WAVELET SIGNAL PROCESSING OF PHYSIOLOGIC WAVEFORMS

A project report submitted in partial fulfillment of the requirements for the degree of

Bachelor of TechnologyIn **Electrical Engineering**

By Rahul Kedia (10502011) Dhananjay Jha (10502043) Nipun Naveen Hembrom (10502048)



Department of Electrical Engineering National Institute of Technology Rourkela 2009

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Under the guidance of Prof. Dipti Patra (Department of Electrical Engineering)



National Institute of Technology Rourkela, 2009



National Institute of Technology Rourkela

CERTIFICATE

This is to certify that the Project entitled "WAVELET SIGNAL PROCESSING OF PHYSIOLOGIC WAVEFORMS" submitted by Rahul Kedia, Dhananjay Jha and Nipun Naveen Hembrom in partial fulfillment of the requirements for the award of Bachelor of Technology Degree in Electrical Engineering at National Institute of Technology, Rourkela (Deemed University) is an authentic work carried out by them under my supervision and guidance.

Place: NIT Rourkela	Prof. Dipti Patra

Date: Department of Electrical Engineering

NIT Rourkela

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CONTENTS

i.	Acknowledgement	i			
ii.	_				
iii.	List of figures	V			
iv.					
Cha	napter 1: Introduction				
	1.1 Introduction	1			
	1.2 Motivation	2			
	1.3 Project Layout	3			
Cha	napter 2: Physiologic Waveforms And Background Theory On ECG				
	2.1 Physiologic Waveforms	4			
	2.2 Electrocardiogram (ECG)	4			
	2.2.1 Arrhythmia	6			
	2.2.2 Waves and Intervals of the ECG	7			
	2.2.3 ECG Monitoring Method	11 11			
	2.2.4 Normal ECG signal	11			
Cha	napter 3: Background Theory on Wavelet Transform and Neural Netw	ork			
	3.1 Wavelets	13			
	3.1.1 Introduction	13			
	3.1.2 The continuous wavelet transforms	14			
	3.1.3 Discrete wavelets	15			
	3.1.4.1 A band-pass filter	17			
	3.1.4.2 The discrete wavelet transforms	19			
	3.1.5 Applications of Wavelets	23			
	3.2 Neural Network	24			
	3.2.1 Artificial Neural Networks	24			
	3.2.2 Biological Neural System	24			
	3.2.3 Artificial Neuron (AN)	25			
	3.2.4 Basic Structure of an Artificial Network	25			
	3.2.5 The Multilayer Perceptron	27			
	3.2.5.1 Back propagation algorithm	27			

Chapter	4: ECG S	Signal A	Analysis	Using	Wavelet	Transforms

	4.1 Proble	em addressed	29
	4.1.1	ECG signal decomposition using discrete wavelet transformation	30
	4.1.2	Feature extraction	32
	4.1.3	Normalization of feature vectors	33
	4.1.4	Classification using feed forward backpropagation neural network	
	(FF)	BNN)	33
Chap		and Simulations s and Simulations	35
Chap	ter 6: Conclus	ion and Future Work	
	6.1 Conclu 6.2 Future		41 41
v.	References		42

ABSTRACT

The prime objective of this piece of work is to devise novel techniques for computer based classification of Electrocardiogram (ECG) arrhythmias with a focus on less computational time and better accuracy.

As an initial stride in this direction, ECG beat classification is achieved by using feature extracting techniques to make a neural network (NN) system more effective. The feature extraction technique used is Wavelet Signal Processing. Coefficients from the discrete wavelet transform were used to represent the ECG diagnostic information and features were extracted using the coefficients and were normalised. These feature sets were then used in the classifier i.e. a simple feed forward back propagation neural network (FFBNN).

This paper presents a detail study of the classification accuracy of ECG signal by using these four structures for computationally efficient early diagnosis. Neural network used in this study is a well-known neural network architecture named as multi-Layered perceptron (MLP) with back propagation training algorithm.

The ECG signals have been taken from MIT-BIH ECG database, and are used in training to classify 3 different Arrhythmias out of ten arrhythmias. These are normal sinus rhythm, paced beat, left bundle branch block. Before testing, the proposed structures are trained by back propagation algorithm.

The results show that the wavelet decomposition method is very effective and efficient for fast computation of ECG signal analysis in conjunction with the classifier.

List of Figures:	Page No
2.1 Components of an ECG signal.	5
2.2 Normal ECG signal	12
3.1 Localization of the discrete wavelets in the time-scale space on a dyadic grid	16
3.2 Touching wavelet spectra resulting from scaling of the mother wavelet in the	
time domain.	18
3.3 One stage of an iterated filter bank.	22
3.5 A biological neuron	24
3.6 Artificial neuron	25
3.7 An artificial neural network	26
4.1 Sub band decomposition of discrete wavelet transform implementation; $g[n]$ is	s the
High-pass filter, $h[n]$ is the low-pass filter	30
4.2 Db2 wavelet	31
4.3 NN structure	34
5.1 Normal Arrythmia	36
5.2 LBBB Arrythmia	36
5.3 Paced Beat	36
5.4 Detail and approximation coefficients of APB ECG signal	38
5.5 Detail and approximation coefficients of PB ECG signal.	40
List of Tables:	Page No
4.1 The no. of segment for each Arrythmia	34

 $5.1\ ECG\ Samples\ used\ from\ MIT-BIH\ database$

35

INTRODUCTION

1.1 Introduction

Many physiological signals may be described either as isolated pulses or as quasi-periodic sequences of isolated pulses. Wavelets are a powerful tool for the representation and analysis of such physiologic waveforms because a wavelet has finite duration (compact support) as contrasted with Fourier methods based on sinusoids of infinite duration.

The Fourier transform is a tool widely used for many scientific purposes, but it is well suited only to the study of stationary signals where all frequencies have an infinite coherence time. The Fourier analysis brings only global information which is not sufficient to detect compact patterns. Gabor introduced a local Fourier analysis, taking into account a sliding window, leading to a time frequency-analysis. This method is only applicable to situations where the coherence time is independent of the frequency. This is the case for instance for singing signals which have their coherence time determined by the geometry of the oral cavity. Morlet introduced the Wavelet Transform in order to have a coherence time proportional to the period.

The wavelet transform or wavelet analysis is probably the most recent solution to overcome the shortcomings of the Fourier transform. In wavelet analysis the use of a fully scalable modulated window solves the signal-cutting problem. The window is shifted along the signal and for every position the spectrum is calculated. Then this process is repeated many times with a slightly shorter (or longer) window for every new cycle. In the end the result will be a collection of time-frequency representations of the signal, all with different resolutions. Because of this collection of representations we can speak of a multi-resolution analysis. In the case of wavelets we normally do not speak about time-frequency representations but about time-scale representations, scale being in a way the opposite of frequency, because the term frequency is reserved for the Fourier transform.

1.2 Motivation

The state of cardiac heart is generally reflected in the shape of ECG waveform and heart rate. It may contain important pointers to the nature of diseases afflicting the heart. However, biosignals being non-stationary signals, the reflection may occur at random in the time-scale (that is, the disease symptoms may not show up all the time, but would manifest at certain irregular intervals during the day). From the practical point of view, for the effective diagnostics, the study of ECG pattern and heart rate variability signal may have to be carried out over several hours. The volume of the data being enormous, the study is tedious and time consuming and the possibility of the analyst missing the vital information is high. Hence, computer based analysis and classification of diseases can be very helpful in diagnosis [1]. Several algorithms have been developed in the literature for detection and classification of ECG beats. Most of them use either time or frequency domain representation of the ECG waveforms, on the basis of which many specific features are defined, allowing the recognition between the beats belonging to different classes. The most difficult problem faced by today's automatic ECG analysis is the large variation in the morphologies of ECG waveforms, not only of different patients or patient groups but also with in the same patient. The ECG waveforms may differ for the same patient to such extend that they are unlike to each other and at the same time alike for different types of beats. This is the main reason that the beat classifier, performing well on the training data generalizes poorly, when presented with different patients ECG waveforms [2]. Here we are using wavelet techniques for less computational time and better accuracy for classification of ECG arrhythmia.

