On the Development of an Automatic ECG Monitoring System for Diabetic Patients

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Abstract. Diabetes has become progressively common throughout the world due to changes in the lifestyle and in the eating habits. Among other consequences, this disease seriously affects the circulatory system, whose complications are the leading cause of death in diabetics. In this paper we present a new device, developed specifically for diabetics, which allows estimating blood glucose levels and, simultaneously, automatically detect potentially pathological electrocardiographic patterns. We will present the entire processing sequence system and will give special importance to the modules targeting the electrocardiogram (ECG) and its analysis. A set of reference databases has been used as support for performance evaluation. The system proved to be able to effectively detect changes in the ECG morphology for occurrences of different nature and in various contexts. The use of the ECG signal, whose acquisition is non-invasive, provides comfort to the user and has the advantage of allowing a continuous patient monitoring.

1 Introduction

Diabetes is a chronic condition that occurs when the pancreas does not produce enough insulin, defined as type 1, or when the body cannot effectively use the insulin it produces, defined as type 2. Most of the diabetics are affected by the latter. Diabetes prevalence has been growing epidemically for both men and women and in all age groups. According to the World Health Organization, around 171M people in the world were diagnosed with diabetes in 2000, and it is estimated that the number will double by 2030 [1]. Most of this increase will occur as a result of a 150% rise in developing countries like India, China and Indonesia (all in the top 10 countries with higher diabetes cases) [2]. The metabolic disturbances associated with this pathology, if not diagnosed and treated, can bring with time, among other complications, severe damages to the circulatory systems. In fact, diabetes has become one of the major causes of premature illness and death in most countries, mainly through the increased risk of cardiovascular disease (CVD). Diabetes confers about a two-fold excess risk for a wide range of vascular diseases, independently from other conventional risk factors. Cardiovascular disease is responsible for between 50% and 80% of deaths in people with diabetes [3]. This article describes a new system, aimed for diabetic patients, that continuously monitors

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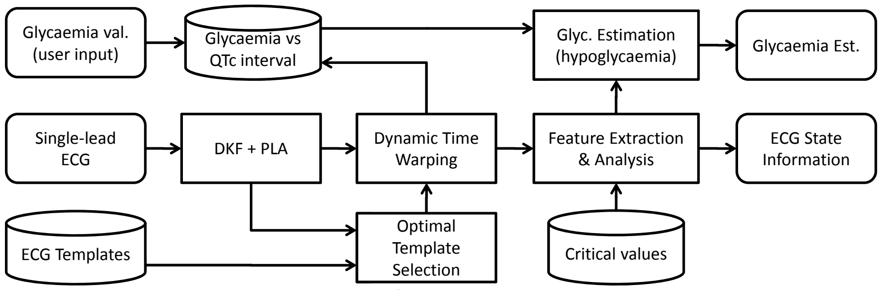

Fig. 1. ECG analysis pipeline.

cardiac function by ECG acquisition and analysis. It can provide, on one hand, estimates of glycaemia, which increases patient's quality of life by decreasing the amount of daily finger pricks, and, on the other hand, can automatically discriminate between a regular ECG morphology or an abnormal pattern requiring the attention of a medical professional. This function is particularly important since several cardiopathic states create confusion, dizziness, fainting or weakness which decreases the ability to react or ask for help. The system is housed in a small autonomous device (around the size of cellular phone), with processing and communication functions, and only requires the connection of external electrodes.

In this paper we will describe the full system giving special detail to the signal processing sub-systems. The next section starts by introducing the used databases during the system's development and then covers the ECG segmentation algorithm as well as the ECG pattern classification sub-system. Additionally a brief description of a signal correction algorithm is also included. Section 3 contains a wide evaluation of the system whose results are then thoroughly discussed. Conclusions and future work are finally presented in Section 4.

