A New Algorithm for Real Time Arrythmias Detection on Embedded Systems-based Auto Diagnostic, Wearable Medical Devices

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Abstract: The approach to perform Digital Signal Processing (DSP) by means of Embedded Systems (ES) is very common, useful, and efficient to design auto diagnostic medical devices as wearable electrocardiograph (ECG). Reliable methods and algorithms developed for auto diagnosis of arrhythmias are always time consuming, especially if they are based on artificial intelligence models, and they are not specifically oriented to real time analysis and ES implementation. Therefore, the aim of this paper is to describe a novel algorithm for real time auto diagnosis of the most common arrhythmias, suitable and optimized for the implementation and quickly running in a FPGA-based ES. A test bench has been developed also in MATLAB & Simulink environment as a GUI. The hardware test has been performed using the evaluation board DE1_SoC by Terasic mounting the Cyclone V 5CSEMA5F31C6 FPGA by Intel.

Keywords: FPGA, Embedded Systems, Digital Signal Processing, MATLAB, Auto Diagnostic ECG.

I. INTRODUCTION

The most useful approach for designing wearable medical devices with auto diagnostic capabilities as long-time heart monitoring electrocardiograph (ECG), is strongly oriented towards the use of the Field Programmable Gate Arrays (FPGA), and Embedded Systems (ES) frequently designed using FPGAs [1, 2] because this approach is suitable to design and market consumer, portable battery-operated, auto diagnostic medical devices.

Portable battery-operated ECG devices for continuous cardiac function assessment can be easily integrated into daily life. These portable point-of-care diagnostic systems can therefore help unveil and treat cardiovascular diseases. With the progress of the high-resolution digital electrocardiography (HRECG), those devices have become more and more accurate, so much so that they become increasingly powerful and indispensable diagnostic tools with more and more advanced diagnostic capabilities.

A complete ECG records 12 channels (or leads) because of distinct diseases manifest differently in each of the leads [3 - 5]. However, the configuration recording only the lead named DII (derivation II, see figure 1) is the most preferred for continuous ECG monitoring as it is the most useful for detecting cardiac arrhythmias (irregular heartbeat) as it lies close to the cardiac axis and allows the best view of P and R waves (detailed in figure 2), thus helping in interpreting rhythms.

The tracing of each heartbeat would consist of several waves or peaks, segments, intervals, and joints as a recurrent wave sequence like which is shown in Figure 2.

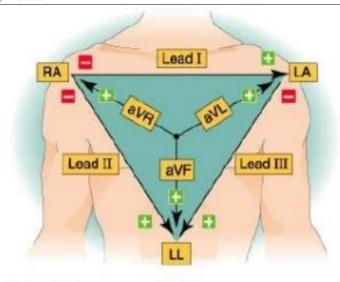


Fig. 1 – ECG leads

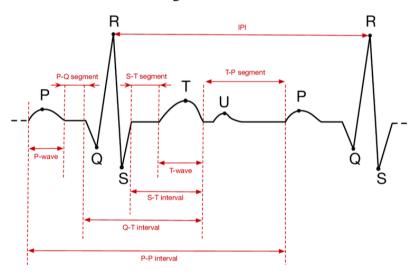


Fig. 2 – ECG typical waveform, parts, and characteristic points

The most relevant wave is the QRS complex which represents the depolarization of the ventricles, i.e.: the diffusion of the electrical stimulus through the ventricular musculature. Each QRS complex presents a peak, named R peak (see fig. 2). R peaks are the most important points in the ECG signal due to their larger amplitude and, also, they are the sharpest components with respect to all the other peaks in a normal II - Leads ECG signal. Therefore, the most used analysis for a basic evaluation of the arrhythmias and then of the basic health status of the heart [6] is usually considered the detection of the position of the R peaks in an ECG signal and then the calculation of the time distance between adjacent R peaks (RR distance or time interval).

The R-R time interval represents the time between two QRS complexes as shown in Figure 2. It is also called as the inter-beat interval (IBI) or beat-to-beat interval and plays a vital role in diagnosing most common heart rhythm irregularities. The number of R peaks in a specific time interval allows to calculate the heart rate in BPM (Beats Per Minute). Moreover, the variation of the RR time interval during a medium-long term recorded ECG signal is called the hearth rate variability (HRV). It is the variation in the time interval between heartbeats. It is also known as "cycle length variability", "RR variability" and "heart period variability".