1.3 Report Layout

The project is organized into following chapters.

Chapter 1, Deals with the formal introduction to the techniques used for transformation and classification of physiologic waveforms (like ECG).

Chapter 2, Deals with the formal description of physiologic waveform and background theory on ECG.

Chapter 3, Background theory of the proposed Techniques for Classification of ECG arrhythmia using Wavelet Transform and Neural Network, presents a critical review of the Wavelet and Neural Network. The proposed techniques are described in detail in this chapter.

Chapter 4, Describes how ECG signal classification is done using Wavelet Transform and Neural Network.

Chapter 5, Results and Simulations, describes the comparative study of the result and simulations of different techniques proposed for the ECG beat classification.

Chapter 6, Conclusions and future scope summarizes the conclusions of the project and outlines several ideas for further work based on the results we achieved.

PHYSIOLOGIC WAVEFORMS AND BACKGROUND THEORY ON ECG

2.1 Physiologic Waveforms

Many physiological signals may be described either as isolated pulses or as quasi-periodic sequences of isolated pulses. Wavelets are a powerful tool for the representation and analysis of such physiologic waveforms because a wavelet has finite duration (compact support) as contrasted with Fourier methods based on sinusoids of infinite duration.

2.2 Electrocardiogram (ECG)

An electrocardiogram (ECG/EKG) is an electrical impulse recording of the heart and is used in the investigation of heart disease. These impulses are recorded as waves called P-QRS-T deflections. Each cardiac cell is surrounded by and filled with a solution that contains, in part, sodium (Na+), potassium (K+), and calcium (Ca++). In its resting condition the interior of the cell membrane is considered negatively charged, with respect to the outside. When an electrical impulse is initiated in the heart, the inside of a cardiac cell rapidly becomes positive in relation to the outside of the cell. The electrical impulse causes this excited state and this change of polarity, is called depolarization. Immediately after depolarization, stimulated cardiac cell returns to its resting state, which is called repolarization. The resting state is maintained until the arrival of the next wave of depolarization. This change in cell potential from negative to positive and back to negative is called an action potential. That action potential initiates a cardiac muscle contraction. The ECG is a measurement of the effect of this depolarization and repolarization for the entire heart on the skin surface, and is also an indirect indicator of heart muscle contraction, because the depolarization of the heart leads to the contraction of the heart muscles. Although the phases of the ECG are due to action potentials traveling through the heart muscle, the ECG is not simply a recording of an action potential. During the heartbeat, cells—fire action—potentials—at different—times,—and—the ECG—reflects patterns of that electrical activity [5]. Figure 2.1 shows ECG waves and intervals as well as standard time and voltage measures on the ECG paper.

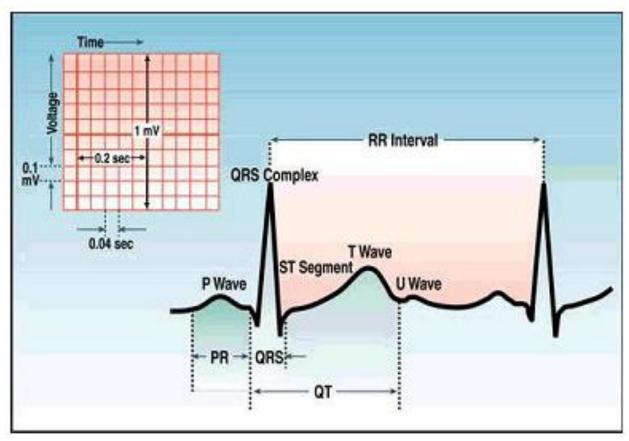


Fig 2.1 Components of an ECG signal.

2.2.1 Arrhythmia

The rhythm of the heart is normally generated and regulated by pacemaker cells within the sinoatrial (SA) node, which is located within the wall of the right atrium. SA nodal 6 pacemaker activity normally governs the rhythm of the atria and ventricles. Normal rhythm is very regular, with minimal cyclical fluctuation. Furthermore, atrial contraction is always followed by ventricular contraction in the normal heart. When this rhythm becomes irregular, too fast (tachycardia) or too slow (bradycardia), or the frequency of the atrial and ventricular beats are different, this is called an arrhythmia. The term "dysrhythmia" is sometimes used and has a similar meaning [6]. About 14 million people in the USA have arrhythmias (5% of the population). The most common disorders are atrial fibrillation and flutter. The incidence is highly related to age and the presence of underlying heart disease; the incidence approaches 30% following open heart surgery. Patients may describe an arrhythmia as a palpitation or fluttering sensation in the chest. For some types of arrhythmias, a skipped beat might be sensed because the subsequent beat produces a more forceful contraction and a thumping sensation in the chest. A "racing" heart is another description. Proper diagnosis of arrhythmias requires an electrocardiogram, which is used to evaluate the electrical activity of the heart. Depending on the severity of the arrhythmia, patients may experience dyspnea (shortness of breath), syncope (fainting), fatigue, heart failure symptoms, chest pain or cardiac arrest.

A frequent cause of arrhythmia is coronary artery disease because this condition results in myocardial ischemia or infarction. When cardiac cells lack oxygen, they become depolarized, which lead to altered impulse formation and/or altered impulse conduction. The former concerns changes in rhythm that are caused by changes in the automaticity of pacemaker cells or by abnormal generation of action potentials at sites other than the SA node (termed ectopic-foci). Altered impulse conduction is usually associated with complete or partial block of electrical conduction within the heart. Altered impulse conduction commonly results in reentry, which can lead to tachy-arrhythmias. Changes in cardiac structure that accompany heart failure (e.g., dilated or hypertrophied cardiac chambers) can also precipitate arrhythmias. Finally, many

different types of drugs (including anti-arrhythmic drugs) as well as electrolyte disturbances (primarily K+ and Ca++) can precipitate arrhythmias.

Arrhythmias can be either benign or more serious in nature depending on the hemodynamic consequence of the arrhythmia and the possibility of evolving into a lethal arrhythmia. Occasional premature ventricular complexes (PVCs), while annoying to a patient, are generally considered benign because they have little hemodynamic effect. Consequently, PVCs if not too frequent, are generally not treated. In contrast, ventricular 7 tachycardia is a serious condition that can lead to heart failure, or worse, to ventricular fibrillation and death.

When arrhythmias require treatment, they are treated with drugs that suppress the arrhythmia. These drugs are called anti-arrhythmic drugs. There are many different types of anti-arrhythmic drugs and many different mechanisms of action. Most of the drugs affect ion channels that are involved in the movement of sodium, calcium and potassium ions in and out of the cell. These drugs include mechanistic classes such as sodium-channel blockers, calcium-channel blockers and potassium-channel blockers. By altering the movement of these important ions, the electrical activity of the cardiac cells (both pacemaker and non-pacemaker cells) is altered, hopefully in a manner that suppresses arrhythmias. Other drugs affect autonomic influences on the heart, which may be stimulating or aggravating arrhythmias.

2.2.2 Waves and Intervals of the ECG

P wave

During normal atrial depolarization, the main electrical vector is directed from the SA node towards the AV node, and spreads from the right atrium to the left atrium. This turns into the P wave on the ECG, which is upright in II, III, and a VF (since the general electrical activity is going toward the positive electrode in those leads), and inverted in a VR (since it is going away from the positive electrode for that lead). A P wave must be upright in leads II and a VF and

inverted in lead a VR to designate a cardiac rhythm as Sinus Rhythm. The relationship between P waves and QRS complexes helps distinguish various cardiac arrhythmias.

- The shape and duration of the P waves may indicate atrial enlargement

 The PR interval is measured from the beginning of the P wave to the beginning of the QRS complex. It is usually 120 to 200 ms long. On an ECG tracing, this corresponds to 3 to 5 small boxes
- A PR interval of over 200 ms may indicate a first degree heart block
- A short PR interval may indicate a pre-excitation syndrome via an accessory pathway that leads to early activation of the ventricles, such as seen in Wolff-Parkinson White syndrome
- A variable PR interval may indicate other types of heart block.
- PR segment depression may indicate atrial injury or pericarditis.
- Variable morphologies of P waves in a single ECG lead are suggestive of an ectopic pacemaker rhythm such as wandering pacemaker or multifocal atrial tachycardia.

