of any pathology in advance.

One aspect to be taken into account and which is seldom mentioned by the companies that

commercialise this type of devices is the impossibility of obtaining a signal free of artefacts while doing sports activities, because the movement of the electrodes in contact with the skin produces distortions in the signal.

The use of compression clothing that restricts the movement of electrodes is usually the most common practice to resolve this problem [10]. However, this does not solve the underlying problem of reducing artefacts from the point of view of signal conditioning, a shortcoming shared with medical equipment.

The developed Smart Holter cannot be used for sports monitoring, even though an important immunity to noise has been achieved, much higher than other commercial equipment, through a dynamic regulation of the filtering in real time.

Although it is not possible to fully condition the signal when doing intense physical activity, it has been possible to dynamically compensate small artefacts produced by light blows to both cables and electrodes, an aspect that other devices are not able to solve and this is one of the design innovations.

Regardless of the number of leads supported, all these systems share the need for a Smartphone to enable processing of the signals in search of some anomaly [11]. This is done through a Smartphone application that connects via Bluetooth to the Holter, which is in charge of sending this information to the cloud for later analysis by professionals.

During the development of the equipment, it was observed that the users who need access to a cardiac monitoring system belong to more elderly age groups, who are less versed in the management of new technologies. Therefore, forcing a user with these characteristics to use a Smartphone application to configure and use the Holter may represent a difficulty for the correct use of the equipment.

Therefore, the developed system does not require a Smartphone to analyse cardiac signals in real time, since all the processing logic is embedded in the device itself, so it can determine the existence of any cardiac pathology (tachycardia, bradycardia, ischemia, atrial fibrillation or extrasystole), sending the part of the signal where the pathology has been detected via WiFi.

In addition, it has been designed to provide medical assistance to the user if required. For this reason, the Holter includes a GPS and a fall detection mechanism that allows, together with the analysis of cardiac signals, to determine if the user needs medical assistance.

The Smart Holter has a modular design, so the acquisition and signal processing stage can be used for the development of new equipment by third parties, which would increase the use of the technology developed.

4. Signal Acquisition Block

The Smart Holter is divided into two different hardware modules: On the one hand, the Signal Acquisition Block, which carries out all the tasks of heart signal collection and conditioning, and on the other hand, the Processing Block, which will host the device's firmware as well as the algorithm for detecting pathologies in real time.

Figure 1. PCB of the signal acquisition block with support for six leads and up to ten external sensors.

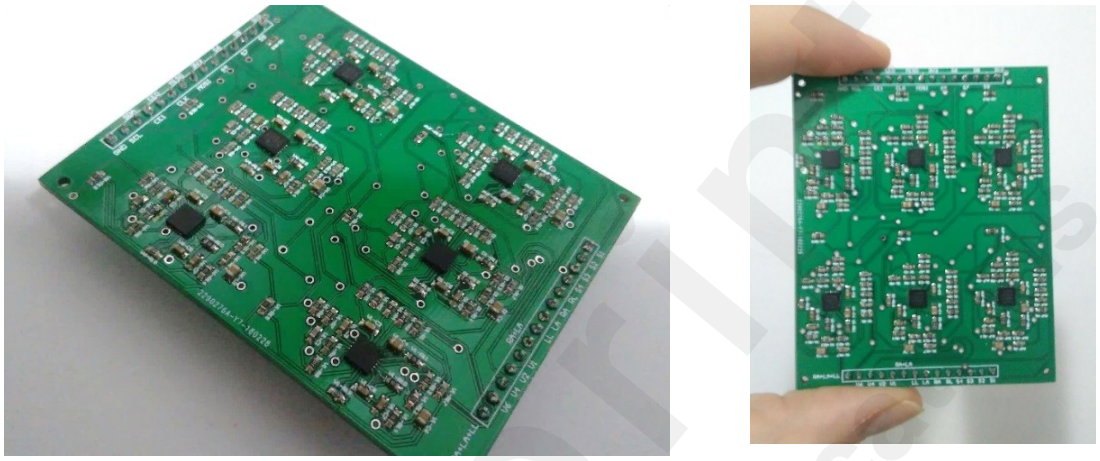
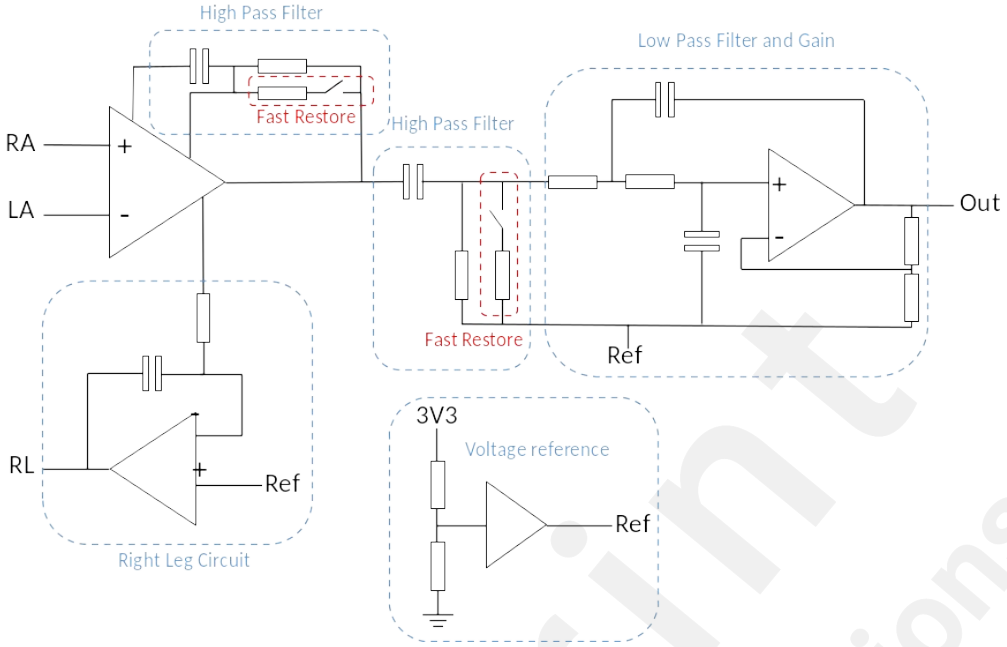


Figure 1 shows the result of the Holter's signal acquisition block which provides the 16 signals (6 leads and 10 sensors) in the form of 10-bit digital signals through SPI (Serial Peripheral Interface) protocol, which means that it can be used by any microcontroller and/or microprocessor in a simple way, making it easier to develop new products.

Since the equipment has been developed for commercial purposes, this paper does not include any detailed schematics, just a simplified view of the main elements, to be able to understand how the acquisition block works for a single lead (Figure 2). However, this section describes the design considerations that must be taken into account to improve signal quality, which is one of the main novelties introduced by the Smart Holter.

Figure 2. Simplified schematic of the acquisition block for one standard lead.



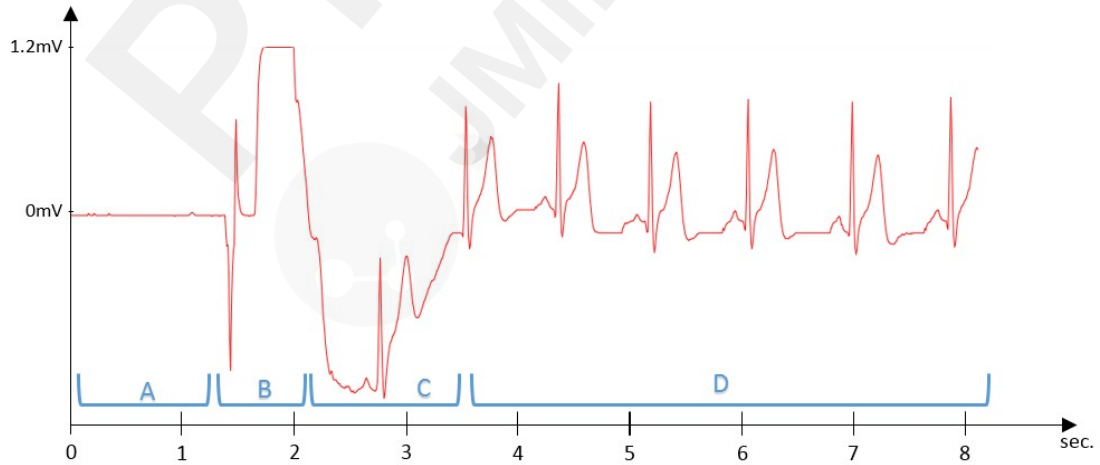
The circuit design used to acquire and condition electrocardiographic signals has not undergone significant changes over the years. All of the designs are based on a signal pre-amplification stage that registers the difference value of a pair of electrodes while applying a certain gain, using a band-pass filter between 0.5 and 40 Hz to remove external noises that may affect the signal quality [12].
In addition, the wide range of systems on the market include the so-called "Right Leg Protection Circuit", whose function is to provide a low impedance path between the user and the amplifier input, recording the common mode signal of the area where the electrode is located, amplifying it and providing negative feedback (microamperes), in order to balance the currents flowing through the body, achieving a significant reduction in the common operational mode.
However, what determines the suitability of equipment for clinical use is the quality of the signals it provides, or in other words, its capability to reduce disturbances. The attenuation level of the artefacts is a limiting factor in the use of the equipment for certain applications, such as sports practice or the detection of pathologies [13].
Therefore, one of the innovations of the Smart Holter is the implementation of a system that not only allows to reduce small artefacts present in the signal, but also to reduce the time of re-establishment of the acquisition after the reconnection of the electrodes, being able to reach the permanent regime of the signal in a much shorter time than the equipment present in the market.