2 System Description

Our wearable acquisition system was based on a custom built instrumentation amplifier that feeds a 10 bit ADC with a sampling rate of 250Hz. An ARM7 controller with a BlueGiga bluetooth module provided a connection to a computer when necessary. The functional system's architecture is depicted in figure 1. The described algorithms can run locally, at the wearable device, or on a remote PC.

2.1 Database

The development of the presented system relied on the QT database [4], widely used in scientific literature and publicly available at the PhysioNet web archives. Besides the data itself the database includes a set of manual and automatic annotations that are useful for performance evaluation and comparison of results. This database contains a statistically significant number of QRST complexes while encompassing a wide variety of wave morphologies. To evaluate the robustness of the system we also used the MIT-BIH Arrhythmia database [5], also available in the PhysioNet archives, which covers distinct situations where arrhythmic episodes can be observed. The rich annotation provided with this database allows the discrimination of specific pathological occurrences that were useful for restricted event-dependent performance evaluation.

2.2 ECG Automatic Segmentation

Segmentation is one of the key steps of any system that aims to evaluate ECG waves characteristics. Several methods have been developed using a wide range of tools (e.g. Dynamic Time Warping, Differentiated ECG) [6–8]. One of the most accepted methods, described by Laguna [6], is based on the differentiated ECG, and it's often used as a reference for performance comparisons between automatic segmentation systems. Regarding automatic segmentation systems, the development of solutions based on the Dynamic Time Warping (DTW) algorithm [9], originally developed for speech signals, showed comparable results with the Laguna's method. Vullings [7] presented a system which combined Piecewise Linear Approximation (PLA) and DTW, in order to reduce noise and enhance the DTW performance on the segmentation procedure. Nevertheless, as described in [7], the application of PLA demands the assumption that the fiducial points are near the points obtained after the linear approximation, which can be associated to an increase of the segmentation error. For the automatic segmentation task, we suggest a hybrid approach which uses the PLA technique combined with a discrete Kalman Filter (DKF), so that the error from the linear approximation can be reduced.

Kalman Filter. From a general point of view, the Kalman Filter is a tool designed for the estimation of a n-dimensional variable, often called as the system's state, based on both a vector of noisy observations and an underlying model of the process. This estimation can be represented in a state-space form that relies on the following equations:

$$\mathbf{x}(k) = \mathbf{A}\mathbf{x}(k-1) + \mathbf{w}(k-1) \tag{1}$$

$$\mathbf{z}(k) = \mathbf{C}\mathbf{x}(k) + \mathbf{v}(k) \tag{2}$$

where $\mathbf{w}$ and $\mathbf{v}$ represent the noises inherent to the process and to the observations, respectively. The vector $\mathbf{C}$ establishes the relationship between the observations $\mathbf{z}(k)$ and the states $\mathbf{x}(k)$, while the matrix $\mathbf{A}$ traduces the system behaviour and is built based on an autoregressive (AR) model according to the following conformation:

$$\mathbf{A} = \begin{bmatrix} a(1) & a(2) & a(3) & \cdots & a(p-1) & a(p) \\ 1 & 0 & 0 & \cdots & 0 & 0 \\ \vdots & \vdots & \vdots & 0 & \vdots & \vdots \\ 0 & 0 & 0 & \cdots & 1 & 0 \end{bmatrix} \tag{3}$$

in which $a(i), i = 1, 2, \ldots, p$ are the AR coefficients used to recover the signal as:

$$x(k) = \sum_{i=1}^{p} a(i)x(k-i) + w(k) \tag{4}$$

From equations (1) and (2), the estimated samples are:

$$\hat{\mathbf{x}}_k = \hat{\mathbf{x}}_{k-1} + \mathbf{G}_k \left(\mathbf{z}_k - \mathbf{C}\mathbf{A}\hat{\mathbf{x}}_{k-1} \right) \tag{5}$$

where a new parameter G_k is defined. This recursively calculated parameter, called the Kalman gain, is obtained from previously defined covariances from both the observations and the states.