The measurement of the HRV helps in evaluating cardiac autonomic regulation and thus provides significant information regarding cardiac irregularities or injuries. So, it is very important to correctly determine the R-R intervals and the HRV for auto diagnosis purposes [6].

For these reasons, researchers and engineers have put an increased effort into developing efficient ECG analysis algorithms to run also within mobile phones and smartwatch or personal computer for post-acquisition diagnosis purposes. Anyway, a simple and quickly running algorithm, performing a real time reliable auto diagnosis and suitable for fast ES implementation, is still a challenge. A wearable ES is more and more reliable than a smartwatch because gets the signal directly form the chest, near the heart.

In fact, compared with other algorithms performing similar tasks, the new one is particularly suitable and optimized for the implementation on microcontrollers and FPGAs and reliably records the DII ECG signal and detects the most common arrhythmias and the HRV in real time.

The purpose of this paper is to describe the algorithm and the core of an auto diagnostic, low cost, wearable, and reliable FPGA-based medical device with real time diagnostic capabilities, implementing the algorithm. The algorithm has been modeled in MATLAB before the implementation in the FPGA for a deep debug purpose and, to this aim, a GUI has been also developed by the author, in MATLAB environment. Therefore, the debug results and the GUI capabilities are also described in this paper. Therefore, in section II it is proposed an overview about the most common arrhythmias and the proposed detection algorithm is detailed; in section III it is described the implementation of the algorithm in the Cyclone V FPGA provided by Intel and the design of the related ES; in section IV are discussed the results of the debug and testing of the ES. Conclusions and future developments are in section V.

II. ARRHYTHMIAS AND THE NOVEL DETECTION ALGORITHM

ECG signal where the rhythm of the heart represents no disease or disorder is called Normal Sinus Rhythm (NSR). Cardiac arrhythmia could be defined as a disorder or disturbance or any abnormality resulting in the normal activation sequence of the myocardium giving rise to irregular heartbeat or abnormal rhythm of the heart that may cause permanent injury to the heart. Although cardiac arrhythmia is one of the leading causes of death, it can be treated if detected on time [7 - 9].

Arrhythmias can take place in a healthy heart having minimal consequence but may also indicate a serious problem that leads to stroke or sudden cardiac death, scarring of heart tissue or change of heart structure or heart blocks or premature beats due to lack of blood flow to the body [6]. Although arrythmias can be of many types [10-13] as summarized in figure 3, there are a few of them fundamental and commonly occurring [12, 13], essential to know the health status of the heart, also treated in the most worldwide available ECG database, as the MIT-HB one [14].

Heart rhythm disturbances visible through the HRV analysis, are [15]:

Bradycardia: occurs if the heart rhythm is regular but the rate observed falls below 40 BPM at rest.

Tachycardia: occurs if the heart rhythm is regular but the rate observed lies above 140 BPM at rest.

Atrial fibrillation: if the ECG signal does not have a regular rhythm and some of the waves, segments and intervals (depicted in figure 2) are either absent or immeasurable at rest, since some features are indiscernible, along with a chaotic rhythm and the duration of each QRS complex of about 0.084s, this could represent atrial fibrillation.

Ventricular tachycardia: if the ECG signal does not have a regular rhythm and some of the waves, segments and intervals are either absent or immeasurable; the rate observed is over 140 BPM at rest and some features are indiscernible and the duration of each QRS Complex is larger than 0.53s and is

wide and bizarre, it can be concluded that this could represent ventricular tachycardia.

In figure 4 are shown examples of the heart-rhythm conditions on the typical ECG signal.

Although there are numerous methods, even very accurate, to diagnose arrhythmias with complex algorithm, including artificial intelligence models [10], however, to reduce the computational burden and for a real-time application, in order to diagnose fundamental arrhythmias through simple, miniaturized and wearable devices, it is not necessary to resort to sophisticated techniques and calculations.