4.1. Fast signal recovery and artefact reduction

The signal restoration time is a common problem of ECG acquisition circuits; it is the time the system needs in order to be able to properly record cardiac signals once the user has placed the electrodes.
This problem is common to most systems irrespective of the number of leads supported [14], where it does not make use of a fast signal recovery system to reduce the time that the user must wait before reaching a stable operating regime.
The origin of this problem lies in the filtering stage of the electrocardiographic signals, since when the system operates at a fixed cut-off frequency, it usually becomes saturated when there is a disturbance in the signal, such as that caused by the reconnection of the electrodes or radioelectric alterations that can be induced by the cables [15].
In order to solve this problem, it was decided to temporarily move the cut-off frequencies of the filter

stage when saturation is detected at the output of the instrumentation amplifier.
This is achieved through a pair of comparators that are activated when the operational output signal is less than 50 mV from the supply voltage. When the saturation condition is detected, a timing circuit is activated which allows the movement of the pole at a higher frequency, thus avoiding the saturation of the system and making it possible to continue operating under those conditions. When saturation is no longer detected, the system restores the original conditions of the filter stage, returning to normal operation.
This fast restoration is only valid if all the electrodes are connected, since otherwise, when an electrode is disconnected, the noise introduced by it can cause saturation, which will be compensated by means of the displacement of the pole. Therefore, each signal acquisition block has been designed in such a way as to only record signals if all the electrodes required for this lead are connected, which is very useful to avoid introducing invalid information to the expert signal processing algorithm [16].
This principle is also valid for the reduction of small artefacts produced by slight movements of electrodes and cables. This was especially important during the development of the equipment, since due to the lack of clothing to host all the electrodes and cables, the performance tests had to be carried out using standard unshielded cables that minimise interference.
The movement of the pole is a common technique in the design of filters when you seek to modify its limits in execution time, however, no equipment on the market uses this technique as a mechanism to reduce the number of artefacts to minimise the stylisation time of the signal in a dynamic way, which is one of the most outstanding design novelties.
Figure 3 clearly shows the operation of this system, where a first zone of null value (A) is displayed, which corresponds to the period of time in which some of the electrodes were not connected. After the connection of the electrodes, a peak of transient instability (B) is produced, where the displacement of the pole starts, in such a way that a heartbeat with a certain deformation (C) can be obtained due to the re-establishment of normal operating conditions (D), giving rise to a clean and stable signal.

Figure 3. Fast recovery of the signal after disconnection and connection of the electrodes.



As mentioned above, this feature also minimises the effect of disturbances in the signal caused by electrical noise and by slight movements or alteration of the electrodes. In order to show how the dynamic disturbance compensation system works, this feature was deactivated in the Acquisition Block, in order to demonstrate the behaviour of the signal without this feature.

Figure 4. ECG with artefacts due to electrode movement.

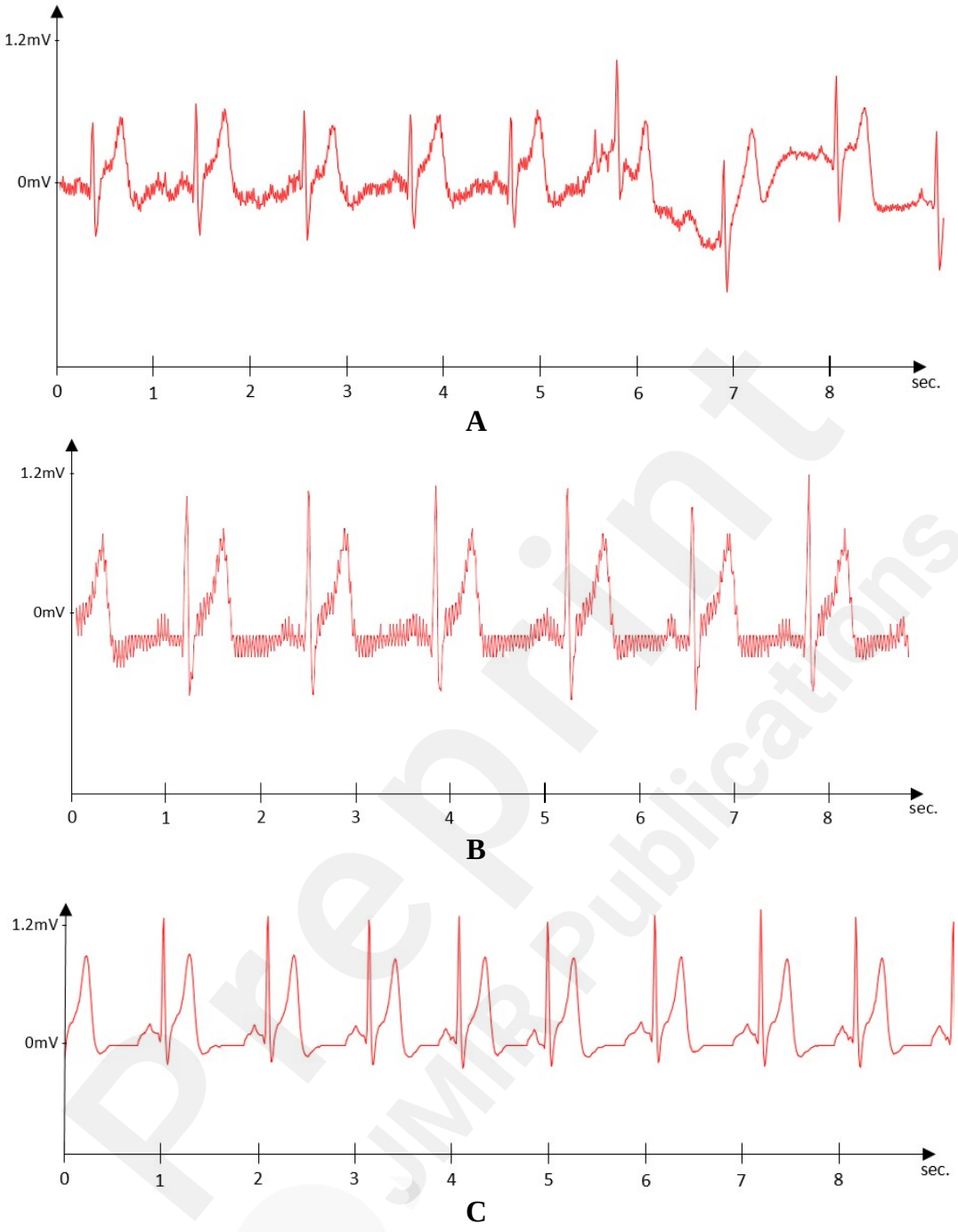


Figure 4 compares the D1 signal obtained without the signal recovery system (Figure 4 A and Figure 4 B) and with the recovery system implemented (Figure 3 C).

As can be seen, the signal in Figure 4 A has artefacts due to the displacement of the electrodes caused by the user's movement while walking. In addition, the signal has a higher ripple, which makes it difficult to see the beginning and end of each wave segment clearly, thus making it difficult to interpret by any automatic anomaly detection system.

The artefacts can also be produced due to proximity to equipment or electromagnetic radiation sources, such as signal repetition stations or electrical transformers. Figure 4 B shows the effect of the electrical network (50Hz) on the D1 branch. Despite the implementation of a filtering stage with cut-off frequencies between 0.5 and 40Hz which should attenuate the effect caused by the electricity network, it is inevitable that the signal obtains a certain ripple.

When the D1 signal is recorded under the same conditions as above (with the fast signal recovery

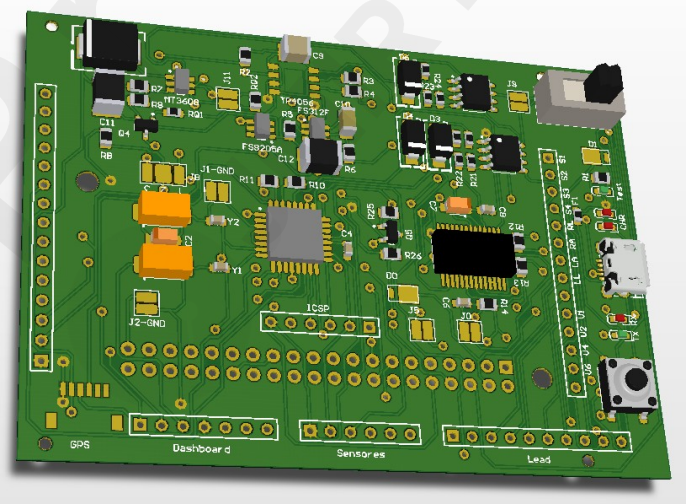
system activated), a cleaner and undisturbed signal is obtained (Figure 4 C), which demonstrates the correct working of the implemented system.

5. Signal Processing Block

Developing a Holter with the capacity to detect cardiac anomalies in real time requires an algorithm to carry out this task. Since the Smartphone is no longer used to host the expert system, it is necessary to provide the Holter with the capacity to run it by itself.
This expert system is included in the "Signal Processing Block", which is used for the analysis and communication with the cloud (Figure 5). This stage has the following features:

- Linux operating system, designed to execute the firmware developed to control the device, as well as the acquisition and processing of ECG signals by means of an algorithm that detects the existence of cardiac anomalies and sends them to the cloud for analysis.
- Accelerometer to detect falls or electrode movements that may distort measurements.
- A GPS to report the patient's position as well as the data of the detected cardiac anomaly, in order to be able to send assistance if necessary.
- Connectivity via WiFi to send the cardiac anomalies detected for final analysis by doctors [17].
- Device configurable via USB through an application compatible with all operating systems, to enable the configuration of parameters such as WiFi connection, the credentials of access to the cloud where the data will be sent, as well as parameters such as age, sex or maximum and minimum heart rate, used by the detection algorithm.
- Control panel with OLED display to visualise parameters and useful information of the device.

Figure 5. 3D view of the signal processing block.



6. Cardiac anomaly detection algorithm

This section describes in detail the algorithm for detecting cardiac anomalies from the point of view of software development, in order to provide the reader with a detailed guide for the development of new systems for detecting cardiac pathologies based on the algorithm described herein. The description focuses on the methods used to detect each of the waves that compose the heartbeat, as

well as the way that said information is evaluated to determine the existence of some pathologies, distinguishing between: Tachycardia, bradycardia, ventricular extrasystole, and ischemia. All this is accompanied by performance data of the algorithm in order to demonstrate that the diagnoses that the software issued are suitable.