QRS complex

The QRS complex is a structure on the ECG that corresponds to the depolarization of the ventricles. Because the ventricles contain more muscle mass than the atria, the QRS complex is larger than the P wave. In addition, because the His/Purkinje system coordinates the depolarization of the ventricles, the QRS complex tends to look "spiked" rather than rounded due to the increase in conduction velocity. A normal QRS complex is 0.06 to 0.10 sec (60 to 100 ms) in duration. Not every QRS complex contains a Q wave, an R wave, and an S wave. By convention, any combination of these waves can be referred to as a QRS complex. However, correct interpretation of difficult ECGs requires exact labeling of the various waves. Some authors use lowercase and capital letters, depending on the relative size of each wave. For example, an Rs complex would be positively deflected, while a RS complex would be negatively deflected. If both complexes were labeled RS, it would be impossible to appreciate this distinction without viewing the actual ECG. The duration, amplitude, and morphology of the QRS complex is useful in diagnosing cardiac arrhythmias,

conduction abnormalities, ventricular hypertrophy, myocardial infarction, electrolyte derangements, and other disease states. Q waves can be normal (physiological) or pathological. Normal Q waves, when present, represent depolarization of the inter-ventricular septum. For this reason, they are referred to as septal Q waves, and can be appreciated in the lateral leads I, a VL, V5 and V6.Q waves greater than 1/3 the height of the R wave, greater than 0.04 sec (40 ms) in duration, or in the right precordial leads are considered to be abnormal, and may represent myocardial infarction.

ST segment

The ST segment connects the QRS complex and the T wave and has duration of 0.08 to 0.12 sec (80 to 120 ms). It starts at the J point (junction between the QRS complex and ST segment) and ends at the beginning of the T wave. However, since it is usually difficult to determine exactly where the ST segment ends and the T wave begins, the relationship between the ST segment and T wave should be examined together. The typical ST segment duration is usually around 0.08 sec (80 ms). It should be essentially level with the PR and TP segment. The normal ST segment has a slight upward concavity. Flat, down sloping or depressed ST segments may indicate coronary ischemia. ST segment elevation may indicate myocardial infarction. An elevation of >1mm and longer than 80 milliseconds following the J-point. This measure has a false positive rate of 15-20% (which is slightly higher in women than men) and a false negative rate of 20-30%.

T wave

The T wave represents the repolarization (or recovery) of the ventricles. The interval from the beginning of the QRS complex to the apex of the T wave is referred to as the absolute refractory period. The last half of the T wave is referred to as the relative refractory period (or vulnerable period). In most leads, the T wave is positive. However, a negative T wave is normal in lead aVR. Lead V1 may have a positive, negative, or biphasic T wave. In addition, it is not uncommon to have an isolated negative T wave in lead III, a VL, or a VF. Inverted (or negative) T waves can be a sign of coronary ischemia, Wellens' syndrome, left ventricular hypertrophy, or CNS disorder. Tall or "tented" symmetrical T waves may indicate hyperkalemia. Flat T waves

may indicate coronary ischemia or hypokalemia. The earliest electrocardiographic finding of acute myocardial infarction is sometimes the hyperacute T wave, which can be distinguished from hyperkalemia by the broad base and slight asymmetry. When a conduction abnormality (e.g., bundle branch block, paced rhythm) is present, the T wave should be deflected opposite the terminal deflection of the QRS complex. This is known as appropriate T wave discordance.

QT interval

The QT interval is measured from the beginning of the QRS complex to the end of the T wave. A normal QT interval is usually about 0.40 seconds. The QT interval as well as the corrected QT interval is important in the diagnosis of long QT syndrome and short QT syndrome. The QT interval varies based on the heart rate, and various correction factors have been developed to correct the QT interval for the heart rate. The most commonly used method for correcting the QT interval for rate is the one formulated by Bazett and published in 1920.

Bazett's formula is,

$$QT_c = \frac{QT}{\sqrt{RR}}$$

Where QTc is the QT interval corrected for rate, and RR is the interval from the onset of one QRS complex to the onset of the next QRS complex, measured in seconds. However, this formula tends to be inaccurate, and over-corrects at high heart rates and under-corrects at low heart rates.

U wave

The U wave is not always seen. It is typically small, and, by definition, follows the T wave. U waves are thought to represent repolarization of the papillary muscles or Purkinje fibers. Prominent U waves are most often seen in hypokalemia, but may be present in hypercalcemia, thyrotoxicosis, or exposure to digitalis, epinephrine, and Class 1A and 3 antiarrhythmics, as well as in congenital long QT syndrome and in the setting of intracranial hemorrhage. An inverted U wave may represent myocardial ischemia or left ventricular volume overload.

2.2.3 ECG Monitoring Method

Electrodes placed on designated areas of the patient's body, and these various combinations of the electrodes used for analysis of the are heart condition. Each separate view of the heart is called an ECG lead. The two ECG monitoring methods are standard 12-lead ECG monitoring [7] and continuous ECG monitoring or holter monitoring [8]. 12-lead ECG consists of three standard leads, designated as lead I,II,III and three augmented leads, designated as lead a VR, a VL and a VF, that view the heart in the frontal plane, and six precordial or chest leads, designated V1 through V2, that view the heart in the horizontal plane. Both the standard leads and the augmented leads are limb leads. The standard leads are called bipolar because they are composed of two electrodes-one that is negative and one that is positive-and the ECG records the difference in electrical potential between them. The standard 12-lead ECG records 12 different views of the same electrical activity on the ECG graph paper. Holter monitoring provides a continuous recording of heart rhythm during normal activity, and the monitor is usually worn for 24 hours. In holter monitoring, electrodes (small conducting patches) are placed on the chest and attached to a small recording monitor that can be carried or in a small pouch worn around the neck.

2.2.4 Normal ECG signal

Here are the normal ECG waves [7].

Normal sinus rhythm

- Each P wave is followed by a QRS complex.
- P wave rate is 60 100 beats per minute (bpm).

If rate is less than 60 bpm, it is called sinus bradycardia. If rate is greater than 100, it is called sinus tachycardia.

Normal P waves

- Height is less than 2.5 mm in lead II
- Width is less than 0.11 s in lead II

Normal PR interval

-0.12 to 0.20 s (3-5 small squares)

Normal QRS complex

- Less than 0.12 s duration (3 small squares)

Normal QT interval

- Calculate the corrected QT interval by dividing the QT interval by the square root of the proceeding R-R interval. Normal is 0.42 s.

Normal ST segment

- No elevation or depression

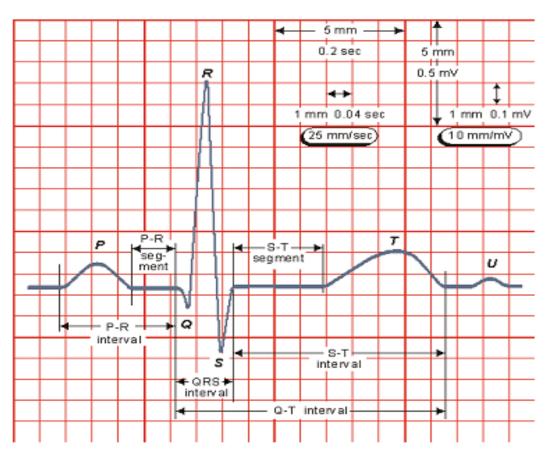


Fig.2.2 Normal ECG signal

BACKGROUND THEORY ON WAVELET TRANSFORM AND NEURAL NETWORK

3.1 Wavelets

3.1.1 Introduction

Wavelets are a powerful tool for the representation and analysis of such physiologic waveforms because a wavelet has finite duration (compact support) as contrasted with Fourier methods based on sinusoids of infinite duration.

