An IoT based ECG system to diagnose cardiac pathologies for healthcare applications in smart cities

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TITLE PAGE

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HIGHLIGHTS

- A smart ECG system is proposed to diagnose cardiac pathologies
- The system is an Ambient Assisted Living solution developed for smart cities
- An IoT approach permits to use the system in telemedicine applications
- Measurement uncertainty is taken into account to improve the diagnosis reliability
- Experimental results show the reliability of the proposed ECG system

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Abstract

The present paper aims to describe the project and development of an ECG monitoring system which is able to diagnose specific cardiac pathologies by adapting the processing algorithm to the monitored patient. The system can work standalone by providing the final diagnosis to the patient by a LEDs set. In addition, an IoT based architecture allows the system to share data and diagnosis with a remote cardiologist in real-time or to store data in a FTP folder, as an Holter monitor, for post-processing and further analysis.

The system consists of two sections: the digital one, based on the *National Instruments MyRIO*, digitalises the signal and processes it in real-time to make a diagnosis on possible occurring cardiac pathologies (bradycardia, tachycardia, infarction, ischemia); the analog section, which performs the acquisition, amplification, and preliminary filtering of a 3-leads electrocardiographic signal. The processing algorithm has been developed in *NI LabVIEW* environment. The main contribution to the state of the art is due to two removable and updatable memory devices. A first memory has been used to store clinical and personal data of patient so to configure the computing algorithm and adapt it to the monitored patient. A second memory has been used to store accuracy and uncertainty specifications of the ECG system in order to improve the reliability of the final diagnosis.

The system aims to provide an electrocardiographic monitoring system for healthcare applications in the smart city context. The possibility to monitor constantly the patient health state at home is an important challenge of the next future smart cities. IoT and automation are the main aspects of the proposed system. Patients having chronic heart diseases need frequent hospitalizations to check their heart health. In this scenario, the proposed system is an Ambient Assisted Living solution developed to encourage the independent life of cardiac subjects by supporting his/her care and wellness during the daily life.

Keywords: ECG; cardiac pathologies; Ambient Assisted Living; healthcare; smart city; IoT.

1. Introduction

Heart diseases are widespread in the world and today they are the leading cause of death of the human beings. Traditional risk factors include diabetes mellitus, hypertension, dyslipidaemia, smoking, obesity and physical inactivity. Emerging and new risk factors include preterm delivery, hypertensive pregnancy disorders, gestational diabetes mellitus, breast cancer treatments, autoimmune diseases and depression.

The rhythmical contractions of ventricles and atria allow the heart to pump regularly the blood into the body so oxygenating the organs and cells in general. Myoelectric impulses regulate the heart activity. Those impulses make the muscles of the heart cavities to rhythmically contract. Arrhythmias occurring in myoelectric signals are symptom of cardiac diseases and pathologies. Typically, heart diseases are the normal consequence of the passing of time, so heart can suffer from possible abnormal rhythm. Sometimes, specific pathologies or sedentary lifestyle may cause arrhythmias, myocardial ischemia or infarction. Nevertheless, an irregular trend of the cardiac myoelectric waves is always symptom of heart faults. The Electrocardiogram (ECG) is the recording of the heart electrical activity. As a consequence, the heart health can be monitored by recording and analysing the ECG waveform. The analysis of the heart electrical activity can provide useful information on possible arrhythmias and cardiac diseases, so frequent (sometime continuous) clinical monitoring is recommended in heart patients.

In literature, several solutions based on ECG measurement systems allow to record and process the cardiac signal by means of skin electrodes displaced on chest and limbs [1]-[4]. The ECG recording is the main non-invasive tool used to make preliminary clinical diagnosis of heart diseases. Further screening tools, such as Doppler ultrasonography, allow to make a more careful diagnosis. The main issue of the ECG systems concerns the use of standard processing algorithms which may be cause of incorrect diagnoses due to possible false positive or false negative answers. Therefore, the use of more suitable algorithms relating to the monitored patient is strongly recommended. To understand deeply this issue, let us consider the heart function. The cardiac activity is regulated by rhythmical myoelectric impulses which propagate along the muscle cell membranes. This allows atria and ventricles to alternatively contract so pumping blood throughout the body. A rhythmical cardiac waveform, visualized with a standard ECG signal, is index of a healthy heart. Nevertheless, specific pathologies such as previous infarctions may be cause of permanent alterations in the electrocardiogram waveform due to the onset of necrotic areas in the heart. This is often cause of false positive diagnoses when processing the acquired signal. The possibility to have available the patient health history, then, could be an important discriminating means to make reliable diagnoses. Subjects having chronic heart diseases need frequent hospitalizations to check their heart health. Continuous monitoring can allow to keep under control constantly the heart and to make an early diagnosis of abnormalities such as infarction and ischemia. As a consequence, the possibility to monitor the patient health state at home is an important challenge of the smart cities of the next future.

The state of the art shows a lot of new devices and instrumentation developed in order to monitor in real-time heart activity, [1]-[4]. Telemedicine and homecare services are today an important alternative to the hospital admission. Some ECG systems perform only the acquisition of the echocardiographic signal, so the diagnosis is made in post-processing by the cardiologist. Only few systems acquire and process in real-time the ECG signal providing a preliminary diagnosis, [5]-[9]. Such systems provide information on the heart state by evaluating the amplitude and duration of the ECG components waves. Arrhythmias are detected by comparing the acquired ECG waveform with a standard ECG signal used as reference model. These references are ranked according to some generic parameters such as sex, age and body mass. As a consequence, the same model is used for several patients having different medical histories, so false positive or false negative diagnoses are possible. The authors have proposed in previous works, [9]-[12], the use of reference models more appropriate to the specific monitored patient. Medical history, information on previous pathologies could optimize the choice of the reference model suitable to the patient. Patient-adaptive systems can reduce the probability of possible false diagnoses. In this paper, the authors propose the project and development of an improved smart ECG system. The system in [9] has been entirely redesigned to improve its features. In detail, IoT paradigm has been implemented to provide an Ambient Assisted Living solution designed for healthcare applications in a smart city framework. The proposed electrocardiographic monitoring system could encourage the independent life of people with heart problems by supporting their care and wellness during the daily life so reducing the hospitalization time. By means of removable memory devices, the system is able to adapt the processing algorithm to the monitored patient. The used reference model is configured according to the medical history of the patient. Information concerning the measurement uncertainty is used to improve the reliability of the diagnosis. A set of 3-leads allow the system to acquire the ECG signal and so to process it by computing specific parameters put in comparison with the corresponding ones of the reference model. Four pathologies can be diagnosed: tachycardia, bradycardia, ischemia, infarction. The diagnosis is showed to the user by means of a set of four led. In an IoT approach, data is also accessible remotely by IP address using a simple web browser. A panel control shows the main parameters of the ECG waveform, its trend over time, the denoised signal and the final diagnosis. Finally, data is stored in an ftp folder of a remote server to collect heart health history of the monitored patient similarly to the Holter monitor.

To make clear the aim of the present paper and its specific contribution to the state of the art, a careful analysis of the current literature has been made by comparing the proposed system with other similar ones. In **Errore. L'origine riferimento non è stata trovata.** the authors report a comprehensive and systematic review of the literature referring to ECG monitoring systems. This review provides a practical guide based on evidence for understanding features and challenges of the most relevant solutions. Moreover, in [13], 42 ECG monitoring systems are classified by considering primary and supporting processes such as signal acquisition, data pre-processing, feature extraction, signal elaboration, result visualization, data compression and storage, modelling and data encryption. A preliminary comparison with the papers cited in [13] shows that few systems perform a features extraction. In addition, even less works provide additional supporting processes such as data storage or encryption. Most of the proposed systems focus attention only on specific processes like data acquisition, pre-processing and signal modelling depending on the application purpose. In detail, only 10 works, [14]-[23], refer to ECG monitoring systems which are able to process in real-time the ECG signals and to store data for further analysis and post-processing. The systems proposed in [14]-[17] are not able to perform the acquisition of the ECG signal, so their main aim is to process data provided by user. In [18] authors propose a cloud-based solution for real time ECG monitoring and analysis, the system is able in addition to encrypt data to preserve privacy of patient. In [19]-[21] the proposed ECG systems are able to acquire and process ECG signal without performing a features extraction of the cardiac signal waveform. Two other manuscripts, [22] and [23], show interesting approaches for real-time cardiovascular diseases detection by acquiring and analysing ECG signals. Although such systems, [14]-[23], are able to store data, no one use stored information in order to customize the processing algorithms to the specific patient so to minimize possible errors during ECG signal analysis. In addition, no information concerning the metrological characteristics of the measurement system are declared. So, information such as accuracy, resolution, measurement uncertainty, and last calibration data is completely disregarded in such systems. Just few of these solutions consider age and sex in order to define specific diagnostic thresholds to be used during the processing stage.