Piecewise Linear Approximation and the Kalman Filter. Koski's Piecewise Linear Approximation, presented in [10], aims to approximate a discrete signal with a set of linear branches, considering a maximum approximation window size and a maximum approximation error. This algorithm searches for the highest value of the approximation window size for which the approximation error does not overcome a specified threshold. As presented earlier in this paper, the application of PLA to ECG usefully removes its' noise, but also introduces an uncertainty regarding the change in the location of the fiducial points [7]. In order to obtain a de-noised ECG signal without considerable changes on the location of the fiducial points, we applied the Kalman Filter structure explained above, where the ECG signal is the set of observations and the output from the PLA is considered as the underlying model of the system. The Kalman Filter is able to estimate the new samples gathering the data from the observations and from the PLA model, relying on these inputs according to their covariances matrices. Thus, the Kalman Filter will produce the new estimates relying on the ECG and its' linear approximation with different and controllable extensions.

Dynamic Time Warping. After the application of the Kalman Filter combined with the PLA, a template matching step is performed, in order to determine which of the previously stored beat templates is morphologically more similar to the beats in the ECG signal. For this purpose a cross-correlation between the templates and the signal was implemented. The template that best suits the morphology of the ECG signal is then used for the segmentation task, applying the DTW algorithm. This algorithm aims to align a template and a test signal in the most efficient way. The efficiency of the alignment can be traduced by a distance, so that the highest efficiency corresponds to the minimization of that distance. This algorithm aligns both the template and the signal by compressing or stretching the temporal axis, thus being an attractive solution to identify patterns where the duration often varies. Considering the signals $S = s_1, s_2, \ldots, s_n$ and $T = t_1, t_2, \ldots, t_m$, as the ECG signal with length *n* and template with length *m*, respectively, an $n \times m$ matrix was built, where each of its' elements is a measure of the alignment between the respective samples. The warping path that minimizes the total sum of the distances between the samples of the two series, the optimal path, in equation 6, provides the best time alignment for the signals.

$$\hat{\Phi} = \arg \min_{\phi_k, \psi_k} \sum_{k=1}^{K} \frac{\delta(s_{\phi_k}, t_{\psi_k}).m_{k,\Phi}}{M_{\Phi}} \tag{6}$$

In equation (6), $\frac{m_{k,\Phi}}{M_{\Phi}}$ represents the specific weight from the element *k*, along one path *Φ*. Nevertheless, these two parameters are often absent and thus, every element

k have the same weight. Our DTW implementation considered as distance between samples $\delta(s_{\phi_k}, t_{\psi_k})$ the quadratic error:

$$\delta(s_{\phi_k}, t_{\psi_k}) = (s_{\phi_k} - t_{\psi_k})^2 \tag{7}$$

This formulation provided the basis that allowed to identify ECG components and their related interest points.

2.3 Glycaemia Estimation

It is known that blood glucose variations can have consequences in the morphology of the ECG wave. In hypoglycaemic states the effects are more direct and conditions such as fluctuation in cardiac frequency and in the ST interval, enlarged QT segment, fusion of T and U waves or decrease in T peak value can be observed [11]. Furthermore, several authors report the existence of a direct correlation between the duration of the QT segment and the blood glucose levels [12, 13]. This knowledges allows the system to provide glucose level estimates using a linear model whose parameters are obtained from the segmentation module and from manually measured glucose levels supplied by the user. The estimates should be calculated only when in bradycardiac rhythms are detected.