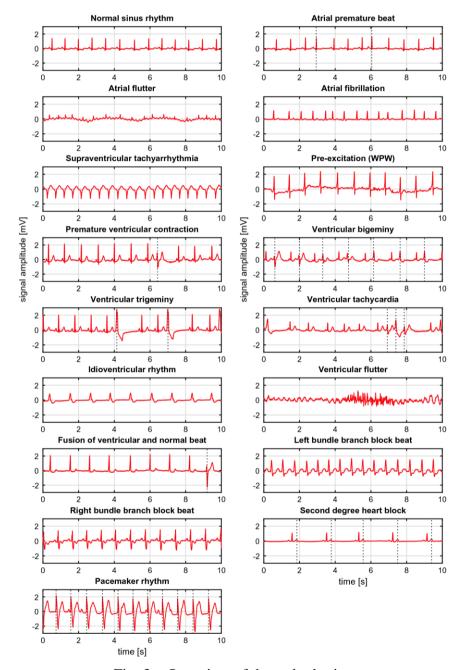


Fig. 3 – Overview of the arrhythmias

Also for determining the R peaks, numerous algorithms, have been proposed in literature [6, 10, 15, 16] but they are all quite time-expensive and not optimized for real-time applications and for FPGA implementation. The methods are based on the extraction of a particular parameter of the QRS wave: the slope, the duration, or the width [17-22].

The method based on the slope of the QRS complex has been discarded as it needs to perform a derivative of the signal and this would introduce high frequency noise components, since the derivative operation corresponds to a high pass filtering. Furthermore, following this approach, complexes with high amplitude and duration may not be detected, since in this case it would not be possible to exceed the threshold value. Furthermore, the derivative operation would require a large amount of RAM memory. On the other hand, measuring the duration of the pulse would risk confusing the T waves (see figure 2) with the ORS complexes.



Fig. 4 – Main cardiac rhythm conditions

For these reasons, this paper proposes a novel algorithm accurate, fast-performing and easy-to-implement in microcontrollers and FPGAs for the auto-diagnosis of fundamental arrhythmias on wearable ECG devices.

The algorithm by processing the DII derivation of the II-Leads ECG signal detects:

- 1) Arrhythmias
- 2) Tachycardia
- 3) Bradycardia
- 4) Arrhythmias in the presence of tachycardia
- 5) Arrhythmias in the presence of bradycardia
- 6) Ectopic heartbeat: generally irregular heartbeat, then tachycardia or bradycardia, then again normal, and so on.

To this aim, after a real time pre-processing step on the raw ECG signal, the characteristics points of the ECG have been detected (ECG segmentation) and QRS complexes have been made impulsive finding R peaks in the ECG and converted into digital 1 of 16 bits each (1111....1 bit, 16 times). For

debug purposes has been analyzed an ECG signal sampled at 1 kbps with a 16-bit resolution and 0.5 microvolts/LSB, lasting about 2 minutes [23]. It follows the description of each processing step of the algorithm.

Pre-processing:

In the preprocessing stage, the noise is removed or suppressed using specific filters to extract the required information from the signal and for noise reduction. Moreover, a filter for the baseline alignment is applied. Anyway, depending on the quality of the acquired, raw ECG signal, we can choose between a lot of filters we have implemented for preprocessing purposes, as shown in fig. 5 in which is depicted the shell of a Matlab GUI designed by the author for debug purposes of the processing chain, step by step and with multiple choices of elaboration blocks. Basic preprocessing steps are baseline alignment (fig. 6), bandpass filtering in 0.2-40 hz band and denoising wavelet (fig. 7).



Fig. 5 – MATLAB GUI for debug purposes of the processing chain implemented with the detail about all filters implemented and allowed to be chosen.

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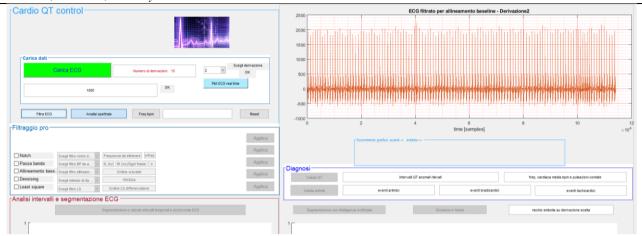


Fig. 6 – Baseline alignment by using wavelet Daubechies 6

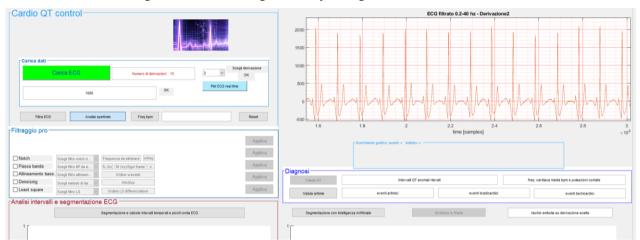


Fig. 7 – Bandpass 0.2-40 hz filtering with order 10 FIR filtering and denosing wavelet by using Coiflets 5

Segmentation

After the pre-processing step and the application of necessary filters, it is possible to perform the signal segmentation (see figure 8), and particularly the localization of points P-Q-R-S-T on each beat of the ECG signal. The starting point is the localization of R peaks. The adopted algorithm is innovative and will be detailed subsequently.