Another interesting review paper, which is reported in [24], performs a literature analysis by using a different classification approach. In detail, a scoping review is proposed by getting access to different bibliographic databases. Objectives, assessments and main findings are listed to highlight the specific contribution of each work. This review paper provides a different view into the field of ECG monitoring systems. Most of the investigated papers are focused on the detection of atrial fibrillation or heart palpitations and arrhythmias. The above paper highlights the need to identify solutions alternative to hospitalization in order to assure primary care. The use of mobile solutions detecting occurring arrhythmias is suggested as the most practical solution to reduce the risk of morbidity and mortality. Specific exclusion criteria have allowed authors to refine the review process by identifying 9 papers over 858 records assessed for eligibility, [25]-[33]. So, our analysis has been focused on these manuscripts. In these works, the respective authors propose different solutions based on the evaluation of the atrial fibrillation detected in ECG records. Some of these systems, [25]-[27], propose to analyse ECG signals recorded in different days in order to detect abnormalities in the records. So, in these cases, previous records are just used to characterize changes in the short time of ECG waveform. Further two papers in [28] and [29] show mobile ECG solutions in order to prove the feasibility to detect atrial fibrillation that will otherwise go undiagnosed. In [30] the authors describe a feasibility study about the use of extended ambulatory electrocardiogram monitoring to diagnose silent atrial fibrillation in high-risk patients. The study reported in [31] describes the efficacy to monitor twice-weekly heart activity by using a single-lead ECG system and processing remotely data. Last two papers [32]-[33] describe different solutions based on an app and an ambulatory ECG monitoring, respectively. These works show the results of experimental studies carried out to characterize premature atrial and ventricular contractions or asymptomatic arrhythmias recognised as predictive factors for the development of atrial fibrillation or stroke events.

Another comprehensive survey is reported in [34], in this paper the authors propose an interesting overview of the current technologies characterising the wireless ECG commercial systems. The aim of the work is to review the solutions described in the literature and commercially available devices useful to setup laboratory prototypes. In [35] the authors propose an IoT solution for the compressed acquisition of electrocardiographic (ECG) signals.

The comparison between these works and the solution proposed in the present paper, shows one again that the main contribution concerns the capability of our ECG monitoring system to adapt the diagnosis criteria according to patient health history. Furthermore, the use of metrological information on the system to get information on the diagnosis reliability is another finding of the present research work that characterizes the system here described in comparison to the current state of the art.

The rest of the paper is organized as follows. The project and development of the proposed ECG system are described in Section 2. Section 3 reports the validation of the system and the experimental results. Final considerations and conclusions are stated in Section 4.

2. The Project and Development of the ECG System

ECG Waveform Description

To describe the design of the proposed ECG system, let us start from the definition of the features of a regular ECG waveform. A standard ECG signal consists of five waves (see Figure 1), i.e. myoelectric impulses, which stimulate the contraction of atria and ventricles of the myocardium during the systolic and diastolic phases, respectively. Such waves have different amplitude and duration values. Each of these waves correspond to a well-defined phase of the rhythmic heart contraction.

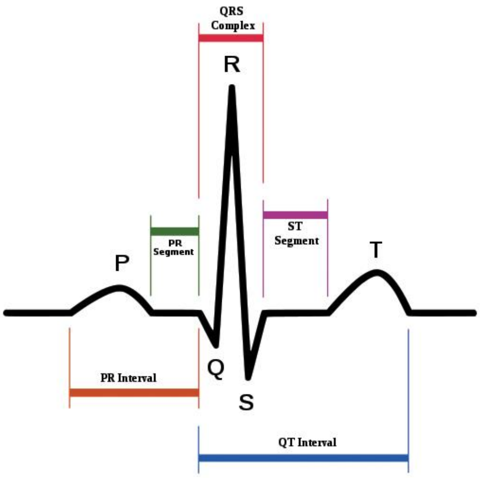

Fig. 1. ECG waveform, [36].

The first phase of the heartbeat is characterized by the atria contraction. This is due to the *P wave*. An irregular *P wave* is index of an abnormal propagation of the myoelectric impulse in the atria due to a possible atrial enlargement. The absence of the *P wave* with a flat baseline may be due to an atrial fibrillation. Then, the myoelectric impulse propagates from atria to ventricles. This phase is represented by the *PR Segment*. The flat portion of the P wave can provide information on a possible propagation delay of the impulse to the ventricles. The successive phase is characterized by the ventricles contraction. The oxygenated blood is pumped towards the whole body. The *QRS Complex* refers to the initial ventricles depolarization. These three waves give information on the ventricular systole. An abnormal *QRS Complex* can be index of hypertrophy of one or both ventricles. This complex is typically analysed to diagnose the occurrence of an infarction or to characterize fibrillations and other common arrhythmias. The final stage of the ventricles contraction is characterized by the presence of the *ST Segment* and the *T wave* in the ECG signal. This part of the waveform can provide information on possible ischemia. In particular, the *T wave* gives relevant information on possible cardiac hypertrophy, infarction and ischemic attack. Further information can be obtained by observing the *QT Interval*, whose amplitude and time duration are useful parameters to diagnose other heart diseases such as cardiac death or sudden and abnormal arrhythmias in response to exercise or stress. The P-QRS-T sequence rhythmically repeats and viewed by the electrocardiogram. Once that the ECG signal is acquired, the processing step has to identify the above waves so evaluating their main features, i.e., amplitude and time duration. Their values are typically put in comparison with reference model ones, based on standard ECG signals classified by sex, age and body mass. Arrhythmias and irregular waves can be identified so to make a diagnosis on a possible cardiac disease.

ECG System Description

The proposed ECG system has been projected according to recommendations of the following IEC and IEEE Standards:

- IEC 60601-2-25:2011, [37];
- IEC 60601-2-27:2011, [38];
- IEC 60601-2-47:2012, [39];
- ISO/IEC/IEEE Standard 21450, 2010, [40];
- ISO/IEC/IEEE Standard 21451-1, 2010, [41];
- ISO/IEC/IEEE Standard 21451-2, 2010, [42];
- ISO/IEC/IEEE Standard 21451-4, 2010, [43];
- ISO/IEC/IEEE Standard 21451-7, 2011, [44].

These Standards have been used to design the filtering features, the system bandwidth and to evaluate the safe currents. Figure 2 shows the general architecture of the ECG system. In detail, the electrodes consist of three skin adhesive $Ag^{+}/Ag^{+}Cl^{-}$ patches to be placed on patient's body (two on torso and one on leg or arm). A standard ECG signal has an amplitude value which is in the range $[0.2 - 2]\ mV$ and its useful bandwidth can range in the interval $[0.5 - 100]\ Hz$. By considering these values, the main contributions of error are due to artifacts and noise. Therefore, the signal is pre-processed by the analog section which performs an amplification and filtering of the acquired ECG signal. A band-pass filter has been designed with a -3dB band set between the lower frequency $f_L = 0.033\ Hz$ and the higher frequency $f_H = 160\ Hz$. At the lower frequencies, this analog filter allows to reject the noise and artefacts in DC due to the DC offset that develops between the electrodes and to remove the low frequency artefacts caused by respiration. At the higher frequencies, this filter allows to remove the common-mode signals that come in the form of line noise or high frequency electromagnetic interferences due to other medical devices. The analog circuit in Figure 3 is powered by a differential DC voltage equal to ±5 V. It has been designed to limit the current driven into the patient body and to isolate him from the power supply so safeguarding him/her from potential harms due to fault currents, according to the guidelines in [37]-[39].

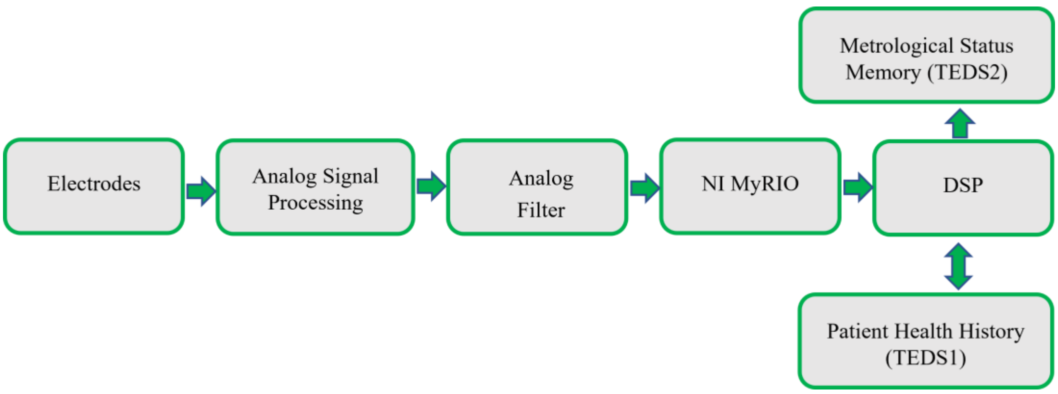

Fig. 2. ECG system architecture.

The digital section consists of a *National Instruments myRIO 1900.* This design choice is due to the specific features of this embedded device with reconfigurable I/O, FPGA and microprocessor which enable real-time signal processing. Further, a Wi-Fi 802.11b,g,n adapter allows the WLAN connection to internet network, so avoiding cables. The digital section performs the analog/digital conversion of the signal by means of a *12 bit A/D converter* with a sampling frequency of $51.2\ kS/s$. To reduce input noise, the signal has been averaged by considering non-overlapping subpopulations with size equal to 100 samples. Two levels of digital filtering have been designed. A preliminary digital filtering of the ECG signal has been performed by using a *-dB6 8-level Wavelet Filter* to denoise the signal so to remove the baseline wandering caused from breathing, motion artifacts and noise due to other myoelectric signals. An additional *band-pass 29-level FIR filter* with cutoff frequencies equal to $5\ Hz$ and $26\ Hz$, respectively, has been used to characterize the *QRS complex*.