2.4 ECG Analysis and Classification

The purpose of the presented ECG analysis is to generate warnings, for the patient and/or for a medical professional, resulting from the automatic detection of an abnormal cardiac function. For class detection we used an SVM classifier. To build a prototype feature vector for feeding the classifier we considered a broad range of wave characteristics that cover intra and inter period informations as well as some of their related statistics. For each ECG period we used the duration of 10 segments plus the corrected QT duration (QTc) calculated according to the Bazett's formula:

$$QTc = \frac{QT}{\sqrt{RR}} \tag{8}$$

where RR represents the interval from the onset of one QRS complex to the onset of the next QRS complex. The non-flat segments P1, P2, T1, T2, R1 and R2 were modelled using linear approximations (slope and origin intersection values) and the peak values for P, Q, R, S and T were also included. By observing the last 10 ECG periods we extract several inter-frame relations. We calculated 4 first-order statistics, namely the average, standard deviation, skewness and kurtosis for all the describes parameters. Additionally, for the peak values P, Q, R, S and T, we extracted a five-point amplitude perturbation quotient (S_5) as the average absolute difference between the amplitude A of a period i and the average of the amplitudes of it and its four closest neighbours (two on each side, $K = 2$), divided by the average amplitude:

$$S_5 = \frac{\frac{1}{N}\sum_{i=1}^{N}\left|A_i - \frac{1}{2K+1}\sum_{k=-K}^{K} A_{i+k}\right|}{\frac{1}{N}\sum_{i=1}^{N} A_i} \tag{9}$$

A similar metric was also calculated for the time instants of the mentioned peaks. This thus yields a final feature vector, with 150 dimensions, composed by all the described characteristics. Since the classifier system was developed to work on a mobile device with low-resource hardware we had to optimize the feature vector in order to reduce calculation complexity. In a first step, considering that the values on each dimension followed a Gaussian distribution, we normalized the feature components by calculating their Z-values. This procedure centred the points in the origin and equalized the range of values. We then defined as outliers all the points who exceed in value two standard deviations, in any vector dimension, and removed them. A variation of the Kolmogorov-Smirnov test was used to verify the initial assumption that the values on each dimension followed a normal distribution. To prune dimensions of the feature space we analysed the discriminative power provided by each feature using a t-test with 90% confidence interval. The test allowed to understand if the mean values of the feature for the two classes were different and if the information provided by a given feature could allow to distinguish between classes. The features that have not passed these tests where discarded. The discriminatory power of the remaining features was individually quantified, for two equiprobable classes, using the Fisher's discriminatory ratio (FDR). With this metric we sorted the features in descending order and built a new feature list using the following procedure:

1. The best ranked feature f_1 is the top-ranked in the FDR's ranked list. The next feature f_2 is obtained by

$$f_2 = \max_j \left\{ w_1 FDR_j - w_2 \rho^2_{f_1,j} \right\}, j \neq f_1 \tag{10}$$

   where FDR_j is the feature's FDR value, $\rho_{f_1,j}$ represents the cross-correlation between the feature in analysis and the remaining features and w_1 and w_2 are used defined weights that allow to adjust the contribution of each criteria to the overall feature ranking (in our case we used $w_1 = 0.3$ and $w_2 = 0.7$).
2. The next feature is selected using an analogous formulation but now considering the average correlations with all the previously selected features:

$$f_k = \max_j \left\{ w_1 FDR_j - \frac{a_2}{k-1} \sum_{r=1}^{k-1} \rho^2_{f_r,j} \right\}, j \neq f_r, r = 1, 2, \ldots, k-1 \tag{11}$$

   with $k = 3, 4, \ldots, m$.

From this multi-criteria ranked feature list we have selected the 20 highest ranked features and performed an exhaustive search for combinations of 10 features using a scatter matrices [14] based approach. As cost function for class separability measurement we used the J_3 criteria defined as:

$$J_3 = trace \left\{ \mathbf{S}_w^{-1} \mathbf{S}_b \right\} \tag{12}$$

where S_w is the intraclass scatter matrix, defined as:

$$\mathbf{S}_w = \sum_{c=1}^{C} P_i \mathbf{S}_i \tag{13}$$

where P_i is the probability of each class c and $\mathbf{S}_i$ is the related covariance matrix. Still in equation 12, $\mathbf{S}_b$ represents the interclass scatter matrix,