Once R peaks have been localized, Q and S peaks are detected by finding out the first local minimum from the left of the positive R wave and the first local minimum from the right of the positive R wave, respectively along with its amplitude, locations and durations followed by finding out the duration of the QRS Complex.

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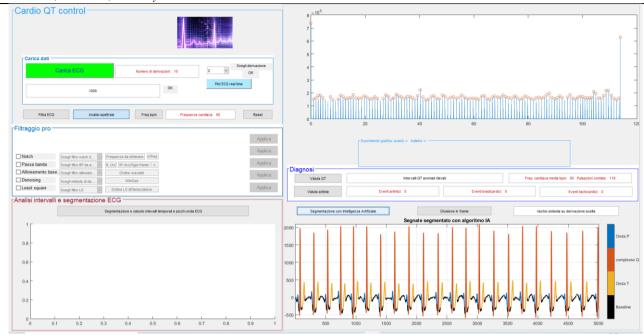


Fig. 8 – Signal segmentation.

In particular, the algorithm and the relevant Matlab code to determine the ECG-waves for each cardiac cycle (heart beat) is the following:

• S wave: the examination range is delimited between the i-th R wave up to the middle of the i-th cardiac cycle. The S wave will correspond to the minimum point that is identified in the range under examination.

```
%onda S
for ii=1: (length(peakRLocend)-1)
    [peakSMagend(ii) peakSLocend(ii)]= min
    (ecg(peakRLocend(ii):(peakRLocend(ii)+(peakRLocend(ii+1)-
    peakRLocend(ii))/2)));
    peakSLocend(ii)=peakRLocend(ii)+peakSLocend(ii);
end
```

• T wave: the examination range is restricted between the i-th S wave up to the middle of the i-th cardiac cycle. The T wave will correspond to the maximum point that is identified in the range under examination.

```
%onda T
for ii=1:(length(peakRLocend)-1)
    [peakTMagend(ii) peakTLocend(ii)]= max
(ecg(peakSLocend(ii):(peakRLocend(ii)+(peakRLocend(ii+1)-peakRLocend(ii))/2)));
    peakTLocend(ii)=peakSLocend(ii)+peakTLocend(ii);
end
```

• Q wave: the examination range is narrowed between half of the i-th previous cardiac cycle and the next R wave. The Q wave will correspond to the minimum point that is identified in the range under examination.

```
%onda Q
for ii=1:(length(peakRLocend)-1)
        [peakQMagend(ii) peakQLocend(ii)]= min
(ecg((peakRLocend(ii)+(peakRLocend(ii+1)-
peakRLocend(ii))/2):(peakRLocend(ii+1))));
        peakQLocend(ii)=peakRLocend(ii)+(peakRLocend(ii+1)-
peakRLocend(ii))/2+peakQLocend(ii);
end
```

• P wave: the examination range is narrowed between half of the i-th cardiac cycle and the next Q wave. The P wave will correspond to the maximum point that is identified in the range under examination.

```
%onda P
for ii=1:length(peakQLocend)
    a=round((peakRLocend(ii+1)-peakRLocend(ii))*2/3);
    [peakFMagend(ii) peakFLocend(ii)]= max
(ecg((peakRLocend(ii)+a):(peakQLocend(ii))));
    peakFLocend(ii)=peakRLocend(ii)+a+peakFLocend(ii);
end
```

An example of the determination of R and S points and of the QT wave are shown in fig. 9 and 10, respectively.