The Fourier transform is a tool widely used for many scientific purposes, but it is well suited only to the study of stationary signals where all frequencies have an infinite coherence time. The Fourier analysis brings only global information which is not sufficient to detect compact patterns. Gabor introduced a local Fourier analysis, taking into account a sliding window, leading to a time frequency-analysis. This method is only applicable to situations where the coherence time is independent of the frequency. This is the case for instance for singing signals which have their coherence time determined by the geometry of the oral cavity. Morlet introduced the Wavelet Transform in order to have a coherence time proportional to the period.

The *wavelet transform* or *wavelet analysis* is probably the most recent solution to overcome the shortcomings of the Fourier transform. In wavelet analysis the use of a fully scalable modulated window solves the signal-cutting problem. The window is shifted along the signal and for every position the spectrum is calculated. Then this process is repeated many times with a slightly shorter (or longer) window for every new cycle. In the end the result will be a collection of time-frequency representations of the signal, all with different resolutions. Because of this collection of representations we can speak of a multiresolution analysis. In the case of wavelets we normally do not speak about time-frequency representations but about time-scale representations, scale being in a way the opposite of frequency, because the term frequency is reserved for the Fourier transform.

3.1.2 The continuous wavelet transforms

The wavelet analysis described in the introduction is known as the *continuous wavelet transform* or *CWT*. More formally it is written as:

$$\gamma(s,\tau) = \int f(t)\psi_{s,\tau}^*(t)dt \tag{1}$$

where * denotes complex conjugation. This equation shows how a function f(t) is decomposed into a set of basis functions, $\psi_{s,\tau}(t)$ called the wavelets. The variables s and τ , scale and translation, are the new dimensions after the wavelet transform. For completeness sake (2) gives the inverse wavelet transform.

$$f(t) = \iint \gamma(s,\tau) \,\psi_{s,\tau}(t) d\tau \tag{2}$$

The wavelets are generated from a single basic wavelet $\psi(t)$, the so-called *mother wavelet*, by scaling and translation

$$\psi_{s,\tau}(t) = \frac{1}{\sqrt{s}} \psi\left(\frac{t-\tau}{s}\right) \tag{3}$$

In (3) s is the scale factor, τ is the translation factor and the factor $s^{-1/2}$ is for energy normalization across the different scales.

3.1.3 Discrete wavelets

Now that we know what the wavelet transform is, we would like to make it practical. However, the wavelet transform as described so far still has three properties that make it difficult to use directly in the form of (1). The first is the redundancy of the CWT. In (1) the wavelet transform is calculated by continuously shifting a continuously scalable function over a signal and calculating the correlation between the two. It will be clear that these scaled functions will be nowhere near an orthogonal basis [6] and the obtained wavelet coefficients will therefore be highly redundant. For most practical applications we would like to remove this redundancy.

Even without the redundancy of the CWT we still have an infinite number of wavelets in the wavelet transform and we would like to see this number reduced to a more manageable count. This is the second problem we have.

The third problem is that for most functions the wavelet transforms have no analytical solutions and they can be calculated only numerically or by an optical analog computer. Fast algorithms are needed to be able to exploit the power of the wavelet transform and it is in fact the existence of these fast algorithms that have put wavelet transforms where they are today.

Let us start with the removal of redundancy.

As mentioned before the CWT maps a one-dimensional signal to a two-dimensional time-scale joint representation that is highly redundant. The time-bandwidth product of the CWT is the square of that of the signal and for most applications, which seek a signal description with as few components as possible, this is not efficient. To overcome this problem *discrete wavelets* have been introduced. Discrete wavelets are not continuously scalable and translatable but can only be scaled and translated in discrete steps. This is achieved by modifying the wavelet representation (3) to create

$$\psi_{j,k}(t) = \frac{1}{\sqrt{s_0^j}} \psi\left(\frac{t - k\tau_0 s_0^j}{s_0^j}\right) \tag{4}$$

Although it is called a discrete wavelet, it normally is a (piecewise) continuous function. In (4) j and k are integers and $s_0 > 1$ is a fixed dilation step. The translation factor τ_0 depends on the dilation step. The effect of discreticizing the wavelet is that the time-scale space is now sampled at discrete intervals. We usually choose $s_0 = 2$ so that the sampling of the frequency axis corresponds to *dyadic sampling*. This is a very natural choice for computers, the human ear and music for instance. For the translation factor we usually choose $\tau_0 = 1$ so that we also have dyadic sampling of the time axis.

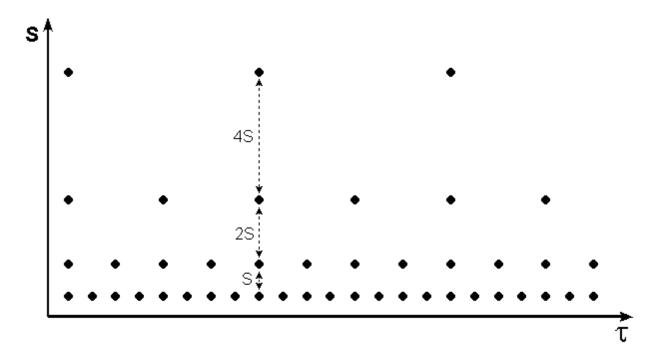


Figure 3.1

Localization of the discrete wavelets in the time-scale space on a dyadic grid..

When discrete wavelets are used to transform a continuous signal the result will be a series of wavelet coefficients, and it is referred to as the *wavelet series decomposition*. An important issue in such a decomposition scheme is of course the question of reconstruction. It is all very well to sample the time-scale joint representation on a dyadic grid, but if it will not be possible to reconstruct the signal it will not be of great use. As it turns out, it is indeed possible to reconstruct a signal from its wavelet series decomposition. In (4) it is proven that the necessary and sufficient condition for stable reconstruction is that the energy of the wavelet coefficients must lie between two positive bounds, i.e.

$$A\big|\big|f\big|\big|^2 \le \sum_{j,k} \big|\langle f, \psi_{j,k}\rangle\big|^2 \le B\big|\big|f\big|\big|^2 \tag{5}$$

where $||f||^2$ is the energy of f(t), A > 0, $B < \infty$ and A, B are independent of f(t). When (5) is satisfied, the family of basis functions $\psi_{j,k}(t)$ with $j, k \in \mathbb{Z}$ is referred to as a *frame* with frame bounds A and B. When A = B the frame is *tight* and the discrete wavelets behave exactly like an orthonormal basis. When $A \neq B$, *then* exact reconstruction is still possible at the expense of a *dual*

frame. In a dual frame discrete wavelet transform the decomposition wavelet is different from the reconstruction wavelet.

We will now immediately forget the frames and continue with the removal of all redundancy from the wavelet transform. The last step we have to take is making the discrete wavelets orthonormal. This can be done only with discrete wavelets. The discrete wavelets can be made orthogonal to their own dilations and translations by special choices of the mother wavelet, which means:

$$\int \psi_{j,k}(t)\psi_{m,n}^*(t)dt = \begin{cases} 1 & \text{if } j = m \text{ and } k = n \\ 0 & \text{otherwise} \end{cases}$$
 (6)

An arbitrary signal can be reconstructed by summing the orthogonal wavelet basis functions, weighted by the wavelet transform coefficients:

$$f(t) = \sum_{j,k} \gamma(j,k) \psi_{j,k}(t)$$
 (7)

(7) Shows the inverse wavelet transform for discrete wavelets, which we had not yet seen.

Orthogonality is not essential in the representation of signals. The wavelets need not be orthogonal and in some applications the redundancy can help to reduce the sensitivity to noise (7) or improve the *shift invariance* of the transform. This is a disadvantage of discrete wavelets: the resulting wavelet transform is no longer shift invariant, which means that the wavelet transforms of a signal and of a time-shifted version of the same signal are not simply shifted versions of each other.

3.1.4.1 A band-pass filter

With the redundancy removed, we still have two hurdles to take before we have the wavelet transform in a practical form. We continue by trying to reduce the number of wavelets needed in the wavelet transform and save the problem of the difficult analytical solutions for the end.