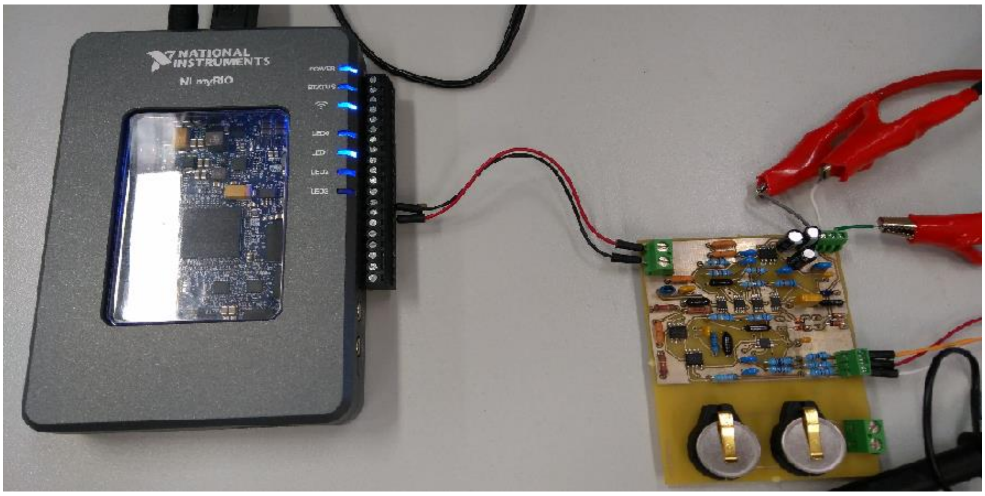

Fig. 3. The developed ECG system.

The digital signal is processed in real-time by the *Digital Signal Processor* (DSP) and the embedded processing algorithm. Two readable and writeable $16\ kb$ EPROMs memory devices (named *Patient Health History* and *Metrological Status Memory*) have been used: they are two *Transducer Electronic Data Sheets* (TEDS1 and TEDS2) [40]-[46]. They have been built-in to store information from the monitored patient medical history and metrological information from the measurement system.

TEDS1 allows system to adapt the processing algorithm to the specific monitored patient. It is important to observe that this memory is specific for the patient. Before using the ECG system, it has to be replaced with the change of the patient or updated if new patient medical history is available. This nonvolatile memory offers a simple solution to store patient data which can be updated on the basis of need. Data on name, age, sex, body mass, previous ECG records, heart rate, R-R variability specific pathologies or congenital arrhythmias and previous heart or ischemic attacks are stored in TEDS1. In addition, this memory stores different standard ECG reference models of healthy individuals. By using the stored information, the system adapts the processing algorithm and selects the best fitted ECG reference model. In this way, abnormal ECG features or specific pathologies of the patient are taken into account during the diagnosis. As a consequence, the system is able to reduce the occurrence of false positive diagnoses by characterizing specific features of the ECG waveform attributable to previous infarctions or ischemic attacks.

The second memory, TEDS2, collects data on accuracy, resolution, measurement uncertainty and last calibration of the system. Before starting the ECG acquisition, the system checks information on the last calibration date in order to understand if an upgrade is required. If the deadline of the next calibration is expired, the system alerts the user by blinking all status led so asking for the next calibration before its use. Information on accuracy, resolution, measurement uncertainty is used to evaluate the integrity of the acquired data and the reliability of the final diagnosis as in [9], [47], [48] (please refer to equation (1) in the following for further detail).

Processing Algorithm Description

In order to describe the processing algorithm, let us consider a middle-aged woman with a standard ECG model. The subject has never had ischemia or heart attacks. After the pre-processing phase, the DSP characterizes the wave components (P-QRS-T) of the patient ECG and evaluates their amplitude and time parameters. The system is able to diagnose four possible pathologies: bradycardia, tachycardia, ischemia and infarction. The evaluated parameters are put in comparison with the reference limits of the selected ECG model. In detail, the used diagnosis criteria are taken from [49]-[51] and reported below:

- **Bradycardia**

  Mean Heart Rate < 60 bpm

- **Tachycardia**

  Mean Heart Rate > 100 bpm

- **Ischemia**

  Amplitude (T wave) > 80% Amplitude (R wave)

  and

  Absolute Amplitude (S wave) > 80% Absolute Amplitude (R wave)

- **Infarction**

  Amplitude (T wave) > 80% Amplitude (R wave)

  and

  Abs Amplitude (S wave) > 80% Abs Amplitude (R wave)

  and

  Time (Q wave) > 0.04 s.

Unfortunately, the measurement uncertainty may be cause of a wrong diagnosis, so false positive and false negative conclusions are possible. If *u* is the standard measurement uncertainty associated to the ECG system, we can estimate it by the B type evaluation choosing a uniform distribution for the parameter under investigation. So, if *m* is the measured value, *l* is the reference limit, *u* the measurement uncertainty and *f(x)* the probability density function chosen for all reasonable value of m, according to the *Guide to the Expression of Uncertainty in Measurement* (GUM),[52], it is possible to evaluate the overcoming probability by a:

$$R_0 = \int_l^b f(x-m)dx \tag{1}$$

where *b* is the upper end of the uniform distribution, as depicted in Figure 4. The above equation allows us to provide quantitative information about the reliability associated with the comparison result between the measured value of the ECG parameter (amplitude or time of the generic wave) and the limit reported in the used ECG reference model. In other words, R_o expresses in the [0 1] range the consistency level of the diagnosis made. For the considered case, the previous integral is reduced to the evaluation of the rectangle area in grey colour as in Figure 4.

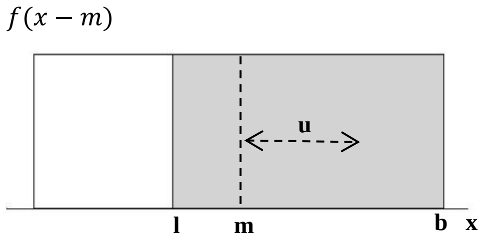

Fig. 4. Probability density function for the measured parameters.

Since the previous diagnosis criteria can refer to more than one parameter, the total *Diagnosis Reliability* (R_D) can be evaluated by means of the minimum of the reliabilities associated to each compared parameter.

$$RD = min(R_{o,i}) \tag{2}$$

IoT and Healthcare Application

The described ECG system offers three different working modalities. It can work stand-alone so providing the diagnosis to the patient by means of a set of LED on the NI MyRIO panel. Each LED is associated to one of the four possible pathologies. In addition, the system can be programmed to contact an Hospital Emergency Room for asking the first aid in case of positive diagnosis. The second working modality needs the connection to an internet network, even wireless. The system requires an IP address that allows a remote user, such as a cardiologist, to get access to the control panel of the system by using a simple web browser, see Figure 5.

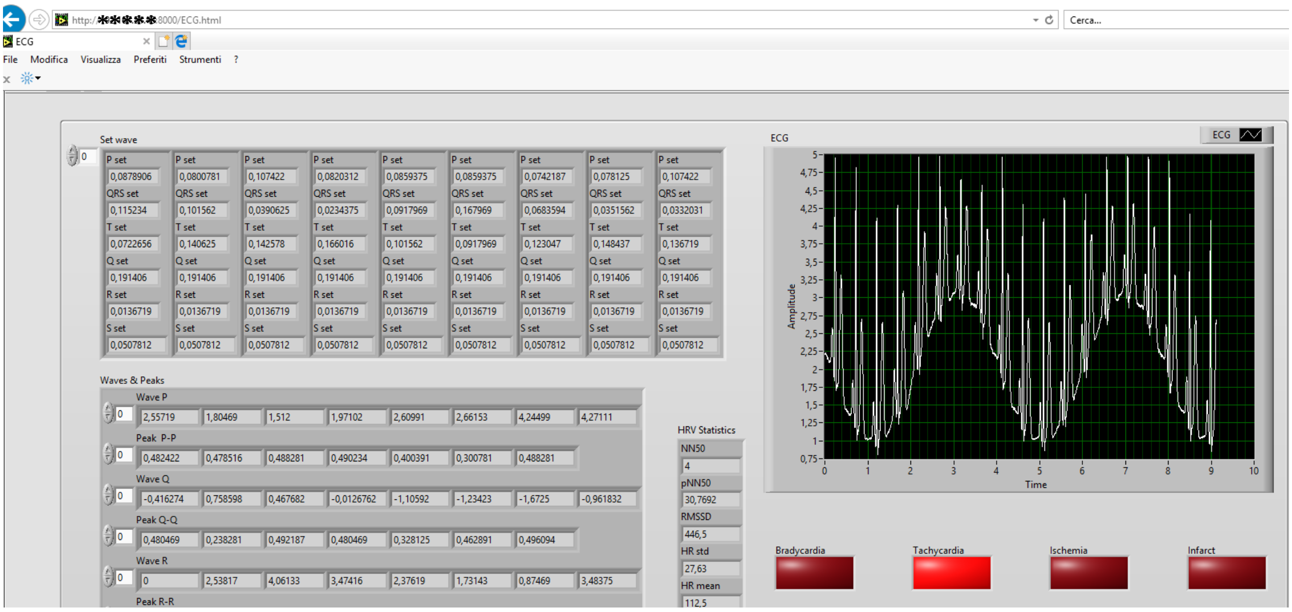

Fig. 5. Remote Access to the Control Panel of the ECG System.

The control panel reports all data concerning the ECG processing, the ECG waveform and the automated diagnosis. In this way, the specialist can perform a further remote analysis in real-time and take a decision about the hospitalization of the patient in case of suspicion of dangerous or potential risk. The third working modality allows the system to store processing data in a FTP folder of a remote server. This utility can permit patient/specialist to get historical medical collection on his/her heart health. It can be used as a Holter monitor for offline post-processing or to get historical data and characterize possible and potentially dangerous drift trends from the standard ECG reference model.

3. Validation and experimental results

The above described ECG system has been validated by performing a set of tests in laboratory. The aim of this experimentation has been to verify the performances of both the analog and digital steps, so to test the sensitivity and the accuracy of the processing algorithm. Several ECG signals have been reproduced in order to simulate the heart activity of healthy subjects and of subjects with specific pathology. Then, the automated diagnosis of the proposed system has been compared with the expected result in order to verify its validity.