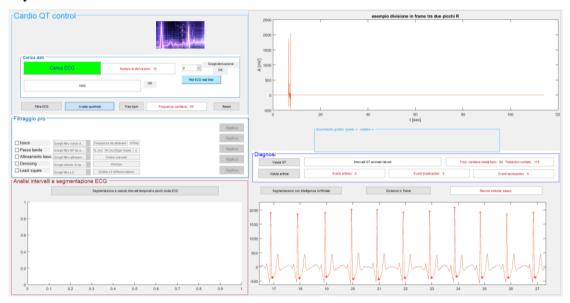


Fig. 9 - RS points determination

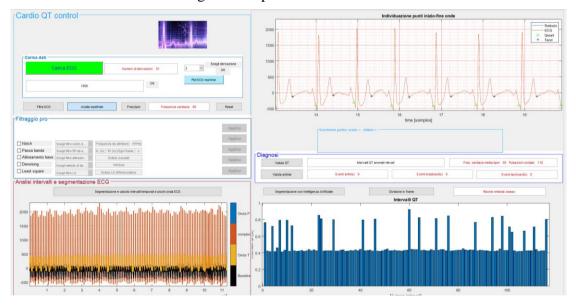


Fig. 10 – QT interval determination

R peak detection and transformation of the ECG in a pulse-train waveform

The starting point of the whole algorithm is the quick and easy detection of the R peaks of each QRS complex. The method adopted is therefore based on the measuring of the R peak width. For the detection of any R peak, it was necessary to set an adequate threshold value. This value is obtained as approximately 70% of the maximum signal amplitude [24]. Once the threshold for the R peak determination has been estimated, the novel algorithm developed by the author to find R peaks is original as described below and depicted in figure 11

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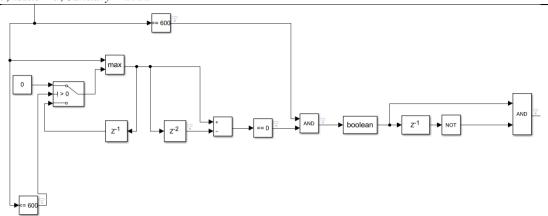


Fig. 11 – processing diagram of the algorithm to localize R peaks

The processing consists in analyzing the local maximum only in the vicinity of the determined amplitude threshold. A switch block was therefore used to force the signal to zero when it is less than the threshold and leave it intact when it is greater. A maximum search function was therefore implemented using a MAX block and a delay of 2 samples. In fact, assuming a non-constant signal, exactly when the outputs of the two blocks coincide, it is certain to have been in a maximum condition (2 samples before). By concatenating this information with the signal level above the amplitude threshold and designing a "rising edges" detector a stable and effective system has been obtained which produces a pulse in the time position of the maximum of every beat. In figure 12, the result of the R peak detection algorithm implemented for debug purposes in Simulink are shown.

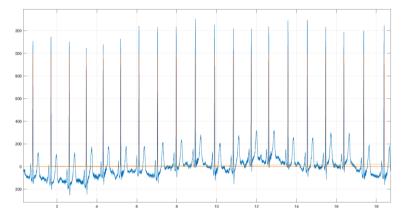


Fig. 12 – Example of R peaks detection applying the proposed algorithm on a sample ECG signal *Auto diagnosis algorithm description*

After finding the R peaks and making the signal impulsive the ECG signal is segmented and finally is processed to extract information about the health status of the heart, according to the algorithm depicted in figure 13 and described below.

As previously stated, a triplet of QRS complexes, i.e.: a triplet at a time of unitary pulses in a pulses-transformed ECG, is analyzed. The heart rate ranging between a minimum and a maximum value, for example between 40 bpm and 140 bpm, can be considered normal. Therefore, a tachycardia occurs in the case in which the heartbeat rises above 140 bpm, and a bradycardia if the heartbeat value is below 40 bpm.

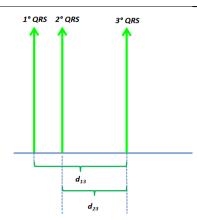


Fig. 13 – Sketch of the algorithm implemented on the ECG signal made impulsive for arrhythmias detection.

By the pulses-transformed ECG signal, it is possible to calculate the instantaneous Heart Rate, expressed in BPM, by the time distance d_{ij} between two adjacent pulses, i.e.: two adjacent R-peaks. In fact, it results:

 $HR = 60/d_{ij}$

being d_{ij} the RR distance between generic i-impulse (i.e.: i-R peak) and its adjacent j-impulse (i.e.: j-R peak).

In quantitative terms, if a value of d_{ij} is lower than 0.43s (60s / 140 bpm), it can be concluded that there is a tachycardia. Similarly, if a value of d_{ij} is greater than 1.5s (60s / 40 bpm) a bradycardia is detected.

Considering each triplet of pulses, i.e.: each triplet of QRS complexes, referring to figure 13, naming d_{12} the time distance among the central pulse of the triplet and the previous one and d_{23} the time distance among the central pulse of the triplet and the subsequent one, arrhythmias occur if the following empirical condition is matched:

 $d_{12} \le 40\%$ d_{13} and the central pulse must be classified as arrhythmic.