Even with discrete wavelets we still need an infinite number of scalings and translations to calculate the wavelet transform. The easiest way to tackle this problem is simply not to use an infinite number of discrete wavelets. Of course this poses the question of the quality of the transform. Is it possible to reduce the number of wavelets to analyze a signal and still have a useful result?

The translations of the wavelets are of course limited by the duration of the signal under investigation so that we have an upper boundary for the wavelets. This leaves us with the question of dilation: how many scales do we need to analyze our signal? How do we get a lower bound? It turns out that we can answer this question by looking at the wavelet transform in a different way.

If we look, we see that the wavelet has a band-pass like spectrum. From Fourier theory we know that compression in time is equivalent to stretching the spectrum and shifting it upwards:

$$F\{f(at)\} = \frac{1}{|a|}F\left(\frac{\omega}{a}\right) \tag{8}$$

This means that a time compression of the wavelet by a factor of 2 will stretch the frequency spectrum of the wavelet by a factor of 2 and also shift all frequency components up by a factor of 2. Using this insight we can cover the finite spectrum of our signal with the spectra of dilated wavelets in the same way as that we covered our signal in the time domain with translated wavelets. To get a good coverage of the signal spectrum the stretched wavelet spectra should touch each other, as if they were standing hand in hand (see <u>figure 3.2</u>). This can be arranged by correctly designing the wavelets.

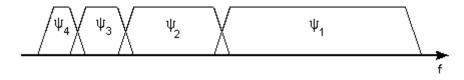


Figure 3.2

Touching wavelet spectra resulting from scaling of the mother wavelet in the time domain.

Summarizing, if one wavelet can be seen as a band-pass filter, then a series of dilated wavelets can be seen as a band-pass filter bank. If we look at the ratio between the center frequency of a wavelet spectrum and the width of this spectrum we will see that it is the same for all wavelets. This ratio is normally referred to as the fidelity factor Q of a filter and in the case of wavelets one speaks therefore of a *constant-Q* filter bank.

3.1.4.2 The discrete wavelet transforms

In many practical applications the signal of interest is sampled. In order to use the results we have achieved so far with a discrete signal we have to make our wavelet transform discrete too. Remember that our discrete wavelets are not time-discrete, only the translation- and the scale step are discrete. Simply implementing the wavelet filter bank as a digital filter bank intuitively seems to do the job. But intuitively is not good enough, we have to be sure.

Previously, we stated that the scaling function could be expressed in wavelets from minus infinity up to a certain scale *j*. If we add a wavelet spectrum to the scaling function spectrum we will get a new scaling function, with a spectrum twice as wide as the first. The effect of this addition is that we can express the first scaling function in terms of the second, because all the information we need to do this is contained in the second scaling function. We can express this formally in the so-called multiresolution formulation or *two-scale relation*:

$$\varphi(2^{j}t) = \sum_{k} h_{j+1}(k)\varphi(2^{j+1}t - k)$$
(9)

The two-scale relation states that the scaling function at a certain scale can be expressed in terms of translated scaling functions at the next smaller scale. Do not get confused here: smaller scale means more detail.

The first scaling function replaced a set of wavelets and therefore we can also express the wavelets in this set in terms of translated scaling functions at the next scale. More specifically we can write for the wavelet at level *j*:

$$\psi(2^{j}) = \sum_{k} g_{j+1}(k) \varphi(2^{j+1}t - k)$$
(10)

which is the two-scale relation between the scaling function and the wavelet.

Since our signal f(t) could be expressed in terms of dilated and translated wavelets up to a scale j1, this leads to the result that f(t) can also be expressed in terms of dilated and translated scaling functions at a scale j:

$$f(t) = \sum_{k} \lambda_{j}(k)\varphi(2^{j}t - k) \tag{11}$$

To be consistent in our notation we should in this case speak of discrete scaling functions since only discrete dilations and translations are allowed.

If in this equation we step up a scale to j-1 (!), we have to add wavelets in order to keep the same level of detail. We can then express the signal f(t) as

$$f(t) = \sum_{k} \lambda_{j-1}(k) \varphi(e^{j-1}t - k) + \sum_{k} \lambda_{j-1}(k) \psi(2^{j-1}t - k)$$
(12)

If the scaling function $\Psi_{j,k}(t)$ and the wavelets $\Psi_{j,k}(t)$ are orthonormal or a tight frame, then the coefficients $\lambda_{j-1}(k)$ and $Y_{j-1}(k)$ are found by taking the inner products

$$\lambda_{i-1}(k) = \langle f(t), \varphi_{i,k}(t) \rangle$$

$$\gamma_{j-1}(k) = \langle f(t), \psi_{j,k}(t) \rangle \tag{13}$$

If we now replace $\Psi_{j,k}(t)$ and $\Psi_{j,k}(t)$ in the inner products by suitably scaled and translated versions [12] of (9) and (10) and manipulate a bit, keeping in mind that the inner product can also be written as an integration, we arrive at the important result:

$$\lambda_{i-1}(k) = \sum_{m} h(m-2)\lambda_{i}(m) \tag{14}$$

$$\gamma_{j-1}(k) = \sum_{m} g(m-2)\gamma_{j}(m) \tag{15}$$

These two equations state that the wavelet- and scaling function coefficients on a certain scale can be found by calculating a weighted sum of the scaling function coefficients from the previous scale. Now recall from the section on the scaling function that the scaling function coefficients came from a low-pass filter and recall from the section on subband coding how we iterated a filter bank by repeatedly splitting the low-pass spectrum into a low-pass and a high-pass part. The filter bank iteration started with the signal spectrum, so if we imagine that the signal spectrum is the output of a low-pass filter at the previous (imaginary) scale, then we can regard our sampled signal as the scaling function coefficients from the previous (imaginary) scale. In other words, our sampled signal f(k) is simply equal to $\lambda(k)$ at the largest scale!

But there is more. As we know from signal processing theory a discrete weighted sum like the ones in (14) and (15) is the same as a digital filter and since we know that the coefficients $\lambda_j(k)$ come from the low-pass part of the splitted signal spectrum, the weighting factors h(k) in (14) must form a low-pass filter. And since we know that the coefficients $Y_j(k)$ come from the high-pass part of the splitted signal spectrum, the weighting factors g(k) in (15) must form a high-pass filter. This means that (14) and (15) together form one stage of an iterated digital filter bank and from now on we will refer to the coefficients h(k) as the *scaling filter* and the coefficients g(k) as the wavelet filter.

By now we have made certain that implementing the wavelet transform as an iterated digital filter bank is possible and from now on we can speak of the *discrete wavelet transform* or *DWT*. Our intuition turned out to be correct. Because of this we are rewarded with a useful bonus property of (14) and (15), the *subsampling property*. If we take one last look at these two

equations we see that the scaling and wavelet filters have a step-size of 2 in the variable k. The effect of this is that only every other $\lambda_j(k)$ is used in the convolution, with the result that the output data rate is equal to the input data rate. Although this is not a new idea, it has always been exploited in subband coding schemes; it is kind of nice to see it pop up here as part of the deal.

The subsampling property also solves our problem, which had come up at the end of the section on the scaling function, of how to choose the width of the scaling function spectrum. Because, every time we iterate the filter bank the number of samples for the next stage is halved so that in the end we are left with just one sample (in the extreme case). It will be clear that this is where the iteration definitely has to stop and this determines the width of the spectrum of the scaling function. Normally the iteration will stop at the point where the number of samples has become smaller than the length of the scaling filter or the wavelet filter, whichever is the longest, so the length of the longest filter determines the width of the spectrum of the scaling function.

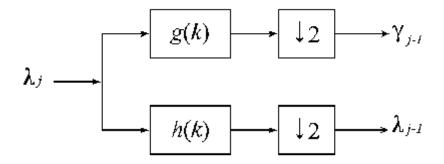


Figure 3.3 one stage of an iterated filter bank

3.1.5 Applications of Wavelets

Wavelet signal processing has a wide range of application. But we are mainly concerned with its application in ECG classification for a better diagnosis. An ECG signal is a non-stationary signal .therefore it can be best extracted by using discrete wavelet transform (DWT) with aid of matlab without any significant loss in valuable information. This data then can be classified by using many algorithms or techniques like neural networks or fuzzy logic or a combination of both.