Analog Tests

Several ECG waveforms have been reproduced in order to analyse the system response. The hardware test bench includes the *National Instruments DAQ Module NI USB-6521* with *Connector Block NI BNC2111*, see Figure 6 for reference.

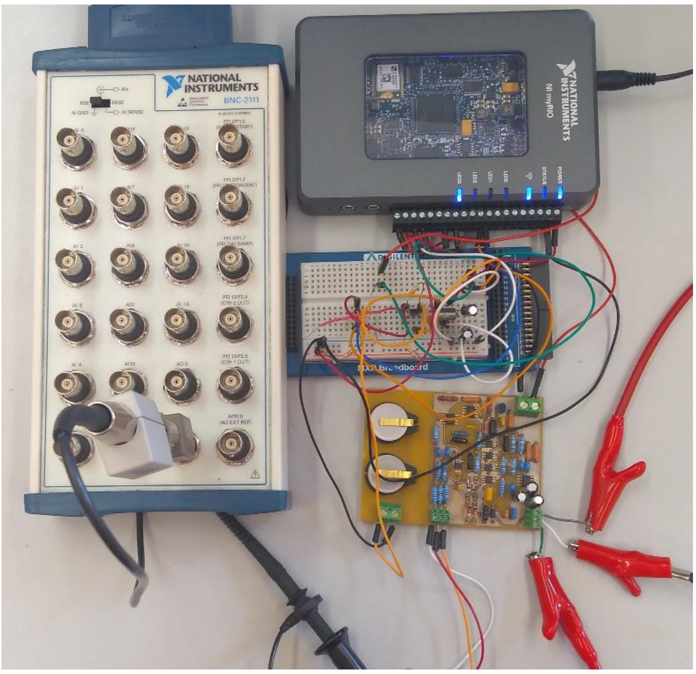

Fig. 6. The test bench used during the system validation.

The used software development environment is the *National Instruments LabVIEW*. The Biomedical Tool of LabVIEW and the two functions "Simulate ECG" and "Biomedical Generation" have been used to simulate and generate the several ECG signals by configuring the features of each waveform as in Figure 7.

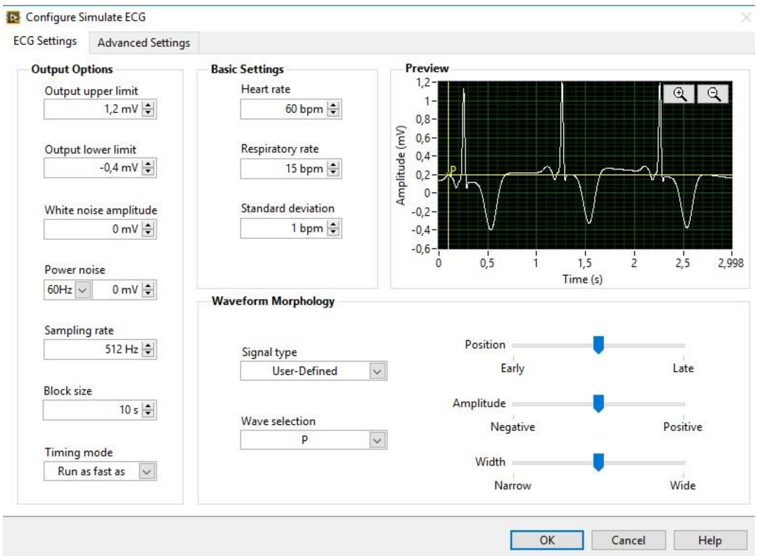

Fig. 7. ECG signal simulation.

Preliminary tests have been performed to check the response of the analog system part. The aim was to check the capability of the measurement system to make reliable diagnoses avoiding false positive or false negative response. For each generated ECG signal, the used sampling rate has been equal to 512 Hz, the respiration rate has been set equal to 15 bpm with standard deviation of 1 bpm. The four cardiac pathologies (bradycardia, tachycardia, ischemia, infarction) have been simulated in the several signals by suitably configuring the ECG features. It is important to observe that the following experimental results do not regard specific patients because of the impossibility to test the system on voluntaries during the occurrence of a cardiac pathology. Therefore, the ECG signals have been generated starting from a normal ECG waveform and by altering the parameters involved in the different diagnoses. Table I reports the results obtained in the several tests by comparing the system response with the expected diagnosis. A green flag has been used to highlight the right diagnoses; a red *x* highlights the wrong diagnoses.

Table I. Results of the analog section tests.

Features of the Applied Analog ECG Signal	**Measured Parameters**	**Automated Diagnosis**	**Expected Diagnosis**
Normal ECG HR= 30 bpm Respiration Rate= 15 bpm	HR mean: 31.1 HR std: 0.9596	Bradycardia ✓	Bradycardia
Normal ECG HR= 59 bpm Respiration Rate= 15 bpm	HR mean: 61.91 HR std: 3.6	No arrhythmia ✗	Bradycardia
Normal ECG HR= 60 bpm Respiration Rate= 15 bpm	HR mean: 61.62 HR std: 0.84	No arrhythmia ✓	No arrhythmia
Normal ECG HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 82.5 HR std: 0.7562	No arrhythmia ✓	No arrhythmia
Normal ECG HR= 100 bpm Respiration Rate= 15 bpm	HR Mean: 106.1 HR std: 13.32	Tachycardia ✗	No arrhythmia
Normal ECG HR= 101 bpm Respiration Rate= 15 bpm	HR mean: 105.3 HR std: 5.462	Tachycardia ✓	Tachycardia
Normal ECG HR= 180 bpm Respiration Rate= 15 bpm	HR mean: 184.9 HR std: 17.65	Tachycardia ✓	Tachycardia
Abnormal ECG Ampl(T wave)=71.68% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 68.93 HR std: 23.65 Ampl(T wave) = 97% Ampl(R wave)	Ischemia ✗	No arrhythmia
Abnormal ECG	HR mean: 82.69	Ischemia	No arrhythmia

Ampl(T wave)=79.68% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR std: 0.4722 Ampl(T wave) = 98.5% Ampl(R wave)	✗	
Abnormal ECG Ampl(T wave)=81.4% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 71.45 HR std: 24.78 Ampl(T wave) = 100% Ampl(R wave)	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=72% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 78.79 HR std: 12.58 Ampl(S wave) = 80% Ampl(R wave)	Ischemia ✗	No arrhythmia
Abnormal ECG Negative S wave Ampl(S wave)=100% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.35 HR std: 7 Ampl(S wave) > Ampl(R wave)	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.037 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 71.37 HR std: 27.49 Ampl(S wave) ~ Ampl(R wave) Ampl(T wave) 95% Ampl(R wave) Q set= 0.037 s	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.042 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 82.22 HR std: 0.77 Ampl(S wave) ~ Ampl(R wave) Ampl(T wave) 95% Ampl(R wave) Q set= 0.037 s	Ischemia ✗	Infarction
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.05 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.5 HR std: 6.2 Ampl(S wave) ~ Ampl(R wave) Ampl(T wave) 95% Ampl(R wave) Q set= 0.044 s	Infarction ✓	Infarction

Legend: HR= Heart Rate; m= mean; std= standard deviation; Ampl= Amplitude.

As an example, Figure 8 shows the normal ECG signal with $HR = 30\ bpm$ and Respiration $Rate = 15\ bpm$ used in the test #1.

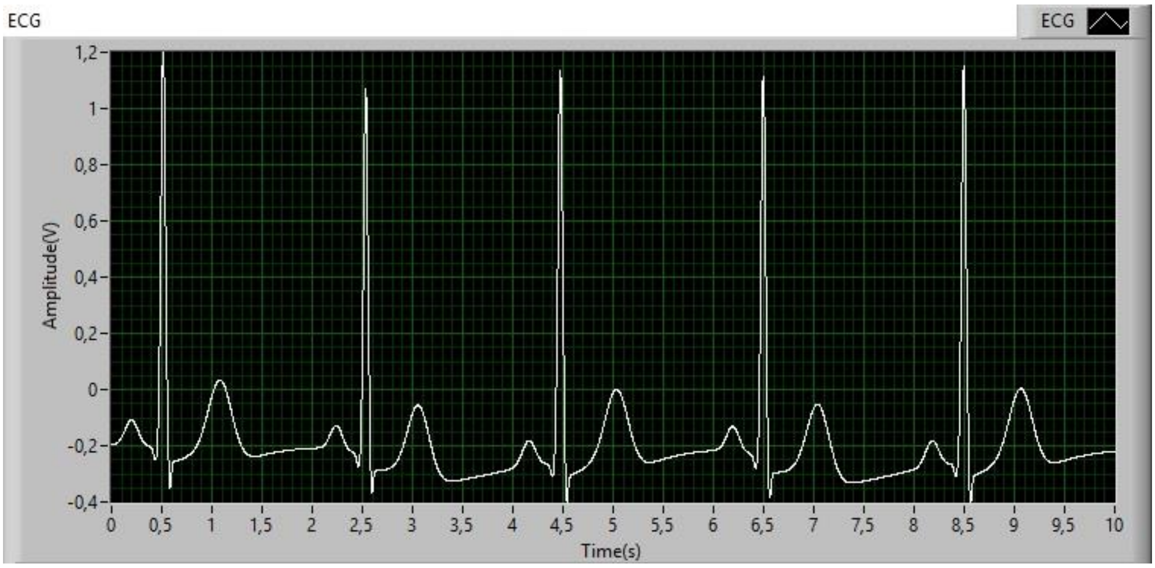

Fig. 8. ECG signal #1.

The response of the ECG system is shown in the Figure 9.