Moreover, if $d_{12} < 0.4 d_{13}$ then an arrhythmia occurs while if the single distances d_{12} and d_{23} exceed or are below the bradycardia or tachycardia thresholds, the central impulse as well as arrhythmic must also be bradycardic or tachycardic.

Once the check on one triplet is completed, the new complex QRS-1 becomes the previous QRS-2, etc. and the check will be repeated on to the subsequent triplet of QRS complexes, i.e.: on to the pulses replacing each of them. It is important to emphasize that as it was designed, this algorithm is also able to detect any presence of arrhythmias in conjunction with tachycardias or bradycardias. This is a very useful method, easily implemented in a FPGA and/or a microcontroller to detect almost in real time any arrhythmic heartbeat. In fact, only three heart beats are required to be examined at a time, as shown in fig. 13, and, therefore, this method allows very easily to perform the almost real time analysis of the ECG.

Once the analysis is complete, the number of identified R peaks, i.e.: QRS complexes, the number of arrhythmias, the number of bradycardias and the number of tachycardias can be counted and displayed.

The average BPM can be also calculated by the formula:

 $HR = 60/RR_{(avg)}$

being RR_(avg) the average distance between R peaks found.

The physiological phenomenon of variation in the time interval between heartbeats is termed as Heart

Rate Variability

(HRV). This is calculated by [15]:

(HRVmax – HRVmin) x100

This information provides the complete diagnosis checked.

III. DESIGN AND DEBUG OF FPGA-BASED EMBEDDED SYSTEM IMPLEMENTING THE NOVEL ALGORITHM

A sequential digital machine using the FPGA CYCLONE V 5CSEMA5F31C6 fabricated by INTEL has been designed to implement the algorithm. For test and debug purposes the design has been deployed on a DE1_SoC development board by TERASIC, mounting the FPGA.

The development suite is Quartus Prime ver. 20.0. The design is portable on FPGA devices provided by any other foundry maintaining all the required functionalities because it is performed in Verilog HDL language. The input of the digital sequential machine is the ECG signal preprocessed and made impulsive by positioning a unit pulse at any detected R peak, as previously described. The preprocessing filters and the R-peaks detection algorithm have been implemented in MATLAB Simulink environment, as previously detailed, and have been automatically translated into HDL language by using the HDL Coder tool. This MATLAB tool is very useful because allows to translate MATLAB functions and Simulink models in HDL language producing a code optimized to run on FPGA devices.

All the preprocessing and R peaks detection section of the sequential machine has been summarized in a ROM block in which the pulses-transformed ECG signal has been stored for the algorithm debug purposes only. If the device runs in real-time mode, the ROM block is removed, and the ECG signal comes directly from the analog interface that acquires the cardiac potentials (II-Leads, ECG device) directly by classical removable Ag/AgCl sensors placed on the chest of the person.

The core of the sequential digital machine performing the auto diagnosis is a "sliding door", i.e., a processing window moving with each pulse of the pulses-transformed ECG. It has an amplitude equal to three pulses, i.e., to three QRS complexes, to analyze a triplet of R peaks at a time, as already explained.

Once the triplet of pulses has been windowed, to the measure and to calculate the time distances d_{12} and d_{23} (and then of $d_{13} = d_{12} + d_{23}$) a reference clock signal at a stable and known frequency is superimposed. In this way, the distance between pulses is evaluated in terms of number of clock periods occurring between them.

The sequential machine consists of three functional modules, as shown in Figure 14.

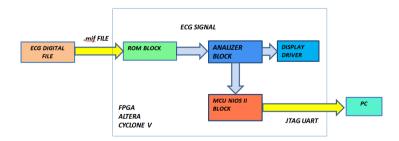


Fig. 14 – Functional block diagram of the sequential machine implemented

There are three functional modules:

- ROM Block: it stores the pulse-transformed ECG. Out of debug process the system runs in real

time and the ROM block is not necessary.

- Analyzer Block: it contains the sequential digital machine performing the auto diagnosis.
- MCU Nios II Block: it is based on the Nios II soft CPU embedded in the FPGA, which collects all diagnosis results.