3.2 Neural Network

3.2.1 Artificial Neural Networks

The brain has the ability to perform tasks such as pattern recognition, perception and motor control much faster than any computer - even though events occur in the nanosecond range for silicon gates and milliseconds for neural systems. An artificial neural network (NN) is a model of biological neural systems that contains similar characteristics.

3.2.2 Biological Neural System

A biological Neural System is comprised of a mass of nerve cells, referred to as a neuron. A neuron consists of a cell body, dendrites and an axon. Neurons are massively interconnected by interconnections between the axon of one neuron and a dendrite of another neuron. This connection is found in the synapse. Signals propagate from the dendrites, through the cell body to the axon, once the signal reaches to a synapse; these signals are propagated to all connected dendrites. A signal is transmitted to the axon of a neuron only when the cell undergoes depolarization and repolarization. A neuron can either inhibit or excite the associated post-symptic neurons [9].

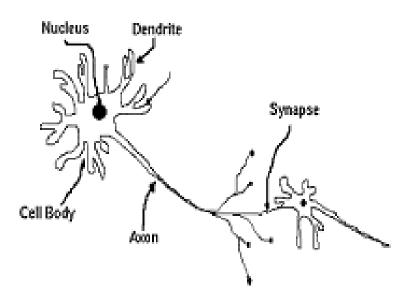


Figure 3.5: A biological neuron

3.2.3 Artificial Neuron (AN)

An artificial neuron (AN) is a model of a biological neuron (BN). Each AN receives signals from the environment or other ANs, and gathers these signals. When the cell is activated, each AN transmits a signal to all connected artificial neurons. Figure (3.6) represents an artificial neuron (AN). Input signals are inhibited or excited through negative and positive numerical weights associated with each connection in the AN. The firing of an AN and the strength of the exciting signal are controlled via a function, called an activation function. The AN collects all incoming signals, and computes a net input signal using the respective weights, then the net signal serves as input to the activation function which calculates the output signal of the AN.

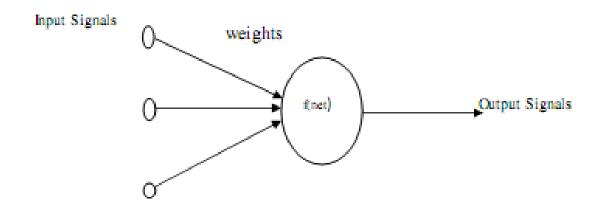


Fig: 3.6: An artificial neuron

3.2.4 Basic Structure of an Artificial Network

An artificial neural network (NN) is a layered network of ANs. An NN consists of an input layer, one or more hidden layers and an output layer. ANs in one layer are connected, fully or partially, to the ANs in the next layer. A typical NN structure is represented in Figure (3.7)

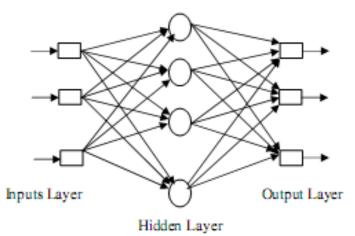


Fig: 3.7: An artificial neural network

The way to calculate the Net input signal is usually computed as the weighted (w_i) sum of all input signals (x_i) in Equation (3.1). These artificial neurons are referred to as summation units (SU) [9].

$$Net = \sum_{i} (w_i x_i) \tag{3.1}$$

Once the net input signal is calculated, the function ${}^{\prime}f_{\rm Net}$, referred to as the activation function, receives it to determine the output of the neuron. Different types of activation functions can be used. The neural network is trained by a set of input data and the desired output, called targets using the back propagation algorithm. The back propagation algorithm, the best known training algorithm for the neural networks, is one in which the input data is continuously fed into the network and the predicted output of the network is compared with the desired output and the error generated. This process is done repeatedly until the error becomes insignificant. The artificial neuron learning techniques are mainly classified into supervised and unsupervised learning, and the back propagation method is a type of supervised learning [9].

• Supervised learning, where the neuron (or NN) is provided with a data set consisting of input vectors and a target(desired output) associated with each input vector. This data set is referred to as the training set. The aim of supervised training is then to adjust the weight values such that the error between the real output of the neuron and the target output is minimized.

• Unsupervised learning, where the aim is to discover patterns or features in the input data with no assistance from an external source. An artificial network has been used for a wide range of applications, including diagnosis of diseases, speech recognition, data mining, composing music, image processing, forecasting, robot control, credit approval, Classification, pattern recognition, planning game strategies, compression and many others [9].

3.2.5 The Multilayer Perceptron

A three-layered feed-forward NN was used and trained with the error back propagation. The input signals of NN were formed by wavelet transformation. Fig. (3.7) shows a general structure of the NN. The back propagation training with generalized delta learning rule is an iterative gradient algorithm designed to minimize the root mean square error between the actual output of a multilayered feed-forward [32], NN and a desired output. Each layer is fully connected to the previous layer, and has no other connection.

3.2.5.1. Back propagation algorithm

- i. Initialization: Set all the weights and biases to small real random values.
- ii. While stopping condition is false, do step 3-10.
- iii. For each training pair do step 4 to 9.

Feed forward

- iv. Each input receives the input signal xi and transmits the signals to all units in the layer.
- v. Each hidden layer $(z_j, j=1,....p)$ sums its weighted input signals .

$$Z_{inj} = V_{oj} + \sum_{i=1}^{n} x_i V_{ij}$$
 (3.2)

Applying activation function

$$Z_i = f(Z_{ini}) \tag{3.3}$$

vi. Each output layer (y k, k=1,.....m) sums its weighted input signals.

$$y_{ink} = Z_{ok} + \sum_{j=1}^{p} Z_{j} W_{jk}$$
 (3.4)

and applying its activation function to calculate the output signals.

$$Y_k = f(y_{ink}) \tag{3.5}$$

Back propagation error

vii. Each output units receives a target pattern corresponding to the input pattern, error information term is calculated as:

$$\delta_k = (t_k - y_k) f(y_{ink}) \tag{3.6}$$

viii. Each hidden unit $(Z_j, j=1, \dots, n)$ sums its delta input from units in the layer above

$$\delta_k = \sum_{k=1}^n \delta_j w_{jk} \tag{3.7}$$

The error information term is calculated

$$\delta_i = \delta_{inj} f(Z_{inj}) \tag{3.8}$$

<u>Updation of Weight and Bias</u>

ix. Each output unit $(y_k, k=1,....m)$, updates its bias and weights (j=0,....p)

The weight correction term is given by:

$$\Delta W_{ij} = \alpha \delta_k Z_j \tag{3.9}$$

And the bias correction is given by:

$$\Delta W_{ij} = \alpha \delta_k$$

Therefore,

$$W_{jk}(New) = W_{jk}(Old) + \Delta W_{jk}$$
(3.10)

$$W_{ok}(New) = W_{ok}(Old) + \Delta W_{ik}$$
(3.11)

Each hidden unit $(z_j, j=1,...p)$ updates its bias and weights (i=0,...n)

The weight correction term:

$$\Delta V_{ij} = \alpha \delta_j x_j$$

The bias correction term:

$$\Delta V_{oj} = \alpha \delta_j$$

Therefore,

$$V_{ii}(new) = V_{ii}(old) + \Delta V_{ii}, \tag{3.12}$$

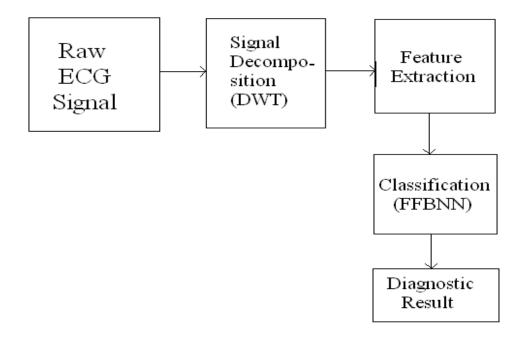
$$V_{oi} (new) = V_i(old) + \Delta V_{oi}$$
(3.13)

x. Test the stopping condition. The stopping condition may be the minimization of the error, number of epochs etc.