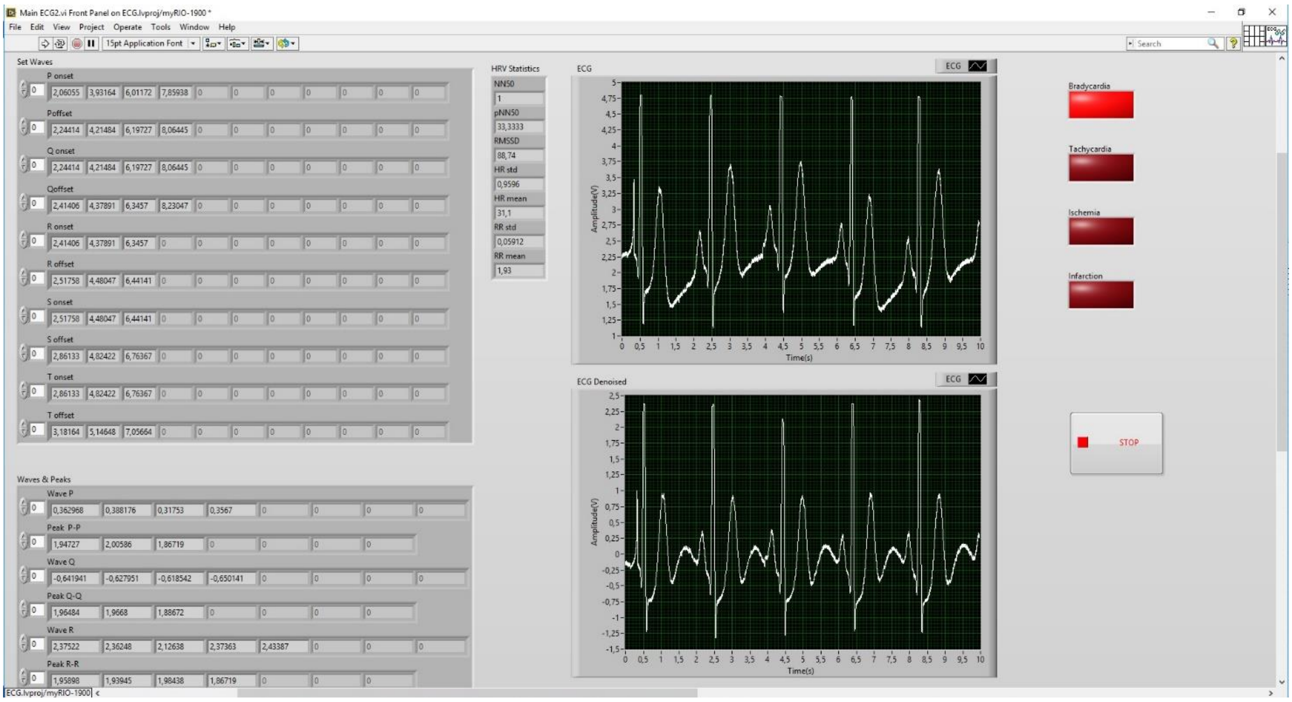

Fig. 9. ECG system response to signal #1.

Figure 10 shows the Abnormal ECG signal with $Amplitude\ (T\ wave) = 81.4\%$ Amplitude (R wave), $HR = 80\ bpm$, Respiration $Rate = 15\ bpm$ used in the test #10.

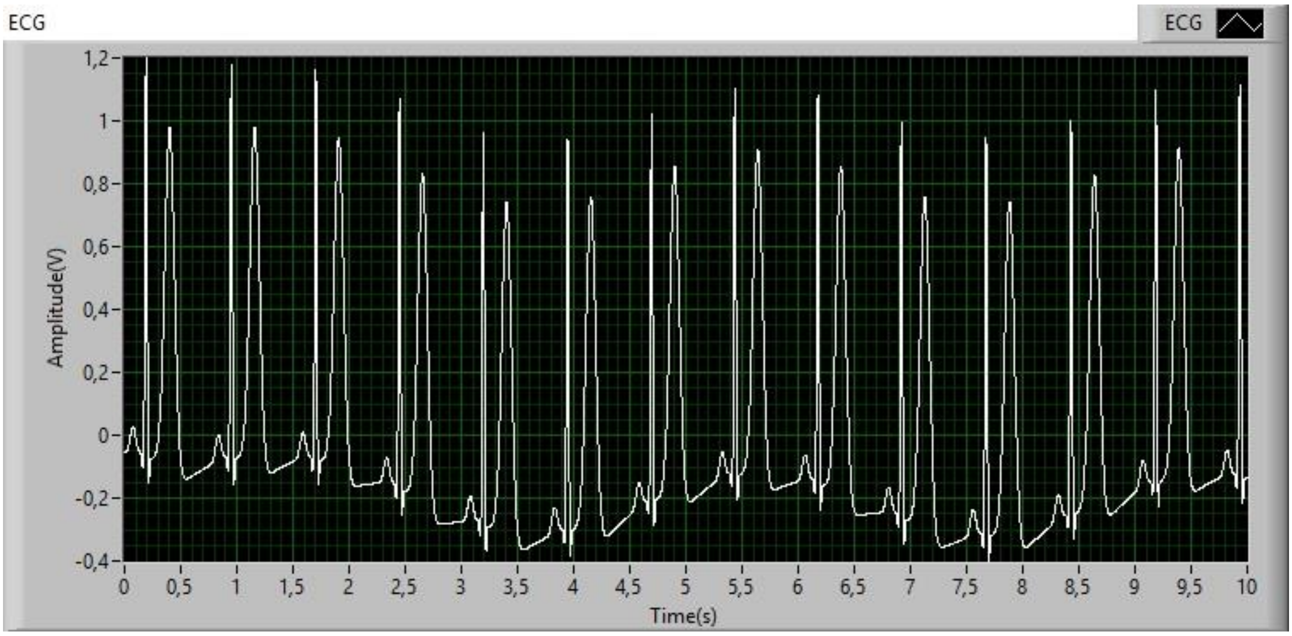

Fig. 10. ECG signal #10.

The response of the ECG system is shown in the Figure 11.

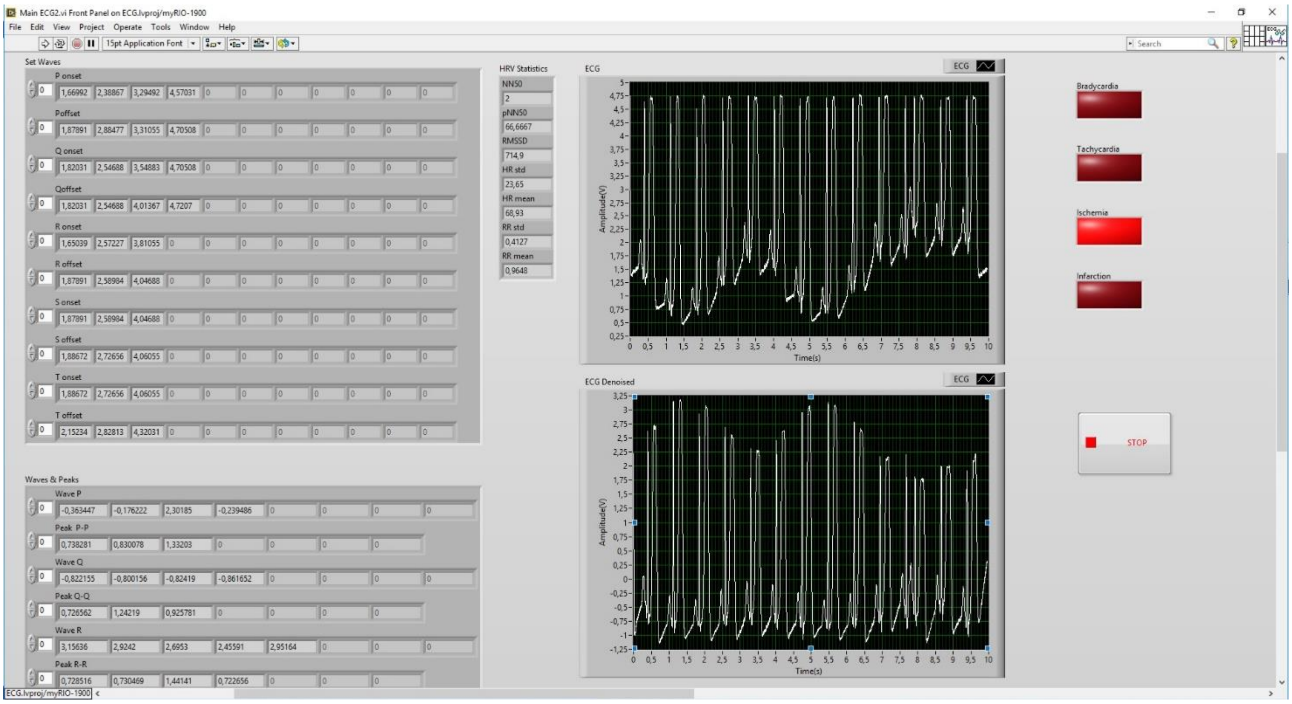

Fig. 11. ECG system response to signal #10.

Figure 12 shows the Abnormal ECG signal with negative $S\ wave$, $Amplitude\ (S\ wave) = 98\%$ Amplitude ($R\ wave$), $Amplitude\ (T\ wave) = 78\%$, $Amplitude\ (R\ wave)$, $Q\ set = 0.042\ s$, $HR = 80\ bpm$, Respiration $Rate = 15\ bpm$ used in the test #14.