The pulses-transformed ECG signal is stored into the ROM bank in a 16-bit words format as:

1111111111111111 -> if an R peak is detected

0000000000000000 -> if no R peak is detected

Figures 15 a-b-c show a simulation of the operation of the analyzer block. Once the first pulse (i.e.: the first R peak) has been locked (fig. 15 a), a window with a duration equal to three pulses (triplet) is opened onto which a reference clock signal is superimposed. Once the first triplet has been analyzed, the system automatically moves to the second (fig. 15 b) and third (fig. 15 c), verifying and reporting any arrhythmias found.

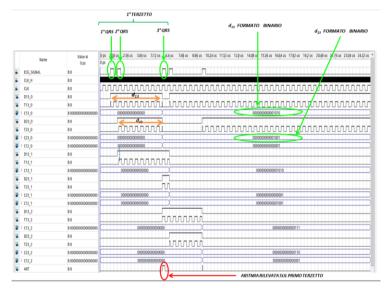


Fig. 15 a - Simulation of the analysis of the first triplet of ECG R-peaks

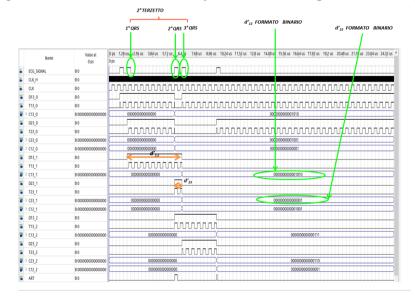


Fig. 15 b - Simulation of the analysis of the second triplet of ECG R-peaks

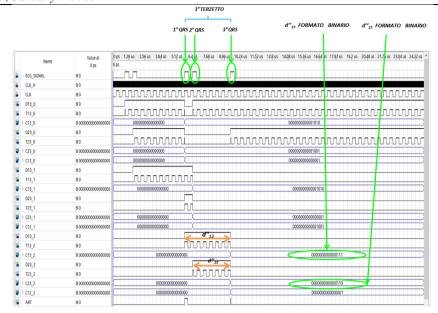


Fig. 15 c - Simulation of the analysis of the third triplet of ECG R-peaks

Simulations show the correct operation of the sliding door and of the sequential machine for auto diagnosis purpose.

IV. FUNCTIONAL TEST AND INSTRUMENTAL CHECKS

Functional tests were carried out with the Signal Tap II Logic Analyzer tool, integrated in Quartus Prime IDE, and with an external USB logic analyzer (ZEROPLUS LAP-C LOGIC ANALYZER). To this aim, a data file was created suitable for ROM storage, with 6 R peaks, suitably spaced to have:

- 6 QRS pulses.
- 1 Bradycardia.
- 1 Tachycardia.
- 2 Arrhythmias.

Then, once the Quartus project has been compiled and the FPGA programmed by using the Quartus programmer, the proper instrumentatal checks have been performed. Then, the DE1_SoC appears like in the photo in figure 16:



Fig. 16 – Photo of the DUT mounted on the DE1_SoC evaluation board

The seven segment displays on DE1_SoC board show the number of QRS waves detected (06), the number of bradycardic heartbeats (1), the number of tachycardic heartbeats (1) and the number of

implemented on FPGA.

arrythmias detected (02). The following figures 17 a - b - c - d, show the results of the analysis of the logic states. Fig. 17 a - b - c - d – results of signal analysis performed by the Signal tap II Logic analyzer, embedded in Quartus prime IDE, and with another external USB logic analyzer. Results match perfectly and demonstrate the proper functioning of the auto diagnostic sequential machine