ECG SIGNAL ANALYSIS USING WAVELET TRANSFORMS

4.1. Problem addressed

The most difficult problem faced by today's automatic ECG analysis is the large variation in the morphologies of ECG waveforms, not only of different patients or patient groups but also with in the same patient. The ECG waveforms may differ for the same patient to such extend that they are unlike to each other and at the same time alike for different types of beats. This is the main reason that the beat classifier, performing well on the training data generalizes poorly, when presented with different patients ECG waveforms [2]. In our study we took number of ECG samples of different diseases and performed the following stages in order to classify the ECG signal efficiently.



Block diagram of the proposed system

4.1.1. ECG signal decomposition using discrete wavelet

transformation

The major advantage of DWT is that it provides good time resolution at high frequency and better frequency resolution at low frequency. One very important application is the ability to compute and manipulate data in compressed parameters, which are often called features. Thus, the ECG signal, consisting of many data points, can be compressed into a few parameters. These parameters characterize the behaviour of the ECG signal. This feature of using a smaller number of parameters to represent the ECG signal is particularly important for recognition and diagnostic purposes. The procedure of multiresolution decomposition of a signal x[n] is schematically shown in Fig. 4.1. Each stage of this scheme consists of two digital filters and two down samplers by 2. The first filter, $g[\cdot]$ is the discrete mother wavelet, high-pass in nature, and the second, $h[\cdot]$ is its mirror version, low-pass in nature. The down sampled outputs of first high- and low-pass filters provide the detail, D_1 and the approximation, A_1 , respectively. The first approximation, A_1 is further decomposed and this process is continued as shown in Fig. 4.1. We choose a Daubechies wavelet of second order i.e. Db2.

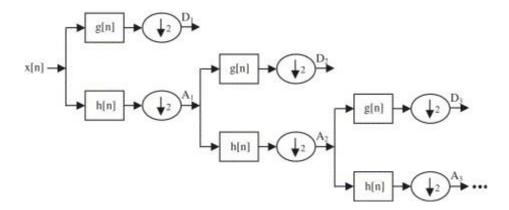
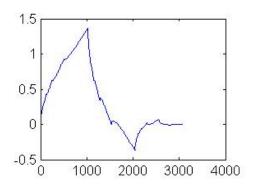
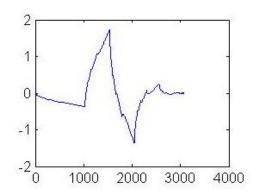


Fig 4.1.Subband decomposition of discrete wavelet transform implementation; g[n] is the highpass filter, h[n] is the low-pass filter

The wavelet, scaling functions and the decomposition and reconstruction filters of Db2 are shown in <u>Fig.4.2</u>. we performed the three level decomposition of the ECG signal and the detail and approximate coefficients were obtained by convoluting the input ecg signals with the Db2 filter followed by down sampling it by 2. Approximation coefficients were obtained from the

lowpass filter h(.) which were further decomposed in the next level. Similarly the detail coefficients were obtained from highpass filters g(.) at each level using matlab wavelet toolbox.

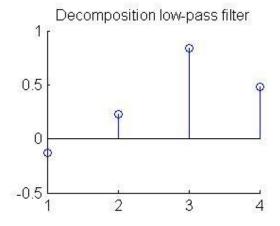


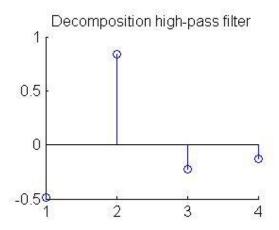


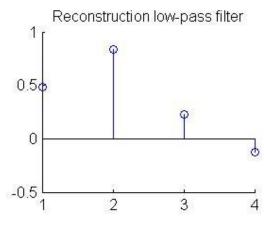
(a) Scaling function

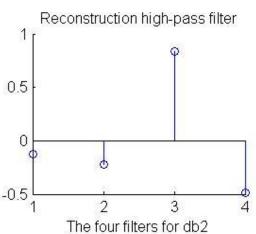
(b) Wavelet function

Fig 4.2 a, b, c - Db2 wavelet (c)









4.1.2. Feature extraction

The three-level discrete wavelet decomposition produces signal components in different subbands. Several features are important in characterizing these signals. First of all, signal variances in a subband represent the averaged AC power in that band. With a discrete-time signal x of N samples, the sample variance is defined as

$$\sigma_x^2 = \frac{1}{N} \sum_{n=1}^{N} [x(n) - \bar{x}]^2$$
 (4.1)

where _x is the sample mean of the signal. We use the variance of the decomposed signal in each subband as the first feature set in our method.

The autocorrelation function is considered as a measure of similarity or coherence between a signal x(n) and its shifted version. If x(n) is of length N, the autocorrelation function is expressed as

$$R_{xx}(l) = \sum_{i}^{N-|k|-1} x(n)x(n-l)$$
(4.2)

where l is the time shift index, i = l, k = 0 for l P 0, and i = 0, k = l for l < 0. The variance of the autocorrelation calculated as the averaged AC power of the autocorrelation function, which measures the coherence of the signal in each subband (Goumas et al., 2002). Thus, we use it as the second feature for subband signals.

The relative amplitude of the decomposed signal x(n) in each subband is defined as

 $\min(x(n))/\max(x(n))$

which represents the morphological characteristics of the signal and is regarded as the third feature for subband signals.

The following statistical features were used to represent the time-frequency distribution of the ECG signals:

1. Mean of the absolute values of the coefficients in each subband.

- 2. Average power of the wavelet coefficients in each subband.
- 3. Standard deviation of the coefficients in each subband.
- 4. Ratio of the absolute mean values of adjacent subbands.

Features 1 and 2 represent the frequency distribution of the signal and the features 3 and 4 the amount of changes in frequency distribution. These feature vectors, which were calculated for the D_1 - D_3 and A_3 frequency bands using the matlab wavelet toolbox, were used for classification of the ECG beats.

4.1.3 Normalization of feature vectors

Because the quantities of the features may be quite different, a normalization process is necessary to standardize all the features to the same level. The formula of the normalization is defined as follows:

$$x'_{ij} = tansig\left(\frac{x_{ij} - \overline{x}_j}{\sigma_{xi}}\right) \tag{4.3}$$

where xij is the jth component of the ith feature vector, $_x$ j and rxj are the mean and standard deviation, respectively, of the jth component of the feature vectors, and tansig(\mathcal{E}) is a hyperbolic tangent sigmoid transfer function. The expression in the brackets makes the jth component to be normal distributed with zero-mean and unity standard deviation. The hyperbolic tangent sigmoid function maps a wide-ranged signal to that with limited range [-1, +1]. In our experiment, the mean and the standard deviation of each component in the feature vectors are calculated from the training dataset and are used throughout the experiments.

4.1.4 Classification using feed forward backpropagation neural network (FFBNN)

We choose ten samples each of Normal ECG, LBBB (Left Bundle Branch Block) and PB(Paced Beat) half of which were used for training and rest for testing. The samples were first decomposed through three levels DWT and the normalised features that were extracted were used for training the neural network. Learning rate and momentum constant were chosen as 0.02 and 0.3 respectively. The size of the training pattern is 15 samples * 200 segments, is presented

to NN. The number of input nodes were determined as 15, further more optimum NN architecture is chosen as 15:30:3. The number of segment chosen is represented in the table 4.1.