Detecting a cardiac anomaly in a patient's electrocardiogram involves the analysis of the waveform of each of the beats recorded. Depending on the cardiac lead to analyse, the waveform of the heartbeat changes, and with it, the criteria that determine the existence or not of any pathology [18].

However, when there is an irregularity in the ECG, for instance, bradycardia, such an anomaly is not detected in a single heartbeat, but is observed throughout a certain number of them, since otherwise it would be an episode with no particular relevance.

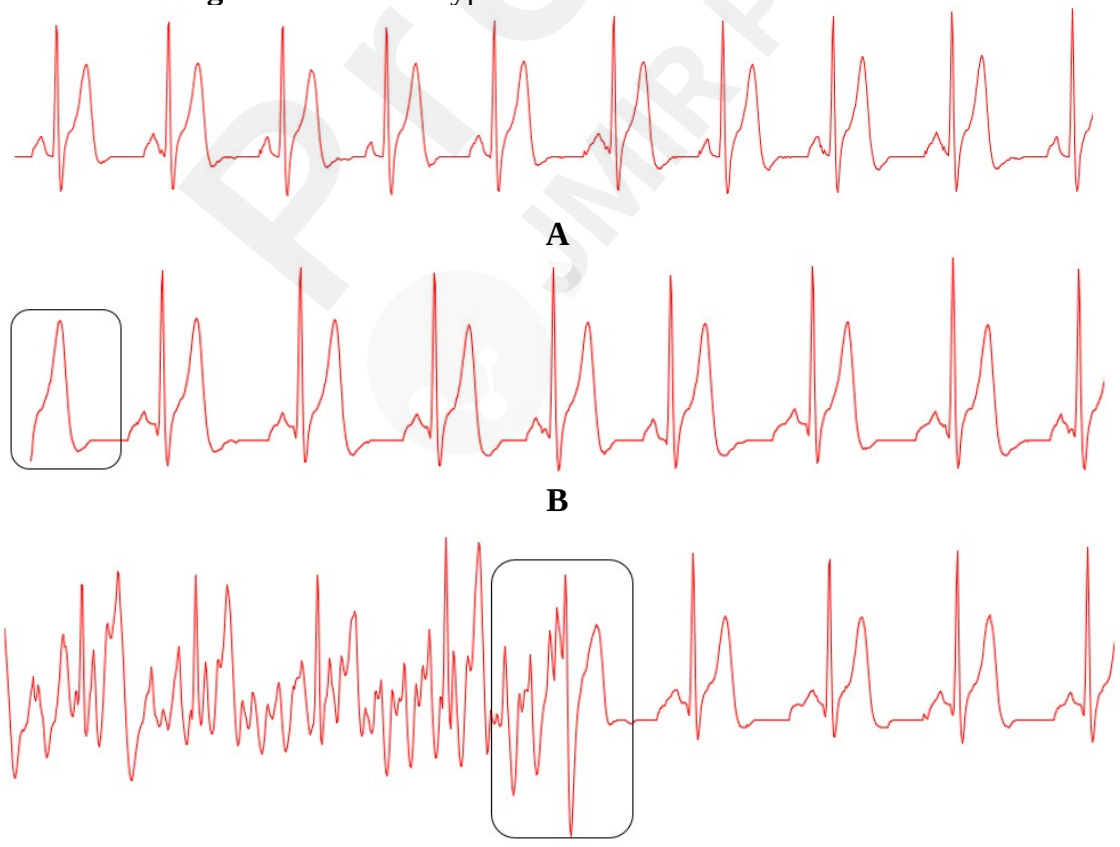
Likewise, analysing the ECG from the moment a pathology is detected is not common practice, yet it is essential to know the behaviour of the heart moments prior to the anomaly taking place.

The Smart Holter developed records the six cardiac leads with a frequency close to 1 KHz, achieving a high resolution of each beat. To know the patient's condition, it is essential to analyse the waveform of the beat, so the first step is to detect and extract each one of the recorded beats.

The Holter sends each of the recorded values in real time as a number of 10bits, which will be turned into voltage values by the algorithm, which stores them temporarily, in different arrays for each lead.

A normal heartbeat lasts about 1 second, so we can state that a heartbeat contains about 1000 points. However, it is necessary to store a greater number of points before being able to start the process of detecting the beat, since we will not always start the acquisition by recording the beginning of a complete beat, as is the case shown in Figure 6.A, but a portion of it, as shown in Figure 6.B, where the acquisition has started detecting at the QS segment, instead of the QRST. Furthermore, it must be taken into account that even if we do detect a full heartbeat, this does not immediately mean that it is valid, proof of that is in Figure 6.C, where due to the presence of artefacts, the highlighted heartbeat cannot be considered valid.

Figure 6. Different types of heartbeat detection scenarios



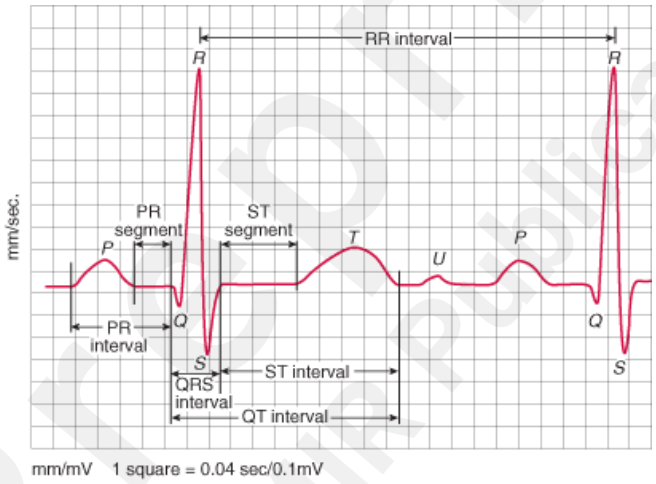
C

This shows the intrinsic difficulty of detecting the existence of a heartbeat in real time, due to factors such as: the variety of ECG signals, noise in the signal, or even the alteration of the baseline.
Over the years, many algorithms have been developed to detect heartbeats. Most of them have been based on the definition of thresholds [19]. Others were based on heuristic systems that detected the heartbeats through the evaluation of the signal inflection points (Q, R and S points) as well as the curvature (P point) [20]. The latter, despite having a high heartbeat detection, does not allow operation in real time.

6.1. Decomposition of an ECG signal

In the study of heartbeat detection systems, it was concluded that the algorithm proposed by Christov [21], based on the definition of adaptive thresholds, provided the best results, and therefore was implemented in the current algorithm.
Each of the heartbeats detected is stored individually in an array, so the algorithm can analyse the properties of each one. The waveform of a heartbeat is made up in points and sections that suffer changes due to the existence of some pathology. Figure 7 shows the different parts of an ECG signal.

Figure 7. Parameters of the QRST Complex of a derivation. [22]

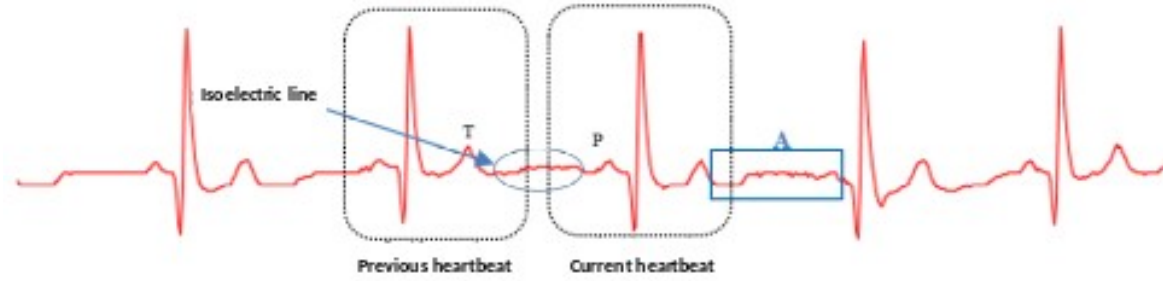


Before the detection of heart problems can begin, a number of heartbeat properties must be determined. For this reason, the algorithm extracts each of the waves that make up a heartbeat; these waves will subsequently be used to determine the existence of a pathology.

6.1.1. Isoelectric Interval

This refers to the time in ms of the signal baseline, in other words, the line that determines the level of zero potential, required in order to know the amplitude of the ECG.
As shown in Figure 8, the interval is measured from the end of the T wave of the previous beat to the beginning of the P wave of the beat that is being analysed. A common problem with the definition of this interval is that poor detection of the end of the T wave can lead to a longer interval than in reality. To solve this, we have taken a point 20 ms away from the detected end of the T wave as the beginning of the isoelectric interval, in order to ensure that the T wave has completely descended.
Another problem lies in the detection of the beginning of the P wave. This can be seen in zone A of Figure 8 where, due to the fact that the beat has fallen lightly in relation to the previous one, there is no clear definition of the P wave, and it is therefore complicated to correctly define its beginning.
The solution has been to take the portion of the signal that is 100ms from the end of the T wave as the isoelectric interval, thus enabling us to resolve the detection of the isoelectric interval if there is some noise in the signal.

Figure 8. Determination of isoelectric range.



6.1.2. R Wave

Detecting the R wave is essential for the correct definition of the rest of the waves. At first, one could think of searching for the maximum value of the signal within each beat and taking it as the peak value of the R wave; however, most times this way of working will lead to detection errors, since it is likely that there are other parts of the signal with a higher value, so this would produce an incorrect detection of the signal.

The best way to determine the position of the R wave is to look for the point of the derivative of the greater signal, in other words, where the greatest slope is reached, which is the R point of the signal.

However, , the S point may be higher in amplitude (as an absolute value) than the R point in a certain heartbeat, so detecting the point of maximum slope may not be enough.