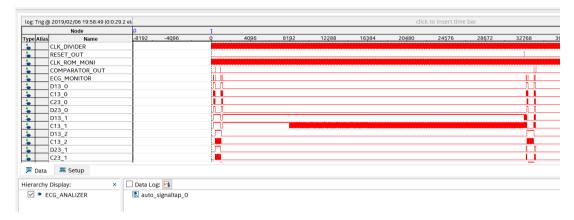


Fig. 17 a

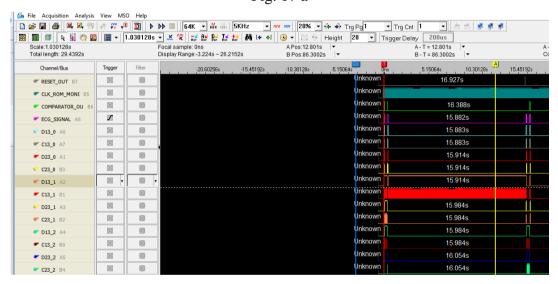


Fig. 17 b -

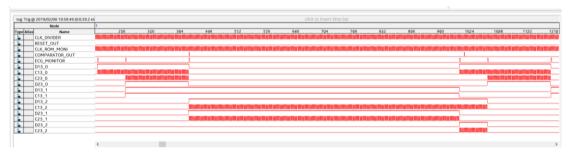
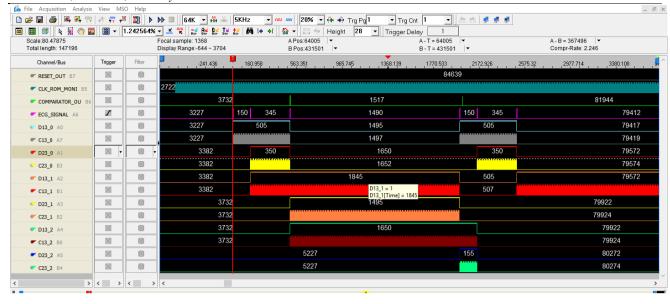


Fig. 17 c



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Fig. 17 d

The analysis results perfectly reflect the specifications and the simulations of the sequential machine performed by using the waveform editor tool of the Quartus IDE and shown in figures 15 a, b, c. Particularly, the R peaks are clearly and reliably detected. Subsequently, the time distances between the R peaks of the pulses-transformed ECG signal are evaluated and compared according to the new described algorithm. If an arrhythmia is detected, the comparator generates a clock signal sent to a counter. At the same time, an analysis is carried out to distinguish bradycardia or tachycardia. The following figures 18 and 19, show the results of the instrumental analysis.

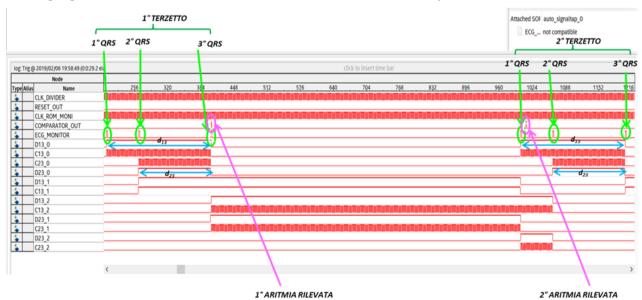


Fig. 18 – Arrhythmias detection by instrumental analysis performed by using the Signal Tap II Logic Analyzer embedded in Quartus Prime IDE

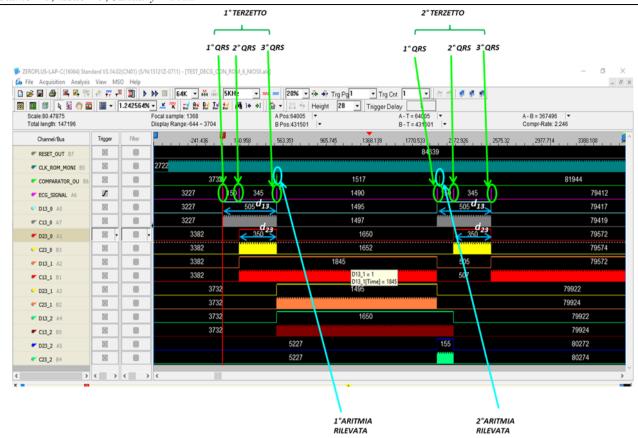


Fig. 19 - Arrhythmias detection by instrumental analysis performed by using the external USB Logic Analyzer

V. CONCLUSIONS AND FUTURE DEVELOPMENTS

In this paper, it has been described a novel algorithm for reliable, real time auto detection of arrhythmias, and suitable to be quickly and easily implemented on FPGA based wearable, battery-operated, medical devices. It has been also explained the procedure to build low cost and low consumption portable ECG devices and an example of the core of an FPGA-based ES implementing the novel algorithm. By engineering the system with a miniaturized PCB and an Ultra-Low-Power FPGA (for example the CYCLONE 10 LP) it would be possible to obtain a life-saving system with low consumption and low maintenance. Furthermore, by equipping the same system with an IoT interface, it will be possible to transmit data and share them with medical specialists for consultations in real time, and to alert prompt rescue in case of heart failure automatic detection.

Conflict of interest: The authors declare that they have no conflict of interest.

Ethical statement: The authors declare that they have followed ethical responsibilities.

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