Arrythmia	In original training set	In new set obtained with Wavelet- NN
N (Normal Sinus Rhythm)	5	5
LBBB(Left Bundle Branch Block)	5	5
PB (Paced Beat)	5	5
Total	15	15

Table 4.1 the no. of segment for each arrythmia

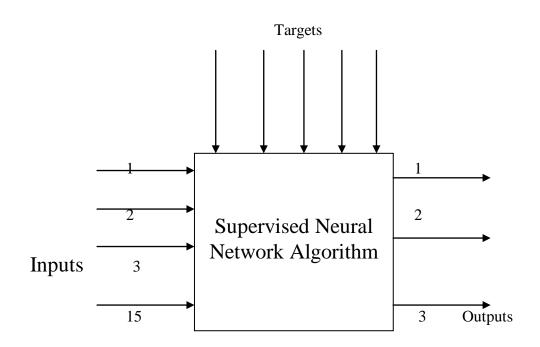


Fig. 4.3 NN structure

RESULTS

5.4. Results and Simulations

The ECG signals are obtained from the MIT-BIH arrhythmia database for recognition. Since most of the diagnostic information lies around the R peak of the ECG signal, hence a portion of signal before it and a portion of signal after it are selected for processing. Herein, the samples extracted from the ECG signals are 0.556 s QRS segments with 0.278 s data lengths both before and after the R point, resulting in 200 points in each segment at a sampling frequency of 360 Hz. Each sample is preprocessed by firstly removing the mean value to eliminate the offset effect, and then dividing with the standard deviation. This process results in normalized signals with zero mean and unity standard deviation, which aims to reduce the possible false decisions due to signal amplitude biases resulting from instrumental and human differences. The ECG data has been taken from MIT-BIH data base which is shown in Table below:

Туре	MIT-BIH data file	Training (file)	Testing (file)
NORM	100,101,108,105	5	5
LBBB	109,214,111,207	5	5
PB	102,104,107,217	5	5
Total		15	15

Table 5.1 ECG Samples used from MIT-BIH database

A total of 30 sample segments attributing to three ECG beat types were selected from the MIT-BIH database, which are shown in the following figures:

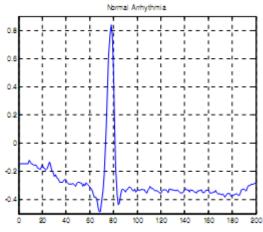


Fig 5.1 Normal Arrythmia

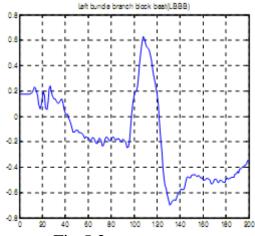


Fig 5.2 LBBB Arrythmia

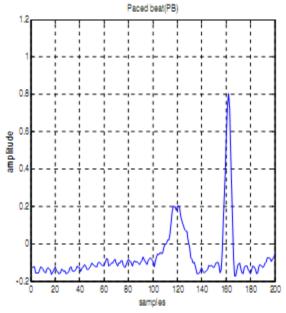
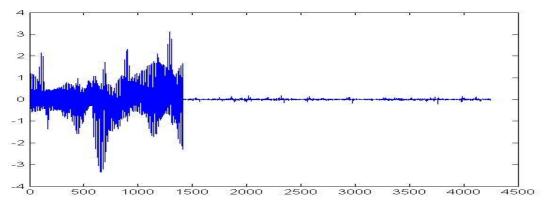
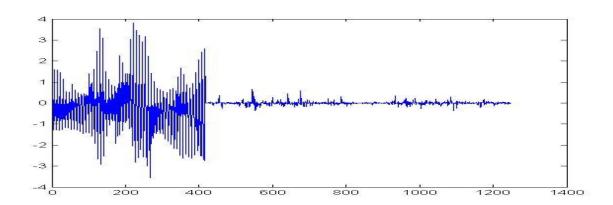


Fig 5.3 Paced Beat

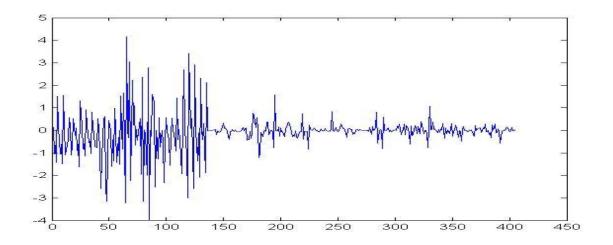
The types and numbers of the ECG beats exploited in the study are summarised in the above table constitute a 15*200 data matrix, then the samples were decomposed using DWT and the following results were obtained.



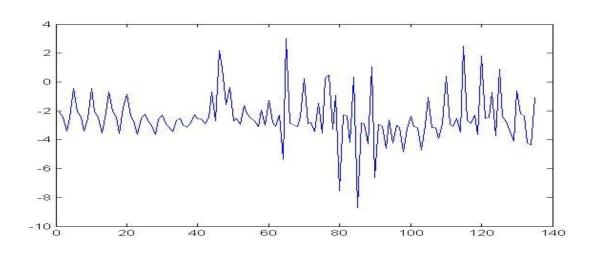
a) Detail coefficient at level 1



b) Detail coefficient at level 2

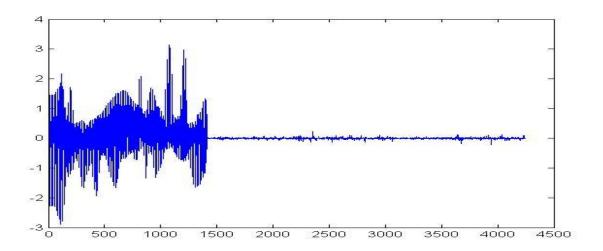


c) Detail coefficient at level 3

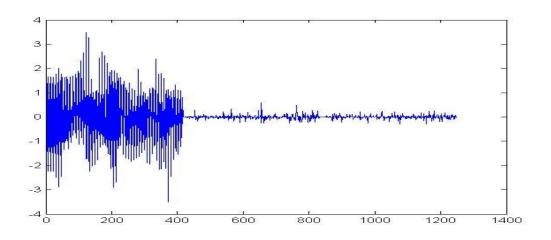


d) Approximation coefficient at level 3

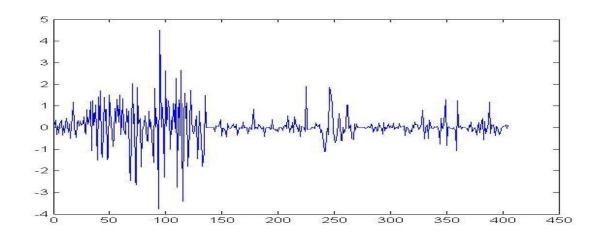
Fig.5.4, a, b, c, d-are detail and approximation coefficients of APB ECG signal.



a) Detail coefficient at level 1



b) Detail coefficient at level 2



c) Detail coefficient at level 3

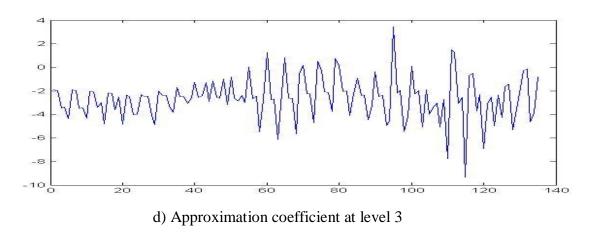


Fig.5.5,a,b,c,d-are detail and approximation coefficients of PB ECG signal.

After the decomposition of the ECG signal the feature vectors were extracted and normalised this normalised feature vectors were used to train the selected NN through experimentation, and thus we will get the desired out put.

CONCLUSION AND FUTURE WORK

6.1. Conclusion

In this piece of work, a novel technique is developed for ECG beat classification. In this context, we have considered a Neural Network (NN) classifier for beat classification. In order overcome the difficulty of intensive computational time taken using NN classifier, attempt has been made to reduce the number of input data points using wavelet transform, which is beneficial for automatic ECG beat classification in real time mode. The aim of using wavelet transform is to decompose the ECG signal for faster computation. The neural network chosen i.e. FFBNN is simple basic neural network having good recognition accuracy and doesn't take longer time to train. The performance of the method will be better, if the number of beats is increased for the training. So it can be said that the proposed method is optimum for ECG beat classification.

6.2. Future scope

Since the application of wavelet transformation in electro cardiology is relatively new field of research, many methodological aspects (Choice of the mother wavelet, values of the scale parameters) of the wavelet technique will require further investigations in order to improve the clinical usefulness of this novel signal processing technique. Simultaneously diagnostic and prognostic significance of wavelet techniques in various fields of electro cardiology needs to be established in large clinical studies.

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