When the maximum slope point (global maximum) is detected, the algorithm searches within an interval of ±50ms with respect to this detected maximum to see if there is a local maximum. If the local maximum has been detected before the global maximum and is higher than a certain threshold defined according to the characteristics of the user, it is considered that the global maximum corresponds to the S point (or close to it) and the new local maximum is the R point. If, on the other hand, the local maximum has been detected after the global maximum, it is considered that this new point corresponds to the S point and therefore, the global maximum is the R point.

Once the R point is detected, it is essential to determine the beginning and end of the wave; however, one must take into account that for certain leads the R wave is negative and for others it is positive, so the algorithm must be able to find the range of the wave in both scenarios.

For a positive R point, the beginning of the wave is obtained by moving the wave in the opposite direction from the R point to locate the place where the slope of the wave function changes from a positive slope to a null or negative value.

The detection of the end of the wave is carried out by scanning the signal in the direction of propagation until the function changes from a positive slope to a null or negative value.

If the R wave is inverted, the process is analogous to the above, except that the points searched for will be those where the derivative of the function changes from being negative to a positive or null value.

6.1.3. Q Wave

The Q point can be determined from the R point previously calculated. As the Q wave precedes the R wave, the signal only has to go back a specific period of time and look for the null slope point, in other words, the minimum of the signal within that interval.

Based on the experience obtained in the development of the Smart Holter, it was observed that the selection of a search interval between the R point and 100 ms of delay made it possible to find the Q point in all cases.

6.1.4. S Wave

Although the process to determine the R point can be used to detect the S point of the signal, the tests

carried out to evaluate the performance of the algorithm have shown that detecting the wave, i.e. the beginning and end of the wave, as well as the peak value (S point), require an independent procedure to detect it correctly.

With the R point as the starting point, it is possible to scan the signal in the direction of propagation, until a point with a null slope. However, the existence of some irregularity in the activity of the myocardium can produce another point in the signal with a higher value (in absolute terms) than the S point, wrongly detecting it as the peak value of the S wave.

It is therefore essential to define a search interval from the calculated R point. Based on the tests carried out throughout the development of the algorithm, it was determined that a search interval of 100 ms from the R point in the direction of propagation always contained the S wave, with that point having a null slope.

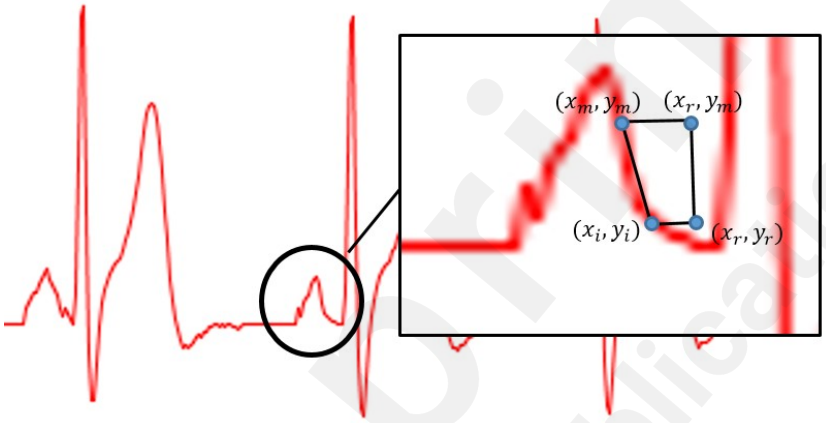
Once the S point has been calculated, it is possible to use it to find the end of the wave. Starting from the S point, it is necessary to find two points that have a difference in their slope within an interval of 70 ms, which will allow us to find the end of the S wave. However, it must be taken into account that if this point has a huge difference in amplitude with respect to the isoelectric interval and the signal is followed by a pronounced positive slope, this point cannot be considered to be the end of the S wave.

It is difficult to find the end of the wave in some pathologies, such as ventricular extrasystoles, which are characterised by the early presence of a wide QRS complex with an atypical morphology, accompanied by minor changes in the ST segment and T wave. This means that there are not a couple of points whose difference in slope is low enough so as to be valid for finding the end of the wave. Under these circumstances, the best results were obtained if the end of the wave is 70 ms from the S point, if that point is close to the isoelectric interval.

6.1.5. T Wave

The T wave is calculated based on the trapeze method proposed by N.I. Ingle as a way to find the final point of the T wave [23].
The method is based on calculating the area of trapezoidal polygons, setting three vertices as constants, whilst modifying one of them $(x¿¿i, y_i)¿$. Through an iterative process, the trapeze with the greatest area is determined, which will be the one whose coordinates x_i, y_i represent the final point of the T wave.
Figure 9 shows the position of the trapezium vertices on a T wave in order to show the calculation process better. The algorithm takes the segment of the signal between the first 20ms and 500ms of the beat as its working area.

Figure 9. Calculation of the end of the T wave by the trapezium method.



The area of the trapeze is calculated by Equation 1:

$$A = \frac{(y_m - y_i) * (2 * x_r - x_i - x_m)}{2} \quad (1)$$

As has been mentioned, three of the four vertices of the trapeze are fixed points that must be calculated at running time.
The point x_m, y_m represents the coordinate where the highest value of the derivative of the function is obtained (in absolute terms) within the T wave and after the last peak, which in normal conditions corresponds to the T point of the wave. It is necessary to make a distinction depending on whether the wave is negative or positive.
For a positive wave, the point x_m, y_m is the one whose derivative is a negative minimum, while for a negative wave, it would be the positive maximum. This difference is essential in order to adapt the algorithm to the different leads supported by the Smart Holter.
The abscissa and the ordinate (x_r, y_r) do not require an exact location to be able to use the method. We merely have to ensure that the selected point is within the T wave.
Once the three vertices have been defined, the algorithm scans the wave segment at intervals of 1ms, calculating the areas of the trapeziums in such a way that the point provided by the polygon with the largest area is located.

6.2. Detection of pathologies

The analysis of ECG signals enables certain pathologies to be detected. The Smart Holter determines the existence of these pathologies and notifies these incidents to the cloud for evaluation by clinical staff, an aspect that is usually shared by monitoring systems [24].
This section describes the methods for detecting the different pathologies that the system can detect,

explaining both the methods as well as the design considerations carried out.

6.2.1. Tachycardia

This pathology involves an elevated cardiac frequency due to a fast contraction of the ventricles. Bioelectric impulses from a group of cells in the right atrium control the contractions.
When there is an abnormality or damage in the electrical conductions, an alteration of the cardiac rhythm is produced and as a result different problems may take place, such as: sinus tachycardia, supraventricular paroxysmal tachycardia, ventricular tachycardia, tachycardia with possible blockage, or indeterminate tachycardia.
In order to determine and classify the different disorders properly, the algorithm uses the P wave, RR amplitude and PR amplitude in ms [25] as the central axis of its analysis.
The detection algorithm requires the analysis of a minimum of 13 beats in order to generate a diagnosis of tachycardia. For this purpose, it rejects beats with a very narrow (less than 40 bpm) or very wide (greater than 250 bpm) QRS, classifying them as artefacts.
Signals with a QRS greater than 110 ms and an amplitude of the R segment (in absolute terms) below 10% of the sinusoidal amplitude of the previous beat are also classified as artefacts. Additionally, beats with an interval of QRS≤110 ms are also analysed.
A required parameter is the average QRS value and the RR interval. In each iteration, the values of QRS and RR for each one of the complete heartbeats are stored in an array, and are used to calculate the average value of the 13 analysed heartbeats regarding these parameters.
Once the means have been determined, it is important to check that the intervals follow a constant regime, i.e. that they have a significant deviation from the mean. Therefore, the algorithm calculates the standard deviation of the segment PR and RR (Equation 2).

$$\sigma_{PR}=\sqrt{\frac{\sum_{i=1}^{n}\left(x_{PRi}-\acute{x}_{PR}\right)^2}{N}} \qquad \sigma_{RR}=\sqrt{\frac{\sum_{i=1}^{n}\left(x_{RRi}-\acute{x}_{RR}\right)^2}{N}} \tag{2}$$

Where:

- x_{PRi} is the value of the PR range relative to each of the beats.
- $\acute{x}_{PR}$ is the mean value of the PR range of the N beats.
- x_{RRi} is the value of the PR range relative to each of the beats.
- $\acute{x}_{RR}$ is the mean value of the RR range of the N beats.
- N is the total number of heartbeats recorded with QRS≤110 ms.

Based on these values, it is possible to determine if the analysed beats have a constant PR and RR interval, taking those beats that verify $\sigma_{PR}<150\,ms$ and $\sigma_{RR}<400\,ms$ into account.
The existence of a P wave is key to determining what kind of tachycardia is detected. However, P-wave detection is unreliable [26]. Therefore, the following condition has been used as a criterion to define the existence of the P wave:

$$\frac{Number\ of\ P\ waves}{N}>50\,\%$$

These criteria are used to define each of the anomalies. Schematically, each of the cardiac anomalies has the following characteristics:

Sinus Tachycardia

- Existence of P wave.
- Regular RR intervals.
- Number of beats between 100 and 150 bpm, in a number of beats above 10.
- Constant PR amplitude.
- The current QRS period is less than or equal to the average QRS for the last 20 heartbeats.

- Progressive increase in the pulse.

Paroxysmal Supraventricular Tachycardia (APT)

- Existence of P wave.
- Regular RR intervals.
- Number of beats between 150 and 200 bpm, in a number of beats above 10.
- Constant PR amplitude.
- The current QRS period is less than or equal to the average QRS for the last 20 heartbeats (and a certain tolerance).
- Sudden increase in heart rate.

Ventricular Tachycardia

- No presence of P wave.
- No presence of T wave.
- Duration of the current QRS higher than the average of the QRS relative to the last 20 beats with a tolerance value, or higher than 110ms.
- Number of BPM between 150 and 240, in more than 10 beats.