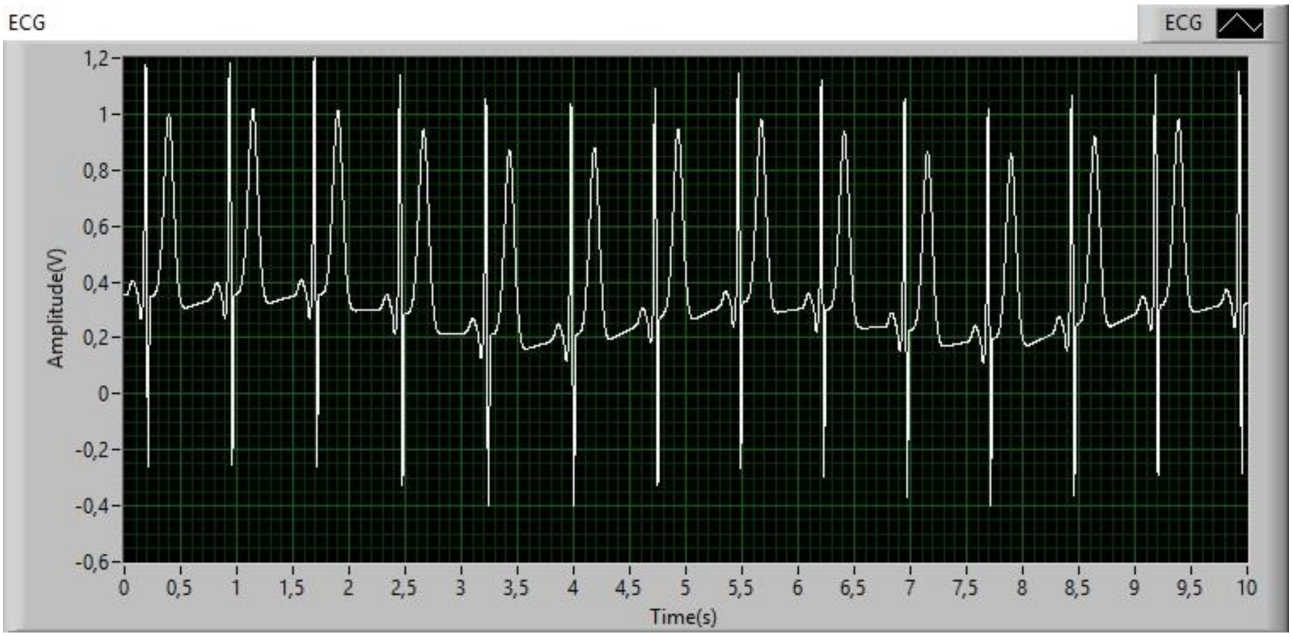

Fig. 12. ECG signal #14.

The response of the ECG system is shown in the Figure 13.

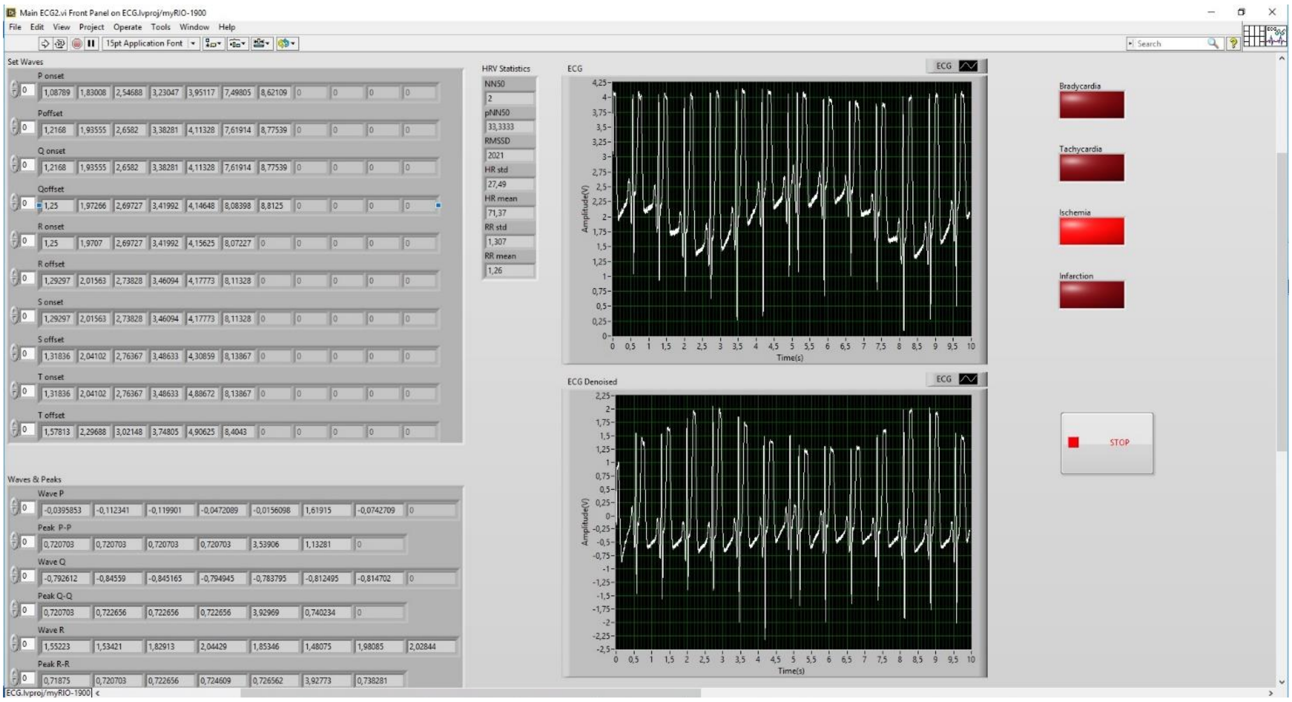

Fig. 13. ECG system response to signal #14.

By analysing the results, it is possible to assess, for example, that bradycardia and tachycardia diagnoses have a sensibility of 1 bpm around the threshold.

Digital Tests

A second set of tests has been carried out in order to characterize the digital part of the system and check the reliability and sensitivity of the processing algorithm with more detail. Table II reports the results obtained from the digital section by generating the same ECG signals used during the test performed in the analog section. In this case, the signals have been only digitally simulated by using the function "Simulate ECG" and configuring the features of each waveform.

Table II. Results of the digital section tests.

Features of the Applied Digital ECG Signal	**Measured Parameters**	**Automated Diagnosis**	**Expected Diagnosis**
Normal ECG HR= 30 bpm Respiration Rate= 15 bpm	HR mean: 30.2 HR std: 0.6642	Bradycardia ✓	Bradycardia
Normal ECG HR= 59 bpm Respiration Rate= 15 bpm	HR mean: 59.17 HR std: 0.45	Bradycardia ✓	Bradycardia
Normal ECG HR= 60 bpm Respiration Rate= 15 bpm	HR mean: 60.19 HR std: 0.4671	No arrhythmia ✓	No arrhythmia
Normal ECG HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.01 HR std: 0.73	No arrhythmia ✓	No arrhythmia
Normal ECG HR= 100 bpm Respiration Rate= 15 bpm	HR Mean: 99.9 HR std: 1.19	No arrhythmia ✓	No arrhythmia
Normal ECG HR= 101 bpm Respiration Rate= 15 bpm	HR mean: 101 HR std: 1.142	Tachycardia ✓	Tachycardia
Normal ECG HR= 180 bpm Respiration Rate= 15 bpm	HR mean: 180.1 HR std: 0.598	Tachycardia ✓	Tachycardia
Abnormal ECG Ampl(T wave)=71.68% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 79.95 HR std: 0.6226 Ampl(T wave) = 71.6% Ampl(R wave)	No arrhythmia ✓	No arrhythmia
Abnormal ECG Ampl(T wave)=79.68% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 79.74 HR std: 0.67 Ampl(T wave) = 79.6% Ampl(R wave)	No arrhythmia ✓	No arrhythmia

Abnormal ECG Ampl(T wave)=81.4% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 76.11 HR std: 12.61 Ampl(T wave) = 81% Ampl(R wave)	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=72% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.2 HR std: 0.93 Ampl(S wave) = 72% Ampl(R wave)	No arrhythmia ✓	No arrhythmia
Abnormal ECG Negative S wave Ampl(S wave)=100% Ampl(R wave) HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.17 HR std: 1.29 Ampl(S wave) > Ampl(R wave)	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.037 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 79.89 HR std: 0.672 Ampl(S wave) 98% Ampl(R wave) Ampl(T wave) 78% Ampl(R wave) Q set= 0.037 s	Ischemia ✓	Ischemia
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.042 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 80.05 HR std: 1.005 Ampl(S wave) 98% Ampl(R wave) Ampl(T wave) 78% Ampl(R wave) Q set= 0.042 s	Infarction ✓	Infarction
Abnormal ECG Negative S wave Ampl(S wave)=98% Ampl(R wave) Ampl(T wave)=78% Ampl(R wave) Q set= 0.05 s HR= 80 bpm Respiration Rate= 15 bpm	HR mean: 79.89 HR std: 0.73 Ampl(S wave) 98% Ampl(R wave) Ampl(T wave) 78% Ampl(R wave) Q set= 0.05 s	Infarction ✓	Infarction

Legend: HR= Heart Rate; m= mean; std= standard deviation; Ampl= Amplitude.