$$\mathbf{S}_b = \sum_{i=1}^{c} P_i(\boldsymbol{\mu}_i - \boldsymbol{\mu}_0)(\boldsymbol{\mu}_i - \boldsymbol{\mu}_0)^T \tag{14}$$

where $\boldsymbol{\mu}_i$ is the class mean vector and $\boldsymbol{\mu}_0$ is the mean vector considering all classes. Using an exhaustive search we combined sets of 10 features from the 20, previously selected, and retained the one that maximized the J_3 criterion. The features that composed our final vector optimized for normal and non-normal cardiac function discrimination were μT1, RpeakS_5, BL3 kurtosis, BL3, R2 skewness, μT2, BPM, R1slope, BPM standard deviation and T1origin.

3 Evaluation and Results

As previously stated, the ECG records, used for template extraction and testing, were extracted from the QT database. As the scope of this article refers to the development of an automatic single-lead ECG system, only records acquired through the same lead have been considered. Sixteen manually annotated templates were extracted from the database and processed according to the suggested method, in order to build a template library. A total of 387 beats were automatically segmented and the point specific results are shown in table 1. The table follows the conformation adopted in [7] in order to provide a more comprehensive comparison. Furthermore, we present the interval duration results regarding the corrected QT interval, as the duration of this interval is specially important. The segmentation is applied in the processed ECG but the final results must report to the raw ECG signal. Figures 2 and 3 show the relationship between the processed and the raw ECG beat and the associated segmentation. We can observe that the proposed hybrid PLA plus Kalman methodology can efficiently enhance the characteristic ECG waves while simultaneously smoothing signal fluctuations.

Table 1. Error (mean and standard deviation), in milliseconds, produced by the automatic segmentation system, for the specific fiducial points and intervals.

	P_{on}	P	P_{end}	Q	R	S
μ	21.98	13.06	8.54	13.16	12.34	11.81
σ	21.06	4.12	5.98	11.61	3.20	3.01
	T_{on}	T	T_{end}	QT	RR	QT_c
μ	14.45	11.42	11.25	10.44	1.76	11.18
σ	20.25	21.53	7.71	10.90	2.07	12.07

The results presented in table 1 show that the suggested segmentation method appears to be suitable for application to an automatic segmentation system. Comparing to the results collected in [7], the mean error produced by our method is comparable but slightly higher than the mean error obtained by both Vulling's and Laguna's methods. Nevertheless, in our approach, the standard deviation results are clearly lower than the

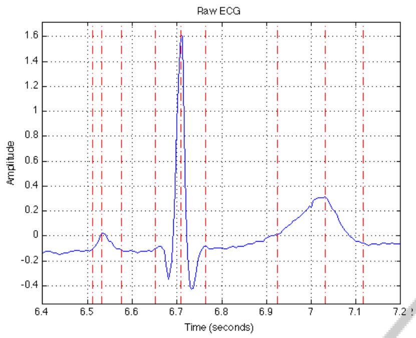

Fig. 2. Segmentation results for one beat on the raw signal.

Fig. 3. Segmentation results for one beat on the processed signal.

results of the other two methods, unless for the onset of the P wave. This fact suggests that our method is promising concerning the improvement of the precision of such automatic segmentation systems. We must highlight that the proposed algorithm relies on the analysis of a single signal which greatly reduces the refinement possibilities when additional signals are considered. Furthermore, regarding the duration of the QT, RR and corrected QT intervals, the obtained results show good possibilities of application in an automatic segmentation system. In any case the system's segmentation accuracy showed enough reliability to robustly feed the following classification module.

To evaluate the automatic warning generator, based on the described classifier system, we trained the system by randomly selecting 80% of dataset records and keeping the remaining 20% for evaluation purposes. This procedure was repeated 100 times in order to obtain confidence intervals for the evaluation results. Table 2 shows the classification confusion matrix as well as the related confidence intervals.