6.2.2. Bradycardia

This cardiac pathology involves the interruption of the electrical impulses that control the rhythm of the heart, and has multiple causes. The result is a reduction in heart rate below 60 ppm. This produces an increase in the RR interval of the recorded waves, making their detection easier.
Under these two premises, to enable bradycardia episodes to be detected, the algorithm analyses a group of 20 beats per cycle, whenever the heart rate falls below a certain threshold of the RR interval [27].
In a normal register, the RR interval values must be between 600-1200 ms. Under this premise, the beats that exceed said thresholds will be verified from the point of view of beats per minute.
The system counts the number of beats that are lower than the minimum heart rate as defined for each patient.
If the number of those beats is above 15, the system generates an alarm to indicate that an episode of bradycardia has happened.

6.2.3. Ischemia

After occlusion of a coronary artery, there is a delay in the repolarisation of the myocardial cells, leading to anomalies in the ST segment.
These anomalies are shown as subendocardial injury, due to a delay in repolarisation at the onset of ischemia, producing higher than normal T segments, as well as an increase in corrected QT, or as subepicardial injury caused by a delay in repolarisation of the myocardium in the affected region, producing a negative or flat T segment [28].
The ischemia detection algorithm starts analysing the waveforms when a number of beats over 50 is reached. At first, the algorithm counts only the number of consecutive up/down ST segments present in each complete beat relative to the nR derivation, setting as a threshold:

$$number\ of\ consecutive\ up\ ST\ segments > 4 \rightarrow Subepicardial\ injury$$

$$number\ of\ consecutive\ down\ ST\ segments > 4 \rightarrow Subendocardial\ injury$$

Table 1 shows the results obtained after analysing 48 records from the Physionet database [29]. However, a total of 483 false positives were detected, most of which were caused by ventricular extrasystole episodes.

Table 1. Ischemia test results with a large number of false positives.

Recor	TPs	FN	TP	FP	Recor	TPs	FN	TP	FP

d			p		d			p	
100	0	0	0	0	201	0	0	0	0
101	0	0	0	0	202	0	0	0	0
102	0	0	0	21	203	0	0	0	8
103	0	0	0	0	205	0	0	0	0
104	0	0	0	0	207	0	0	0	53
105	0	0	0	0	208	0	0	0	0
106	0	0	0	4	209	0	0	0	0
107	0	0	0	0	210	0	0	0	23
108	0	0	0	25	212	0	0	0	15
109	0	0	0	0	213	0	0	0	30
111	0	0	0	54	214	0	0	0	2
112	0	0	0	0	215	0	0	0	0
113	0	0	0	0	217	0	0	0	3
114	0	0	0	37	219	0	0	0	42
115	0	0	0	0	220	0	0	0	3
116	0	0	0	0	221	0	0	0	0
117	0	0	0	0	222	0	0	0	0
118	0	0	0	40	223	0	0	0	15
119	0	0	0	0	228	0	0	0	7
121	0	0	0	0	230	0	0	0	16
122	0	0	0	0	231	0	0	0	0
123	0	0	0	0	232	0	0	0	22
124	0	0	0	26	233	0	0	0	37
200	0	0	0	0	234	0	0	0	0
					Sum	**0**	**0**	**0**	**483**

A common problem in the diagnosis of this type of pathology is the correct detection of the amplitude of the ST segment during ventricular extrasystolic episodes, where obtaining the J point is key to correctly defining the segment.

In a ventricular extrasystole, the ST segment has a negative value. The analytical determination of the amplitude of the segment leads to the J point being detected in a lower position than the real one, this makes the amplitude of the ST segment higher than it really is, thus giving a false positive when surpassing the isoelectric line plus a certain threshold, accounting for a descent of the ST segment when in fact there is no such descent.

In order to solve this problem, the algorithm checks the width of the QRS complex. During an episode of ventricular extrasystole, the length of the QRS complex is above 110 ms, whilst in a subendocardial injury it remains within normal values. Therefore, a descending segment is only counted if its QRS is within normal values.

On the other hand, more exhaustive analysis showed that there was a correlation between the ischemic episodes with the V1 and V6 leads. The algorithm therefore counts the consecutive number of ascending/descending segments from the V1 and V6 leads. From the analysis of multiple electrocardiograms which presented this type of pathology, the following thresholds were defined for each of the three leads used by the algorithm (D1, V1, and V6), although the Smart Holter can acquire up to six leads; however, not all of them are used at this stage of development.

$$D1 \left| \begin{cases} number\ of\ consecutive\ up\ ST\ segments > 11 \rightarrow Subepicardial\ Injury \in D1 \\ number\ of\ consecutive\ down\ ST\ segments > 8 \rightarrow Subendocardial\ lesion \in D1 \end{cases} \right.$$

$$V1 \left| \begin{cases} number\ of\ consecutive\ up\ ST\ segments > 14 \rightarrow Subepicardial\ Injury \in V1 \\ number\ of\ consecutive\ down\ ST\ segments > 14 \rightarrow Subendocardial\ lesion \in V1 \end{cases} \right.$$

$$V6\left|\begin{cases} number\ of\ consecutive\ up\ ST\ segments > 14 \rightarrow Subepicardial\ Injury \in V6 \\ number\ of\ consecutive\ down\ ST\ segments > 14 \rightarrow Subendocardial\ lesion \in V6 \end{cases}\right.$$

These improvements in the algorithm led to 40% fewer false positives. The results are shown in Table 2.

Table 2. Results of ischemia analysis with reduction of false numbers.

Record	TPs	FN	TPp	FP	Record	TPs	FN	TPp	FP
100	0	0	0	0	201	0	0	0	0
101	0	0	0	0	202	0	0	0	0
102	0	0	0	1	203	0	0	0	28
103	0	0	0	0	205	0	0	0	0
104	0	0	0	0	207	0	0	0	23
105	0	0	0	0	208	0	0	0	0
106	0	0	0	4	209	0	0	0	0
107	0	0	0	0	210	0	0	0	12
108	0	0	0	9	212	0	0	0	14
109	0	0	0	0	213	0	0	0	52
111	0	0	0	25	214	0	0	0	1
112	0	0	0	0	215	0	0	0	0
113	0	0	0	0	217	0	0	0	2
114	0	0	0	1	219	0	0	0	48
115	0	0	0	0	220	0	0	0	3
116	0	0	0	0	221	0	0	0	0
117	0	0	0	0	222	0	0	0	0
118	0	0	0	9	223	0	0	0	40
119	0	0	0	0	228	0	0	0	4
121	0	0	0	0	230	0	0	0	164
122	0	0	0	0	231	0	0	0	0
123	0	0	0	0	232	0	0	0	1
124	0	0	0	16	233	0	0	0	1
200	0	0	0	0	234	0	0	0	0
					Sum	**0**	**0**	**0**	**282**

6.2.4. Atrial Fibrillation

In a normal regime, an electrical signal is sent from the sinus node to the right atrium to quickly propagate through both atria, causing them to depolarise at almost the same time, producing an atrial contraction. This atrial depolarisation is observed in the P segment of the electrocardiogram.
However, in an atrial fibrillation episode, the electromyography signals become disorganised, resulting in multiple small contractions that block the flow of blood to the ventricles. This is observed through the existence of an erratic P wave with points on both sides of the isoelectric line.
In order to detect this cardiac anomaly, we analyse the previous 100 beats, where each one is selected based on whether the recorded signal was due to an artefact or not.
From the beats that exceed the previous filter, the RR value in ms is recovered, as well as the beats per minute for each beat. These parameters are used to discriminate whether the heartbeat corresponds to or does not correspond to an atrial fibrillation episode, through the definition of three thresholds:

- Root Mean Square of Successive Differences (RMSSD).
- Turning Point Ratio (TPR).
- Shannon's Entropy.

Prior to calculating it a new array is created, which contains the values of the RR interval once the atypical data have been deleted. This is carried out after removing the eight smallest and the eight highest values within the 100 detected beats.
The RMSSD is calculated by Equation 3, where N is the value of the RR interval in ms of each beat.

$$MSSD=\sqrt{\frac{\sum_{i=0}^{n-1}\left(N_i-N_{i+1}\right)^2}{n-1}} \quad (3)$$

The TPR is calculated by using the array of RR values that includes the atypical values, which can be calculated by equation 4.

$$TPR=\frac{Turning\,Point}{n-2} \quad (4)$$

Where n is the total number of elements present in the array of RR values and the Turning Point is a variable that counts the number of times the following condition is satisfied:
$\left(N_i-N_{i-1}\right)*\left(N_i-N_{i+1}\right)>0$
Where N represents the value of the RR interval in ms for each beat.
The Shannon's entropy is determined by Equation 5 [30].

$$H\left(x\right)=-\sum_{i=1}^{n}P\left(x_i\right)*\log_2 P\left(x_i\right) \quad (5)$$

Where $P\left(x_i\right)$ is the probability of a certain RR value appearing. For this purpose, each value is checked by counting the number of times that value is repeated, and then dividing by all the data included in the RR values array.
Once the values of each of the thresholds have been calculated, it is possible to discriminate whether the heartbeat belongs to an atrial fibrillation episode or not. It has been concluded empirically that the heartbeat must meet all of the following conditions:

- $RMSSD>160$
- $TPR\geq 0.62$
- $Entropy\geq\begin{cases}0.70 \rightarrow If\ the\ last\ heartbeat\ belonged\ a\ fibrillation\ episode\\ ¿\\ 0.75 \rightarrow If\ the\ last\ heartbeat\ did\ not\ belo\end{cases}$

The algorithm was validated by analysing a total of 48 records from the Physionet database and

comparing them with the diagnoses carried out by MIT researchers.
The result is shown in Table 3, which shows a large number of false positives (65).

Table 3: Validation results of Atrial Fibrillation without BPM correction.