The analysis of the results reported in Table II highlights an optimal sensitivity and accuracy of the processing algorithm in the digital domain. In fact, data show a rate of correct detection and identification of the four pathologies equal to 100%. On the contrary, the results in Tables I, concerning the analog section tests, show the presence of some false positive and false negative diagnoses. In one case, the presence of a wrong diagnosis has been even highlighted. The incoherent results of the analog tests can be imputable to the effect of the measurement uncertainty during the comparison process. Indeed, the presence of uncertainty in the measurement result makes complex the comparison between the measured value and the limit, since the measured value is represented by an interval of possible values attributable to the measurand and to its real value. In order to take into account, the possible effect of the measurement uncertainty, the proposed ECG system has been equipped with a memory device storing information on the metrological features of the system (TEDS2) (please make reference to the previous Section for further details). In particular, equations (1) and (2) allow the system to get information on the reliability of the final diagnosis. So, to improve the system performances and reduce the occurrence of false diagnoses, the processing algorithm has been optimized by setting a limit to the minimum reliability value R_D to be considered suitable to assume reliable the diagnosis made. Therefore, let us fix this minimum value equal to 80%. In this way, any diagnosis which gets a reliability $R_D\% \geq 80\%$ is considered reliable and so it is displayed by the system. With this assumption, the optimized processing algorithm is able to characterize the false diagnoses so showing a full accordance with the applied ECG signals. As a consequence, the revised system shows a rate of correct detection and identification of the four pathologies equal to 100% for both the analog and digital components of the system.

Data Analysis

The measurement results obtained from the two set of tests described above have been then analysed to obtain information on the frequency content of the ECG signal. As said in [53], [54], to have the frequency content information and even those ones on the heart rate variability, a continuous set of data of at least five minutes long is required. From the ECG signal, the tachogram can be extracted, which is a sequence carrying the information on the RR intervals, and from the tachogram it is possible to calculate the Power Spectral Density (PSD) which carries information on the power distribution as function of the frequency. The heart rate variability (HRV) is given by the differences in RR intervals and the resulting instantaneous changes, in response to factors such as position, movement, breathing rhythm, emotional states, and activities of the sympathetic and parasympathetic system. In particular, the sympathetic activation produces a sudden increase in the heart rate, while the parasympathetic activation causes a decrease in it.

For this analysis, a post processing routine measures the RR intervals evaluated on the filtered ECG signals lasting five minutes. The identification of R peaks is made by discriminating all peaks with an amplitude greater than 0.9 V. The tachogram so obtained is a discrete sequence of the RR intervals, and a resampling of the signal is necessary to perform the frequency analysis apt to obtain the PSD. The algorithm resamples the tachogram at a sampling frequency of 10 Hz and performs a spline interpolation on the samples obtained. The resampled signal has been filtered with a sixth order Butterworth low-pass filter with a cut-off frequency of 0.5 Hz, since all the frequency components of a tachogram generally fall below this cut-off. The time domain signal thus obtained and filtered is then processed through the FFT routine to obtain its power spectral density. The Figures from 14 to 17 show respectively the tachogram and the power spectral density obtained for the signals #1 and #10 reported in the Tables I and II. The figures show the traces obtained from the digital and analogue simulations and, as it easily can be seen, the results are identical.

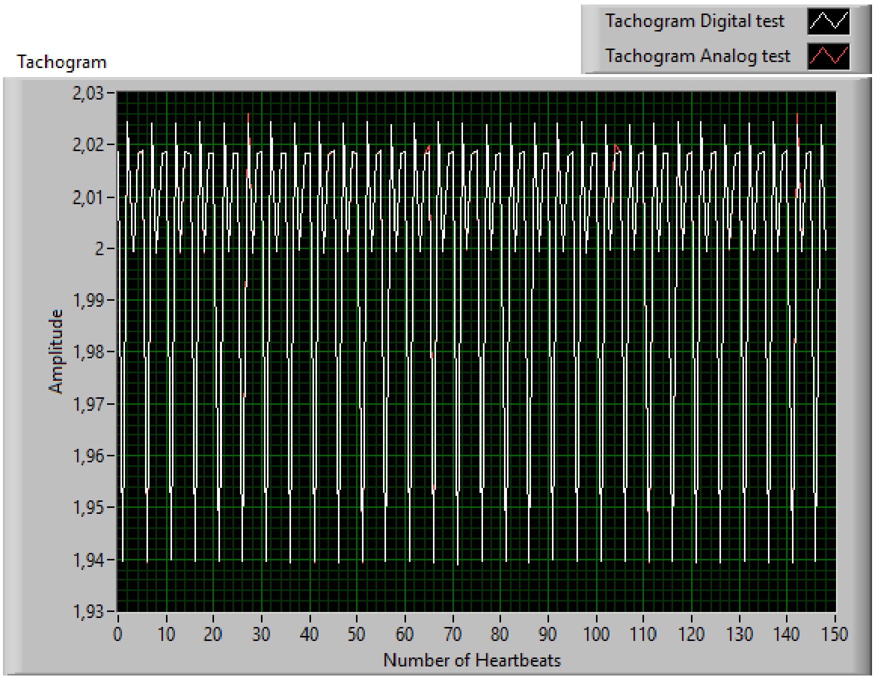

Fig. 14. Tachogram of signal #1.

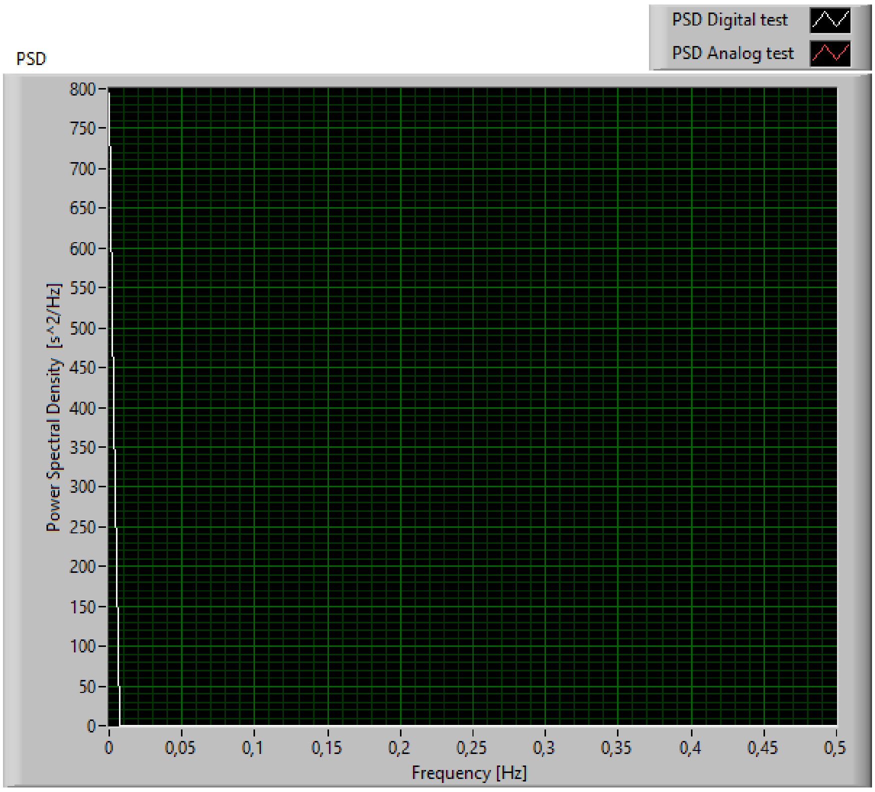

Fig. 15. PSD of signal #1.

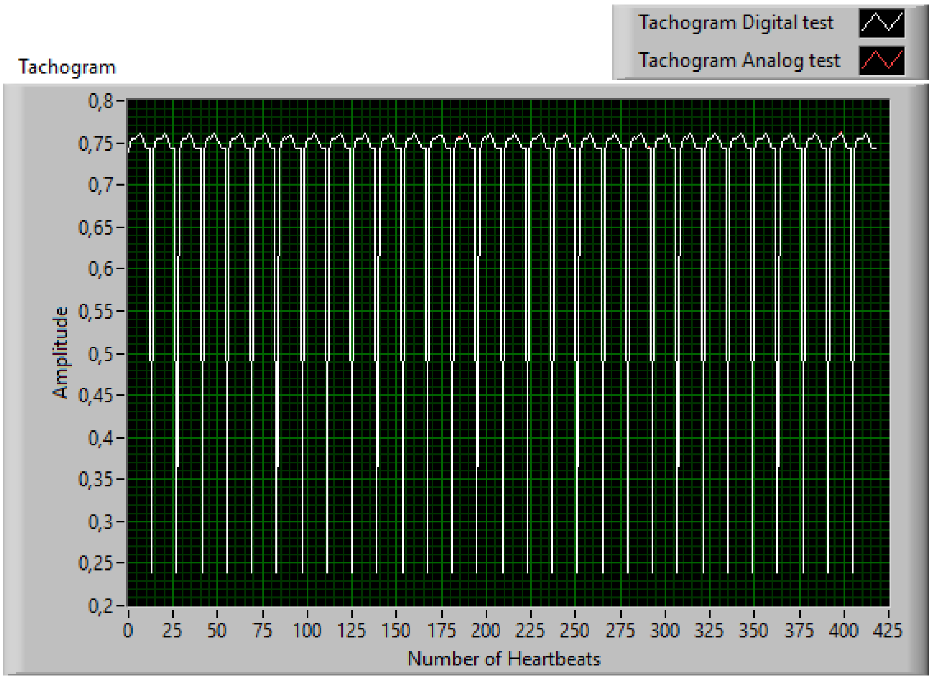

Fig. 16. Tachogram of signal #10.