Table 2. Confusion matrix for cardiac function classifier. (Values are in percentage and the number of actual occurrences in the database was used as reference for the calculation. The two columns on the right represent the actual situations as found on the reference dataset.)

	QTdb		QTdb noise corrupted	
Predicted	Normal	Not-Normal	Normal	Not-Normal
Normal	$77.3 \pm 8.3\%$	$20.6 \pm 6.2\%$	$75.2 \pm 8.8\%$	$23.9 \pm 8.1\%$
Not-Normal	$22.7 \pm 8.3\%$	$79.4 \pm 6.2\%$	$24.8 \pm 8.8\%$	$76.1 \pm 8.1\%$

The proposed framework provided promising results despite the very high diversity of ECG morphologies. The number of correctly predicted situations is high even when the signal is polluted with Gaussian additive noise (SNR=14dB). In scientific literature there are very few works that address the described problem with the proposed objectives. Most works are directed to medical instrumentation systems that only grasp a single pathology whereas few cover broad spectrum classification tasks based on simple, low resource, wearable devices.

The number of false negatives and false positives is an issue for real users because in can reduce the confidence in the system's judgement. However the system was evaluated in conditions that are distant from a real daily usage in a single patient. In most real cases the number of cardiopathic patterns that can be observed in a single patient is very limited which highly reduces the discriminatory difficulty. In these restricted domains the system is able to perform much better. In table 3 we present the obtained results when considering a specific cardiac dysfunction. (For evaluation we used a bootstraping technique due to the reduce number of records.) We can observe that the number of correctly identified situations is much higher as is the number of false predictions.

Table 3. Confusion matrix for cardiac dysfunction detection when the development domain was reduced to a single pathological context. (Values are in percentage and the number of actual occurrences in the database was used as reference for the calculation. The two columns on the right represent the actual situations as found on the reference dataset.)

Context	Predicted	Normal	Not-Normal
Atrial Premature Contraction	Normal	80.3 ± 10.3%	19.2 ± 3.2%
	Not-Normal	19.7 ± 10.3%	80.8 ± 3.2%
Premature Ventricular Contraction	Normal	91.5 ± 3.7%	9.2 ± 4.6%
	Not-Normal	8.5 ± 3.7%	90.8 ± 4.6%
Bundle-Branck Block	Normal	85.9 ± 6.4%	16.5 ± 5.1%
	Not-Normal	14.1 ± 6.4%	83.5 ± 5.1%
Ventricular tachycardia	Normal	88.7 ± 5.2%	18.1 ± 8.2%
	Not-Normal	11.3 ± 5.2%	81.9 ± 8.2%
Sinus bradicardia	Normal	93.6 ± 4.9%	7.7 ± 4.0%
	Not-Normal	6.4 ± 4.9%	92.3 ± 4.0%

4 Conclusions and Future Work

Arrhythmias or abnormal heart rhythms are common cardiac disorders and may cause serious health risks. These disorders are characterized by the change in rate or rhythm of the heartbeat and their prevalence is highly increased by diabetes. In this paper we present a new device, developed specifically for diabetics, which allows estimating blood glucose levels and, simultaneously, automatically detect potentially pathological electrocardiographic patterns. We have presented the functional system's architecture and provided a thoroughly explanation of the main modules. The system's performance was evaluated with widely used methodologies and the obtained results were compared with those reported by other authors. Both segmentation and classification modules showed comparable results with better marks in some points. The proposed device uses the information from a single ECG lead which increases the analysis difficulty but represents a low discomfort for the user. The daily usage of the proposed device can increase the user's quality of life and reduce the risk of cardiac related emergencies.

The system is still under development and some further improvements are already envisioned. For example, to reduce the number of false alarms we are introducing the possibility of adapting the classification system using a medically supervised error correction procedure.

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