Record	TPs	FN	TPp	FP	Record	TPs	FN	TPp	FP
100	0	0	0	0	201	1	2	2	8
101	0	0	0	0	202	2	2	2	10
102	0	0	0	0	203	11	6	15	3
103	0	0	0	0	205	0	0	0	0
104	0	0	0	0	207	0	0	0	1
105	0	0	0	0	208	0	0	0	9
106	0	0	0	5	209	0	0	0	0
107	0	0	0	0	210	2	7	2	0
108	0	0	0	2	212	0	0	0	0
109	0	0	0	0	213	0	0	0	0
111	0	0	0	0	214	0	0	0	0
112	0	0	0	0	215	0	0	0	0
113	0	0	0	0	217	0	22	0	0
114	0	0	0	0	219	4	5	3	1
115	0	0	0	0	220	0	0	0	0
116	0	0	0	0	221	8	3	18	0
117	0	0	0	0	222	8	16	7	6
118	0	0	0	0	223	0	0	0	0
119	0	0	0	5	228	0	0	0	5
121	0	0	0	0	230	0	0	0	0
122	0	0	0	0	231	0	0	0	0
123	0	0	0	0	232	0	0	0	0
124	0	0	0	0	233	0	0	0	1
200	0	0	0	19	234	0	0	0	0
					Sum	**36**	**63**	**49**	**65**

In order to reduce the number of false positives, the existence of an erratic heartbeat regime was used as a crucial parameter, calculating the average of all heartbeats. Due to the fact that the pulse rate is highly atypical during an atrial fibrillation episode, the mean value of the first 30 heartbeats was used as the reference threshold, setting as a normal rate any BPM between 20% above the mean and 19% below it as a normal rate. As a result, 63% fewer false positives were obtained, and a 7.2% improvement in false negatives was achieved. (Table 4)

Table 4. Results of validation Atrial Fibrillation with BPM correction.

Record	TPs	FN	TPp	FP	Record	TPs	FN	TPp	FP
100	0	0	0	0	201	1	2	1	2
101	0	0	0	0	202	1	3	1	1
102	0	0	0	0	203	14	3	7	1
103	0	0	0	0	205	0	0	0	0
104	0	0	0	0	207	0	0	0	0
105	0	0	0	0	208	0	0	0	1
106	0	0	0	5	209	0	0	0	0

107	0	0	0	0	210	0	9	0	0
108	0	0	0	2	212	0	0	0	0
109	0	0	0	0	213	0	0	0	0
111	0	0	0	0	214	0	0	0	0
112	0	0	0	0	215	0	0	0	0
113	0	0	0	0	217	0	22	0	0
114	0	0	0	0	219	3	6	2	1
115	0	0	0	0	220	0	0	0	0
116	0	0	0	0	221	4	7	5	0
117	0	0	0	0	222	12	12	5	2
118	0	0	0	0	223	0	0	0	3
119	0	0	0	1	228	0	0	0	0
121	0	0	0	0	230	0	0	0	0
122	0	0	0	0		0	0	0	0
123	0	0	0	0	232	0	0	0	0
124	0	0	0	0	233	0	0	0	0
200	0	0	0	5	234	0	0	0	0
					Sum	**35**	**64**	**21**	**24**

7. Results

This section describes the performance of the Holter from an electronic point of view, showing the results obtained from the six leads supported: AvF, D1, V1, V2, V4, and V6, although as previously mentioned, it is possible to measure other leads by placing the electrodes in the appropriate positions [31]. In addition, the results related to the performance of the expert algorithm are also analysed.

A study group of 10 people between the ages of 22 and 78 was selected to be monitored throughout the eight weeks to evaluate the performance of the Smart Holter.

Since only a small number of devices were developed, it was not possible to monitor the entire study group at the same time. Therefore, the patients attended a specific hospital in groups of two for two weeks, in daily one-hour sessions, in which the patient had to carry out different physical activities in order to evaluate the performance of the Smart Holter in different scenarios.

In order to show the accuracy of the signals measured by the Smart Holter, this section shows the six leads acquired by the equipment, which belong to one of the study subjects selected randomly.

Through an SPI-USB gateway, the ECG signals from each of the derivations have been plotted using visualisation software created for the development.

A cardiac signal, or lead, is the result of the difference in potential measured between two points of the body. This point of view is defined by the placement of the electrodes. In medical practice, a total of ten electrodes are used to measure the twelve leads used in medical practice. There are different types of cardiac signals or leads:

- Monopolar derivations, measured between one limb and the mean of the potential of two other limbs, defined by the Einthoven triangle.
- Limb derivations, obtained by means of two electrodes located between two limbs.
- Precordial derivations, which are those obtained by placing electrodes on the chest, where the potential difference is obtained between a specific point in the thoracic cavity and the Wilson central terminal, which is obtained through the interconnection of the RA, LA and LL electrodes.

Commercial equipment, as used for clinical purposes, automatically calculates the average potential between two limbs, as well as from the Wilson central terminal, by shorting the RA, LA, RL and LL electrodes, according to the signal that we wish to measure. Our own device also has this capacity.

The results of each of the electrocardiographic signals measured are shown, as are the connections of

the electrodes used, in order to show that the same positions have been used as in medical practice.

7.1. Monopolar derivations (AvF, AvR)

The determination of the AvF, AvR and AvL signals is carried out through Einthoven's Triangle (Figure 10), where these signals are measured as a vector whose direction is determined by the combination of power of the electrodes of the limbs.

Figure 10. Einthoven's Triangle.

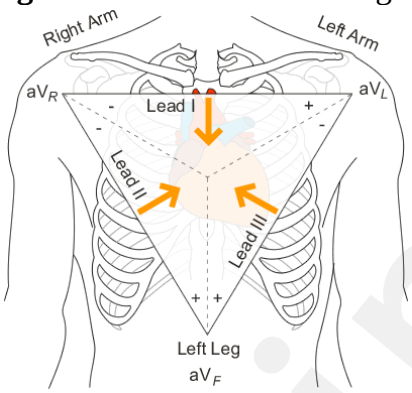
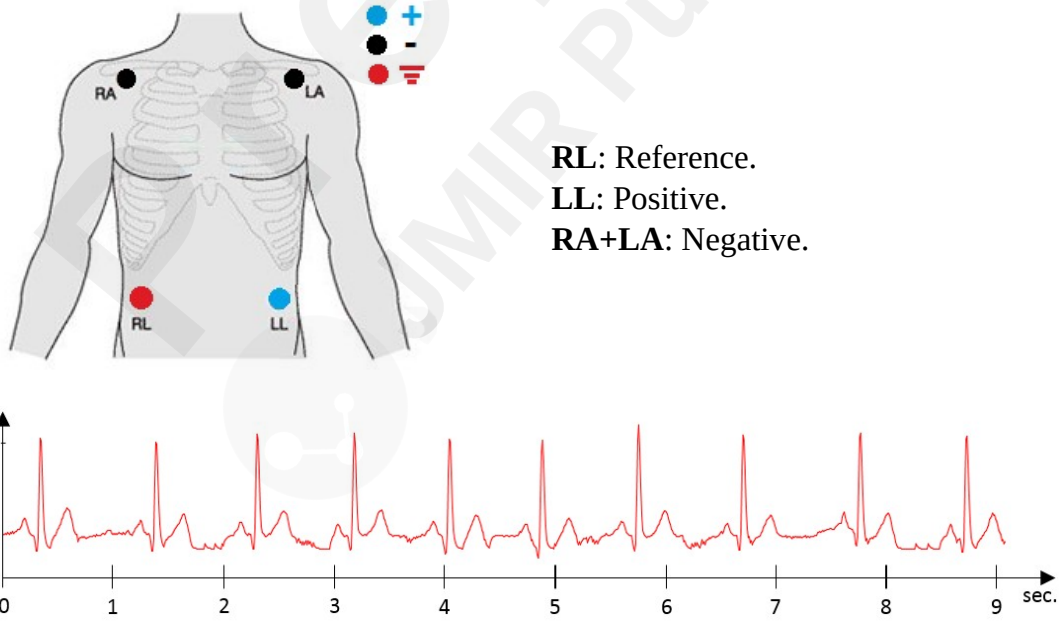


Figure 11 shows both the placement of the electrodes for the AvF signal as well as the response obtained.

As shown, the definition of the "negative" terminal is carried out by shorting the right and left arm electrodes in order to obtain the potential equivalent to the centre of both limbs. The positive corresponds to the left leg terminal (LL) and the reference (RL) must be placed at a distance greater than 10 cm from the heart, hence it is standard practice to place it on or near the left leg (lower right floating rib, hip, rectus anterior muscle or ankle).

Figure 11. Recorded AvF signal and electrode placement.

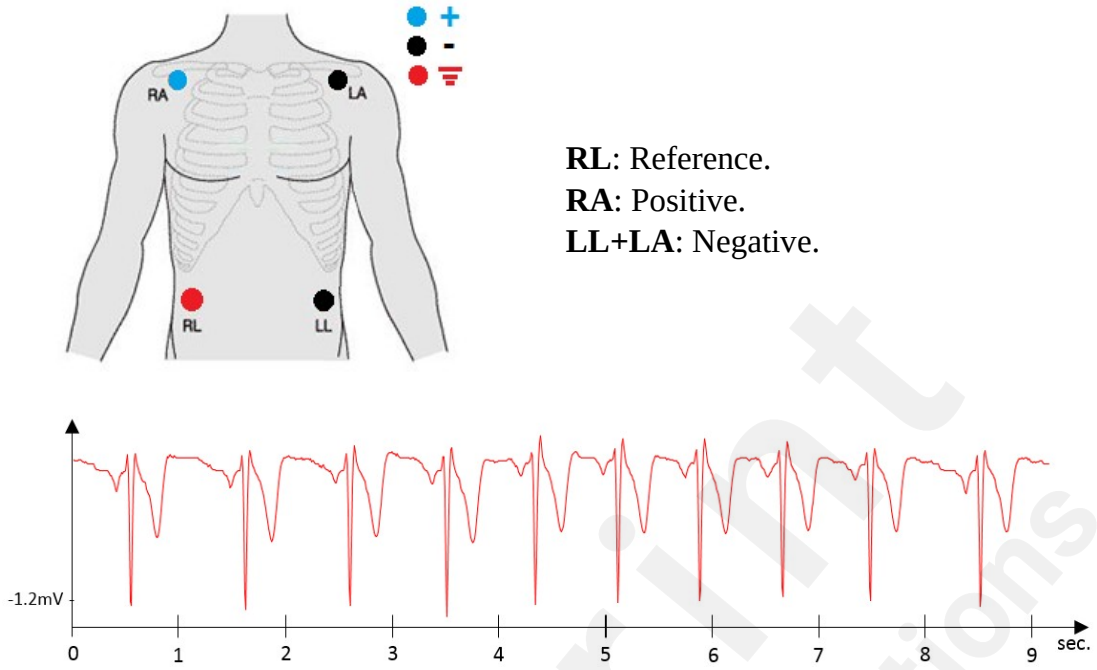


RL: Reference.
LL: Positive.
RA+LA: Negative.