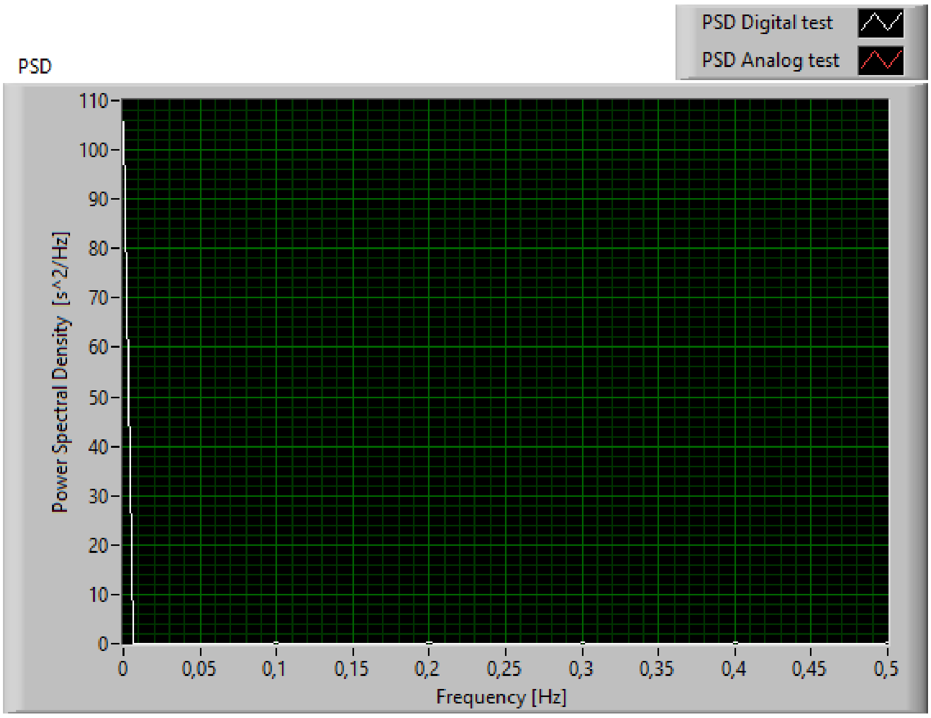

Fig. 17. PSD of signal #10.

As it can be seen in Figures 14 and 17, the main contribution is given by the very low frequency components in both cases. To analyse the contribution of the other components, the reconstructed tachogram was further filtered with a sixth order high pass Butterworth filter with a cutoff frequency of 0.02 Hz, as suggested in [55]. The results are reported in the Figures 18 and 19.

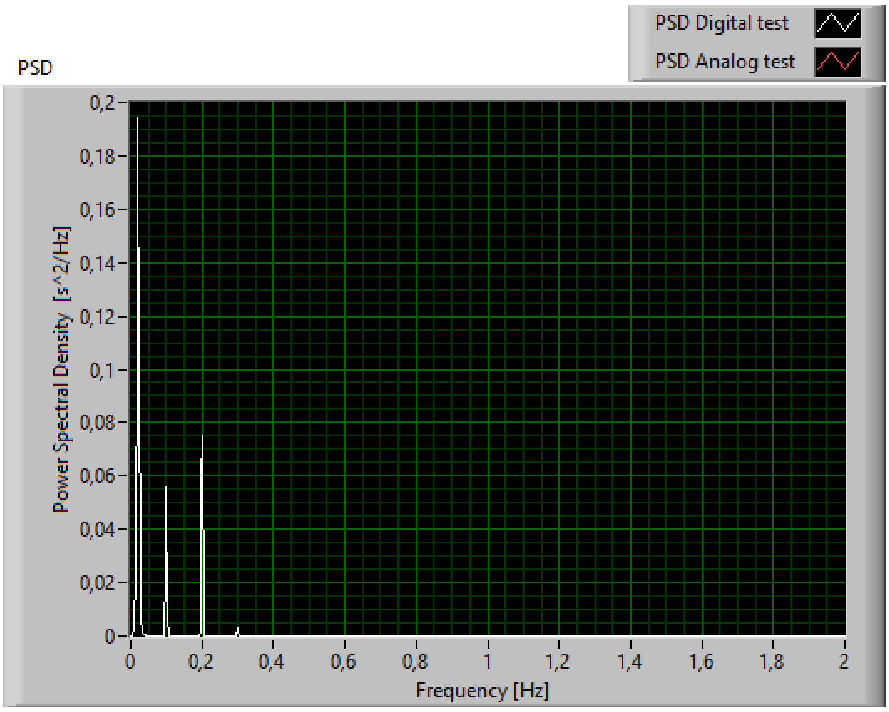

Fig. 18. PSD of signal #1, high pass filtered.

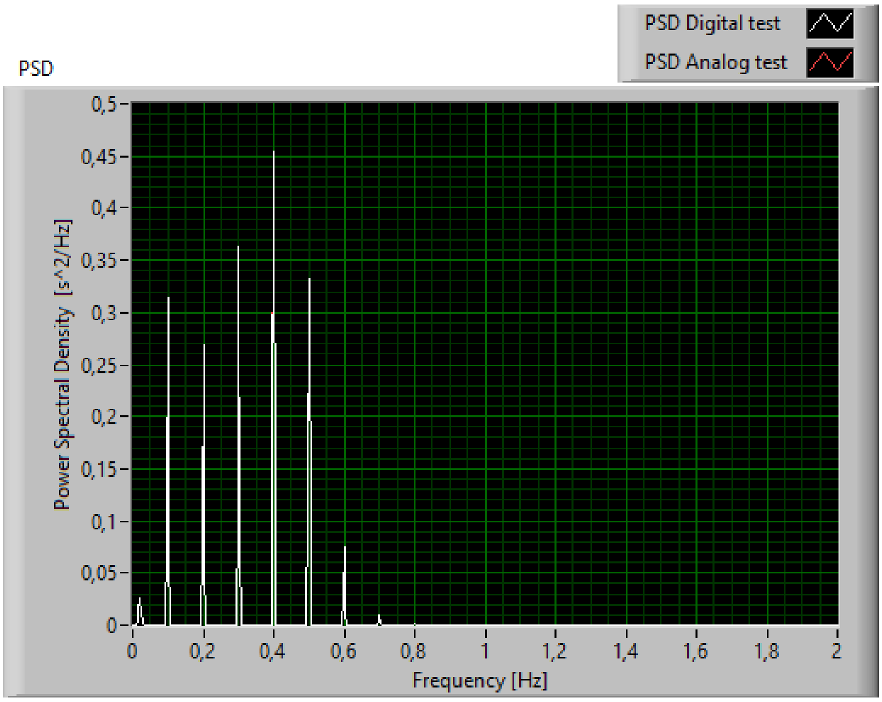

Fig. 19. PSD of signal #10, high pass filtered.

4. Final Considerations and Conclusions

In the paper, the authors have described the developments and research results obtained in the field of the healthcare. The research team challenge is to provide innovative technologies and solutions for telemedicine applications. The proposed system aims to provide an electrocardiographic system to constantly monitor patients with heart pathologies. In the smart cities scenario, the proposed system is an *Ambient Assisted Living* solution developed to encourage and help the independent life and care of subjects with cardiac pathology during the daily life. By means of the IoT paradigm, the system assures remote assistance to the patient in order to limit the hospitalization only to borderline cases.

The designed ECG system acquire and process the patient ECG signal able to give a reasonable diagnosis in the case of four common cardiac pathologies (bradycardia, tachycardia, ischemia, infarction). The system offers three different working modalities. It can work standalone showing the diagnosis by a set of led placed on the system display; by internet network, a cardiologist can get remote access to the system data in order to make a further evaluation and decide about patient hospitalization; last, the system can work as a Holter monitor collecting patient ECG records over time so to characterize abnormal drifts in the ECG waveform. In case of emergency, the system can be programmed to call for first aid.

Since several life factors can alter the regular shape of the ECG waveform, the use of standard ECG models has to be discouraged because false diagnoses may occur. Often, in scientific literature, sex, age and physical constitution are the only parameters considered during the diagnosis. However, previous heart attacks, for example, can be cause of necrosis of heart tissues because of the oxygen lack. This is typically the reason of permanent marks in the subject ECG waveform. In this case, alterations in the *Q wave* are visible. So, only a cardiologist can make a reliable diagnosis by analysing the patient ECG. For this reason, the proposed processing algorithm adapts itself to the monitored patient by using data stored in the *Patient Health History (*TEDS1). Patient information concerning his/her personal data and clinical history, such as previous ECG records, are used to select and fit the ECG reference model to be used during the diagnosis process. By replacing the TEDS1, the system can be used for another patient. The *Metrological Status Memory* (TEDS2) stores the metrological characteristics of the system to optimize the processing algorithm so reducing the occurrence of possible false positive or false negative diagnoses. For this purpose, the system can alert user when it has to be re-calibrated. In addition, the system can use the information on measurement uncertainty to evaluate the reliability of the diagnosis. In fact, the measurement uncertainty plays an important role during the comparison between measured values and reference limits and often it may be cause of false diagnoses. So, the processing algorithm has been optimized by considering plausible only those diagnoses which have a reliability value greater than 80%.

By means of a comprehensive analysis of the current literature dealing with the design and development of ECG monitoring systems, the above features are the main contribution and finding of the system here proposed. In fact, although other solutions in literature are able to store ECG records, no system uses such additional information to customize the processing algorithms to the specific monitored patient. In addition, metrological information such as accuracy, measurement uncertainty, resolution and calibration data are completely disregarded. Such additional feature highlight the originality of the system described here.

The final scope of the authors is to guide developers and designers during the project of medical devices by disseminating the research group expertise in this specific field. By considering the current heterogeneity of the solutions proposed in literature and the lack of standardization on this specific topic, this paper wants to propose an original approach and a different perspective based on metrology issues in order to improve the reliability of the current standalone ECG monitoring systems.

Regarding current tendencies in biomedical wearables and signal processing [56], designed IoT system is a prerequisite for further studies oriented towards real-time arrhythmias classification and multi-function monitoring, e.g. characterisation of critical events during sleep from ECG signals or sport activity monitoring, [57]-[60].

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