Figure 12 shows both the placement of the electrodes for the measurement of the AvR signal as well as the response obtained. The algorithm that analyses and processes the cardiac signals does not require the AvR shunt to work, hence no specific support has been included to record this signal. However, in order to demonstrate that the system is able to measure other cardiac signals, the connection of the electrodes has been reconfigured to show the acquisition of the AvR signal.

In a similar way to the previous one, the negative terminal is the result of the combination of two electrodes (LA and LL) as shown in the Einthoven's Triangle in Figure 10.

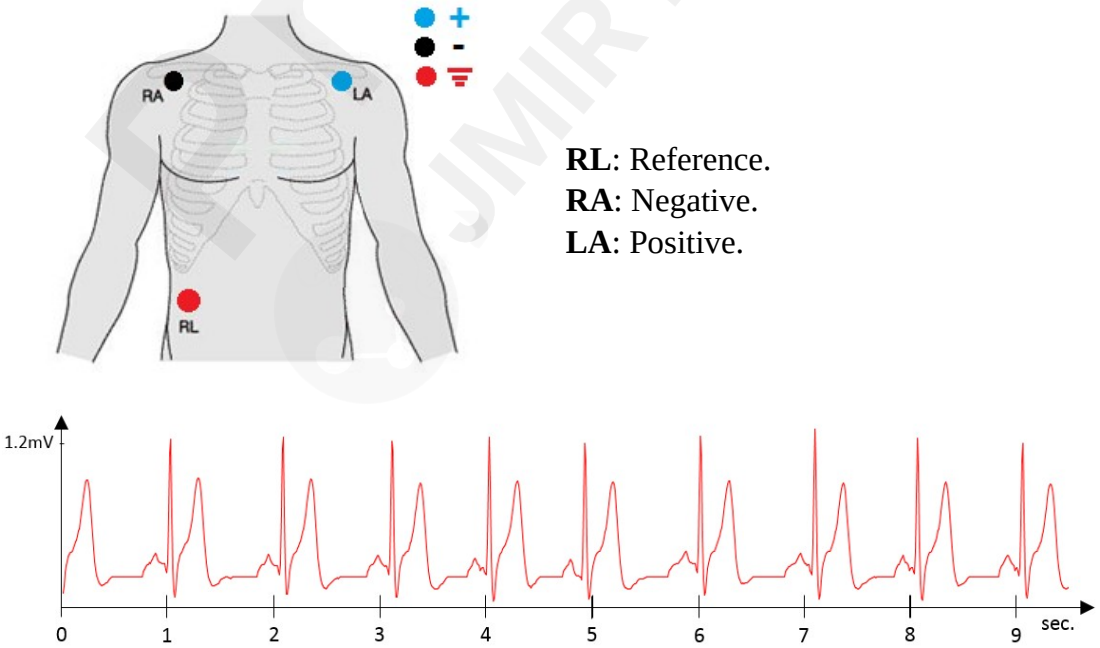
Figure 12. AvR signal and electrode placement.



7.2. Limb derivations (D1)

Limb derivations (D1, D2, D3) are easier to register. Unlike the previous ones, they do not require the interconnection of electrodes. Due to the needs of the algorithm, the D1 signal (Figure 13) was the only one required among the limb leads to carry out the analysis of the state of the heart, hence it is the only supported limb derivation, although it is possible to measure D2 and D3 through the proper placement of the electrodes.

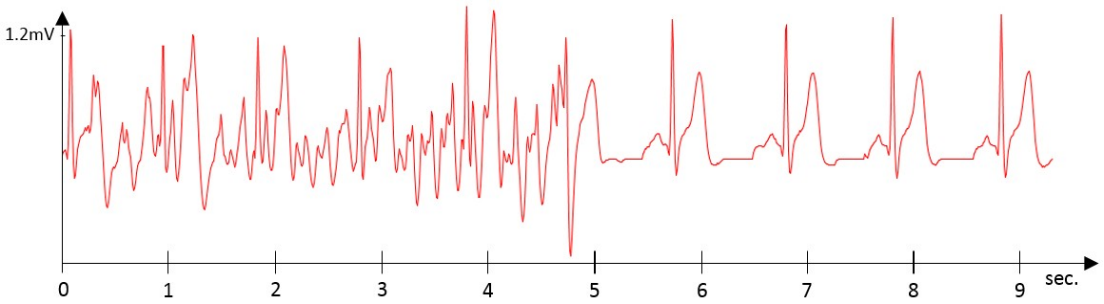
Figure 13. Signal D1 and electrode placement.



The signals shown in Figure 14 have a low noise level, despite the poor quality of the cables used to acquire these signals, which have no protection against interference. The signal shows a perturbation as a result of hitting the electrodes to simulate external interference. Thanks to the fast recovery

system, once the interference has disappeared, the signal is immediately restored [33].

Figure 14. D1 signal with interference in the cables at the beginning of acquisition.

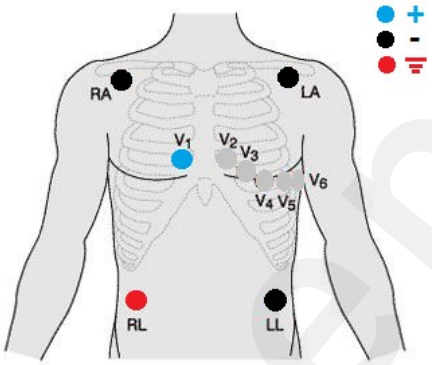


7.3. Precordial derivations (V1, V2, V4, and V6)

Precordial leads are measured by the potential difference between the Wilson central terminal and several points on the chest. The determination of this centre point is achieved by the interconnection of the electrodes: RA, LA, and LL.

The results of V1, V2, V4, and V6, and the connection of the electrodes are shown in Figures 15, 16, 17, and 18, respectively.

Figure 15. Signal V1 and electrode placement.



RL: Reference.
V1: Positive.
RA+LA+LL: Negative.

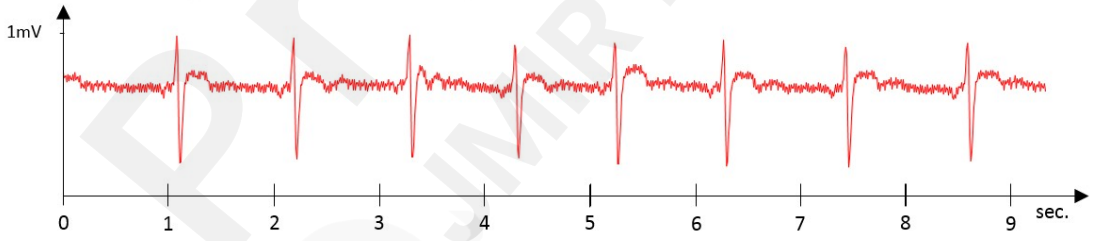
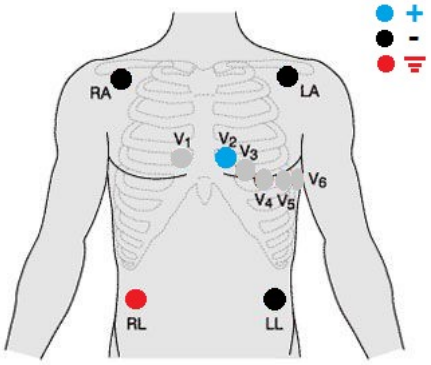


Figure 16. Signal V2 and electrode placement.



RL: Reference.
V2: Positive.
RA+LA+LL: Negative.

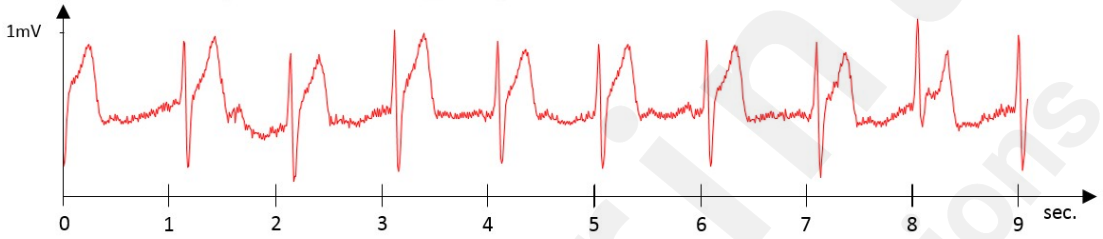
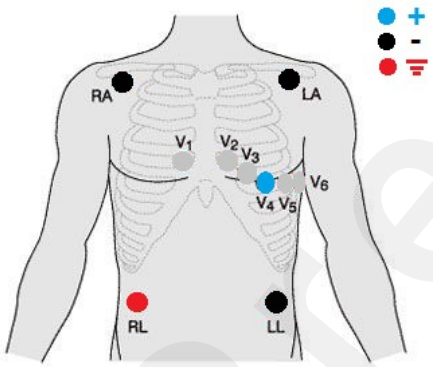


Figure 17. Signal V4 and electrode placement.



RL: Reference.
V4: Positive.
RA+LA+LL: Negative.

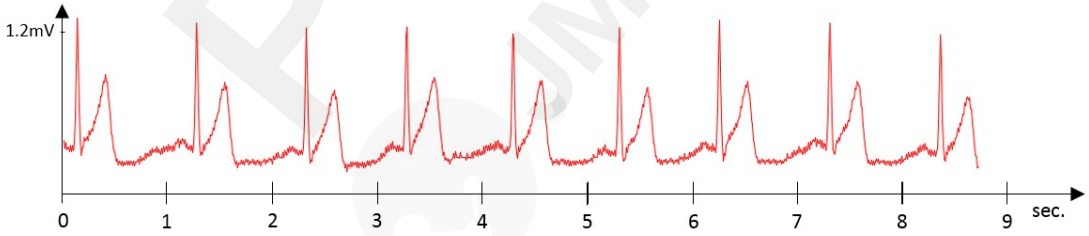
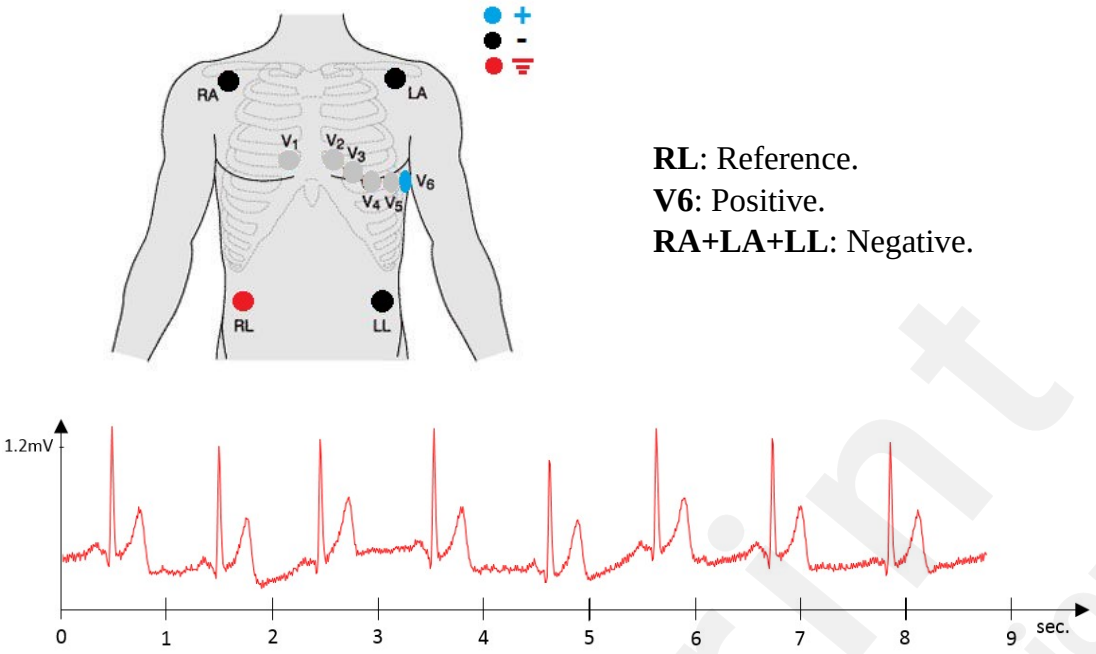


Figure 18. Signal V6 and electrode placement.



7.4. Performance of the pathology detection algorithm

The algorithm described in section six has shown a high success rate, both during the tests carried out with the Physionet database (Table 1, 2 and 4), as well as in the tests based on real monitoring data of the users under study, in the device development.

The algorithm detected the existence of some anomalies during the monitoring of the study group. Thanks to the visualisation software developed to evaluate the performance of the algorithm, it has been possible to observe the diagnosis emitted by the algorithm in real time, as well as the segment of the signal containing the anomaly.

Figure 19 shows the detection of sinus tachycardia, along with an extrasystole in the signal. The algorithm provides useful information such as the duration of each of the segments that compose the signal, as well as the heartrate and the heartbeat where the pathology has been detected.

Figure 19. Sinus Tachycardia detection.

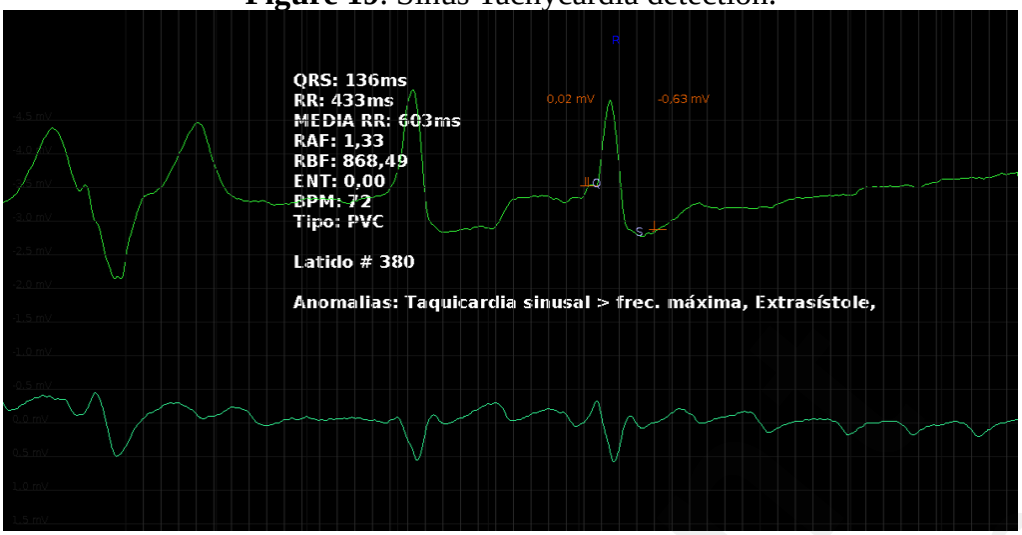
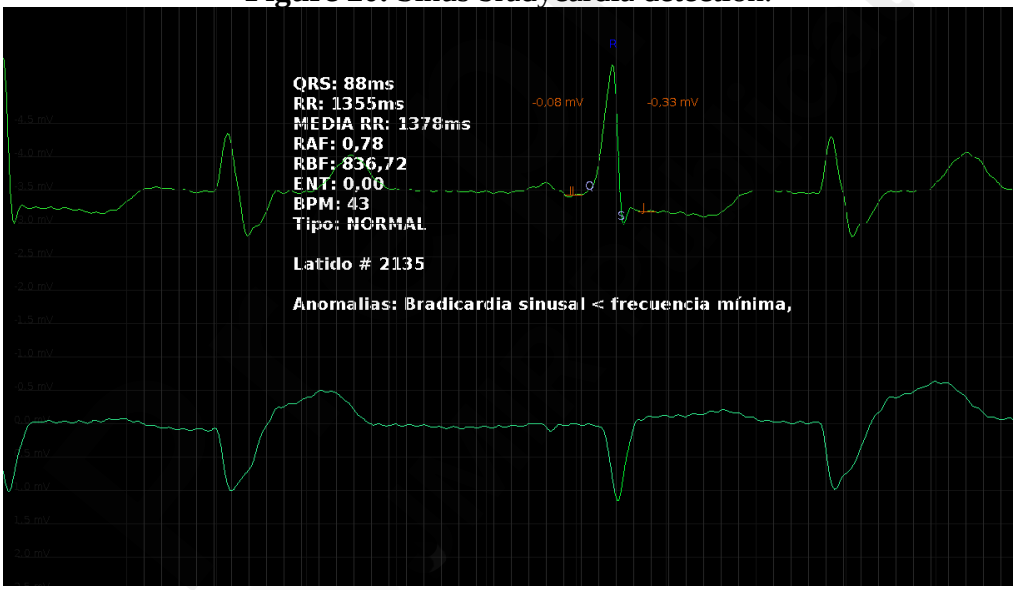


Figure 20 shows the existence of sinus bradycardia, which has been determined after detecting at least 15 consecutive beats with pulsations lower than 55ppm (43ppm in the case shown in Figure 20), which represents the minimum heart rate established for the patient that is being analysed.

Figure 20. Sinus bradycardia detection.



This shows that the Smart Holter is useful for doctors when making a diagnosis and also for high-risk patients, since it allows early detection of anomalies, increasing the chances of survival and the user's quality of life [33-34].

8. Conclusions

In this paper we have described a medical Holter for the constant monitoring of patients outside the hospital setting, with an acquisition capacity comparable to the equipment used in medical practice, but with the dimensions, consumption, costs and ease of use which characterise portable devices.

In spite of still being in the development phase, and therefore lacking full integration among all of its elements (algorithm and hardware), the preliminary performance tests of the equipment are promising, and establish the basis for the integration of new features and functionalities in the future.

After analysing the main devices on the market, it is clear that the Smart Holter developed offers better characteristics, because it resolves a wide range of issues inherent in that type of equipment, mainly in terms of signal quality.

One aspect to highlight is the improvement in noise immunity of the equipment. Although it is not possible to compensate large artefacts produced while playing sports, which still remains a challenge for current monitoring systems, an important step has been taken in the right direction to achieve even greater attenuation in the future, through the use of dynamic filtering systems controlled digitally, unlike the systems currently present on the market.

In addition, the equipment is able to analyse cardiac signals in order to search for anomalies in real time, without the need for a Smartphone to carry out the analysis. This has simplified the usability of the device, making it more accessible to population groups with poor knowledge of the management of new technologies.

Performance tests of the algorithm have shown a high rate of success in detecting the main cardiac anomalies, however, despite being able to record a total of six cardiac leads, the algorithm developed only makes use of three of them for the detection tasks; this has led to a high rate of successful detections. However, the inclusion of all the derivations supported by the Smart Holter, as well as data from configurable external sensors, has not been developed yet.

These extra data will enable us to obtain more accurate early detection, with a reduced number of false positives, as well as making the detection of new pathologies possible, thus making the device even more useful.

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